# PhD in Clinical Translational Science

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# Table of Contents

## Proposed PhD Program: Clinical Translational Science

### 1. Designation

The program will offer a doctoral degree (PhD) in Clinical Translational Science.

***1.1 Rationale:***
There is substantial delay and innumerable barriers between biomedical discovery, application of that discovery to clinical practice, and dissemination of practice to the community necessary to improve human health. The National Institutes of Health (NIH) and other organizations charged with the nation's health have prioritized the urgent need for a transformed research enterprise in order to accelerate translating discovery into application to benefit the individual patient and population at large. In its funding initiatives, the NIH has also emphasized that the transformed research enterprise must be transdisciplinary and team oriented.

In that context, clinical translational science has emerged as a new scientific discipline with a unique theoretical framework and specific repertoire of research methodologies that are necessary for efficient and effective translation of scientific discoveries into effective clinical and community practice. Clinical translational science represents two highly integrated domains that go hand in hand. Clinical science seeks to promote health and to understand, prevent, and treat human disease and illness. Translational science translates or transforms discoveries made in the laboratory or clinic into new procedures, therapies, medications, and ultimately, into new community-wide practices and policies, and through this process also brings the wisdom of the practice community into the clinical research process. Clinical translational science thus represents the field of knowledge that accelerates clinical work "from bench to bedside to sidewalk" (Figure 1a), or in other words, along the discovery, development, delivery, dissemination, and adoption continuum (Figure 1b).

In response to the call by NIH, 22 US universities across the nation have already launched PhD programs to provide rigorous training in this new discipline, including 6 of the top 25 schools of medicine (Appendix 1). Guided by the NIH's definition of clinical and translational research (Appendix 2), these new programs focus on enhancing skills to design and conduct research that is patient-oriented (conducted with humans or materials of human origin, for whom an investigator interacts with subjects, and which includes mechanisms of disease, therapeutic interventions, clinical trials, and the development of new technologies) and translational (applying discoveries generated through laboratory and preclinical studies to the development of trials and studies in humans, and conversely, applying novel observations in clinical settings about disease processes to new laboratory or basic investigations). As such, clinical translational science is distinct from the other established fields such as epidemiology, public health, and population science, which typically focus on disease etiology, health, illness, and health care on population or community levels. Also, clinical translational science's orientation on patients distinguishes it from fields that focus on the basic life sciences, which are primarily laboratory-based (e.g., neuroscience, immunology).

The proposed program at Case Western Reserve University (CWRU) will train and graduate clinical-translational scientists to meet the need for a transformed clinical and translational enterprise. Students

in the program will be rigorously trained in the theory and practice of clinical translational science in order to make significant clinical discoveries and to move these discoveries across the translational continuum. CWRU is well situated to implement the doctoral program: its faculties in diverse scientific and professional fields as well as the presence of collaborating local medical centers (Cleveland Clinic Foundation, University Hospitals Case Medical Center, MetroHealth Medical Center, and Louis Stokes Veterans Administration Medical Center) represent partner institutions in the Cleveland Clinical and Translational Science Collaborative (CTSC), one of over 60 sites nationwide funded by the NIH to accelerate clinical translational research and training. The Cleveland CTSC has been top-ranked among its peers.

Figure 1a: Clinical Translational Process from Bench to Practice[1]

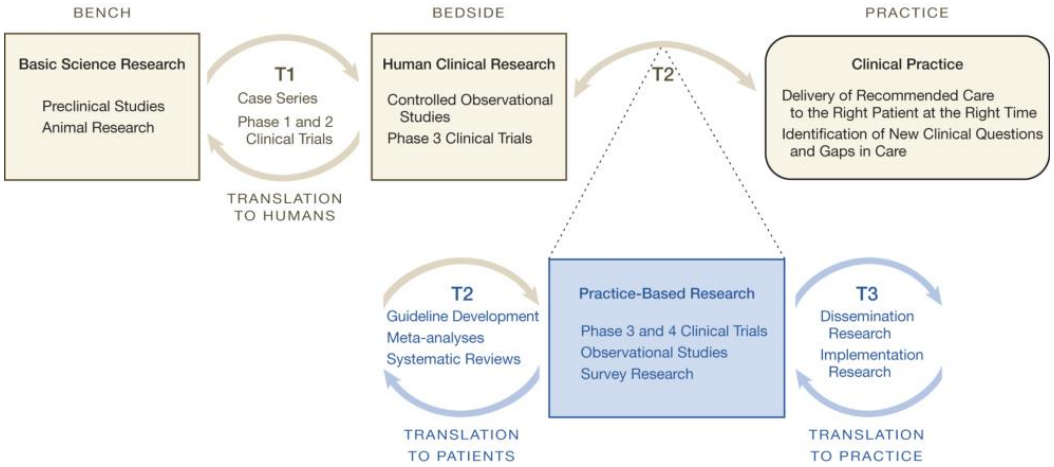
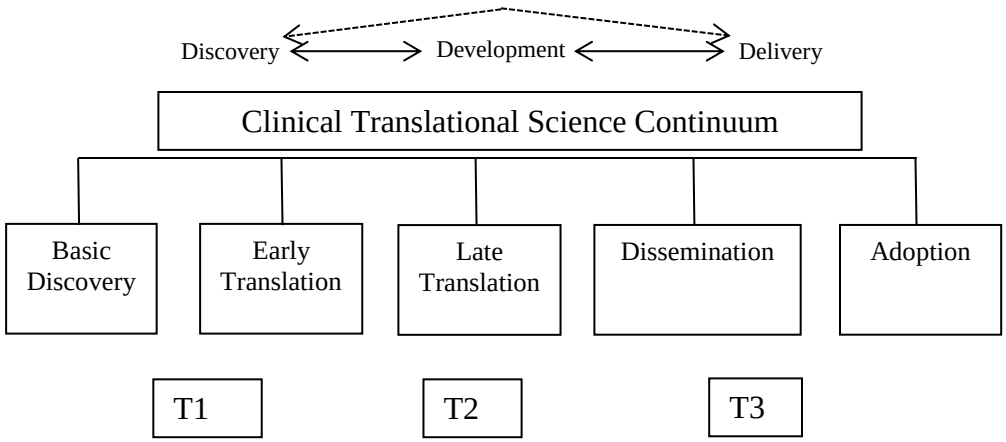



Figure 1b: Clinical Translational Science Continuum[2]




[1]From Mitchell et al. A thematic analysis of theoretical models for translational science in nursing: Mapping the field. *Nurs Outlook*. 2010;58:287-300.

[2]From Westfall et al. Practice-based research: "Blue highways" on the NIH roadmap. *JAMA*. 2007;297:403-406.

To further support the implementation of the proposed program, CWRU's longstanding Medical Scientist Training Program (MSTP), the oldest combined MD-PhD training program in the country, launched a sister program named the Clinical and Translational Scientist Training Program (CTSTP). The CTSTP provides research training in more clinical and translational fields (e.g., biomedical engineering, epidemiology, bioethics, and systems biology) and has collaborated with several CWRU academic departments to develop PhD programs for individuals entering the CTSTP. The proposed PhD in Clinical Translational Science will be the PhD option of the CTSTP that focuses specifically on the field of clinical translational science.

***1.2 Purpose*:**
The overall goal of the program is to produce successful clinical-translational scientists who will lead sustained, innovative research agendas to address the challenging health and medical problems facing the US and world. Program graduates will be able to: (1) independently lead, design, execute, manage, and interpret multidisciplinary clinical-translational research in a conceptually, methodologically, ethically, and regulatory sound manner; (2) assume leadership roles in both academic and industry settings; and (3) establish national reputations as leaders in a given area of expertise. The doctoral program's training is consistent with the core competencies defined by NIH for conducting clinical translational research and adheres to NIH-promoted principles of multidisciplinarity and team science.

***1.3 Applicant Pool:***
The program is designed for three categories of research scholars: (1) individuals with an advanced clinical degree seeking rigorous training in clinical translational science; (2) individuals enrolled in dual clinical-research degree programs, such as the MSTP-CTSTP and DMD-PhD programs, whose interests and career goals align with the PhD in Clinical Translational Science; and (3) individuals with an existing MS in a health-related field who seek a PhD in Clinical Translational Science.

## 2. Description of Proposed Curriculum

***2.1 Overview:***
The proposed curriculum will furnish students with the necessary knowledge, skills, and experience to become productive researchers in the field of clinical translational science. Essential elements of the proposed curriculum are: (1) coursework providing students with the theory and practice of clinical and translational research; and (2) continued, longitudinal immersion in research through laboratory rotations (MSTP-CTSTP students), research practicums, and a research dissertation. The curriculum is based on a set of nationally-developed core competencies to guide the nationwide training of clinical and translational scientists. The competencies are grouped into 1 of 12 core thematic areas or domains representing key knowledge bases and skill sets for clinical and translational investigation (Table 1). The competencies developed for the proposed PhD program build upon our experience with the existing Clinical Research Scholars Program (CRSP), which currently offers a Master's degree in Clinical Research, but constitute substantially more in-depth theory and skill training plus a vigorous research experience necessary to produce high-level investigators.

## Table 1: PhD Program Competencies

| Core Domain | Competencies |
|---|---|
| Theory-Based Problem Assessment & Formulation | • Develop innovative, testable clinical and translational research questions<br>• Formulate sound hypotheses<br>• Frame research questions and hypotheses that engage interest and participation of practice communities and other key players at appropriate translation loci (e.g., T1, T2, T3) |
| Critical Literature Review & Synthesis | • Conduct comprehensive, systematic, evidence-based critique of the scientific literature, identifying potential sources of bias and knowledge gaps<br>• Synthesize results of scientific literature using meta-analytic and other appropriate techniques<br>• Place studies in context of existing research along a translation continuum (e.g., laboratory to population) |
| Study Design & Measurement | • Based on assessment of strengths and weaknesses of possible designs, develop all aspects of an appropriate study design to address a testable clinical and translational research question<br>• Determine resources needed to implement the selected study design<br>• Evaluate validity and reliability of all study measures<br>• Identify and minimize threats to study validity<br>• Implement appropriate quality assurance and control systems for a selected study design |
| Study Implementation | • Utilize design strategies that optimize feasibility, efficiency and ability to derive unbiased inferences from clinical and translational study designs<br>• Assess threats to internal validity in any planned or completed clinical and translational study<br>• Conduct studies that integrate elements of translational research into the protocol that could provide the basis for future research, such as collection of biological specimens, nested studies, and the development of community-based interventions<br>• Secure resources needed to implement the selected study design |
| Funding | • Demonstrate knowledge of funding agencies and the peer review system<br>• Develop effective applications for funding from appropriate governmental and/or nongovernmental sources |
| Statistical Approaches | • Determine and justify the appropriate statistical technique(s) for a specific research question and concomitant study design<br>• Build effective statistical expertise into research teams<br>• Develop and use appropriate early stopping rules in clinical trials |
| Health Informatics | • Identify modern information systems for collecting, organizing, managing, and accessing clinical data<br>• Utilize best practices in informatics for the organization and management of biomedical/health information<br>• Build effective bioinformatics expertise into clinical/translational research teams |
| Translational and Patient-Oriented Research | • Learn and apply the principles of responsible conduct of research<br>• Learn and apply the principles of IRB review and communication<br>• Develop and implement research designs that account for demographic, cultural, geographic, ethnic features within communities and populations<br>• Articulate the clinical impact of the research on the health of individuals or populations<br>• Understand the intimate relationship between clinical design and translational research related to pathogenesis or etiology |
| Scientific Communication | • Effectively communicate clinical and translational research findings to different groups of individuals (colleagues, students, lay public, policymakers, mass media)<br>• Translate research findings into effective guides for development of clinical practice and governmental policy<br>• Explain utility and mechanism of commercialization for research findings, patent processes, and technology transfer |
| Leadership | • Lead a multidisciplinary team in all fiscal, personnel, regulatory compliance and problem-solving aspects<br>• Catalyze innovation and creativity in the research team<br>• Mentor beginning scientists |
| Team Science | • Create the optimum interdisciplinary/multidisciplinary team for a given research problem<br>• Use group decision-making and conflict resolution techniques in team management<br>• Foster multiple points of view and clarify language differences across disciplines<br>• Understand the language(s) used in other disciplines comprising the research team<br>• Engage practice communities in the choice and framing of research questions, design, conduct, interpretation, implementation, and dissemination of clinical translational research |
| Cultural Diversity | • Demonstrate sensitivity and professionalism with participants from diverse social and cultural backgrounds<br>• Communicate effectively across cultures, languages, and literacy levels |

## Table 2: PhD in Clinical Translational Science Proposed Curriculum

The proposed curriculum consists of a minimum of 54 credit hours: 36 credit hours of courses (of which at least 24 hours are graded) and 18 credit hours of dissertation research.*

**REQUIRED COURSES**

| **Course #** | **Course title** | **Units** | **Grading** |
|---|---|---|---|
| **New Course** | Translational and Patient-Oriented Research Theory | 3 | Graded |
| **New Course** | Meta-analysis and Evidence Synthesis | 2 | Graded |
| CRSP 401** | Introduction to Clinical Research | (3) | Graded |
| NURS 630 | Advanced Statistics: Linear Models | 3 | Graded |
| CRSP 407 | Logistic Regression and Survival Analysis | 3 | Graded |
| CRSP 603 | Research Ethics and Regulation | 2 | Graded |
| **TOTAL GRADED** | | **16 (13)** | |
| **New Course** | Seminar in Multidisciplinary Clinical and Translational Research | 0 | P/F |
| CRSP 501 | Team Science | 1 | P/F |
| CRSP 412 | Communication in Clinical Research I – Grant Writing | 1 | P/F |
| CRSP 413 | Communication in Clinical Research II – Oral Presentation, Posters, and the Mass Media | 1 | P/F |
| **TOTAL P/F** | | **3** | |

**CORE ELECTIVES**

Students must take a minimum of 2 credit hours of courses from the list below, depending on their specific needs and mentor approval.

| | | | |
|---|---|---|---|
| CRSP 402 | Study Design and Epidemiologic Methods | 3 | Graded |
| CRSP 502 | Leadership Skills for Clinical Research Teams | 2 | Graded |
| **New Course** | Clinical Informatics | 3 | Graded |
| EPBI 450 | Clinical Trials and Intervention Studies | 3 | Graded |
| EPBI 467 | Comparative and Cost-Effectiveness Research | 2-3 | Graded |

**ELECTIVES**

Students will take electives and CRSP 601 Research Practicum to satisfy the graded and pass/fail course requirements and to advance to candidacy. These courses are selected based on students' needs and mentor approval. Any CWRU credit-bearing course may qualify. The courses could be 'field specific' or include other core elective courses not taken as part of the requirement above. The following list is for illustrative purposes:

| | | | |
|---|---|---|---|
| IBIS or other | Field specific, e.g. Immunology, Physiology, Pathology | Up to 18 | Graded |
| NURS 518 | Qualitative Nursing Research | 3 | Graded |
| SASS 614 | Models of Qualitative Research | 3 | Graded |
| CRSP 504 | Managing Research Records - A System's Approach | 2-3 | P/F |
| CRSP 510 | Health Disparities | 3 | P/F |
| CRSP 500 | Design and Analysis of Observational Studies | 3 | Graded |
| CRSP 505 | Investigating Social Determinants of Health | 2-3 | P/F |
| EPBI 400 | Statistics as Integral to the Scientific Method | 3 | P/F |
| EPBI 411 | Introduction to Health Behavior | 3 | Graded |
| CRSP 410 | Independent Study (e.g., laboratory, clinic, community based) | Variable | P/F |

**RESEARCH COMPONENT**

| | | | |
|---|---|---|---|
| CRSP 601 | Research Practicum | Variable | P/F |
| CRSP 701 | Dissertation Research | 18 | S/U |

* Per School of Graduate Studies Guidelines, programs of study for dual clinical-research degree students (e.g., MSTP-CTSTP, DMD-PhD) and for students entering with an approved master's degree may be modified to reflect credit for concurrent and/or previous coursework.
**Waived for MD/PhD students in the CTSTP program or by petition with sufficient background from previous coursework.

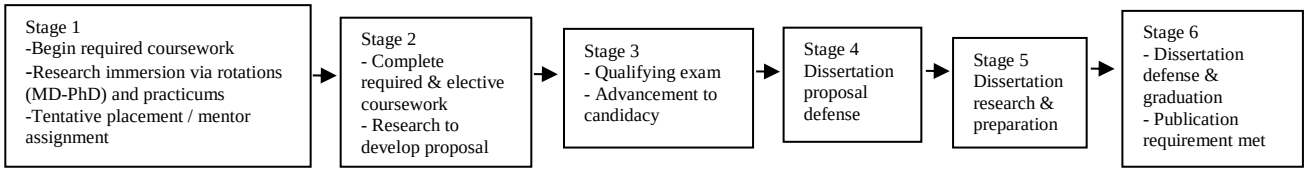
Credit hour requirements for the program conform to regulations established by CWRU's School of Graduate Studies. The proposed standard curriculum (Table 2) consists of a minimum of 36 credit hours of courses, of which at least 24 hours are graded. The 36 credit hours consist of 19 credit hours of required coursework, a minimum of 2 credit hours of core electives, and an additional 15 credit hours of electives, which include research practicums (CRSP 601 "Independent Research"). Research rotations (e.g., for individuals in the MSTP-CTSTP program, see below) and/or independent research practicums will enable students to be immersed in continued research activities throughout the pre-dissertation stages of their programs.

In addition to 36 credit hours of course work, all students will take 18 credit hours of dissertation research. The complete curriculum, including course descriptions, is listed in Appendix 3.

***2.2 PhD Program Stages:***

A schematic of the overall program is provided in Figure 2. A description of each program stage follows:

**Figure 2: Program Overview**




2.2.1 Stage 1: Required Coursework, Initial Research Experiences, & Tentative Mentor Selection:

*2.2.1.1 Coursework:*

All students take 19 credit hours of required courses, unless waived by the PhD Program Steering Committee in light of a student's previous or concurrent coursework taken in another degree-granting program (see Section 2.2.1.2 Curricular Provisions for Students with an Existing Research Graduate Degree and Section 2.2.1.3 Curricular Provisions for MSTP-CTSTP Students). The required coursework for the PhD program consists of courses in four key domains: (1) clinical and translational theory and practice; (2) research methods; (3) statistical science; and (4) professional development & conduct (Table 3). Two courses developed specifically for the PhD program will directly address clinical and translational theory and practice. "Translational and Patient-Oriented Research Theory" will provide students with the underlying theoretical framework guiding patient-oriented translational research and introduce students to the rationale for and processes and challenges of multidisciplinary clinical translational science. The "Seminar in Multidisciplinary Clinical and Translational Research" will be held biweekly each spring and fall semester. The seminar will be attended by all PhD students throughout their entire programs of study and core faculty. The seminar will consist of a presentation by an invited speaker on a research study or topic involving clinical and translational science, followed by discussion. Presentation and discussion of active clinical translational studies occurring at Case Western Reserve University and other local institutions (e.g., Cleveland Clinic Foundation, the MetroHealth Center, University Hospitals Case Medical Center, and Louis Stokes Veterans Administration Medical Center) will enable students to examine clinical translational science in action.

**Table 3: Clinical Translational Science PhD Coursework**

| Domain | Required | Core Electives | Possible Electives* |
|---|---|---|---|
| Multidisciplinary and Translational Perspectives | • CRSP Translational and Patient-Oriented Research Theory (3) (**new**)<br>• CRSP Seminar in Multidisciplinary Clinical & Translational Research (0) (**new**) | | • CRSP 503 Innovation and Entrepreneurship (1)<br>• CRSP 510 Health Disparities (3)<br>• EPBI 411 Introduction to Behavioral Health (3)<br>• EPBI 474 Principles of Practice-based Network Research (3) |
| Research Methods | • Meta-analysis and Evidence Synthesis (2) (**new**)<br>• CRSP 401 Introduction to Clinical Research (3) | • CRSP 402 Study Design and Epidemiologic Methods (3)<br>• EPBI 450 Clinical Trials and Intervention Studies (3)<br>• EPBI 467 Comparative & Cost-Effectiveness Analysis in Health Care (1-3) | • CRSP 500 Design & Analysis of Observational Studies (3)<br>• CRSP 505 Investigating Social Determinants of Health (2-3)<br>• NURS 518 Qualitative Nursing Research (3)<br>• SASS 614 Models of Qualitative Research (3)<br>• EPBI 434 Community-Engaged Research (3) |
| Computing & Informatics | | • CRSP Clinical Informatics (3) (**new**) | • CRSP 504 Managing Research Records – A Systems Approach (2-3)<br>• CRSP 406 Introduction to R Programming (2) |
| Statistics | • NURS 630 Advanced Statistics: Linear Models (3)<br>• CRSP 407 Logistic Regression & Survival Analysis (3) | | • EPBI 400 Statistics as integral to the Scientific Method (3) |
| Professional Development & Conduct | • CRSP 501 Team Science – Working in Interdisciplinary Research Teams (1)<br>• CRSP 412 Communication in Clinical Research I-Grant Writing (1)<br>• CRSP 413 Communication in Clinical Research II- Oral Presentations, Posters, and the Mass Media (1)<br>• CRSP 603 Research Ethics and Regulation (2) | • CRSP 502 Leadership Skills for Clinical Research Teams (2) | • IBMS 500 Being a Professional Scientist (1) |
| *The electives listed do not represent all possible electives. With the approval of their advisors, students in the program may take any university course relevant to their program of study. | | | |

Concerning the research methods domain, another new course developed for the PhD program, "Meta-Analysis and Evidence Synthesis," will teach meta-analytic skills and other techniques to synthesize clinical translational evidence to guide research. "Introduction to Clinical Research" (CRSP 401) introduces students to the language and concepts of clinical investigation and teaches foundational skills in the design and conduct of studies. The statistical methods courses cover the application of statistical techniques to the biomedical sciences. Four courses (CRSP 603, 501, 412, 413) are specifically designed to enhance professional skills critical to clinical and translational investigation: (1) research ethics and regulations; (2) leading and collaborating in multidisciplinary scientific teams; and (3) scientific grant/article writing and other forms of scientific communication to peers, press, and public. As a practical matter, it is advantageous that many of the required courses have already been developed through the Clinical Research Scholar Program (CRSP). In addition to the required courses, students must take a minimum of 2 credit hours of core electives, a set of courses that consist of a range of specific research approaches and methods (e.g., study design and epidemiologic methods, clinical trials and intervention studies, comparative and cost-effectiveness research, clinical informatics) and leadership skills. Selection of the specific core elective(s) to be taken will depend on a student's individual needs, with guidance from the student's academic advisor(s).

It should be noted that the program will not be initiated until the all new courses have been approved by the School of Medicine.

Students will also take up to 15 credit hours of elective courses in order to satisfy the School of Graduate Studies graded and pass-fail course requirements. Any relevant CWRU credit-bearing course may qualify, and may include core elective courses not taken as part of the core-elective requirement described above, as well as CRSP 601 Independent Research credit hours. Per School of Graduate Studies' approval, Integrated Biological Sciences (IBIS) courses from the CWRU MD curriculum will satisfy this requirement for MSTP-CTSTP students. The selection of specific electives will be based on the individual student's needs and research interests, and approved by the student's academic advisor. A sample program of study for a full-time student with an advanced professional clinical degree is included (Appendix 4).

*2.2.1.2 Curricular Provisions for Students with an Existing Research Graduate Degree*:
Students entering the program with an existing MS in Clinical Research or other relevant research graduate degree will not need to repeat courses required for the doctoral degree that they have already successfully taken to obtain their advanced degree. However, per the School of Graduate Studies' academic requirements, these students must successfully complete a minimum of 18 credit hours of coursework, 12 of which must be graded. Students must petition the PhD program steering committee to obtain a waiver for a required course. Evidence for a waiver will consist of the student's transcript showing the course and grade received as well as the syllabus for the course. The CWRU instructor teaching the course petitioned for waiving will also be consulted as needed. Selection of the specific courses to achieve the minimum 18 credit hours of courses will depend on the student's individual needs and will be subject to his or her academic advisor's (mentor's) approval. A sample program of study for an individual entering the program with a relevant research graduate degree is included (Appendix 5). In this example, the student is able to progress more rapidly through the program because (a) her/his MS in Clinical Research allows waiver of 18 credit hours of coursework; and (b) s/he is entering the program with a clearly defined dissertation topic.

*2.2.1.3 Curricular Provisions for MSTP-CTSTP Students*:
For individuals simultaneously seeking both a PhD in Clinical Translational Science and an MD, curricula of the two degree programs will be integrated following the successful example of CWRU's Clinical Translational Sciences Training Program currently implemented via the CTSC. These individuals will take a total of 39 credit hours of coursework: 16 credit hours of required courses (the 3 credit hour course CRSP 401 "Introduction to Clinical Research" is waived because its material is covered by the medical school curriculum), 2 credit hours of core electives, up to 18 hours of research practicum (CRSP 601) or electives, and 6 credit hours of research rotations. MD-PhD students also receive 18 credit hours from portions of their medical school curricula (IBIS courses). A sample program of study is included as Appendix 6.

*2.2.1.4 Research Immersion*:
The proposed PhD program includes a compulsory, active research component throughout each student's entire program of study. During the required coursework phase, students will begin their participation in research activities necessary for successful completion of the program. For example, students entering the program with an advanced clinical degree will select an academic advisor based on their research interests, who will guide the student in research practicums to pursue their research

interests. Practicums may involve a range of activities (e.g., assisting with an ongoing study, conducting a literature review, assisting with the preparation of a scientific manuscript) and are not necessarily linked to a student's specific dissertation project. Independent research credits (CRSP 601) will constitute the mechanism through which students can conduct these research practicums and receive course credit. Students entering the program through the MSTP-CTSTP program will initially participate in 1-4 research rotations that expose them to several research areas and will select a mentor based on their interest. CRSP 601 will also constitute the mechanism through which the combined MD-PhD students may receive course credits for research practicums before advancement to candidacy. The PhD Program's Steering Committee will approve all faculty who host research rotations and practicums prior to student placement.

2.2.2 Stage 2: Completed Coursework & Research to Develop Proposal:
During this phase of the program, students will complete all required and elective courses to meet overall credit hour requirements of the CWRU School of Graduate Studies for a PhD. Elective courses taken by students will vary based on students' interests, educational and experiential backgrounds, and needs. Students will focus their research activities on needed groundwork to develop a dissertation proposal.

2.2.3 Stage 3: Qualifying Examination & Advancement to Candidacy:
Per CWRU School of Graduate Studies requirements, after completion of required coursework, students must pass a qualifying examination, which enables a student to advance to candidacy for the PhD and formally begin the dissertation research phase of the program. In the proposed doctoral program, to advance to candidacy for the PhD, all students will be required to pass a written qualifying examination, which will assess a student's ability to conduct clinical translational research as defined by the curriculum's core competencies (Table 1). The qualifying examination will be administered by an examination committee, consisting of 5 core faculty members who are appointed by the program steering committee and who serve on the committee for a 2-year term. Each year, a pool of examination questions will be prepared by the core faculty and submitted to the examination committee, who will select the questions to appear on the examination.

To schedule the candidacy examination, the student should have completed required course work and have a GPA of 3.0 or higher. The examination requires the student to demonstrate the knowledge she or he has obtained as result of completing the PhD curriculum. The examination itself will consist of two parts: a closed-book, in-class written examination followed by a take-home examination. The examination will test the depth and breadth of the student's knowledge of clinical translational theory and practice, and comprehensive ability to synthesis and apply that knowledge. Although individual questions will change across administrations of the examination, the content foci of the candidacy exam will be uniform for all students and reflect PhD program competencies, specifically: (1) clinical translational research theory; (2) methods for conducting clinical translational science, including analytical methodologies and team-science approaches; (3) ethical conduct of research.

Advancement to candidacy status is based on the candidacy committee's recommendation and signed by the PhD Program Director. Students who attain candidacy status are able to register for dissertation credit hours (CRSP 701) and are expected by the School of Graduate Studies to complete their dissertation and defense within five calendar years from the date the first dissertation credit hour is taken.

A student who fails the candidacy examination may be permitted to retake the examination following completion of additional course work and/or a written response to questions from the committee. The candidacy committee has the responsibility to determine which option should be selected for a specific student and to inform the student of the course of action verbally and in writing. The candidacy committee chairperson will inform the PhD Program Director in writing of the selected course of action. Students may retake the examination the following semester, and must retake the examination within one calendar year. A student who is refused admission to candidacy may not undertake further study for credit toward the Ph.D. With the approval of both the Program Director and the School of Graduate Studies, such a student may apply her/his credit hours towards completion of the Master's degree in Clinical Research.

2.2.4 Stage 4: Formation of Dissertation Committee and Proposal Defense:
Befitting a research doctorate, the curriculum includes a substantial focus on learning to conduct research by conducting mentored, hypothesis-driven dissertation research. Students who have advanced to candidacy may begin registering for dissertation credit hours (CRSP 701), and all students will be required to successfully complete 18 credit hours of dissertation credit.

Per School of Graduate Studies' regulations, each student will form a dissertation committee, consisting of a minimum of four members of the university faculty. At least one committee member will belong to the core faculty, and at least one member will not have a faculty appointment at the Center for Clinical Investigation. The committee chairperson will be selected by the student in consultation with the student's mentors and must: (1) hold the rank of Assistant Professor or above; (2) be tenured or on the tenure-track; and (3) have considerable expertise in the student's content and/or research area. Expertise is determined by the faculty member's authorship of research publications in refereed journals and recognition by peers as an expert in the student's research area. The student must consult with the chairperson to identify and select three additional individuals with research doctorates to serve as committee members. Selection of these three members should be based on faculty expertise in the student's substantive area of study, theoretical and conceptual expertise, or methodological expertise. The PhD Program Steering Committee must approve the composition of the dissertation committee. Before initiating their dissertation research, students will submit to their dissertation committee for approval a detailed, written research proposal in the NIH or NSF style and conduct an oral dissertation proposal defense.

2.2.5 Stage 5: Dissertation Research & Preparation:
After successful defense of the proposal, doctoral degree candidates will conduct their dissertation research with guidance from their mentors. Based on this research, they will prepare a dissertation that will: (1) demonstrate a thorough description and critical understanding of the literature in the student's topic area; (2) clearly describe an original thesis, methods used, results and implications in terms of the thesis/study questions; (3) identify and describe further research or future directions; (4) describe theoretical and clinical translational significance.

It should be noted that the length of time to complete the dissertation is likely to be variable, and students entering the doctoral program with substantial research experience and training will likely complete the dissertation in a shorter time period (see for example, Appendix 5). The proposed program does not have a fixed length of time for the dissertation research. However, per School of Graduate Studies' requirements, students have five consecutive calendar years from the semester of the first

credited CRSP 701 registration, including leaves of absence, to complete all requirements for the doctorate.

2.2.6 Dissertation Topics:

Dissertations in the proposed program will be hypothesis driven and encompass key components of original clinical translational research continuum from the conceptualization of hypothesis, design, and implementation of research; interpretation of results; preparation of scientific reports and publications. More specifically, the research hypothesis will be formulated by the student, based on comprehensive synthesis of the scientific literature, in consultation with their advisors for plausibility and feasibility. Theses will be translational, and clinical and/or population-oriented, bridging two or more domains of translational research, and will emphasize the process of team science The student will be responsible for collecting (if necessary) and analyzing data to test the hypothesis, developing manuscripts, and will be the lead author for any publication coming out of the thesis research. Examples of such topics from existing programs in clinical translational science in other institutions include:

- "The Effect of Obesity on Chronic Wound Healing," University of Colorado, Denver:
- "Autoantibodies and Inflammatory Markers in the Prediction of Time of Future Onset of Symptomatic Rheumatoid Arthritis," University of Colorado, Denver:
- "A Translational Study of Different β-blockers and Oral Contraceptives on the Risk of Cardiac Events in Patients with Long QT Syndrome," University of Rochester School of Medicine and Dentistry
- "Investigating the Role of Plasmodium Falciparum Equilibrative Nucleoside Transporter 1 in Malarial Physiology and Anti-Malarial Activity," Albert Einstein College of Medicine
- "Investigation of Genotype and Phenotype Associations of Diabetic Retinopathy in Multi-Ethnic Populations," Cedar Sinai Medical Center
- "Use of Multinational Registries to Assess and Compare Outcomes of Patients with Acute Coronary Syndromes," University of Massachusetts Medical School
- "Bone Health and Coronary Heart Disease in Postmenopausal Women with Breast Cancer Treated with Tamoxifen," University of Massachusetts Medical School
- "Early Detection and Treatment of Acute Clinical Decline in Hospitalized Patients: An Observational Study of ICU Transfers and an Assessment of the Effectiveness of a Rapid Response Program," University of Massachusetts Medical School
- "Modeling Co-Occurring Depression and Anxiety in Patients with an Acute Coronary Syndrome," University of Massachusetts Medical School
- "Patterns, Probability and Predictors of Recovery from Disability in Activities of Daily Living among Community-dwelling Older Persons," Yale University
- "Toll-Like Receptors in Older Adults and Response to Vaccination," Yale University
- "Exploring Novel Mechanisms for Dietary Prevention of Breast Cancer," University of Arkansas for Medical Sciences
- "Maternal Epigenetic and Genetic Factors in Congenital Heart Defects," University of Arkansas for Medical Sciences

- "Course of illness and the development of vascular disease in individuals with bipolar disorder," University of Iowa
- "Towards Translational Biomedical Informatics: Interpretable Models of Etiology, Early Diagnosis, and Prognosis," Medical College of Wisconsin
- "Preclinical and Clinical Development of Intratumorally Administered UH14.18-1L2 as Treatment for Neuroblastoma and Melanoma: The Importance of Tumor Infiltrating Leukocytes in Tumors Treated with HU14.18-1L2," Medical College of Wisconsin

In most cases, dissertation research will require institutional review board (IRB) approval. As needed, PhD students will be certified by the Continuing Research Education Credit (CREC) Program in human subjects research, develop the IRB-required protocols, and obtain IRB approval before initiating their dissertation research.

2.2.7 Stage 6: Dissertation Defense, Publication Requirement, & Graduation:
Candidates will defend their dissertation before their dissertation committee. The dissertation committee will insure that the dissertation has the scientific merit and rigor of doctoral-level research, reflects mastery of the core competencies in clinical and translational research, and meets all School of Graduate Studies' standards and requirements. Mastery will also be demonstrated by candidates meeting a publication requirement: in order to graduate, candidates must have at least two first-authored research papers published or accepted for publication in a reputable, peer-reviewed scientific journal. Candidates who have successfully completed the dissertation and the publication requirement will be eligible for graduation. The Director of the Center for Clinical Investigation will sign off on completed dissertations, which will then be submitted to the School of Graduate Studies.

***2.3 Evaluation/Monitoring of Student Progress:***
We anticipate that students will meet regularly with their primary mentors, who will monitor their students' progress. Students will be required to meet with their advisors at least once per semester. At the end of each spring semester (academic year), a student's full dissertation committee will meet formally with the student to assess the student's progress. The committee will generate a report and submit this report to the steering committee for its review. If progress is not suitable, the steering committee will meet with the student and his/her dissertation committee to identify remedies for identified deficiencies. Moreover, at the end of each academic year, students will be given a structured questionnaire to complete regarding their evaluation of the dissertation committee. These reports will be considered confidential and will be reviewed by the steering committee, which will meet as needed with the student and his/her committee to resolve any issues.

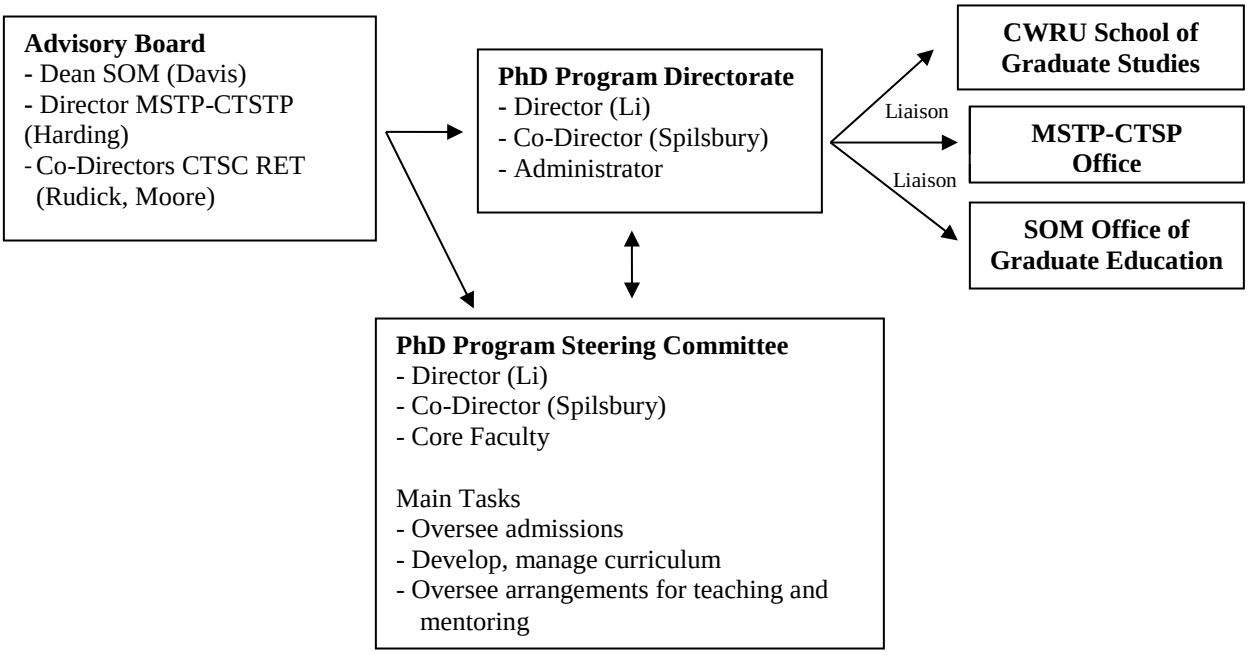
***2.4 Program Flexibility:***
The proposed program has been designed with flexibility to account for the diverse educational and experiential backgrounds of persons anticipated to enroll in the program. Thus, the selection of core electives, electives, and specific research practicums will be based on a student's needs in consultation with and approval by the student's advisors. Students who believe they have already taken coursework that covers a required course may petition the program's steering committee to be waived from taking the course. However, students will still be required to meet the credit hour requirements for the degree set forth by the School of Graduate Studies.

***2.5 Program Identity and Cohesion:***
Interactions among students, between students and faculty, as well as students' sense of belonging to and identifying with an academic program are all necessary components of a successful PhD program. To address this need, a clinical translational science core faculty will be created to provide program identity, with each faculty member having at least a secondary appointment to the Center for Clinical Investigation. Moreover, the ongoing, monthly "Seminar in Multidisciplinary Clinical and Translational Research" will provide a venue where all students in the PhD program and the program's core faculty will meet and interact regularly. This mechanism will help achieve a sense of identity and membership in an academic home for both students and faculty. Other academic and social events will be held periodically to further promote a sense of cohesion among clinical and translational science students and faculty.

## 3. Administrative Arrangements for Program

The program will be subject to the School of Graduate Studies' regulations regarding doctoral programs. The program will be administered through the Center for Clinical Investigation. It should be noted that CWRU regulations allow for doctoral programs to be implemented from centers instead of departments, and there is precedence for other doctoral programs being administered in this manner. The Center for Clinical Investigation is a fitting locus for the proposed program because it has primary and secondary faculty appointments and is the academic home of the Cleveland CTSC. The program will be administered by a Program Director, co-Director, Program Steering Committee, Advisory Board, and Program Administrator (Figure 3).

**Figure 3: Clinical Translational Science PhD Administrative Structure**



The Program Director will be appointed by the Dean of the School of Medicine. The proposed director, Dr. Li Li, is Associate Professor of Family Medicine and Community Health, Epidemiology and Biostatistics at CWRU, Associate Director for Prevention Research at the Case Comprehensive Cancer Center (CCCC), and attending physician of family medicine at the University Hospitals Case Medical Center. He is also co-director of the highly successful CCCC Computational Genomic Epidemiology of Cancer training program (R25). His research interests primarily involve cancer molecular/genetic epidemiology and prevention, with focus on gene-environment interaction, energy imbalance, screening and early detection of colon neoplasia, and risk prediction modeling in breast cancer. He oversees population research at the CCCC that cuts across all aspects of translational cancer research, ranging from epidemiology, psychosocial and behavioral sciences, genomics, biomarker discovery and validation, to the application of novel discoveries from both wet and dry laboratories to screening and early detection, prevention and intervention. He has been instrumental in making minority cancer disparities research one of the top priorities of the CCCC's strategic plan and is working with CCCC leadership to establish the Office of Cancer Disparities Research at the CCCC.

The proposed co-director is Dr. James Spilsbury, Assistant Professor and Director of the Center for Clinical Investigation's Academic Development Core. Dr. Spilsbury currently manages the Center's interdisciplinary educational and training activities, which are offered to enhance the research community's expertise in conducting clinical and translational research. In this capacity, he currently directs the Master's Degree Program in Clinical Research at CWRU and has served as the faculty advisor/mentor for scholars in the Master's program. He has also served on the dissertation committee of PhD candidates from CWRU's College of Arts and Sciences and School of Applied Social Science. His research interests involve understanding how characteristics of the socio-cultural environment, including family and community violence, shape children's sleep behavior and other aspects of their health and well-being. The nature of the phenomena he studies necessitates multi-disciplinary approaches and expertise from diverse disciplines, and Dr. Spilsbury has experience in developing and managing multi-disciplinary research teams.

Drs. Li and Spilsbury are responsible for the overall direction and management of the program. Also, the directors, with assistance from core faculty members as needed, will be responsible for handling any student or faculty concerns as they arise.

The PhD Program Steering Committee will consist of the Program Director, who will chair the committee, the co-Director, and the core faculty. The PhD Program Steering Committee will oversee admissions, administration and content of the curriculum, approve courses and syllabi, oversee program requirements and faculty arrangements for teaching courses and mentoring students, and periodically review the curriculum and modify as needed to assure maintenance of academic standards.

The PhD Advisory Board will initially consist of the Dean of the School of Medicine, the Co-Directors of the Clinical Translational Science Collaborative's Education Core, and the Director of the MSTP-CTSTP. The Advisory Board will meet with the Steering Committee every 6 months to provide guidance on the implementation of the program and will also serve as an advocate for the program as needed.

The program administrator will provide necessary administrative support for the director and steering committee, as well as track student performance, schedule events, assist with budgeting, and maintain

student admission, financial, and other records necessary for the program. Also, the program administrator will liaise with the MSTP-CTSTP office, the School of Medicine's Office of Graduate Education, the CWRU School of Graduate Studies, and other institutions, departments, and centers as needed to assure smooth implementation of the PhD program.

## 4. Evidence of Need

The proposed program is in direct response to the NIH's call for transformation in the manner in which clinical and translational research is conducted. Clinical translational science is a growing, recognized discipline: 2008 saw the birth of a peer-reviewed scientific journal devoted to the field titled *Clinical Translational Science*. Similarly, in 2009 the journal *Science* added *Science Translational Medicine*. The Center for Clinical Investigation has conducted two surveys to assess interest in a doctoral program among recent graduates of the MS program in Clinical Research (Clinical Research Scholars Program) as well as recipients of K development awards. Two of 22 MS graduates (14%) and 7 of 23 (30%) K awardees indicated that they were interested or would have been interested in a PhD program in Clinical Translational Science if it were available.

### *4.1 Relevant Local Programs*:

A MS in Clinical Research is currently offered at CWRU through the Clinical Research Scholars Program. However, the PhD Program in Clinical Translational Science will provide substantially greater research experience (pre-dissertation & dissertation) as well as further training that results in in-depth knowledge and greater skill to conduct clinical and translational research. Moreover, as opposed to a master's level thesis or project, students' successful completion of the rigorous PhD dissertation process will lead to a higher level of training, which will produce successful, independent researchers leading the field of clinical translational science.

In terms of existing doctoral programs, three existing PhD programs in the greater Cleveland area possess elements of clinical translational science. First, the PhD in Molecular Medicine is overseen by CWRU and administered through the Department of Molecular Medicine at the Cleveland Clinic Lerner College of Medicine. It has been developed to increase translational science but focuses extensively on training in the basic life sciences. Hence, it is primarily laboratory based, and its students are non-clinical, straight PhD students. Second, the Northeastern Ohio Universities Colleges of Medicine and Pharmacy (NEOUCOM) has established a joint doctoral program in biomedical sciences with Kent State University and the Cleveland Clinic's Lerner Research Institute. However, it is heavily focused on cellular biology, biochemistry, and pathobiology. Third, CWRU's Department of Epidemiology and Biostatistics offers a PhD in Epidemiology and Biostatistics, including areas of concentration in (1) health behavior and prevention; (2) health care organization, outcomes, and policy (formerly health services research); (3) genetic epidemiology and bioinformatics; and (4) biostatistics.

The proposed PhD program in Clinical Translational Science differs significantly from these existing programs in several ways. First, its core curriculum provides more extensive training in clinical research methodology as opposed to methodologies in life sciences, epidemiology, or health services research. Second, the proposed program focuses more extensively on patient-oriented research, involving disease processes and mechanisms, while the epidemiology and biostatistics program focuses more on population-level research. Third, the existing doctoral program in molecular medicine focuses primarily

on the "Discovery" phase of the clinical translational science continuum, often laboratory-based, while clinical translational science encompasses the entire continuum (Figure 1).

It should be noted that both the chair of the CWRU Department of Epidemiology and Biostatistics and the director of the PhD program on Molecular Medicine have reviewed the proposed PhD Program on Clinical Translational Science and strongly support its implementation (see Appendix 7, Letters of Support).

Given the major clinical institutions located in the immediate area – University Hospitals Case Medical Center, Case Western Reserve University, MetroHealth Medical Center, the Cleveland Clinic Foundation, and the Louis Stokes Veterans Administration Medical Center– we expect an adequate and distinct pool of potential students interested specifically in clinical translational research. Doctoral students' practicums could occur within any of these major institutions.

***4.2 Comparable Regional Programs:***
At present, there is currently no comparable doctoral program in Northeast Ohio. Beyond our region, a comparable doctoral program is offered at the University of Pittsburgh, which is also the home of a CTSA award. The Ohio State University offers a PhD in Integrated Biomedical Science (IBS) with a specialization in translational research. It has some similarities to the proposed program. However, the Ohio State University IBS program is heavily oriented to the biological life sciences and concomitant laboratory-based research, with substantially less focus on clinical research methods than the proposed doctoral program at CWRU. The University of Cincinnati was awarded a CTSA in 2009 and offers a masters degree program in clinical and translational research. However, it does not offer a doctoral program. Thus, we do not expect competition for students from programs that are located in the region.

## 5. Prospective Enrollment

The PhD program is designed for individuals who seek a doctoral-level research degree to further a career in clinical and translational research and who (1) have an advanced clinical degree (e.g., MD, DMD, MSN), or (2) are obtaining an advanced clinical degree via a dual degree program, or (3) have a Master's degree in clinical investigation or in other relevant health-related fields, and desire the greater expertise and independence in conducting clinical and translational research afforded by the PhD in Clinical Translational Science. It should be noted that these individuals will enter the program with a substantial number of post-baccalaureate credit hours earned towards the completion of their advanced degree. For individuals pursuing a dual-degree, following the CTSTP's well established, successful approach for its existing dual-degree programs, the clinical translational science and clinical degree (MD, DMD, DNP) curricula will be carefully integrated to accelerate completion of both programs and foster a synergistic training experience for students pursuing dual degrees.

***5.1 Admissions Criteria & Process:***
Admission to the program for individuals with an advanced clinical degree or graduate research degree will follow the guidelines established by the School of Graduate Studies and will be based upon assessment of an applicant's academic record, 3 letters of reference, a personal statement or essay, and an interview. The thrust of the PhD program is to prepare its students to become independent investigators in clinical and translational science. Thus, in addition to excellent previous academic and/or clinical preparation and recommendations, the PhD program is seeking students with

demonstrated clinical translational research interest and experience. To this end, applicants' personal statements must include a detailed description of their research interests and relevant research experience. Additionally, the personal statement should describe how the program of study will help them enhance their ability to achieve career goals and conduct independent, investigator-initiated clinical and translational research in their area of interest As part of the assessment, the admissions working group will consider the appropriateness of the applicant's training in mathematics and statistics, assuring that candidates for admission have suitable background for the program's statistical science courses.

Per the School of Graduate Studies requirements, international applicants will be required to submit their score on the Test of English as a Foreign Language (TOEFL) and attain at least the minimum required score established by the School of Graduate Studies (90 on internet-based version, 577 on paper version). The Graduate Record Examination will not be required: possession of an advanced degree will be considered ample evidence of the individual's ability to complete graduate-level work.

Applications will be rigorously reviewed by an admissions working group of approximately 6 members of the PhD Program Steering Committee. This working group will carefully review an applicant's previous training and research experience, transcripts, recommendations, and personal statement. Candidates will be interviewed by the working group members, and may also be interviewed by PhD program mentors and other CWRU faculty whose area of interest match that of the candidates. All faculty conducting interviews will prepare a written assessment of each candidate. At a steering committee meeting, the admissions working group will present their assessment of each candidate to the entire committee along with a recommendation (accept, decline). The steering committee will then vote on each candidate, with a majority vote necessary for admission.

For individuals seeking the combined MD-PhD degree training, the PhD Program Steering Committee will defer admissions decisions to the MSTP-CTSTP Steering Committee, which currently handles all admissions procedures for CWRU's MD-PhD program. However, to provide input into the admissions process, one representative of the clinical translational science core faculty will be added to the MSTP-CTSTP steering committee. Moreover, any combined degree applicant who seeks the PhD in Clinical Translational Science will also be assessed by at least one member of the PhD program's core faculty, and this assessment will be considered by the MSTP-CTSTP steering committee as it reviews applicants.

***5.2 Recruitment Activities:***

Although we anticipate a large number of prospective applicants will work and reside in Northeast Ohio, the program will engage a number of activities to recruit highly qualified applicants nationally and even internationally: e.g., (1) program advertisements in selected electronic and printed journals and publications; (2) recruitment at relevant scientific conferences and meetings, such as the annual Translational Science Meeting in Washington, DC; (3) mailings to other institutions. Program resources will include funds for recruitment activities.

***5.3 Projected Enrollment:***

As stated earlier, MS graduates in Clinical Research and K awardees have voiced strong interest in a PhD program were it available. Initially, we expect 4-5 students with an advanced clinical degree or existing graduate research degree to enroll per year and a constant number of clinicians who desire a

strong foundation in clinical research and translational skills will be drawn to the program. Moreover, we project 1-2 incoming students per year from the MSTP-CTSTP program. As the program evolves, we anticipate increase in student enrollment over time as individuals become aware of it.

### *5.4 Access and Retention of Underrepresented Groups:*

We expect that the part- and full-time students who currently participate in the Master's degree program in Clinical Research will broadly reflect the initial applicant pool's demographic characteristics. Sixty-two percent of the Master's students are female, and approximately 14% belong to historically underrepresented racial/ethnic groups (7% African American, 7% are Latino/Hispanic).
Also, approximately 6% of the students are international students.

Diversity is recognized as a core value of CWRU, as demonstrated by the 2009 creation of the Office of the Vice President for Inclusion, Diversity, and Equal Opportunity to spearhead activities across the university to reach out to underrepresented populations. Moreover, the longstanding Office of Multicultural Programs (OMP) has since its creation in 1971 expanded opportunities for minorities in medical education and biomedical research careers. With the OMP's assistance, the CWRU School of Medicine has one of the highest proportions of African American students of the top-ranked US medical schools. Besides admissions, the OMP also provides academic, social, emotional, and financial support to minority students.

In addition to the two university offices, the Minority Graduate Student organization was officially formed in 2005 to foster support to minority students over the course of their education at CWRU. Members of this organization consist of medical students, graduate students, as well as postdoctoral fellows and come from numerous departments in the Case School of Medicine as well as the University Hospitals Case Medical Center. The organization meets regularly to hear invited speakers from the US and abroad on research topics of interest, foster a group identity and shared values, and develop a network of supportive relationships across the university. The PhD program will work with these organizations to encourage applicants to its program as well as to develop strategies for effectively reaching out to minority populations outside CWRU.

## 6. Faculty and Facilities Available for Program and their Adequacy

### *6.1 Faculty:*

The PhD program will engage faculty from numerous schools throughout CWRU, including the School of Medicine, the Francis Payne Bolton School of Nursing, the School of Dental Medicine, the School of Law, the Weatherhead School of Management, the School of Engineering, and the Mandel School of Applied Social Sciences. Faculty from the Cleveland Clinic Lerner College of Medicine, MetroHealth Medical Center, University Hospitals, and the Louis Stokes Veterans Administration Medical Center will also be included. This highly multidisciplinary faculty will provide expertise in clinical and translational research domains, including study design, statistical and epidemiological methods, informatics, comparative and cost effectiveness, population and team sciences, leadership, innovation and entrepreneurship in clinical translational science, and the responsible conduct of research.

6.1.1 Core faculty:

The core faculty will consist of 22 members, each a highly accomplished, independent investigator with expertise and an active research program/track record of funded clinical translational science (Table 4 and Appendix 8). Biosketches of proposed core faculty members may be reviewed in Appendix 10.

**Table 4: Core Faculty Members**

| Name | Title | Institution | Field(s) of Expertise |
|---|---|---|---|
| Barnholtz-Sloan, Jill, PhD | Associate Professor, Case Comprehensive Cancer Center | SOM | Genetic/molecular epidemiology of complex disease, cancer and genetic ancestry |
| Blackstone, Eugene, MD | Professor, Surgery | CCLCM | Thoracic and cardiovascular surgery and research related to thoracic and cardiovascular surgery |
| Bonomo, Robert, MD | Professor, Molecular Biology & Microbiology | SVAMC/SOM | Infectious diseases and antimicrobial resistance |
| Cooper, Gregory, MD | Professor, Medicine | UH/SOM | Heath service research in GI malignancies |
| Dawson, Neal, MD | Professor, Medicine | MHMC/SOM | Medical decision making, survival prediction of seriously ill |
| Dolansky, Mary, PhD, RN | Associate Professor, Epidemiology & Biostatistics | SON | Cardiac rehabilitation |
| Drumm, Mitchell, PhD | Professor, Pediatrics | UH/SOM | Genetics & molecular biology, cystic fibrosis |
| Einstadter, Douglas, MD | Professor, Medicine | MHMC/SOM | Quality care for Medicaid patients, behavioral intervention for co-morbid SMI and diabetes patients, accessible health care |
| Iyengar, Sudha, PhD | Professor, Epidemiology & Biostatistics, Genetics; | SOM/UH | Genomic epidemiology of nephropathy and diabetes, and Fuchs' endothelial corneal dystrophy. |
| Keri, Ruth, PhD | Associate Professor, Pharmacology | SOM | Breast cancer genetics, signal transduction, and pharmacogenetics |
| Lederman, Michael, MD | Professor, Medicine | UH/SOM | Infectious Disease, HIV/AIDS, and innate immunity |
| Li, Li, MD, PhD | Associate Professor, Family Medicine & Community Health | UH/SOM | Public health, cancer prevention through molecular/genetic epidemiology, gene-environment interaction |
| McComsey, Grace, MD | Professor, Pediatrics and Medicine | UH | Pediatric HIV research, thymidine – NRTI associated mitochondrial dysfunction in HIV-lipodystrophy syndrome, and inflammation in HIV associated atherosclerosis and osteoporosis |
| Moore, Shirley, PhD, RN, FAAN | Professor, Nursing | SON | Behavioral intervention |
| Nelson, Suchitra, PhD | Professor, Community Dentistry | SDM/SOM | Oral health disparities in poor, minority, special needs children |
| Ransohoff, Richard, MD | Professor, Molecular Medicine | CCLCM/ SOM | Neuroinflammation research, multiple sclerosis, Alzheimer disease |
| Rudick, Richard, MD | Professor, Div. General Medicine Sciences | CCLCM/SOM | Neurology, Multiple Sclerosis |
| Sehgal, Ashwini, MD | Professor, Medicine | MHMC/SOM | Disparities research, risks and factors related to dialysis and/or kidney transplant |
| Spilsbury, James, PhD | Assistant Professor, Center for Clinical Investigation | UH/SOM | Medical anthropology, effects of socio-cultural environment on children's sleep and well-being |
| Stange, Kurt, MD, PhD | Professor, Family Medicine & Community Health, Epidemiology & Biostatistics, Sociology, and Oncology | SOM | Primary care, health services research, public health and community research, practice-based research networks, multimethod research. |
| Wang, Binchechg, PhD | Professor, Medicine | MHMC/SOM | Molecular mechanisms governing tumor cell dissemination, and drug development |
| Wang, Zhenghe, PhD | Associate Professor, Genetics & Genome Science | SOM | Genetics, colorectal cancer |
| Zhu, Xiaofeng, PhD | Professor, Epidemiology and Biostatistics | SOM | Genetics of hypertension in African Americans |

It is envisioned that the core faculty may also function as primary and co-mentors for doctoral students. Moreover, the core faculty's active programs will provide the opportunities for research practicums

taken by students, thereby assuring the students' immersion in the conduct of research throughout the course of their PhD program. It should be noted that core faculty will be approved by the PhD Program Steering Committee for hosting students for research rotations or practicums. Core faculty members will hold a secondary appointment in the Center for Clinical Investigation. Core faculty members will also participate in the monthly "Seminar in Multidisciplinary Clinical and Translational Research" as both discussants and presenters.

Qualifications to be a core faculty member consist of:

- Expertise in clinical translational investigation
- Track record of independence and resources:
    - PI on R01 (or equivalent) grants from NIH, corporations, foundations;
    - Project Leader on another individual's grant, but with distinct role and with demonstrated authority (e.g., trainee able to be first author on manuscripts under purview of Project Leader)
- Productivity in publishing in a clinical investigation domain

***6.2 Mentoring:***

Mentoring is an essential component of the PhD program, critical to both students' success in the program as well as to their overall career development. The transdisciplinary nature of clinical translational science necessitates that students receive expertise from multiple disciplines. Thus, the proposed PhD program will utilize a two-mentor model, in which a primary mentor and co-mentor will collectively provide complementary guidance and perspective to each student. In some instances, additional mentors may be added for students whose transdisciplinary research requires more diverse experience and expertise. We anticipate that core faculty may function as advisors/mentors for students admitted into the program. The advising and mentoring process is explained below:

6.2.1 Program advisor:

Upon matriculation into the program, each student will select, with oversight from the PhD Program Steering Committee, a program advisor. This individual will be a member of the core faculty and will advise students over the initial year of the program regarding selection of courses and research practicums. The program advisor will also assist students in identifying and selecting appropriate primary and co-mentors. We anticipate that program advisors may often become primary and co-mentors for their students if the advisors' research interests are aligned with those of the students. As students move through the program, each will select a primary and co-mentor based on research and career interests.

6.2.2 Primary mentor:

Each student will have a primary mentor, whose field of interest and area of expertise closely match that of the student's dissertation area. A student's primary mentor will be selected by the student and takes primary responsibility for guiding the student's PhD research and training. The primary mentor functions in the role of 'advisor' for School of Graduate Studies' purposes: e.g., approving course of study, signing necessary approval documents. The primary mentor could include faculty from any of CWRU's schools and departments, as well as individuals from the Cleveland Clinic Lerner College of Medicine, MetroHealth Medical Center, University Hospitals, Veteran's Administration Medical Center, or MetroHealth with appropriate faculty appointments.

We anticipate that most students will have selected their primary mentor by the end of program Year 1, but all students will be required to select a primary mentor by the end of Year 2.

6.2.3 Co-Mentor:
The co-mentor's role is to provide complementary guidance for the student's overall course of study, as well as career plans and overall professional development. Initially, a co-mentor will be assigned to each incoming student based on students' scientific interests and will approve the student's program of study up until the time a primary mentor is identified. Students will be permitted to change co-mentors with approval from the PhD Program Steering Committee. Like the primary mentors, co-mentors could include faculty from any of CWRU's schools and departments, as well as individuals from the Cleveland Clinic Lerner College of Medicine, MetroHealth Medical Center, University Hospitals, Louis Stokes Veteran's Administration Medical Center, or with appropriate faculty appointments. We anticipate that core faculty may also function as co-mentors for students admitted to the program.
Both the primary and co-mentor will serve on the student's dissertation committee, with one functioning as committee chairperson. Per School of Graduate Studies' regulations, the committee chairperson must be a tenured or tenure-track faculty member. A list of potential primary and co-mentors is attached (Appendix 9 and biosketches of potential mentors may be review in Appendix 10). Qualifications to be a primary or co-mentor in the PhD program consist of the following:

- Faculty appointment at CWRU (tenured or on tenure-track).
- Substantial mentoring experience, with a demonstrated track record of successfully mentoring students and trainees through doctoral programs.
- Expertise in a field or content area specific to a doctoral student's dissertation topic.
- Track record of independent funding from NIH, corporations, foundations.
- Productivity in publishing in a clinical investigation domain.

It should be noted that a faculty member could serve as both initial advisor and primary or co-mentor for a single student, depending on that student's field of interest. Each student's mentoring team, and changes to that team, will be approved by the PhD Program Steering Committee.

In cases where a student has a research topic not aligned with any of the expertise of the existing core faculty, the program steering committee will work with the student to identify faculty members across CWRU schools and departments, as well as individuals with appropriate CWRU faculty appointments based at other local institutions with the appropriate expertise to function as a mentor. These individuals will be invited to join the program's core faculty.

## 7. Need for Program Development, Institutional Support, and Plans for Meeting Requirements

Although existing CRSP faculty provide a strong foundation for the PhD program, additional faculty support will be necessary to provide coursework in the following areas:

1. Translational and Patient-Oriented Research Theory
2. Meta-analysis and Evidence Synthesis
3. Seminar in Multidisciplinary Clinical & Translational Research

In addition to faculty support, successful implementation of the PhD program will require support for a program director (15%), co-director (15%), and Program Administrator (70%). The program

administrator will maintain admission and financial records, schedule courses and other program events, track student performance, act as initial point of contact for information about the program, and publicize the program. Moreover, funds will be needed for speakers for an outside seminar series on clinical translational science, as well as funds for applicant recruitment, program publicity, program-wide activities, and attendance at national conferences on translational-science education.

**7.1 *Institutional Support for Program:***
Expertise in the three new content areas is present at CWRU and the other partners of the CTSC. To meet the instructional needs, the School of Medicine will provide necessary resources to support development and teaching if the Steering Committee must recruit instructors from outside the School of Medicine (see letter of support from Dean Davis). The School of Medicine has also committed to providing necessary salary and administrative support, as well as support for publicity, recruitment, and other necessary programmatic activities.

**7.2 *Financial Support for Students:***
Because of the nature of the program, funding for students will be varied, based on the mechanisms through which the students entered the program.

7.2.1 MSTP, K, T32, Fellowship Trainees:
Individuals who have enrolled in the PhD in Clinical Translational Science as part of the dual clinical-research program (e.g., MSTP-CTSTP) will be fully funded. It should be noted that the dean of the School of Medicine supports the current MD-PhD program with substantial institutional funds, well over $2 million per year. We anticipate that individuals who have enrolled in the program with an advanced clinical or research degree will be supported through a variety of mechanisms: e.g. KL2 or T32 training programs, individual career development (K) awards, fellowships, and research assistantships. Other additional revenue to support the PhD program may include training grants and fundraising.

7.2.2. Self-Support:
Individuals who have not received financial support outlined above but who are willing to self-support program expenses and meet admission qualifications will be admitted into the program. During their programs of study, the steering committee and core faculty will assist self-supporting students identify possible sources of support as they become available: e.g., research assistantships from new grant awards, new training grants and fellowships.

**8. Letters of Support**

The following individuals have provided letters of support for the proposed program: the Deans of the Schools of Medicine, Nursing, Dental Medicine, and Engineering; the School of Medicine's Vice Dean for Research; Chair of the Epidemiology & Biostatistics Department; Chair of the Pathology Department and Director of the MSTP-CTSTP Program, Director of the PhD program in Molecular Medicine; Co-Directors of the Cleveland CTSC Training, Education, and Career Development Core and Multidisciplinary Clinical Research Training Program (KL2). (Appendix 7)

## Appendix 1
## Current Doctoral Programs: Clinical and Translational Sciences

| | Institution | Name of PhD |
|---|---|---|
| 1 | Albert Einstein College of Medicine of Yeshiva University | Clinical Investigation |
| 2 | Cedars-Sinai Medical Center | Biomedical Science and Translational Medicine |
| 3 | Johns Hopkins University* | Clinical Investigation |
| 4 | Mayo Clinic College of Medicine | Clinical & Translational Science |
| 5 | Medical College of Wisconsin | Basic and Translational Science |
| 6 | Mount Sinai School of Medicine* | Clinical Research |
| 7 | Rockefeller University | Life Sciences |
| 8 | The Ohio State University | Integrated Biomedical Science with specialization in Translational Research |
| 9 | Tufts University | Clinical & Translational Science |
| 10 | University of Arkansas for Medical Sciences | Interdisciplinary Biomedical Sciences |
| 11 | University of California, San Francisco* | Epidemiology & Translational Science |
| 12 | University of Colorado, Denver* | Clinical Science |
| 13 | University of Iowa | Translational Biomedicine |
| 14 | University of Kentucky | Clinical & Translational Science |
| 15 | University of Massachusetts Medical School | Clinical and Population Health Research |
| 16 | University of Pittsburgh* | Clinical & Translational Science |
| 17 | University of Rochester School of Medicine and Dentistry | Translational Biomedical Science |
| 18 | University of Texas Health Science Center, San Antonio | Translational Science |
| 19 | University of Texas Medical Branch | Clinical Science |
| 20 | University of Wisconsin-Madison | Clinical Investigation |
| 21 | Virginia Commonwealth University | Clinical &Translational Sciences |
| 22 | Yale University* | Investigative Medicine |

*A “top 25” school of medicine
Source: January 2012, University of Pittsburgh CTSI Survey: Doctoral Programs for Training Future Leaders in Clinical and Translational Sciences

# Appendix 2
# NIH Definitions of Clinical and Translational Research

***Clinical Research.***

1. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies.
2. Epidemiologic and behavioral studies.
3. Outcomes research and health services research.[1]

***Translational Research***

Translational research includes two areas of translation.[2] One area of translation is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science.

Sources:
[1]http://grants.nih.gov/grants/peer/tree_glossary.pdf. [Last accessed May 3, 2012]
[2]http://grants.nih.gov/grants/guide/rfa-files/RFA-RM-07-007.html [Last accessed May 3, 2012]

# Appendix 3: Curriculum, Course Descriptions

The proposed curriculum consists of a minimum of 54 credit hours: 36 credit hours of courses (of which at least 24 hours are graded) and 18 credit hours of dissertation research.*

**REQUIRED COURSES**

| Course # | Course title | Units | Grading |
|---|---|---|---|
| **New Course** | Translational and Patient-Oriented Research Theory | 3 | Graded |
| **New Course** | Meta-analysis and Evidence Synthesis | 2 | Graded |
| CRSP 401** | Introduction to Clinical Research | (3) | Graded |
| NURS 630 | Advanced Statistics: Linear Models | 3 | Graded |
| CRSP 407 | Logistic Regression and Survival Analysis | 3 | Graded |
| CRSP 603 | Research Ethics and Regulation | 2 | Graded |
| **TOTAL GRADED** | | **16 (13)** | |
| **New Course** | Seminar in Multidisciplinary Clinical and Translational Research | 0 | P/F |
| CRSP 501 | Team Science | 1 | P/F |
| CRSP 412 | Communication in Clinical Research I – Grant Writing | 1 | P/F |
| CRSP 413 | Communication in Clinical Research II – Oral Presentations, Posters, and the Mass Media | 1 | P/F |
| **TOTAL P/F** | | **3** | |

**CORE ELECTIVES**

Students must take a minimum of 2 credit hours of courses from the list below, depending on their specific needs and mentor approval.

| | | | |
|---|---|---|---|
| CRSP 402 | Study Design and Epidemiologic Methods | 3 | Graded |
| CRSP 502 | Leadership Skills for Clinical Research Teams | 2 | Graded |
| **New Course** | Clinical Informatics | 3 | Graded |
| EPBI 450 | Clinical Trials and Intervention Studies | 3 | Graded |
| EPBI 467 | Comparative and Cost-Effectiveness Research | 2-3 | Graded |

**ELECTIVES**

Students will take electives and CRSP 601 Research Practicum to satisfy the graded and pass/fail course requirements and to advance to candidacy. These courses are selected based on students' needs and mentor approval. Any CWRU credit-bearing course may qualify. The courses could be 'field specific' or include other core elective courses not taken as part of the requirement above. The following list is for illustrative purposes:

| | | | |
|---|---|---|---|
| IBIS or other | Field specific, e.g. Immunology, Physiology, Pathology | Up to 18 | Graded |
| NURS 518 | Qualitative Nursing Research | 3 | Graded |
| SASS 614 | Models of Qualitative Research | 3 | Graded |
| CRSP 504 | Managing Research Records - A System's Approach | 2-3 | P/F |
| CRSP 510 | Health Disparities | 3 | P/F |
| CRSP 500 | Design and Analysis of Observational Studies | 3 | Graded |
| CRSP 505 | Investigating Social Determinants of Health | 2-3 | P/F |
| EPBI 400 | Statistics as Integral to the Scientific Method | 3 | P/F |
| EPBI 411 | Introduction to Health Behavior | 3 | Graded |
| CRSP 410 | Independent Study (e.g., laboratory, clinic, community based) | Variable | P/F |

**RESEARCH COMPONENT**

| | | | |
|---|---|---|---|
| CRSP 601 | Research Practicum | Variable | P/F |
| CRSP 701 | Dissertation Research | 18 | S/U |

* Per School of Graduate Studies Guidelines, programs of study for dual clinical-research degree students (e.g., MSTP-CTSTP, DMD-PhD) and for students entering with an approved master's degree may be modified to reflect credit for concurrent and/or previous coursework.
**Waived for MD/PhD students in the CTSTP program or by petition with sufficient background from previous coursework.

## Required Courses

## Domain: Multidisciplinary and Translational Perspectives

**Course Title: Translational and Patient-Oriented Research Theory NEW**
**Offered:** Fall semester
**Duration:** One semester
**Credits:** 3 graded credits
**Instructor(s):** Li Li, Kurt Stange, James Werner, other Core Faculty
**Description:** Clinical (patient-oriented) and translational science has emerged as a new scientific discipline aimed to accelerate scientific discovery into effective practice. This course provides an overview of the theoretical framework, rationale, process, methodologies, and ethics of clinical and translational research. An integral feature of this course is the participation of a transdisciplinary teaching team, whose expertise and perspective will contribute to providing real-world insights into the complexities of translational and patient-oriented research.

**Course Title: Seminar in Multidisciplinary Clinical and Translational Research NEW**
**Offered:** Every semester
**Duration:** Throughout a student's program of study
**Credits:** 0 credits
**Instructor(s):** Li Li, James Spilsbury, other Core Faculty
**Description:** This seminar occurs every semester (once per month) and will consist of a presentation with discussion of a research study or topic involving clinical and translational science. The seminar will introduce students to the processes and challenges of multidisciplinary clinical/translational science, through which discoveries in the laboratory or in early clinical studies are transformed into interventions, treatments, and ultimately, best practices and policies on national and international levels. The course will use a case-based approach. Examination of active projects at Case Western Reserve University, Cleveland Clinic Foundation, the MetroHealth Medical Center, University Hospitals Case Medical Center, and the Louis Stokes Veterans Administration Medical Center will enable students to investigate clinical translational science in action.

## Domain: Research Methods

**Course Title: Meta-Analysis and Evidence Synthesis NEW**
**Offered:** Spring semester
**Duration:** One semester
**Credits:** 2 graded credits
**Instructor(s):** Core Faculty
**Description:** Becoming a successful investigator in clinical translational science requires the ability to synthesize scientific information in one's field of interest. Moreover, the growing use of systematic methods for the synthesis of evidence to answer clinical and translational research questions highlights the need for health-care professionals to understand and critique these techniques. This course provides foundational training in the purposes and methods of meta-analysis and other techniques currently utilized to synthesize scientific evidence. The course is designed to support students' research and could lead to manuscripts that are publishable.

**CRSP 401**
**Course Title: Introduction to Clinical Research**
**Offered:** Every Summer
**Duration:** 3 weeks, 5 days per week
**Credits:** 3 graded credits
**Instructor(s):** D. Einstadter
**Description:** This course is designed to familiarize physician-scientists and other health professionals with the language and concepts of clinical investigation and statistical computing, as well as provide opportunities for problem-solving and practical application of the information derived from the lectures. The material is organized along the internal logic of the research process, beginning with mechanism of choosing a research question and moving into the information needed to design the protocol, implement it, analyze the findings, and draw and disseminate the conclusion(s).

**CRSP 402**
**Course Title: Study Design and Epidemiologic Methods**
**Offered:** Every Fall
**Duration:** One semester
**Credits:** 3 graded credits
**Instructor(s):** D. Einstadter
**Description:** This course covers the methods used in the conduct of epidemiologic and health services research. The course begins with how to quantify disease frequency and compare it across populations, often as a way to generate hypothesis about what factors may cause a given condition. The course will introduce methodological issues that need to be considered in the design and conduct of epidemiologic studies, including classification of disease and exposure status, types and consequences of misclassification, effect modification and related concepts. Additional sessions will focus on the control of confounding and on the three main types of study designs: randomized trials, cohort studies, and case-control studies. Topics include: Measures of disease frequency, measures of effect, classification and misclassification, cross-sectional studies, case-control studies, cohort studies, randomized controlled trials, confounding, bias, effect modification and select topics.

**EPBI 450**
**Course Title: Clinical Trials and Intervention Studies**
**Offered:** Every Spring
**Duration:** One semester
**Credits:** 3 graded credits
**Instructor(s):** M. Schluchter
**Description:** Issues in the design, organization, and operation of randomized, controlled clinical trials and intervention studies. Emphasis on long-term multicenter trials. Topics include legal and ethical issues in the design; application of concepts of controls, masking, and randomization; steps required for quality data collection; monitoring for evidence of adverse or beneficial treatment effects; elements of organizational structure; sample size calculations and data analysis procedures; and common mistakes.

## Domain: Computing & Informatics

**Course Title: Clinical Informatics NEW**
**Offered:** Fall Semester
**Duration:** One Semester
**Credits:** 3 graded credits
**Instructor:** To Be Determined
**Description:** This course provides a comprehensive overview of the current status of information systems in health. Coursework emphasizes the modeling of concepts and of processes to build information systems that process clinical and other health-related data in useful ways. The creation and adaptation of specific algorithms to assist in the automation of complex application tasks will also be covered. Specific session topics will include information architectures, public health and clinical applications, information retrieval, security and other key standards. The course will use examples from real-world practice and experience.

## Domain: Statistics

**NURS 630**
**Course Title: Linear Models**
**Offered:** Every Fall
**Duration:** One semester
**Credits:** 3 graded credits
**Instructor:** C. Burant
**Description:** This course is focused on advanced procedures for data analysis and statistical inference in health research. The course is devoted to discussion of linear models, including simple and multiple regression, logistic regression, and application to study design. The role of assumptions and theory in guiding the analysis plan is emphasized through lecture, readings, and critical evaluation of published research in the student's area of interest.

**CRSP 407**
**Course Title**: Statistical Methods: Logistic Regression & Survival Analysis
**Offered:** Every Spring
**Duration:** One semester
**Credits:** 3 graded credits
**Instructor:** D. Babineau
**Description:** This course introduces two commonly used statistical modeling techniques found in the medical, epidemiologic, and public health research fields; logistic regression and survival analysis. The course emphasizes summarizing and analyzing binary and time-to-event outcomes. The focus is on establishing a foundation for when and how to use these modeling techniques as well as an understanding of interpreting results from analyses. Two course projects will involve problem specification, data collection, analysis, and presentation. Students will use statistical software extensively and will be exposed to output from SAS. Planned topics include contingency tables, logistic regression models and diagnostic measure, analyzing ordinal outcomes, estimating of the survival curve, Cox proportional hazard regression models and diagnostic measures, and sample size estimation.

## Domain: Professional Development & Conduct

**CRSP 501**
**Course Title: Team Science – Working in Interdisciplinary Research Teams**
**Offered:** Every Fall
**Duration:** 3 days
**Credits:** 1 credit, pass/fail
**Instructor**: S. Moore
**Description:** This course will assist learners to understand why and how different professional disciplines, each representing a body of scientific knowledge, must work together to develop and disseminate knowledge. Learners will develop a set of skills specific to being an effective member and leader of an interdisciplinary research team, including working with different value and knowledge sets across disciplines, running effective meetings, managing conflict, giving and receiving feedback, and group decision-making techniques. Using the small group seminar approach and case studies, learners will practice individual and group communication, reflective and self-assessment techniques, and engage in experiential learning activities regarding effective teamwork in interdisciplinary research teams. Techniques to increase group creativity and frame new insights will be discussed.

**CRSP 502**
**Course Title: Leadership Skills for Clinical Research Teams**
**Offered:** Every Spring
**Duration:** One semester
**Credits:** 2 graded credits
**Instructor:** T. Lingham
**Description:** Successful multidisciplinary research in the 21st century requires that investigators learn skills and attitudes to lead and work effectively in teams. This semester-long course uses methods of Intentional Change Theory to engage students in a series of self-assessment activities to gain insights into their behavior and its effect on others, and to learn a set of skills to be an effective member and leader of an interdisciplinary research team. Such skills include working with different values and knowledge sets across disciplines, running effective meetings, conflict management, giving and receiving feedback, and group decision making techniques. This small group series of sessions includes case-based learning and sequentially introduces three sets of sessions: at the conclusion of the first set, students develop a Personal Vision essay; the second set, a Personal Balance Sheet, and in the third set, a Personal Learning Plan, including components leading to effective leadership skills and skill building in teamwork. As an example, the focus of a case study in developing a "program project"-type grant proposal highlights the effect of disciplinary-specific language on multidisciplinary research team functioning, and the need to create a "common language" for team use.

**CRSP 412 and 413**
**Course Title: Communication in Clinical Research, Parts I & II**
**Offered:** 412 Every Spring, 413 Every Fall
**Duration:** Two semesters
**Credits:** 2 credits, pass/fail
**Instructor:** J. Spilsbury

**Description:** Sound research only has strong impact when communicated effectively to various types of readers, listeners, and viewers. This requires knowing what receivers need and expect. CRSP 412 focuses on writing grant proposals in the NIH style. CRSP 413 deals with preparing and delivering oral, and poster, presentations, including modern statistical graphics and tables. The course also covers how clinical translational scientist's best interact with the mass media.

**CRSP 603**
**Course Title: Research Ethics and Regulation: Emerging Issues and Ongoing Challenges**
**Offered:** Every Fall
**Duration:** One semester
**Credits:** 2 graded credits
**Instructor:** J. Berg
**Description:** This course is designed to introduce students to the ethical, policy, and legal issues raised by research involving human subjects. It is intended for law students, post-doctoral trainees in health-related disciplines and other students in relevant fields. Topics include (among others): regulation and monitoring of research; research in third-world nations; research with special populations; stem cell and genetic research; research to combat bioterrorism; scientific misconduct; conflicts of interest; commercialization and intellectual property; and the use of deception and placebos. Course will meet once per week for 2 hours throughout the semester. Grades will be given based on class participation and a series of group projects and individual short writing assignments.

## Possible Elective Courses

## Domain: Multidisciplinary and Translational Perspectives

**CRSP 503**
**Course Title: Innovation and Entrepreneurship**
**Offered:** Every Summer
**Duration:** 2 days/6.5 hrs per day
**Credits:** 1 graded credit
**Instructor:** S. Shane
**Description:** The purpose of this course is to acquaint and ultimately engage clinical researchers with the business of innovation and entrepreneurship. Goals include: (1) to provide researchers with many of the skills that they would need to translate academic research into commercial uses; (2) to sensitize clinical researchers to the goals of the business community and facilitate their ability to work with the private sector on technology development; and (3) to make clinical researchers aware of the processes of academic technology development and transfer. Sessions consist of a lecture and case discussion facilitated by one of the co-directors. Many sessions include members of the business community as lecturers. As an example, students discuss successful commercial ventures with individuals in the regional biotechnology industry; they also will have opportunities to discuss goals and strategies with local venture capitalists. Student products include a team-generated business plan in which they apply their new knowledge about commercialization of scientific discoveries.

**EPBI 510**
**Course Title: Health Disparities**
**Offered:** Every Fall
**Duration:** One semester long
**Credits:** 3 graded credits
**Instructor:** M. Petrick
**Description:** This course aims to provide theoretical and application tools for students from many disciplinary backgrounds to conduct research and develop interventions to reduce health disparities. The course will be situated contextually within the historical record of the United States, reviewing social, political, economic, cultural, legal, and ethical theories related to disparities in general, with a central focus on health disparities. Several frameworks regarding health disparities will be used for investigating and discussing the empirical evidence on disparities, research and outcome measurement issues, policy and policy formation concerns, and intervention practices. While racial/ethnic disparities in health and health outcomes will be an important focus of this course, disparities among other subgroups (e.g., the poor, women, uninsured, disabled, and non-English speaking populations) will also be included and discussed. Students will be expected to develop a research proposal (observational, clinical, and/or intervention) rooted in their disciplinary background that will incorporate materials from the

various perspectives presented throughout the course, with the objective of developing and reinforcing a more comprehensive approach to current practices within their fields.

**EPBI 411**
**Course Title: Introduction to Behavioral Health**
**Offered:** Every Spring
**Duration:** One semester
**Credits:** 3 graded credits
**Instructor:** E. Trapl
**Description:** Using a biopsychosocial perspective, the course provides an overview of the measurement and modeling of behavioral, social, psychological, and environmental factors related to disease prevention, disease management, and health promotion.

## Domain: Research Methods

**CRSP 500**
**Course Title: Design and Analysis of Observational Studies**
**Offered:** Every Spring
**Duration:** One semester
**Credits:** 3 graded credits
**Instructor:** T. Love
**Description:** An observational study is an empirical investigation of treatments, policies or exposures and the effects that they cause, but it differs from an experiment because the investigator cannot control treatment assignment. We introduce design, data collection and analysis methods appropriate for clinical investigators, preparing students to design and interpret their own studies, and those of others in their field. Technical formalities will be minimized, and the presentations will focus on the practical application of methodologies and strategies. A course project involves the completion of an observational study, and substantial use of statistical software. Topics include randomized experiments and how they differ from observational studies, planning and design for observational studies, adjustments for overt bias, sensitivity analysis, methods for detecting hidden bias, and propensity methods for selection bias adjustment, including multivariate matching, stratification, weighting, and regression adjustments, along with some comparison of these methods with instrumental variables approaches.

**CRSP 505**
**Course Title: Investigating Social Determinants of Health**
**Offered:** Every Summer
**Duration:** 3 days
**Credits:** 2-3 credits, pass/fail
**Instructor:** J. Spilsbury
**Description:** The biopsychosocial model highlights the inter-related roles that biological, psychological, and social factors play in health and illness. This course is geared towards clinicians and other health professionals who would like to incorporate aspects of the "social context" in their research. The course will examine the conceptualization, measurement, and effects of several key socio-cultural determinants of health and illness. Sample studies that incorporate social determinants of health will be reviewed. The course will also consider strategies and techniques to conduct clinical research involving social factors in socially and ethnically diverse settings. Students will be encouraged to develop a prototypical study design to incorporate social determinants in their research.

**EPBI 434**
**Course Title: Community-Engaged Research: Principles, Methods, and Applications**
**Offered:** Spring
**Duration:** One semester
**Credits:** 3 graded credits
**Instructor:** E. Borawski
**Description:** Community-engaged research is a partnership approach to research that equitably involves community members, organization representatives, and academic researchers in all aspects of the research process. This course is designed to provide an overview of community-based participatory research (CBPR) and will familiarize students with the core principles, concepts and methods as it applies to health-related outcomes. Using a class format that includes lectures,

discussion, case studies, small group exercises, and fieldwork projects, we will examine and discuss key methodological considerations in each phase of the research process from partnering with communities to planning for research, data gathering, and dissemination of results. Examples of applications in both public health and clinical settings will be highlighted.

**EPBI 467**
**Course Title: Comparative and Cost Effectiveness in Health Care**
**Offered:** Every Summer
**Duration:** 5 days
**Credits:** 1-3 graded credits
**Instructor:** M. Singer
**Description:** Comparative effectiveness research is a cornerstone of healthcare reform. It holds the promise of improved health outcomes and cost containment. This course is presented in a convenient 5-day intensive format in June. There are reading assignments due prior to the 1st session. Module A, Days 1-2: Overview of comparative effectiveness research (CER) from a wide array of perspectives: individual provider, institution, insurer, patient, government, and society. Legal, ethical and social issues, as well as implications for population and public health, including health disparities will also be a component. Module B, Day 3: Introduction to the various methods, and their strengths, weaknesses and limitations. How to read and understand CER papers. Module C, Days 4-5: Cost-Effectiveness Analysis. This will cover costing, cost analysis, clinical decision analysis, clinical decision analysis, quality of life and cost-effectiveness model. The full 3-credit course is for taking all 3 modules. Modules A or C can be taken alone for 1 credit. Modules A and B or Modules B and C can be taken together for a total of 2 credits. Module B cannot be taken alone. If taking for 2 or 3 credits, some combination of term paper, project and/or exam will be due 30 days later.

**EPBI 474**
**Course Title: Principles of Practice-Based Network Research**
**Offered:** Fall
**Duration:** One Semester
**Credits:** 3 graded credits
**Instructor:** K. Stange and J. Werner
**Description:** Practice-based research networks (PBRNs) are organizations of community-based healthcare practices that engage in clinical research and practice improvement. In the U.S., there are more than 100 of these dynamic, collaborative organizations that enable the translation of research into practice and practice into research. They also frequently engage in developing and refining methods to improve healthcare quality. This course is designed to provide students with a foundation in PBRN methods and principles, including: introduction to PBRNs, methods for collaborating with community practices, PBRN-building strategies, PBRN data collections methods, statistical issues in network research, community-based participatory research, human subjects' protection issues in PBRNs, quality improvement research in PBRNs, funding for PBRN research, and writing PBRN research findings for publication. Each 2.5 hour class session will feature a lecture followed by a discussion of readings from the literature. Students will develop a PBRN research or quality improvement proposal during the semester.

**NURS 518**
**Course Title: Qualitative Nursing Research**
**Offered:** Every Spring
**Duration:** One semester
**Credits:** 3 graded credits
**Instructor:** C. Manacci
**Description:** This course is a study of qualitative research approaches directed toward the development of nursing knowledge. This course will include methods and issues in data collection, analysis, and critique of research findings. It will focus on the philosophical and epistemological foundations of qualitative research, present an overview of various methodological approaches, examine in depth the criteria for rigor, and analyze ethical issues in qualitative methodologies.

**SASS 614**
**Course Title: Models of Qualitative Research**
**Offered:** Every Spring
**Duration:** One semester
**Credits:** 3 graded credits

**Instructor:** A. Santiago
**Description:** This course introduces students to the principles, approaches, methods, and analytical techniques utilized when conducting qualitative research in the social sciences. Five models of qualitative research design and methodology are studied, including narrative analysis, case study, ethnography, and grounded theory and phenomenology. This course is designed to provide students with the tools to critically evaluate as well as to enhance the academic rigor or "quality" of qualitative data.

## Domain: Computing and Informatics

**CRSP 406**
**Course Title: Introduction to R Programming**
**Offered:** Every Summer
**Duration:** One month
**Credits:** 2 credits, pass/fail
**Instructor:** S. Lewis
**Description:** This course will provide students with an introduction to R. Major topics will include session management, reading and writing data, R data objects, combining and restructuring data frames, data aggregation, statistical functions, and R traditional graphics. Students will learn R programming conventions, how to troubleshoot R code, as well as how to interpret R output. Small research datasets will be used in class examples, computer laboratory sessions, and homework assignments. Each session will include a lecture immediately followed by a computer lab to reinforce the concepts introduced. Students will work in small groups or individually.

**CRSP 504**
**Course Title: Managing Research Records - A System's Approach**
**Offered:** Every Spring
**Duration:** One semester
**Credits:** 2-3 credits, pass/fail
**Instructor:** C. Apperson-Hansen
**Description:** This course will provide an approach to managing data for research studies. Major topics will include a discussion of a research study system including database design and development, data management, and clinical data management; how to evaluate the data needs of a study including the impact of required regulations; summary of key regulations; the role of the data manager including protocol review, development of a data management plan, CRF design, data cleaning, locking studies and ensuring best practices. Each session will include a lecture, class discussion, and student presentation.

## Domain: Statistics

**EPBI 400**
**Course Title: Statistics as Integral to the Scientific Method**
**Offered**: Every semester
**Duration:** One semester
**Credits:** 3 credits, pass/fail
**Instructor:** R. O'Brien
**Description:** Modern statistical thinking and methods and how they are integral to the scientific method. Designing studies (statistical planning), analyzing data, interpreting results, and presenting statistical material effectively and truthfully, often via graphics far more informative and truthful than those still commonly appearing in scientific publications. Mathematically, only ordinary algebra is needed to understand the key statistical concepts and models. Extensive use of R (via RStudio), an open-source (free) system that runs under Windows, Mac OS, and Linux, and is now a standard environment used widely throughout the scientific world. All R programs used in the lectures are provided to students, so they can modify them to conduct their own analyses. However, this course does not focus on the technical details underlying those computations. Almost all student work is based on using R to apply the methods to real/realistic problems in their own research areas and then develop and give oral presentations. This includes learning that sticks.

## Domain: Professional Development & Conduct

**IBMS 500**
**Course Title: Being a Professional Scientist**
**Offered:** Every Spring
**Duration:** One semester
**Credits:** 1 credit, pass/fail
**Instructor:** N. Deming
**Description:** The goal of this course is to provide graduate students with an opportunity to think through their professional ethical commitments before they are tested on the basis of the scientific community's accumulated experience with the issues. Students will be brought up-to-date on the current state of professional policy and federal regulations in this area and, through case studies, will discuss practical strategies for preventing and resolving ethical problems in their own work. The course is designed to meet the requirements for instruction about responsible conduct in research for BSTP and MSTP students supported through NIH/ADAMHA institutional training grant programs at CWRU.

## Appendix 4: Sample Program of Study
## for Matriculant with Advanced Clinical Degree but No Previous Research Experience

| Curriculum Components | # of credits |
|---|---|
| Exemptions allowed for previous coursework | 0 |
| Required coursework* | 19 (16 are graded) |
| Core Electives | 2 (6 are graded) |
| Electives, independent study, pre-dissertation research | 11 (2 need to be graded) |
| PhD Dissertation 701 | 18 |
| Total minimum # of credits | 54 |

| Semester & Year | Course | Title | Credits | Graded or P/F |
|---|---|---|---|---|
| **Year 1 Summer** | CRSP 401* | Introduction to Clinical Research | 3 | Graded |
| | RSCH 750 | Pre-dissertation research | 0 | P/F |
| | | Total | **3** | |
| **Year 1 Fall** | CRSP TBD* | Translational & Patient-Oriented Research Theory (new) | 3 | Graded |
| | CRSP 402 | Study Design and Epidemiologic Methods | 3 | Graded |
| | NURS 630* | Linear Models | 3 | Graded |
| | CRSP TBD* | Seminar in Multidisciplinary C & T Research (new) | 0 | P/F |
| | | Total | **9** | |
| **Year 1 Spring** | CRSP 407* | Logistic Regression & Survival Analysis | 3 | Graded |
| | CRSP 412* | Communication in Clinical Research Part I | 1 | P/F |
| | CRSP TBD * | Meta-Analysis and Evidence Synthesis (new) | 2 | Graded |
| | CRSP 601 | Research Practicum (and/or electives) | 3 | P/F or graded |
| | CRSP TBD* | Seminar in Multidisciplinary C & T Research (new) | 0 | P/F |
| | | Total | **9** | |
| **Year 2 Summer** | RSCH 750 | Pre-dissertation research | 0 | P/F |
| | | Total | **0** | |
| **Year 2 Fall** | CRSP 603* | Research Ethics & Regulation | 2 | Graded |
| | CRSP 501* | Team Science | 1 | P/F |
| | CRSP TBD | Clinical Informatics (new) | 3 | Graded |
| | CRSP 601 | Research Practicum (and/or electives) | 2 | P/F |
| | CRSP 413* | Communication in Clinical Research Part II | 1 | P/F |
| | CRSP TBD* | Seminar in Multidisciplinary C & T Research (new) | 0 | P/F |
| | | Total | **9** | |
| **Year 2 Spring** | CRSP 601 | Research Practicum (and/or electives) | 6 | P/F or graded |
| | CRSP TBD* | Seminar in Multidisciplinary C & T Research (new) | 0 | P/F |
| | | Total | **6** | |
| | **Examination & Advancement to Candidacy** | | | |
| **Total coursework** | | | **36** | **24 graded** |
| **Year 3 Fall** | CRSP 701 | PhD Dissertation | 4 | S/U |
| | CRSP TBD* | Seminar in Multidisciplinary C & T Research (new) | 0 | P/F |
| **Year 3 Spring** | CRSP 701 | PhD Dissertation | 5 | S/U |
| | CRSP TBD* | Seminar in Multidisciplinary C & T Research (new) | 0 | P/F |
| **Year 4 Fall** | CRSP 701 | PhD Dissertation | 4 | S/U |
| | CRSP TBD | Seminar in Multidisciplinary C & T Research (new) | 0 | P/F |
| **Year 4 Spring** | CRSP 701 | PhD Dissertation **(Defense)** | 5 | S/U |
| | CRSP TBD | Seminar in Multidisciplinary C & T Research (new) | 0 | P/F |
| **Total Dissertation** | | | **18** | |

* Required courses.

## Appendix 5: Sample Program of Study for Matriculant with a Relevant Master's Degree (e.g., MS Clinical Research)

| **Curriculum Components** | **# of credits** |
|---|---|
| Exemptions allowed for prior coursework | Up to 18 |
| Required coursework* | 5 (5 are graded) |
| Electives, independent study, pre-dissertation research | 13 (7 must be graded) |
| PhD Dissertation 701 | 18 |
| Total minimum # of credits | 54 |

| Semester & Year | Course | Title | Credits | Graded or P/F |
|---|---|---|---|---|
| **Year 1 Summer** | RSCH 750 | Pre-dissertation research | 0 | P/F |
| | | Total | **0** | |
| **Year 1 Fall** | CRSP TBD * | Translational and Patient-Oriented Research Theory (new) | 3 | Graded |
| | CRSP 601 | Research Practicum (and/or electives) | 6 | Graded |
| | CRSP TBD* | Seminar in Multidisciplinary C & T Research (new) | 0 | P/F |
| | | Total | **9** | |
| **Year 1 Spring** | CRSP TBD * | Meta-Analysis and Evidence Synthesis (new) | 2 | Graded |
| | CRSP 601 | Research Practicum (and/or electives) | 7 | P/F or graded |
| | CRSP TBD* | Seminar in Multidisciplinary C & T Research (new) | 0 | P/F |
| | | Total | **9** | |
| **Total coursework** | | | **18** | **12 graded** |
| **Year 2 Fall** | CRSP 701 | PhD Dissertation | 4 | S/U |
| | CRSP TBD* | Seminar in Multidisciplinary C & T Research (new) | 0 | P/F |
| | **Examination & Advancement to Candidacy** | | | |
| **Year 2 Spring** | CRSP 701 | PhD Dissertation | 5 | S/U |
| | CRSP TBD* | Seminar in Multidisciplinary C & T Research (new) | 0 | P/F |
| **Year 3 Fall** | CRSP 701 | PhD Dissertation | 4 | S/U |
| | CRSP TBD | Seminar in Multidisciplinary C & T Research (new) | 0 | P/F |
| | | | | |
| **Year 3 Spring** | CRSP 701 | PhD Dissertation **(Defense)** | 5 | |
| | CRSP TBD | Seminar in Multidisciplinary C & T Research (new) | 0 | P/F |
| **Total Dissertation** | | | **18** | |

* Required courses. Note that students entering the program with a MS in clinical research or related health field may be exempted from required courses as appropriate and substitute them with elective coursework. Per School of Graduate Studies' requirements, they must complete a minimum of 18 credit hours of coursework, of which 12 credit hours must be graded.

## Appendix 6: Sample Program of Study
## MSTP-CTSTP Program (Combined MD/PhD)

| Curriculum Components | # of credits |
|---|---|
| Research Rotations | 6 |
| Graduate credits for portions of Medical School (IBIS courses) | 18 (18 are graded) |
| Required PhD coursework* | 16 (13 are graded) |
| Core Electives | 2 |
| Electives or Research Practicums 601 | 9 |
| PhD Dissertation 701 | 18 |
| **Total # of credits** | **69** |

| Semester & Year | Course | Title | Credits | Graded or P/F |
|---|---|---|---|---|
| Year 1 Summer | MSTP 400 | Research rotation[1] | 0 | P/F |
| Year 1 Fall | IBIS 401 | Integrated Biological Sciences I | 4 | G |
| | IBIS 411 | Clinical Science I | 2 | G |
| | MSTP 400 | Research Rotation[1] | 3 | P/F |
| | | Total | **9** | |
| Year 1 Spring | IBIS 402 | Integrated Biological Sciences II | 4 | G |
| | IBIS 412 | Clinical Science II | 2 | G |
| | MSTP 400 | Research Rotation[1] | 3 | P/F |
| | | Total | **9** | |
| Year 2 Summer | MSTP 400 | Research rotation[1] (one or two labs/rotations) | 0 | P/F |
| Year 2 Fall | IBIS 403 | Integrated Biological Sciences III | 4 | G |
| | IBIS 413 | Clinical Science III | 2 | G |
| | CRSP TBD* | Translational and Patient Oriented Research Theory (new)[2] | 3 | G |
| | CRSP TBD* | Seminar in Multidisciplinary Clinical & Translational Research (new) | 0 | P/F |
| | | Total | **9** | |
| Year 2 Spring | CRSP 601 | Research Practicum (and/or electives) | 7 | P/F |
| | CRSP TBD* | Meta-analysis and Evidence Synthesis | 2 | G |
| | CRSP TBD* | Seminar in Multidisciplinary Clinical & Translational Research (new) | 0 | |
| | | Finish Medical School Y2 and complete USMLE Part 1 | | |
| | | Total | **9** | |
| Year 3 Summer | RSCH 750 | | 0 | P/F |
| Year 3 Fall | CRSP 501* | Team Science | 1 | P/F |
| | NURS 630* | Linear Models | 3 | G |
| | CRSP 402 | Study Design and Epidemiologic Methods or other core elective | 3 | G |
| | CRSP 603* | Research Ethics and Regulation | 2 | G |
| | CRSP TBD* | Seminar in Multidisciplinary Clinical & Translational Research (new) | 0 | |
| | | Total | **9** | |
| Year 3 Spring[3] | CRSP 601 | Research Practicum (and/or electives) | 5 | P/F or G |
| | CRSP 407* | Logistic Regression and Survival Analysis | 3 | G |
| | CRSP 412* | Communication in Clinical Research, Part 1 | 1 | P/F |

| | | | | |
|---|---|---|---|---|
| | CRSP TBD* | Seminar in Multidisciplinary Clinical & Translational Research (new) | 0 | |
| | | Total | **9** | |
| Complete qualifying examination and thesis proposal by summer following Year 3 | | | | |
| Summer Year 4 | RSCH 750 | | 0 | |
| Year 4 Fall[4] | CRSP 701 | PhD Dissertation | 6 | S/U |
| | CRSP TBD* | Seminar in Multidisciplinary Clinical & Translational Research (new) | 0 | |
| | CRSP 413* | Communication in Clinical Research, Part II | 1 | P/F |
| | | Total | **7** | |
| Year 4 Spring | CRSP 701 | PhD Dissertation | 6 | S/U |
| | CRSP TBD* | Seminar in Multidisciplinary Clinical & Translational Research (new) | 0 | |
| | | Total | 6 | |
| Year 5 Fall | CRSP 701 | PhD Dissertation | 4 | S/U |
| | CRSP TBD* | Seminar in Multidisciplinary Clinical & Translational Research (new) | 0 | |
| | | Total | **4** | |
| Year 5 Spring | CRSP 701 | PhD Dissertation (Defense) | 2 | S/U |
| | CRSP TBD* | Seminar in Multidisciplinary Clinical & Translational Research (new) | 0 | |
| | | Total | **2** | |
| | | Total Credits for PhD Program | | |
| Additional PhD phase semesters if necessary- schedule as for Year 5 | | | | |
| All PhD requirements must be completed before starting Med Year 3 | | | | |
| Year 6 | 3rd year Medical School Curriculum | | | |
| Year 7 | 4th year Medical School Curriculum | | | |

* Required Courses for PhD. MD/PhD students will be exempt from taking CRSP 401because this content is covered in Block 1 of the MD Curriculum.

[1]A minimum of 3 research rotations is required.
[2]Research Rotations and Theory course and seminar could be swapped with a research rotation if advantageous to the student.
[3]Spring electives could include (but are not limited to): CRSP 505 Design and Analysis of Observational Studies (3); CRSP 504 Managing Research Records – A System's Approach (2-3); CRSP 505 Investigating Social Determinants of Health (2-3); EPBI 411 Introduction to Behavioral Health (3).
[4]Graduate school regulations allow for students to take coursework following their advancement to candidacy. The specific course(s) taken would depend on an individual student's program.

# Appendix 7
# Letters of Support

The following individuals have provided letters of support for the proposed program: the Deans of the Schools of Medicine, Nursing, Dental Medicine, and Engineering; Vice Dean of Research; Chairs of the Epidemiology & Biostatistics and Bioethics Departments, Chair of Pathology Department and Director of the MSTP-CTSTP Program, Director of the PhD program in Molecular Medicine; Director of the Cleveland CTSC Training, Education, and Career Development Core; and Co-Directors of the Multidisciplinary Clinical Research Training Program (KL2).

1. Pamela Davis, MD, PhD., Dean of the CWRU School of Medicine, Vice President for Medical Affairs
2. Mary E. Kerr, PhD, RN, FAAN, Dean of the CWRU Frances Payne Bolton School of Nursing
3. Jerold Goldberg, DDS, Dean of the CWRU School of Dental Medicine
4. Jeffrey Duerk, PhD, Dean of the CWRU School of Engineering
5. Mark R. Chance, MD, PhD, Vice Dean of Research, CWRU School of Medicine
6. Cliff Harding, MD, PhD, Kahn Professor and Chair of the Department of Pathology, Director of the CWRU Medical Scientist Training Program (MSTP), Director of the Clinical and Translational Scientist Training Program (CTSTP)
7. Paul E. DiCorletti, PhD, Sherwin-Page Chair, Lerner Research Institute, Cleveland Clinic, Chair of the Department of Molecular Medicine
8. Robert D. Elston, PhD, Chair of the Department of Epidemiology & Biostatistics
9. Richard A. Rudick, MD, Co-Principal Investigator, Clinical Translational Science Award, Co-Director, Cleveland CTSC Training, Education, and Career Development Core and Multidisciplinary Clinical Research Training Program (KL2)
10. Shirley M. Moore, PhD, RN, FAAN, Edward J. and Louise Mellen Professor of Nursing and Associate Dean of Research at CWRU's Frances Payne Bolton School of Nursing

Pamela B. Davis, M.D., Ph.D.
Dean
Vice President for Academic Affairs

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May 23, 2013

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James Spilsbury, Ph.D., M.P.H.
Assistant Professor & Director
Academic Development Core, Center for Clinical Investigation
Case School of Medicine
2103 Cornell Rd., Room 6127
Cleveland, OH 44106-7291

Dear Drs. Li and Spilsbury:

I write this letter to express my strong support for the proposed Ph.D. program in Clinical Translational Science Clinical Translational Science has recently emerged as a distinct discipline to accelerate the translation of scientific discovery into effective clinical practice and policy. Although this discipline clearly relates to other scientific fields, Clinical Translational Science has its own theoretical framework and methodologies, and the proposed program will complement existing PhD programs available at CWRU. By providing this program, our institution will join the efforts of over 20 other universities nationwide to train a new generation of clinical investigators to make significant clinical discoveries and move these discoveries into practice and policy.

I understand that this program will require administrative support of about 0.7FTE at equilibrium which will be provided by the CRSP administrator, as well as salary support for you as program director and associate director. Moreover, for the courses to be taught by faculty outside the School of Medicine, some salary support beyond that collected from tuition may be necessary. We will be able to provide all of this support for the program. I believe your document details expectations for stipend and tuition support for the students from various sources depending on the origin of the students. Nevertheless, I would like to highlight here the fact that SOM currently provides over $3,000,000 per year to support unfunded scholarship, stipend, student support, and administrative support for the Medical Scientist Training Program (MSTP). A portion of this financial commitment will, in effect, be used to support those dual degree students who choose Clinical Translational Science as their PhD option in the MSTP.

In summary, the Ph.D. program in Clinical Translational Science is an invaluable addition to the educational programs offered by our university. I enthusiastically support this proposal and am eager to see it implemented.

Sincerely,

Pamela B. Davis, M.D., Ph.D.

SCHOOL OF MEDICINE
CASE WESTERN RESERVE UNIVERSITY

FRANCES PAYNE BOLTON
SCHOOL OF NURSING
CASE WESTERN RESERVE
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Li Li, MD, PhD
James Spilsbury, PhD

May 14, 2013

RE: Proposal for PhD in Clinical Translational Sciences

Dear Drs. Li and Spilsbury:

It is my pleasure to endorse the proposed PhD program in Clinical Translational Science. The field of clinical translational science is an important focus of research to improve the health of society. I expect that many health professionals will seek this degree as preparation for their research careers. Research preparation with a focus in clinical translational science will assist clinician scientists to function in and lead the multidisciplinary, translational research teams of the future to address complex health problems.

The proposed PhD program in Clinical Translational Science will provide an important education dimension for the CWRU Clinical and Translational Sciences Collaborative, which has as one of its aims to design and support the research infrastructure needs for the advancement of translational research. The competencies of the clinical translational researcher have been clearly defined over the past six years and now form the basis for the CWRU KL2 postdoctoral training program in clinical translational research. The propose PhD program is an important component in the training pipeline for clinical translational researchers.

The Frances Payne Bolton School of Nursing has been actively involved in the development of the training programs in clinical translational science at CWRU and supports the proposed PhD program in Clinical Translational Science as essential to continue development of this new area of science.

Sincerely,

Mary E. Kerr

Mary E. Kerr, PhD, RN, FAAN
Dean and May L. Wykle Endowed Professor

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April 8, 2013

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Dear Drs. Li and Spilsbury:

I would like to convey my enthusiastic support for the proposed PhD program in Clinical Translational Science. Clinical Translational Science is an emerging scientific field of great importance to dental medicine, and I am pleased that CWRU proposes to join numerous other universities across the nation in providing a new generation of investigators with the necessary theoretical framework and methodological skills to make significant clinical discoveries and move these discoveries into practice and policy. Dental students have already benefitted from CWRU's existing Master's program in Clinical Research, and I am sure that this proposed program will serve as a valuable resource for investigators in dental medicine who desire more sophisticated training in clinical and translational methodologies. Moreover, the program's multidisciplinary nature and quality of mentoring will be real strengths, and I am pleased that the proposed program will include faculty mentors from the School of Dental Medicine.

This proposed program will not only enhance the ability of each participating school and institution to contribute to knowledge and practice, but will also increase opportunities for future collaboration and synergistic investigations among participants. I strongly support your proposal and am eager to see it implemented.

Sincerely,

Jerold S. Goldberg, DDS
Dean

SCHOOL OF DENTAL MEDICINE
CASE WESTERN RESERVE UNIVERSITY

CASE WESTERN RESERVE UNIVERSITY EST. 1826

*School of Engineering*

Jeffrey L. Duerk, Ph.D.
Dean, Case School of Engineering
Leonard Case Professor

April 29, 2013

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James Spilsbury, PhD, MPH
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Academic Development Core, Center for Clinical Investigation
Case School of Medicine
2103 Cornell Rd., Room 6127
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Dear Drs. Li and Spilsbury:

I am pleased to write this letter in support of the proposed PhD program in Clinical Translational Science. This is a new field of great importance to the health of our nation, and by providing this program, Case Western Reserve University will join the growing number of universities across the county that are training the next generation of clinical researchers to make significant clinical discoveries and move these discoveries into practice and policy.

As you know, the School of Engineering already collaborates extensively with clinical researchers across the Case community, as well as investigators located in the University Hospitals Case Medical Center, the Cleveland Clinic Foundation, the MetroHealth Medical Center, and the Louis Stokes VA Medical Center. Implementation of this program will provide additional opportunities for collaboration and even synergy between training programs offered at the School of Medicine and the School of Engineering. Two critical strengths of the proposed PhD program are the quality of its proposed mentors and the program's multidisciplinary nature. To these ends, I am pleased that faculty from the School of Engineering are willing to serve as core faculty and mentors for this program's students.

In short, the PhD program in Clinical Translational Science is an invaluable addition to the educational programs offered by our university. I enthusiastically support this proposal and am eager to see it implemented.

Sincerely,

Jeffrey L. Duerk
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SCHOOL OF MEDICINE
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May 30, 2013

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Dear Drs. Li and Spilsbury:

It is my pleasure to write this letter in strong support of the proposed PhD program in Clinical Translational Science. The NIH and other key institutions entrusted with the nation's health have highlighted the need to accelerate the process through which scientific discoveries become effective clinical practice. To meet this challenge, Clinical Translational Science has emerged as a new scientific discipline with a unique theoretical framework and methodology aimed to reduce the time it takes to transform discovery into practice and policy. Although this discipline clearly relates to other scientific fields for which PhD programs currently exist at CWRU, its distinct perspective will make the PhD in Clinical Translational Science an invaluable addition to the university's educational portfolio. I am excited that our university will join numerous other universities nationwide in the endeavor to provide the next generation of clinical investigators with these new skills.

In summary, I believe the PhD program in Clinical Translational Science is a vital addition to the PhD programs offered by CWRU. I enthusiastically support this proposal and look forward to its implementation.

Sincerely,

Mark Chance, Ph.D.
Vice Dean for Research
Charles W. and Iona A. Mathias Professor of Cancer Research
Director, Case Center for Proteomics and Bioinformatics

University Hospitals
Case Medical Center

CASE WESTERN RESERVE
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March 22, 2013

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Dear Li and Jim,

I would like to express my strong support for the proposed PhD program in Clinical Translational Science. Clinical Translational Science has emerged as a distinct scientific field that is enhancing our understanding of important scientific issues that form the foundation for therapeutic and diagnostic approaches, and this field has great promise to accelerate translation of scientific discovery into effective clinical practice. I note that this field has advanced considerably over the past decade, and PhD programs in this field have been launched at a number of universities. While the field of Clinical and Translational Science has connections with other scientific fields, e.g. public health, epidemiology, nursing, engineering and basic science biomedical fields, this is clearly a new field of training that is distinct from the other fields in which we currently train PhD students. None of our existing PhD programs encompass the goals, curriculum and mentor pool that is proposed for this program. This is a field of growing importance, and I consider it essential to launch a PhD program in this field in order to promote the success of the overall academic and intellectual portfolio of training and research activities at our School of Medicine, and I anticipate that it will synergize with training in our Schools of Nursing, Engineering and Dental Medicine.

While I am not personally engaged in research that would be encompassed within this new PhD program, I have substantial academic perspective on the development of this field of training and issues that relate to the planning of this new PhD program. I have been closely engaged at the local and national level in training of MD-PhD and PhD students. In the past decade, I reorganized the Pathology PhD program and developed it into three distinct curricular tracks, the Molecular and Cellular Basis of Disease Training Program (which continues the prior design of the Pathology PhD program), the Immunology Training Program (which I launched in 2006 and has a curriculum focused on Immunology), and the Cancer Biology Training Program (which I proposed and helped design in collaboration with faculty in the Cancer Center; also launched in 2006). These experiences have provided me with an extensive perspective on development of PhD programs. Since 2001 I have been the Director of the CWRU Medical Scientist Training Program (MSTP) (the oldest MD-PhD program in the world) and since 2007 I have been the Director of the Clinical and Translational Scientist Training Program (CTSTP), our CTSA TL-1-funded program that supports research training in clinical and translational fields in combined

degree programs including MD-PhD, DNP-PhD (with the School of Nursing) and a program in planning the School of Dental Medicine for DMD-PhD training. My efforts for the MSTP and CTSTP engaged me with PhD programs in the Schools of Medicine, Nursing, Engineering and Arts and Sciences, and this has given me extensive perspective on PhD programs at CWRU. Furthermore, I have been extensively engaged with the American Association of Medical Colleges (AAMC) MD-PhD Section (I just completed a 3-year term on the Steering Committee) and the AAMC GREAT (Graduate Research Education and Training) Group, which has given me exposure at the national level on development of graduate programs. This exposure has clarified to me the importance of developing a PhD program in the burgeoning field of Clinical and Translational Science.

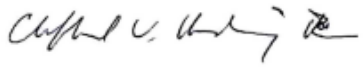
The effort to design the curriculum for the PhD program in Clinical and Translational Science has been extensive and thoughtful. Feedback from a prior round of discussion and evaluation was used to extensively reevaluate and redesign the curriculum plan. The plan for this PhD program was presented twice over the last year to the MSTP Steering Committee, which provided constructive criticism that was incorporated into the curriculum plan to address a number of issues regarding the coursework plan, flexibility, extent of time for research experiences early in the program, time to degree considerations, and a number of other issues. At the last review, the MSTP Steering Committee provided additional suggestions to fine tune the proposal and indicated its support for the launch of a PhD program in Clinical and Translational Science, which we anticipate will become an important option for training of MSTP and CTSTP students (as well as trainees who have already completed a clinical degree and will subsequently due the PhD, constituting the other training sequence for the proposed PhD program).

There should be ample institutional support for the launch of this new PhD program. Dean Davis has expressed her firm commitment to the launch of this program, and she has personally committed time and resources to ensure its success. The Center for Clinical Investigation (CCI) will be the administrative home of the PhD program, and there is already administrative support dedicated to the PhD program from the CCI. Combined degree PhD trainees will be supported in ways similar to other MSTP and CTSTP students, including support from mentors and their departments, training grant support (e.g. the CTSA TL1), individual fellowships, and institutional support provided to the MSTP/CTSTP from the School of Medicine. The trainees who do PhD training after they complete a clinical degree will have an overlapping set of support sources, as well as others, e.g. our CTSA KL2 program and support from a number of departments that have consistently made commitments to the support of KL2 trainees.

As discussed with Drs. Li and Spilsbury, I will be pleased to serve on the proposed PhD program's Advisory Board, which will meet periodically with the program's Steering Committee to provide guidance on the overall implementation of the program. I will of course serve as an advocate for the program as needed.

In summary, the PhD program in Clinical Translational Science will be an invaluable addition to the educational programs offered by our university, and I am pleased that CWRU will join over 20 other institutions nationwide that provide a PhD program in this field. This program will launch a new generation of investigators with the necessary theoretical framework and methodological skills to make significant clinical discoveries and move these discoveries into practice and policy. I enthusiastically support this proposal and am eager to see it implemented.

Sincerely,



Clifford V. Harding, MD, PhD
Kahn Professor and Chair of Pathology
Case Western Reserve University/University Hospitals Case Medical Center

**Cleveland Clinic**
**Lerner Research Institute**

**Paul E. DiCorleto, PhD**
Sherwin-Page Chairman
Lerner Research Institute

March 20, 2013

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Dear Drs. Li and Spilsbury:

I am writing to offer my enthusiastic support for Case Western Reserve University's proposed PhD program in Clinical Translational Science. As Chair of the Lerner Research Institute, administrative home to all research at Cleveland Clinic and partner in the Cleveland Clinical and Translational Science Collaborative, I cannot overemphasize the importance of training high-caliber researchers who can bridge the gap between bench and bedside. The NIH has highlighted an urgent need to accelerate scientific, or "bench," discoveries into applications that will benefit patients and has supported this priority with funding initiatives for highly collaborative, translational research programs. A key to achieving this goal is training experts in the emerging field of clinical translational science, which marries two highly integrated disciplines of science that share a common goal of improving human health.

CWRU's proposed PhD program in Clinical Translational Science will train innovative, competitive researchers who can conceptualize, lead, and execute successful research programs that will expedite the development of therapeutic applications. The rigorous program will specifically target individuals who already have advanced clinical and research degrees and whose interests and career goals align with the mission of the program. Candidates will be trained in the theory and practice of clinical translational science; participate in intensive, patient-focused research in collaboration with CWRU research faculty; complete and defend a dissertation; and author at least two publications in respected, peer-reviewed journals. To my knowledge, this program will not overlap or compete with existing doctoral programs at CWRU or in Ohio. It nicely complements our highly successful Molecular Medicine doctoral program, which in a sense leaves off where this one begins.

The Cleveland Clinic Foundation
Lerner Research Institute

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CWRU's reputation as a pillar of research and education; diverse, multidisciplinary faculty; and partnerships with top hospitals such as Cleveland Clinic, University Hospitals Case Medical Center, and MetroHealth Medical Center make it ideally suited for an integrative training program in clinical and translational science such as this. Twenty-two other U.S. universities have already launched similar PhD programs; in my opinion, CWRU must join them in order to retain its leadership role and to be on the forefront of education and translational discovery.

Sincerely,

Paul E. DiCorleto, Ph.D.
Sherwin-Page Chair
Lerner Research Institute, Cleveland Clinic
Chairman, Department of Molecular Medicine
Case Western Reserve University School of Medicine

PED/jg

SCHOOL OF MEDICINE
CASE WESTERN RESERVE UNIVERSITY

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Distinguished University Professor and Chairman
Department of Epidemiology and Biostatistics

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May 23, 2013

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2103 Cornell Rd., Room 6127
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Dear Drs. Li and Spilsbury:

I write this letter to express my strong support for the proposed PhD program in Clinical Translational Science. Clinical Translational Science has recently emerged as a distinct discipline to accelerate the translation of scientific discovery into effective clinical practice, and the proposed program will complement existing PhD programs available at CWRU. By providing this program, our institution will join the efforts of over 20 other universities nationwide to train a new generation of clinical investigators to make significant clinical discoveries and move these discoveries into practice and policy.

Three key features of the proposed program are its flexibility, quality of mentoring, and multidisciplinary nature, and I am pleased that faculty from my department have already expressed their willingness to serve as mentors for the program's students. Moreover, given the distinct nature of this new field, I do not anticipate issues of overlap to arise between the PhD in Clinical Translational Science and the existing PhD offered by my department.

In summary, the PhD program in Clinical Translational Science is an invaluable addition to the educational programs offered by our university. I enthusiastically support this proposal and am eager to see it implemented.

Sincerely,

R.C. Elston,

Robert C. Elston, Ph.D.
Distinguished University Professor and Chair
Amasa B. Ford MD Professor of Geriatric Medicine
Department of Epidemiology and Biostatistics
Case Western Reserve University

CTSC
Clinical & Translational Science Collaborative

CASE WESTERN RESERVE UNIVERSITY
SCHOOL OF MEDICINE

3/25/2013

Li Li, MD, PhD

James Spilsbury, PhD

RE: Proposal for PhD in Clinical Translational Sciences

Dear Drs. Li and Spilsbury:

I strongly endorse the proposed PhD program in Clinical Translational Science. Having participated over the past several months on the program development group, I believe the proposal is rigorous and meritorious.

My interest in this program stems from my experiences with the Clinical Research Scholar Program (CRSP – initially developed through an NIH K30 award); my leadership role as Principal Investigator on the NIH Roadmap Multidisciplinary Clinical Research Training Program (the MCRTP K12 program), which was a collaborative program integrating clinical and translational research training at the post-doctoral level across the University, Cleveland Clinic, University Hospitals Case Medical Center, MetroHealth Medical Center, and the Cleveland VA; and more recently as Co-PI on the CWRU Clinical and Translational Sciences Collaborative (for which I also serve as the Education Director). In these positions, I've observed the "evolution" of clinical and translational sciences into a distinct professional discipline, as initially envisioned in the RFA for the MCRTP K12 program.

According to RFA-HD-04-006 (released October 20, 2003): "Clinical research is a complex endeavor that is ideally performed by a multidisciplinary team using an integrated team approach. A multidisciplinary approach brings experts from diverse disciplines (for example, clinician, clinical trialist, statistician, medicinal chemist, and pharmacologist) to address collectively a common complex problem. There is a well-recognized shortage of well-trained physicians and other health professionals (e.g., dentists, behavioral scientists, clinical pharmacologists, statisticians, nurses, study coordinators, and data managers) performing clinical research in a rigorous, highly collaborative, team-oriented environment. This initiative will support the development and implementation of integrated Multidisciplinary Clinical Research Career Development Programs (referred to as Program in the following) that provide CR Scholars with knowledge and skills of the discipline of clinical research that are applicable to all diseases and organ systems. Programs should be designed to provide a flexible and efficient entrance into clinical research for doctoral-level individuals with a variety of disciplinary, specialty, or sub-specialty backgrounds, should emphasize the development of the entire clinical research team, and should reflect the prolonged time to develop and support the development of competent and independent clinical researchers. By providing this career

development experience in a multidisciplinary setting, it is hoped that those completing the Program will be better prepared for the multidisciplinary real world requirements of clinical research."

In 2006, the MCRTP K12 program was folded into the much larger CTSA program as the KL2 component, and drastically expanded from 14 sites in 2006 to 60 sites currently. The program was also expanded from its exclusive focus on post-doctoral training to an additional focus on pre-doctoral training. The emphasis on developing Clinical Translational research into a distinct scientific discipline was maintained in the CTSA program, and strengthened. According to the most recent call for proposals for CTSA programs from the new National Center for Advancing Translational Sciences (NCATS) (RFA-TR-12-006): "In this portion of the application, the applicant should present a broad vision of the workforce needed to drive future innovation and implement effective clinical and translational research.

Objectives of the CTSA training program include addressing future workforce needs, implementing a team science approach for research training, offering research curriculum aligned to core competencies, and providing support and career guidance to trainees and scholars. Early exposure to collaboration and career guidance may serve to enhance the team approach necessary to meet the multidisciplinary challenges of clinical research. The CTSA training programs should serve as a pipeline introducing postgraduate students to translational science, and promoting scientific curiosity and discovery among postdoctoral clinician scientists. The applicant institution should provide a comprehensive description of the existing or proposed higher degree-granting programs such as Masters or PhD in Clinical and Translational Research…."

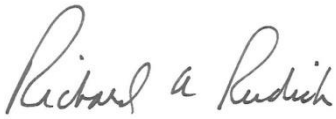
During the past 10 years, competencies have been defined for education and training programs in clinical translational research, and 22 PhD programs have been established, including a new PhD program at Ohio State University. Case Western Reserve University and its clinical affiliates are well positioned to provide doctoral level training for multidisciplinary clinical and translational research.

The program you have developed is rigorous, but also flexible enough to accommodate the varied students and professionals who will find this training indispensible for their career goals. Importantly, the program as conceived will not compete with or detract from our other excellent more traditional PhD training programs in disciplines relevant to clinical translational research. On the contrary, students and graduates in the new program will be highly desired collaborators and partners for graduates of the existing programs, and in that way will strengthen the clinical research training enterprise at Case Western Reserve University.

I am personally looking forward to participating in this program in my CTSC role, and as a faculty member and mentor.

Thank you for your work on this program, and let me know how I can help as it evolves.

Sincerely,



Richard A. Rudick, M.D.
Co-Principal Investigator
Clinical Translational Science Award

Case Western Reserve University
10900 Euclid Avenue
Cleveland, Ohio 44106-4904
Phone 216-368-5978
Fax 216-368-3542
smm8@case.edu

Li Li, MD, PhD

James Spilsbury, PhD

May 12, 2013

RE: Proposal for PhD in Clinical Translational Science

Dear Drs. Li and Spilsbury:

I am pleased to write this letter in support of the proposed PhD in Clinical Translational Science Program at Case Western Reserve University. As co-director of the Education Core of the CWRU Clinical Translational Science Collaborative (CTSC) and a faculty member in the KL2 Clinical Translational postdoctoral training program, I have been pleased to see the progress on this PhD program proposal over the past several months, especially its consistency with other PhD programs nationally in this new field of Clinical Translational Science.

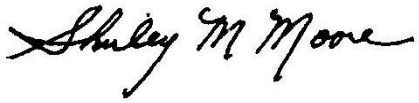
I serve on the national CTSA Education Committee and have participated as a member of the committee that has developed the competencies and corresponding curricula for the clinical translational researcher. In my work with this group, we have developed competencies for masters-, PhD- and postdoctoral-level training in clinical translational research. These competencies have been accepted nationally and were used as the basis for the focus and curriculum of the PhD in Clinical Translational Science that is now proposed at CWRU.

I currently serve on the faculty leadership team of the Clinical Research Scholar Program (CRSP) at CWRU and teach the Team Science course in that program. This course also is a requirement for our KL2 Postdoctoral Scholars. This Team Science course will form the basis for continued training in cross-disciplinary research that is proposed in the PhD in Clinical Translational Science program. It addresses important topics such as techniques for learning about the mental models of persons trained in other disciplines, formation of research projects that address problems from a multi-disciplinary and multi-site perspective, conflict management (difference between intellectual conflicts versus personality conflicts), team decision-making techniques, and creativity in teams.

The program you propose draws on the strengths at Case Western Reserve University and its clinical affiliates and will provide a much needed option for doctoral study for health care professionals seeking training in clinical translational research.

I have reviewed the proposal for the proposed PhD program and believe that it is both rigorous and feasible. I look forward to participating in as a leader, faculty member and mentor. I look forward to assisting in moving this program forward.

Sincerely,



Shirley M. Moore, RN, PhD, FAAN
Edward J. and Louise Mellen Professor of Nursing
Associate Dean for Research
Frances Payne Bolton School of Nursing

# Appendix 8
# Proposed Core Faculty Members

| Name | Title | Institution | Field(s) of Expertise |
|---|---|---|---|
| Barnholtz-Sloan, Jill, PhD | Associate Professor, Case Comprehensive Cancer Center | SOM | Genetic/molecular epidemiology of complex disease, cancer and genetic ancestry |
| Blackstone, Eugene, MD | Professor, Surgery | CCLCM | Thoracic and cardiovascular surgery and research related to thoracic and cardiovascular surgery |
| Bonomo, Robert, MD | Professor, Molecular Biology & Microbiology | SVAMC/SOM | Infectious diseases and antimicrobial resistance |
| Cooper, Gregory, MD | Professor, Medicine | UH/SOM | Heath service research in GI malignancies |
| Dawson, Neal, MD | Professor, Medicine | MHMC/SOM | Medical decision making, survival prediction of seriously ill |
| Dolansky, Mary, PhD, RN | Associate Professor, Epidemiology & Biostatistics | SON | Cardiac rehabilitation |
| Drumm, Mitchell, PhD | Professor, Pediatrics | UH/SOM | Genetics and molecular biology, cystic fibrosis |
| Einstadter, Douglas, MD | Professor, Medicine | MHMC/SOM | Quality care for Medicaid patients, behavioral intervention for co-morbid SMI and diabetes patients, accessible health care |
| Iyengar, Sudha, PhD | Professor, Epidemiology & Biostatistics, Genetics; | SOM/UH | Genomic epidemiology of nephropathy and diabetes, and Fuchs' endothelial corneal dystrophy |
| Keri, Ruth, PhD | Associate Professor, Pharmacology | SOM | Breast cancer genetics, signal transduction, and pharmacogenetics |
| Lederman, Michael, MD | Professor, Medicine | UH/SOM | Infectious Disease, HIV/AIDS, and innate immunity |
| Li, Li, MD, PhD | Associate Professor, Family Medicine & Community Health | UH/SOM | Public health, cancer prevention through molecular/genetic epidemiology, gene-environment interaction |
| McComsey, Grace, MD | Professor, Pediatrics and Medicine | UH | Pediatric HIV research, thymidine – NRTI associated mitochondrial dysfunction in HIV-lipodystrophy syndrome, and inflammation in HIV associated atherosclerosis and osteoporosis |
| Moore, Shirley, PhD, RN, FAAN | Professor, Nursing | SON | Behavioral intervention |
| Nelson, Suchitra, PhD | Professor, Community Dentistry | SDM/SOM | Oral health disparities in poor, minority, special needs children |
| Ransohoff, Richard, MD | Professor, Molecular Medicine | CCLCM/ SOM | Neuroinflammation research, multiple sclerosis, Alzheimer disease |
| Rudick, Richard, MD | Professor, Div. General Medicine Sciences | CCLCM/SOM | Neurology, multiple sclerosis |
| Sehgal, Ashwini, MD | Professor, Medicine | MHMC/SOM | Disparities research, risks and factors related to dialysis and/or kidney transplant |
| Spilsbury, James, PhD | Assistant Professor, Center for Clinical Investigation | UH/SOM | Medical anthropology, effects of socio-cultural environment on children's sleep and well-being |
| Stange, Kurt, MD, PhD | Professor, Family Medicine & Community Health, Epidemiology & Biostatistics, Sociology, and Oncology | SOM | Primary care, health services research, public helath and community research, practice-based research networks, multimethod research. |
| Wang, Binchechg, PhD | Professor, Medicine | MHMC/SOM | Molecular mechanisms governing tumor cell dissemination, and drug development |
| Wang, Zhenghe, PhD | Associate Professor, Genetics & Genome Science | SOM | Genetics, colorectal cancer |
| Zhu, Xiaofeng, PhD | Professor, Epidemiology and Biostatistics | SOM | Genetics of hypertension in African Americans |

# Appendix 9
# Potential Mentors

| Core Mentor Members | | | |
|---|---|---|---|
| **Name** | **Faculty Status** | **Institution** | **Field(s) of Expertise** |
| Barnholtz-Sloan, Jill, PhD | Associate Professor, Case Comprehensive Cancer Center | SOM | Genetic/molecular epidemiology of complex disease, cancer and genetic ancestry |
| Beall, Cynthia MD, PhD | Professor, General Medical Sciences | AS/SOM | Physical anthropology, nitric oxide at high altitude and its role in genetics adaptive traits and human evolution |
| Blackstone, Eugene, MD | Professor, Surgery | CCLCM | Thoracic and cardiovascular surgery and research related to thoracic and cardiovascular surgery |
| Bonomo, Robert, MD | Professor, Molecular Biology & Microbiology | SVAMC/SOM | Infectious diseases and antimicrobial resistance |
| Boom, Willem Henry, MD | Professor, Medicine | UH/SOM | Infectious disease, tuberculosis |
| Calabrese, Joseph, MD | Professor, Psychiatry | SOM/UH | Mood disorder/bipolar disorder |
| Chak, Amitabh, MD | Professor, Medicine | UH/SOM | Gastroenterology, Barrett's Esophagus and family medical history |
| Chance, Mark MD, PhD | Professor, General Medicine Sciences | SOM | Molecular targets related to diabetes, protein-protein interaction in the biology of disease, biomarkers & protein interaction with colon cancer, immunology & adaptive immune response to HIV |
| Cooper, Gregory, MD | Professor, Medicine | UH/SOM | Heath service research in GI malignancies |
| Cooper, Kevin, MD | Professor, Dermatology | UH/SOM | Skin diseases |
| Daly, Barbara, PhD | Professor, Oncology Nursing | SON/UH/SOM | End of life care (i.e. health services, racial differences), reduce readmission of the chronically critically ill, chronically/critically ill, caregivers/decision makers psychological issues |
| Dawson, Neal, MD | Professor, Medicine | MHMC/SOM | Medical decision making, survival prediction of seriously ill |
| Dolansky, Mary, PhD, RN | Associate Professor, Epidemiology & Biostatistics | SOM | Cardiac rehabilitation |
| Donahue, J. Kevin, MD | Professor, Medicine | MHMC/CSE/ SOM | Biomedical Engineering, Physiology & Biophysics, development of therapies for cardiac arrhythmias and chronic atrial fibrillation |
| Drumm, Mitchell, PhD | Professor, Pediatrics | UH/SOM | Genetics and molecular biology, cystic fibrosis |
| Dweik, Raed, MD | Associate Professor, Medicine | CCLCM | Pulmonary Vascular, pulmonary hypertension |
| Einstadter, Douglas, MD | Professor, Medicine | MHMC/SOM | Quality care for Medicaid patients, behavioral intervention for co-morbid SMI and diabetes patients, accessible health care |
| Elston, Robert, PhD | Professor, Epidemiology & Biostatistics | SOM | Epidemiology and biostatics, statistical genetics/genetic epidemiology (statistical methods for genetic epidemiology) |
| Eng, Charis, MD, PhD, FACP | Professor, Genetics & Genome | CCLCM/SOM | Oncology, genetics and molecular genetics |
| Erzurum, Serpil, MD | Professor, General Medical Sciences | CCLCM/SOM | Asthma and pulmonary vascular diseases |

| | | | |
|---|---|---|---|
| Fiocchi, Claudio, MD | Professor, Molecular Medicine | CCLCM/UH/ SOM | Investigation of mucosal immunity and inflammatory bowel disease (IBD) pathogenesis, immunenon-immune cell interaction, angiogenesis and lymphangiogenesis, Cytokines, Mucosal immunity |
| Fitzpatrick, Joyce, PhD, MBA, RN, FAAN | Professor, Nursing | SON | Nursing job satisfaction, nursing practice and procedures, patient safety peri-operative, HIV – preventive and education, spiritual care, collaboration work among medical professionals |
| Gary, Faye, EdD, RN, FAAN | Professor, Psychiatry | UH | Nursing, vulnerable and at risk persons, healthcare system disparities among races and the mentally ill, depression in African American cancer patients |
| Ghannoum, Mahmoud, MD | Professor, Pathology | UH/SOM | Dermatology, Mycology/microbial physiology (i.e. Candida albicans effects on monocytes and in vetro and in vivo), infectious disease |
| Higgins, Patricia, RN, PhD | Associate Professor , Nursing | SON/UH /SVAMC | Nursing – research focused on geriatrics - improving the health and quality of life of older adults with chronic illness, effect of circadian light on the sleep-wake cycles of persons with dementia |
| Ismail-Beigi, Faramarz, MD, PhD | Professor, Physiology/Biophysics | UH/SOM | Cellular metabolism and physiology, thyroid hormone action, glucose transporter biology, insulin action, type 2 diabetes, BARI-2D and ACCORD trials |
| Iyengar, Sudha, PhD | Professor, Epidemiology & Biostatistics, Genetics | SOM/UH | Genomic epidemiology of nephropathy and diabetes, and Fuchs' endothelial corneal dystrophy |
| Jain, Mukesh, MD | Professor, Physiology/Biophysics | UH/SOM | Cardiac research – KLFs roles in cardiovascular biology, systemic metabolic homeostasis and innate immunity |
| Kattan, Michael, MD, PhD | Professor, Medicine | CCLCM/SOM | Cost-effectiveness and decision analysis of specific treatments in cancer patients, quality of life of cancer patients |
| Kazura, James, MD | Professor, Medicine | SOM/UH | Immunologic and genetic aspects of infectious diseases of high public health significance in tropical developing countries |
| Keri, Ruth, PhD | Associate Professor, Pharmacology | SOM | Breast cancer genetics, signal transduction, and pharmacogenetics |
| Killion, Cheryl, PhD, RN, FAAN | Associate Professor | SON | Anthropology and nursing, poverty and procreation among women – implications for healthcare providers, cultural aspects of healthcare (i.e. race, abuse, sex) |
| King, Charles, MD | Professor, General Medical Sciences, | SOM/UH | Infectious disease specialist and epidemiologist, population-based vector-borne disease control, providing optimal delivery of available prevention to high risk populations, prevention of 'subtle' morbidities of chronic parasitic infection, schistosomiasis in Kenya, disease risk for young children |
| Lederman, Michael, MD | Professor, Medicine | UH/SOM | Infectious Disease, HIV/AIDS, and innate immunity |
| Li, Li, MD, PhD | Associate Professor, Family Medicine & Community Health | UH/SOM | Public health, cancer, cancer prevention through molecular/genetic epidemiology, gene-environment interaction |
| Ludington, Susan, PhD, CNM, FAAN | Professor, Pediatric Nursing | SON | Sleep quality, brain maturation and complexity, outcomes of skin-to-skin contact in late preterm infants |
| Madigan, Elizabeth, PhD | Professor, Nursing | SON | Nursing, patient outcomes in Medicare home care |
| Markowitz, Sanford, MD | Professor, Div. Gen. Med. Sciences, | UH/SOM | Colon cancer |
| Martin, Richard, MBBS | Professor, Pediatrics | UH/SOM | Developmental Respiratory Neurobiology |

| | | | |
|---|---|---|---|
| McComsey, Grace, MD | Professor, Pediatrics and Medicine | UH | Pediatric HIV, role of thymidine-NRTI associated mitochondrial dysfunction in HIV-lipodystrophy syndrome, role of inflammation & Vitamin D insufficiency in two common co-morbidities in HIV – atherosclerosis & osteoporosis |
| Meropol, Neal, MD | Professor, Cancer Research and Therapeutics | UH/SOM | Oncology and health services research, gastrointestinal cancers, cancer patients decision making |
| Moore, Shirley, PhD, RN, FAAN | Professor, Nursing | SON | Behavioral interaction |
| Musil, Carol, PhD | Professor, Nursing | SON | Parenting/caregiver stress and coping mechanisms, technology-dependent children, grandmothers raising grandchildren |
| Nelson, Suchitra, PhD | Professor, Community Dentistry | SDM/SOM | Oral health disparities in poor, minority, and special needs children |
| Ransohoff, Richard, MD | Professor, Molecular Medicine | CCLCM/SOM | Neuroinflammation research, multiple sclerosis, Alzheimer disease |
| Rich, Jeremy, MD | Professor, Molecular Medicine | CCLCM/SOM | Neurology, stem cell, brain cancer |
| Roizen, Nancy, MD | Professor, Pediatrics | UH | Developmental/Behavioral Pediatrics and Psychology |
| Rudick, Richard, MD | Professor, Div. General Medicine Sciences | CCLCM/SOM | Neurology, multiple sclerosis |
| Salata, Robert, MD | Professor, Medicine | UH/SOM | AIDS (women and race related) |
| Sedor, John, MD | Professor, Physiology/Biophysics | MHMC/SOM | Nephrology, diabetes and kidney functions |
| Sehgal, Ashwini, MD | Professor, Medicine | MHMC/SOM | Disparities research, risks and factors related to dialysis and/or kidney transplant |
| Smyth, Kathleen, PhD | Associate Professor, Epidemiology & Biostatistics, Neurology | SOM/UH | Neurology, Alzheimer's Disease – both patient and caregiver studies |
| Spilsbury, James, PhD | Assistant Professor, Center for Clinical Investigation | UH/SOM | Medical anthropology, effects of socio-cultural environment on children's sleep and well-being |
| Stange, Kurt MD, PhD | Professor, Epidemiology & Biostatistics | SOM | Quality of health care in inner-city, healthcare practices-improving and understanding, practice-based research |
| Strohl, Kingman, MD | Professor, Physiology/Biophysics | UH/SOM | Sleep wake and ventilator regulation in health and disease, genetic and functional control of ventilatory behavior, pharmacologic manipulation on abnormal rhythmogenesis |
| Tisch, Daniel, PhD, MPH | Assistant Professor, Epidemiology & Biostatistics | SOM | Infectious disease, global health research and training, Lymphatic filariasis monitoring and elimination in Papua New Guinea, malaria in Papua New Guinea |
| Wang, Bincheng, MD, PhD | Professor, Medicine | MHMC/SOM | Molecular mechanisms governing tumor cell dissemination, and drug development |
| Wang, Zhenghe, PhD | Associate Professor, Genetic & Genome Science | SOM | Genetics, colorectal cancer |
| Winkelman, Chris, PhD, RN | Associate Professor | SON | Nursing, position and mobility therapy in critically ill adults and obese patients, preventing patient suffering, decreasing family distress |
| Wright, Jackson, MD, PhD | Professor, Div. Gen. Med. Sciences, | UH/SOM | Internal Medicine, kidney disease and hypertension in African Americans |

| | | | |
|---|---|---|---|
| Zauszniewski, Jaclen, PhD, RN-BC, FAAN | Professor, Community Health Nursing | SON | Nursing, researching/teaching resourcefulness skill in/to older adults, characteristics of depressive cognition in women, grandmothers care giving of grandchildren |
| Zhang, Amy, PhD | Associate Professor, Urology | UH | Mental health services, differences in mental health services between races and communities, cancer's affect on family function and communication, depression in cancer patients - differences between races |
| Zhang, Guo-Qiang, MD, PhD | Professor, General Medicine Sciences | SOM/UH | Computer Scientist, algorithms, programming, ontology, image analysis, biomedical informatics, MIMI and Physio-MIMI systems |
| Zhu, Xiaofeng, PhD | Associate Professor, Epidemiology and Biostatistics | SOM | Genetics of hypertension in African Americans |

# Appendix 10
# Biosketches – Core Faculty and Mentors

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Barnholtz-Sloan, Jill Suzanne** | POSITION TITLE<br>Associate Professor |
| eRA COMMONS USER NAME **AI2192** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| The University of Florida, Gainesville, FL | BS | 1994 | Mathematics |
| The University of Texas at Austin, Austin, TX | MS | 1995 | Statistics |
| The University of Texas School of Public Health, Houston, TX | PhD | 2000 | Biostatistics/Statistical Genetics |

## A. Positions and Honors

**Positions and Employment**

1998-2000 National Cancer Institute Predoctoral Fellow, Department of Epidemiology, The University of Texas M.D. Anderson Cancer Center, Houston, Texas
2000-2004 Assistant Professor, Population Studies and Prevention Program, Department of Internal Medicine, Wayne State University School of Medicine & Karmanos Cancer Institute
2004-2007 Assistant Professor, Cancer Control and Population Sciences, Department of Interdisciplinary Oncology, University of South Florida School of Medicine and H. Lee Moffitt Cancer and Research Institute
2007-2011 Assistant Professor, Division of General Medical Sciences (Oncology), Department of Epidemiology and Biostatistics, & Center for Proteomics and Bioinformatics, Case Western Reserve University School of Medicine, Cleveland, OH
2007- Member, Case Comprehensive Cancer Center, Cleveland, OH
2011- Associate Professor (with tenure), Division of General Medical Sciences (Oncology), Department of Epidemiology and Biostatistics, & Center for Proteomics and Bioinformatics, Case Western Reserve University School of Medicine, Cleveland, OH
2012- Co-Director, Biostatistics and Bioinformatics Core Facility, Case Comprehensive Cancer Center
2012- Co-Leader, Brain Tumor Program in Development, Case Comprehensive Cancer Center

**Other Experience and Memberships**

American Association for Cancer Research, American Society of Human Genetics, American Statistical Association, International Biometric Society (ENAR), International Genetic Epidemiology Society, Society of Neuro-Oncology

**Honors**

1996-2000 Public Health Federal Traineeship, The University of Texas School of Public Health
1998-2000 National Cancer Institute Pre-Doctoral Fellowship in Cancer Prevention Research, The University of Texas M.D. Anderson Cancer Center
2002-2008 NIH Clinical Research Loan Repayment Award Recipients
2004-2007 NIH Epidemiology and Neuroepidemiology and Aging (NAME) Study Section, Ad-hoc Member
2004- Central Brain Tumor Registry of the United States Scientific Advisory Board, Member
2005-2007 Member, University of South Florida Medical Institutional Review Board (IRB) 01d
2006-2007 Member, Moffitt Cancer Center Scientific Review Committee
2007- Member, Case Comprehensive Cancer Center Protocol Review and Monitoring Committee
2009- Editorial Board Member, Cancer Epidemiology, Biomarkers & Prevention

2009-2012 Elected US Vice President, Brain Tumor Epidemiology Consortium (BTEC)
2012-2014 Elected US President, Brain Tumor Epidemiology Consortium (BTEC)
2010-2012 Member, Case Cancer Institutional Review Board (IRB)
2011- Associate Editor, Frontiers in Applied Genetic Epidemiology
2011-2012 Elected Chair, Faculty Council, Case Western Reserve University School of Medicine
2012- Member, University Hospitals of Cleveland Cancer Institutional Review Board (IRB)
2012- Review Editor, Frontiers in Neuro-Oncology
2012- Member, Board of Directors, Ohio Neuro-Oncology Consortium (ONOC)
2012 Mather Spotlight Prize for Women's Scholarship Award, Case Western Reserve University

**B. Selected Peer-reviewed Publications (Selected from >98 peer-reviewed publications)**

1. de Andrade M, **Barnholtz JS**, Amos CI, Adatto P, Spencer C, Bondy ML. Segregation analysis of cancer in families of glioma patients. Genet Epidemiol. 2001 Feb;20(2):258-70.
2. **Barnholtz-Sloan JS**, Tainsky MA, Abrams J, Severson RK, Qureshi F, Jacques SM, Levin N, Schwartz AG. Ethnic differences in survival among women with ovarian carcinoma. Cancer. 2002 Mar 15;94(6):1886-93.
3. **Barnholtz-Sloan JS**, Sloan AE, Schwartz AG. Racial differences in survival after diagnosis with primary malignant brain tumor. Cancer. 2003 Aug 1;98(3):603-9.
4. **Barnholtz-Sloan JS**, Schwartz AG, Qureshi F, Jacques S, Malone J, Munkarah AR. Ovarian cancer: changes in patterns at diagnosis and relative survival over the last three decades. Am J Obstet Gynecol. 2003 Oct;189(4):1120-7.
5. Pfaff CL, **Barnholtz-Sloan J**, Wagner JK, Long JC. Information on ancestry from genetic markers. Genet Epidemiol. 2004 May;26(4):305-15.
6. **Barnholtz-Sloan JS**, Sloan AE, Davis FG, Vigneau FD, Lai P, Sawaya RE. Incidence proportions of brain metastases in patients diagnosed (1973 to 2001) in the Metropolitan Detroit Cancer Surveillance System. J Clin Oncol. 2004 Jul 15;22(14):2865-72.
7. **Barnholtz-Sloan JS**, Chakraborty R, Sellers TA, Schwartz AG. Examining population stratification via individual ancestry estimates versus self-reported race. Cancer Epidemiol Biomarkers Prev. 2005 Jun;14(6):1545-51.
8. **Barnholtz-Sloan JS**, Williams VL, Maldonado JL, Shahani D, Stockwell HG, Chamberlain M, Sloan AE. Patterns of care and outcomes among elderly individuals with primary malignant astrocytoma. J Neurosurg. 2008 Apr;108(4):642-8.
9. **Barnholtz-Sloan J**, Sloan AE, Land S, Kupsky W, Monteiro AN. Somatic alterations in brain tumors. Oncol Rep. 2008 Jul;20(1):203-10.
10. McKean-Cowdin R, **Barnholtz-Sloan J**, Inskip PD, Ruder AM, Butler M, Rajaraman P, Razavi P, Patoka J, Wiencke JK, Bondy ML, Wrensch M. Associations between polymorphisms in DNA repair genes and glioblastoma. Cancer Epidemiol Biomarkers Prev. 2009 Apr;18(4):1118-26. PMCID: PMC2667563.
11. Chak A, Falk G, Grady WM, Kinnard M, Elston R, Mittal S, King JF, Willis JE, Kondru A, Brock W, **Barnholtz-Sloan J**. Assessment of familiality, obesity, and other risk factors for early age of cancer diagnosis in adenocarcinomas of the esophagus and gastroesophageal junction. Am J Gastroenterol. 2009 Aug;104(8):1913-21. PMCID: PMC2864226.
12. **Barnholtz-Sloan J**, Chance MR. Frontiers of oncology: biobanking resources for the 21st century. J Clin Bioinforma. 2011 May 8;1(1):13. PMCID: PMC3164606.
13. Nickel GC*, **Barnholtz-Sloan J***, Gould MP, McMahon S, Cohen A, Adams MD, Guda K, Cohen M, Sloan AE, LaFramboise T. Characterizing mutational heterogeneity in a glioblastoma patient with double recurrence. PLoS ONE 2012; 7(4): e35262. PMCID: PMC3335059.
14. Chak A, Chen Y, Vengoechea J, Canto MI, Elston R, Falk GW, Grady WM, Guda K, Kinnard M, Markowitz S, Mittal S, Prasad G, Shaheen N, Willis JE, **Barnholtz-Sloan JS**. Variation in Age at Cancer Diagnosis in Familial versus Nonfamilial Barrett's Esophagus. Cancer Epidemiol Biomarkers Prev. 2012 Feb;21(2):376-83. PMCID: PMC3275661.

15. **Barnholtz-Sloan JS**, Yu C, Sloan AE, Vengoechea J, Wang M, Dignam JJ, Vogelbaum MA, Sperduto PW, Mehta MP, Machtay M, Kattan MW. A nomogram for individualized estimation of survival among patients with brain metastasis. Neuro Oncol. 2012 Jul;14(7):910-8. PMCID: PMC3379797.

## C. Research Support

**Ongoing**

NIH/NCI 2R01CA129359-06 (Schiemann, PI) 08/17/12-06/30/17
Integrin-Mediated Regulation of TGFbeta Signaling and Tumorigenesis. The goal of this project on the triple-negative breast cancers (TNBC) is to determine the role of integrins and focal adhesion complexes in conversion of TGFbeta from tumor suppressor to tumor promoter, the role of lysyl oxidase family members in mediating oncogenic TGFbeta signaling in TNBCs, map the transcriptome and epigenetic events coupled to TNBC development and metastatic progression, and visualize TGFbeta signaling during metastatic progression of triple-negative breast cancers.
Role: Co-Investigator (Statistics)

NIH/NCI 1U54 CA163060-01 (Chak, PI) 09/26/11-08/30/16
Barretts Esophagus Translational Research Network (BETRNet). The goal of this project is to achieve a better understanding of barretts esophagus and esophageal adenomcarinoma biology, and improve cancer risk stratification, prediction and prevention. This BETRNet project is comprised of 4 translational research projects and 2 cores.
Role: Bioinformatics Core Director

NIH/NCI 1P50 CA150964-01 (Markowitz, Berger, PIs) 09/14/11-08/31/16
Case GI Specialized Program of Research Excellence (SPORE). The Case GI SPORE is comprised of 4 translational Research Projects to bring new molecular advances to patients with GI Cancers and a series of 4 core resources will enable these research projects and will also establish a strong programmatic infrastructure for translational research in GI malignancies.
Role: Biostatistics Core Director

NIH/NCI HHSN261201000057C (Barnholtz-Sloan, PI) 09/27/10-02/23/12
(no cost extension until 9/30/14)
RECOVERY – Networks of Tissue Source Site (TSS) in Support of The Cancer Genome Atlas (TCGA) Program. The goal of this project is to extend the ongoing collaborations within the Ohio Brain Tumor Study to become a prospective network of Tissue Source Sites for accrual of glioma patients. Role: PI

NIH/NCI 5R01 CA142081-02 (Schildkraut, PI) 06/01/10-04/30/15
Epidemiology of Ovarian Cancer in African American Women. The goal of this project is to distinguish genetic associations of African American women with ovarian cancer from their European American counterparts.
Role: Subcontract PI

NIH/NCI 7R01 CA139020-03 (Bondy, PI) 03/18/10-12/31/14
International Case-Control Study of Malignant Glioma. The goal of this project is to build upon and expand the Gliogene infrastructure to recruit more than 6000 glioma cases and 6000 controls and collect biologic samples from 14 participating Gliogene sites to have a sufficiently large data set to further our understanding of the underlying mechanisms of the development of this devastating disease. Role: Subcontract PI

NIH/NCI 5P30 CA043703-22 (Gerson, PI) 09/30/91-03/31/13
Comprehensive Cancer Center Support Grant. The objectives of the Center are: 1) to improve the prevention, diagnosis, and therapy of cancer through research; 2) to stimulate and support innovative, coordinated, interdisciplinary research on cancer diagnosis, treatment, and control; 3) to develop clinical applications of research discoveries and to make these applications available as quickly as possible; and 4) to develop cancer prevention and control activities to contribute to the reduction of cancer morbidity and mortality in Northeast Ohio and the surrounding region and nation.
Role: Biostatistician; Co-Director – Biostatistics and Bioinformatics Core Facility

NIH/NIBIB2R01EB000489-09 (Lu, PI) 12/01/02-02/28/15
Biodegradable Macromolecular Blood Pool Contrast Agents. The goal of this research project is to design and develop a new generation of biodegradable macromolecular MRI contrast agents with high kinetic chelation stability for non-invasive evaluation of the efficacy of cancer therapies. Role: Co-Investigator (Statistics)

NIH/NHLBI 1R21HL112666-01 (Schmaier, PI) 04/01/12-3/31/14
Prolylcarboxypeptidase is a Risk Factor for Cardiovascular Disease. The goal of this research project is to determine if prolylcarboxypeptidase is a risk factor for hypertension and/or myocardial infarction/stroke with and without adjustment for body type.
Role: Co-Investigator (Statistics)

The Skirball Foundation (Barnholtz-Sloan & Chance, PIs) 06/13/12-06/12/14
Proteomics of Treatment Response in Brain Tumors. The goal of this private foundation grant in the amount of $200,000 is to support the subject research program.
Role: Co-PI

The Ohio Colorectal Cancer Prevention Initiative (OCCPI) (Hampel, PI) 05/09/12-05/08/15
The Ohio State University (OSU) Pelotonia Philanthropic Fund. The goal of this research project is to use our existing experience on the Ohio hospital network for ovarian cancer and apply to OSU and assist OSU to set up a statewide rapid case ascertainment (RCA) system to accrue colon cancer patients.
Role: Consortium PI

Centers for Disease Control and Prevention 5U58DP003831-02 (Kruchko, PI) 09/30/11-09/29/16
Integration of Best Practices for Collection and Reporting of Primary Malignant and Non-Malignant Central Nervous System. This project aims at data enhancement and expansion of current infrastructure of state central cancer registries with CNS tumor data to expedite capturing and reporting of cases within weeks of diagnosis and to further prevention, early detection, and treatment efforts.
Role: Subcontract PI

Central Brain Tumor Registry of the United States CWRU01 (Kruchko, PI) 1/1/13-12/31/16
CBTRUS Statistical Analysis. The goal of this Core Contract with CBTRUS is for the CWRU contracted PI and her team to conduct statistical analysis for CBTRUS using the NPCR-CSS data files and NCI/SEER Research file.
Role: Contract PI

**Completed**

NIH/NCI 5R01 CA114343-05 (Sellers, PI) 03/15/07-02/28/12
Haplotype-Based Genome Screen for Ovarian Cancer Loci. The major goal of this project is to combine the resources and expertise of two large familial cancer registries and four population-based case control studies of ovarian cancer that have collected genomic DNA on participants.

NIH/NIDA 5P20 DA026133-03 (Chance, PI) 04/15/09-03/31/12
Case Proteomics Center for HIV/AIDs and Drug Abuse. The goals of this study are to examine the role of innate immunity, proteomics, genomics and HIV/AIDs infection in drug addiction.

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME CYNTHIA M. BEALL | POSITION TITLE |
| eRA COMMONS USER NAME cbeall | PROFESSOR OF ANTHROPOLOGY |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| Univ. of Pennsylvania, Philadelphia, PA | B.A. | 1970 | Biology |
| The Pennsylvania State Univ., Univ. Park | M.A. | 1972 | Anthropology |
| The Pennsylvania State Univ., Univ. Park | Ph.D. | 1976 | Anthropology |

**A. Positions and Honors**

**Positions and Employment**

1976-1982 Assistant Professor, Department of Anthropology, Case Western Reserve University
1982-1987 Associate Professor (with tenure), Department of Anthropology, Case Western Reserve University
1987-1994 Professor, Department of Anthropology, Case Western Reserve University
1994- S. Idell Pyle Professor of Anthropology, Case Western Reserve University
1995- Professor of Anatomy, Case Western Reserve University, adjunct appt.
2003- Professor of Global Health and Disease, Case Western Reserve University, adjunct appt.
2005- Adjunct Staff, Department of Pathobiology, Cleveland Clinic Foundation
2010- Distinguished University Professor, Case Western Reserve University

**Other Experience and Professional Memberships**

1976- Member, American Association for the Advancement of Science, American Anthropological Association, American Association of Physical Anthropologists, Human Biology Council, Society for the Study of Human Biology, International Mountain Medicine Society
1992-1994 President, Human Biology Council (now Human Biology Association)
1998-2001 Member, U. S. National Committee for the International Union of Biological Sciences
2001-2003 Chair, U. S. National Committee for the International Union of Biological Sciences
2002-2005 Councilor, National Academy of Sciences
2002-2005 Chair, Anthropology Section (51), National Academy of Sciences
2002- 2005 Member, Advisory Committee for the Social, Behavioral and Economic Sciences (SBE) Directorate of the National Science Foundation
2003 - 2008 Chair, National Academy of Sciences, National Research Council, Board on International Scientific Organizations (BISO), member since 2001
2005 – 2007 Elected Member, Executive Board, International Council on Science (ICSU)
2010 – 2012 Chair-elect, Chair and Retiring Chair, Section on Anthropology, American Association for the Advancement of Science (AAAS)
2010 – 2013 Advisory Council Member, Division of Behavioral and Social Sciences and Education, National Research Council, National Academy of Sciences
2011 Chair, Nominating Committee, National Academy of Sciences.
2012 – 2015 Advisory Council Member, Wenner Gren Foundation for Anthropological Research

**Honors**

1996 Elected to membership, National Academy of Sciences
1997 Elected Fellow, American Association for the Advancement of Science

2001 Elected to membership, American Philosophical Society
2009 Franz Boas Award for Distinguished Lifetime Achievement, Human Biology Association
2011 Guggenheim Fellowship
2012 Raymond Pearl Award for contributions to human biology, Human Biology Association

**B. Selected peer-reviewed publications (in chronological order).**

1. 1981 Beall, C.M. Optimal Birthweights in Peruvian Populations at High and Low Altitudes. Am. J. Physical Anthropol.56(3):209-216.
2 . 1987 Beall, C.M., M.C. Goldstein and the Tibetan Academy of Social Sciences. Hemoglobin Concentration of Tibetan Nomads Permanently Resident at 4,850-5,450m. Am. J. Physical Anthropol. 73(4): 433-438.
3. 1990 Beall, C.M., G.M. Brittenham, F. Macuaga, M. Barragan.Variation in hemoglobin concentration among samples of high altitude natives in the Andes and the Himalayas. Am. J. Human Biol. 2(6): 639-662.
4. 1992 Beall, C.M. and M.C. Goldstein. High prevalence of excess fat and central fat patterning among Mongolian pastoral nomads. Am. J. Human Biol 4(6): 747-756.
5. 1997 Beall, C. M., A. Gebremedhin, G. M. Brittenham, and M. Shamebo. Blood pressure variation among Ethiopians on the Simien Plateau. Ann. Hum. Biol. 24(4): 333-342.
6. 1997 Beall, C. M., K. P. Strohl, J. Blangero, S. Williams-Blangero, G. M. Brittenham, and M. C. Goldstein. Quantitative genetic analysis of arterial oxygen saturation in Tibetan Highlanders. Hum. Biol. 69(5): 597-604.
7. 2000 Beall, C. Oxygen saturation increases during childhood and decreases during adulthood among high altitude native Tibetans residing at 3800-4200m High Altitude Medicine and Biology 1(1): 25-32.
8. 2001 Beall, C., Laskowski, D., Strohl, K. P., Soria R., Villena, M., Vargas, E., Alarcon, A. M., Gonzales, C. and Erzurum, S. C. Pulmonary nitric oxide in mountain dwellers. Nature 414: 411-412.
9. 2002 Beall CM, Decker MJ, Brittenham GM, Kushner I, Gebremedhin A and Strohl KP. An Ethiopian pattern of human adaptation to high-altitude hypoxia. Proc Natl Acad Sci 99: 17215-17218
10. 2004 Beall, C. M., Song, K., Elston, R. C., Goldstein, M. C. Higher offspring survival among Tibetan women with high oxygen saturation genotypes residing at 4000m. Proc. Nat. Acad. Sci. 101(39):14300-4
11. 2005 Hoit BD, Dalton ND, Erzurum SC, Laskowski D, Strohl KP, Beall CM. Jul 14; Nitric Oxide and Cardio-Pulmonary Hemodynamics in Tibetan Highlanders. J. Appl Physiol. 99:1796-1801. First published July 14, 2005; doi: 10.1152/japplphysiol.00205.2005.
12. 2006 Brown, D., Beall, C.M., Strohl, K. P., Mills, P.S., Exhaled nitric oxide decreases upon acute exposure to high-altitude hypoxia. Am J Hum Biol. 18(2): 196-202.
13. 2007 Erzurum, S.C., Ghosh, S., Janocha, A.J., Xu, W., Bauer, S., Bryan, N.S., Tejero, J., Hemann, C., Hille, R., Stuehr, D.J., Feelisch, M., Beall, C.M Higher blood flow and circulating NO products offset high-altitude hypoxia among Tibetans. Proceedings of the National Academy of Sciences 104, 17593.
14. 2009 Vitzthum VJ, Worthman CM, Beall CM, Thornburg J, Vargas E, Villena M, Soria R,Caceres E, Spielvogel H. Seasonal and circadian variation in salivary testosterone in rural Bolivian men. Am J Hum Biol. 21(6):762-8.
15. 2005 Geoff Childs, M.C. Goldstein, Ben Jiao, C.M. Beall. Tibetan Fertility Transitions in China and south Asia. Population and Development Review (31):2: 337-351.
16. 2006 Beall, C. M. Andean, Tibet, and Ethiopian Patterns of Adaptation to High-Altitude Hypoxia. Journal of Integrative and Comparative Biology [Advance Access, January 6, 2006] Integrative and Comparative Biology 2006 46(1):18-24; doi:10.1093/icb/icj004
17. 2006 Brown, D. E., Beall, C. M., Strohl, K. P., and Mills, P. S. Exhaled Nitric Oxide Decreases upon Acute Exposure to High-Altitude Hypoxia. American Journal of Human Biology 18(2): 196-202
18. 2007 Beall, C.M. Two routes to functional adaptation: Tibetan and Andean high-altitude natives. Proc Natl Acad Sci U S A. 2007 May 15;104 Suppl 1:8655-60. Epub 2007 May 9.
19. 2007 Beall, C.M. Detecting natural selection in high-altitude human populations. Respir Physiol Neurobiol. 158: 161-171. [2007 Jun 8; Epub ahead of print]

20. 2007 Erzurum, S.C., Ghosh, S., Janocha, A.J., Xu, W., Bauer, S., Bryan, N.S., Tejero, J., Hemann, C., Hille, R., Stuehr, D.J., Feelisch, M., Beall, C.M Higher blood flow and circulating NO products offset high-altitude hypoxia among Tibetans. Proceedings of the National Academy of Sciences 104, 17593.
21. 2009 Vitzthum VJ, Worthman CM, Beall CM, Thornburg J, Vargas E, Villena M, Soria R, Caceres E, Spielvogel H. Seasonal and circadian variation in salivary testosterone in rural Bolivian men. Am J Hum Biol. 21(6):762-8.Apr 14. [Epub ahead of print]
22. 2009 Laskowski D, Beall CM, Dweik R, Strohl KP, Hutte R, Erzurum SC. Response to "Measuring exhaled nitric oxide at high altitude. Respir. Physiol Neurobiol 167: 292-298". Respir Physiol Neurobiol. 2010 Jan 31;170(1):1-2 [Epub 2009 Nov 14.]
23. 2010 Beall CM, Strohl KP, Laskowski D, Hutte R, Erzurum SC . Response to "Lowered exhaled nitric oxide in acute hypobaric than in normobaric hypoxia by T. Hemmingsson and D. Linnarsson. Respir. Physiol. Neurobiol 169: 74-77". Respir Physiol Neurobiol. 2010 Feb 1. [Epub ahead of print]
24. 2010 Hancock AM, Witonsky DB, Ehler E, Alkorta-Aranburu G, Beall C, Gebremedhin A, Sukernik R, Utermann G, Pritchard J, Coop G, Di Rienzo A. Colloquium paper: human adaptations to diet, subsistence, and ecoregion are due to subtle shifts in allele frequency. Proc Natl Acad Sci U S A. 2010 May 11;107 Suppl 2:8924-30. Epub May 5. PubMed PMID: 20445095.
25. 2010 Beall CM, Cavalleri GL, Deng L, Elston RC, Gao Y, Knight J, Li C, Li JC, Liang Y, McCormack M, Montgomery HE, Pan H, Robbins PA, Shianna KV, Tam SC, Tsering N, Veeramah KR, Wang W, Wangdui P, Weale ME, Xu Y, Xu Z, Yang L, Zaman MJ, Zeng C, Zhang L, Zhang X, Zhaxi P, Zheng YT. Natural selection on EPAS1 (HIF2alpha) associated with low hemoglobin concentration in Tibetan highlanders. Proc Natl Acad Sci U S A. 107(25):11459-64. Epub 2010 Jun 7. PubMed PMID: 20534544; PubMed Central PMCID: PMC2895075.
26. 2011 Hoit BD, Dalton ND, Gebremedhin A, Janocha A, Zimmerman PA, Zimmerman AM, Strohl KP, Erzurum SC, Beall CM. Elevated pulmonary artery pressure among Amhara highlanders in Ethiopia. Am J Hum Biol. 2011 Mar-Apr;23(2):168-76. doi: 10.1002/ajhb.21130. Epub 2010 Dec
27. 2011 Janocha AJ, Koch CD, Tiso M, Ponchia A, Doctor A, Gibbons L, Gaston B, Beall CM, Erzurum SC. Nitric oxide during altitude acclimatization. N Engl J Med. 2011 Nov 17;365(20):1942-4. PMID: 22087700
28. Beall, C. M., D. Laskowski, et al. (2012). "Nitric oxide in adaptation to altitude." Free Radical Biology and Medicine 52(7): 1123-1134.
29. Alkorta-Aranburu, G., C. M. Beall, et al. (2012). "The genetic architecture of adaptations to high altitude in ethiopia." PLoS Genet 8(12): e1003110.
30. Beall CM. 2013 Human adaptability studies at high altitude: Research designs and major concepts during fifty years of discovery. Am J Hum Biol. 25(2): 141-147. doi: 10.1002/ajhb.22355. [Epub ahead of print] PubMed PMID: 23349118.

**C. Research support**

## Ongoing research support

National Science Foundation Grant No. BCS-0924726 2009-2012
PI: Nitric oxide and the microcirculation in the Tibet Autonomous Region. Examination of microcirculation among Tibetans living in high altitude conditions.

National Science Foundation Grant No. BCS-1153911 2012 – 2015
PI: Genes and the fertility of Tibetan women at high altitude in Nepal. Testing for the association of single nucleotide polymorphisms in candidate genes with measures of reproductive fitness in women 40 or more years of age.

**BIOGRAPHICAL SKETCH**

| NAME **Blackstone, Eugene H., MD** | POSITION TITLE<br>Head, Clinical Investigations, Heart & Vascular Institute<br><br>Staff, Dept. of Thoracic and Cardiovascular Surgery and Dept. of Quantitative Health Sciences |
|---|---|
| eRA COMMONS USER NAME<br>BLACKSE | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| University of Chicago | SB | 1959-1963 | Biology |
| University of Chicago | MD | 1962-1966 | Medicine |
| University of Chicago | Fellowship | 1966-1968 | Research |

## A. Positions and Honors

**Positions and Employment**

1968-1969 Intern, University of Alabama at Birmingham
1969-1972 Major, U.S. Army Medical Research and Development Command, Chief, Cardiology Branch, Ft. Rucker, Alabama
1972-1975 Assistant Professor, Dept. of Surgery, University of Alabama at Birmingham
1975-1980 Associate Professor, Dept. of Surgery, University of Alabama at Birmingham
1980-1997 Professor, Dept. of Surgery, University of Alabama at Birmingham; and The Cardiovascular Surgical Research Professor (endowed)
1997-present Staff, Dept. of Thoracic and Cardiovascular Surgery, Cleveland Clinic
1997-present Staff, Dept. of Quantitative Health Sciences, Cleveland Clinic
1997-present Professor, Dept. of Surgery, University of Toronto
2002-present Staff, Transplant Center, Cleveland Clinic, Cleveland, Ohio
2007-present Head, Clinical Investigations, Heart and Vascular Institute, Cleveland Clinic
2008-present Professor of Surgery, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University

**Other Experience and Professional Membership**

Alpha Omega Alpha
American Association for Thoracic Surgery
American College of Cardiology (Fellow)
American Physiological Society
Congenital Heart Surgeons Society
Associate Editor, Journal of Thoracic and Cardiovascular Surgery
Consultant to FDA Circulatory System Devices Panel
Member of Research Education, Clinical Education, and Advanced Clinical Education Committees of the Cleveland Clinic Lerner College of Medicine
CTSA KL2 MAC and Mentorship Committees

**Honors**

1998 Distinguished Service Award, University of Chicago
2003 Maria and Sam Miller Professional Excellence Award, Scientific Achievement Award in Clinical Research
2007 The Kenny Gee and Paula Shaw, Ph.D. Chair in Heart Research

2010 Excellence in Research Education Award, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University

**B. Selected peer-reviewed publications** (selected from 580 peer-reviewed publications)

1. Li Z, Rice TW, Liu X, Goldblum JR, Williams SJ, Rybicki LA, Murthy SC, Mason DP, Raymond DP, Blackstone EH. Intramucosal esophageal adenocarcinoma: Primum non nocere. J Thorac Cardiovasc Surg 2012. [ePub ahead of print]
2. Mihaljevic T, Pattakos G, Gillinov AM, Bajwa G, Planinc M, Williams SJ, Blackstone EH. Robotic posterior mitral leaflet repair: neochordal versus resectional techniques. Ann Thorac Surg 2012. [ePub ahead of print]
3. Rader F, Pujara AC, Pattakos G, Rajeswaran J, Li L, Castel L, Chung MK, Gillinov AM, Costantini O, Van Wagoner DR, Blackstone EH. Perioperative heart-type fatty acid binding protein levels in atrial fibrillation after cardiac surgery. Heart Rhythm 2012. [ePub ahead of print]
4. Desai RR, Vargas Abello LM, Klein AL, Marwick TH, Krasuski RA, Ye Y, Nowicki ER, Rajeswaran J, Blackstone EH, Pettersson GB. Tricuspid regurgitation and right ventricular function after mitral valve surgery with or without concomitant tricuspid valve procedure. J Thorac Cardiovasc Surg 2012. [ePub ahead of print]
5. Kappetein AP, Head SJ, Genereux P, Piazza N, van Mieghem NM, Blackstone EH, Brott TG, Cohen DJ, Cutlip DE, van Es GA, Hahn RT, Kirtane AJ, Krucoff MW, Kodali S, Mack MJ, Mehran R, Rodes-Cabau J, Vranckx P, Webb JG, Windecker S, Serruys PW, Leon MB. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. J Am Coll Cardiol 2012;60:1438.
6. Blackstone EH. Demise of a vital resource. J Thorac Cardiovasc Surg 2012;143:37-8.
7. Roselli EE, Abdel Azim A, Houghtaling PL, Jaber WA, Blackstone EH. Pulmonary hypertension is associated with worse early and late outcomes after aortic valve replacement: Implications for transcatheter aortic valve replacement. J Thorac Cardiovasc Surg 2012;144:1067-1074.
8. Lindsay AJ, Xu M, Sessler DI, Blackstone EH, Bashour CA. Lactate clearance time and concentration linked to morbidity and death in cardiac surgical patients. Ann Thorac Surg 2012. [ePub ahead of print]
9. Fraser Jr. CD, Jaquiss RD, Rosenthal DN, Humpl T, Canter CE, Blackstone EH, Naftel DC, Ichord RN, Bomgaars L, Tweddell JS, Massicotte MP, Turrentine MW, Cohen GA, Devaney EJ, Pearce FB, Carberry KE, Kroslowitz R, Almond CS, and Berlin Heart Study Investigators. Prospective trial of a pediatric ventricular assist device. N Engl J Med 2012;367:532.
10. Tong BC, Huber JC, Ascheim DD, Puskas JD, Ferguson Jr. TB, Blackstone EH, Smith PK. Weighting composite endpoints in clinical trials: essential evidence for the heart team. Ann Thorac Surg 2012;94:1908-1913.
11. Pattakos G, Koch CG, Brizzio ME, Batizy LH, Sabik JF, Blackstone EH, Lauer MS. Outcome of patients who refuse transfusion after cardiac surgery: a natural experiment with severe blood conservation. Arch Intern Med 2012;172:1154-60.
12. Koch CG, Nowicki ER, Rajeswaran J, Gordon SM, Sabik JF 3rd, Blackstone EH. When the timing is right: antibiotic timing and infection after cardiac surgery. J Thorac Cardiovasc Surg 2012;144:931-937.
13. Vargas Abello LM, Klein AL, Marwick TH, Nowicki ER, Rajeswaran J, Puwanant S, Blackstone EH, Pettersson GB. Understanding right ventricular dysfunction and functional tricuspid regurgitation accompanying mitral valve disease. J Thorac Cardiovas Surg 2012. [ePub ahead of print]
14. Mason DP, Rajeswaran J, Li L, Murthy SC, Su JW, Pettersson GB, Blackstone EH. Effect of changes in postoperative spirometry on survival after lung transplantation. J Thorac Cardiovasc Surg 2012;144:197-203.
15. Shafii AE, Gillinov AM, Mihaljevic T, Stewart W, Batizy LH, Blackstone EH. Changes in left ventricular morphology and function after mitral valve surgery. Am J Cardiol 2012;110:403-408.

## C. Research Support

**Ongoing Research Support**

1R01HL103552-01A1 Eugene H. Blackstone, MD (PI) 08/10/2011 to 05/31/2015
Funding Agency: NIH/NHLBI
*Ancillary Comparative Effectiveness of Atrial Fibrillation Ablation Surgery*
The objectives of this ancillary study are to develop and disseminate novel and innovative analytic methods for longitudinal data, of which cardiac rhythm data for the parent trial is one important example.

**Recently Completed Projects**

1U01HL088955-01 Eugene H. Blackstone, MD (PI) 7/1/2007 to 6/30/2012
Funding Agency: NIH
*Cleveland Clinic Cardiothoracic Collaborative Clinical Center - C6 (CTSN)*
The major goal of the Cleveland Clinic Cardiothoracic Collaborative Clinical Center (C6) is to participate fully in each clinical protocol as a priority in a Network for Cardiothoracic Surgical Investigations in Cardiovascular Medicine as both a Clinical Center and a Clinical Research Skills Development Core.

Sub-Award
NHLBI 7U01 HL088942-02 10/15/2008 to 6/30/2012
The Mount Sinai School of Medicine of New York University
*Evaluation of Outcomes Following Mitral Valve Repair/Replacement in Severe Chronic Ischemic Mitral Regurgitation*

Sub-Award
NHLBI 7U01 HL088942-02 10/15/2008 to 6/30/2012
The Mount Sinai School of Medicine of New York University
*Surgical Interventions for Moderate Ischemic Mitral Regurgitation*

Sub-Award
NHLBI 7U01 HL088942-02 10/15/2008 to 6/30/2012
The Mount Sinai School of Medicine of The New York University
*Surgical Ablation versus No Ablation for Patients with Non-Paroxysmal Atrial Fibrillation Undergoing Mitral Valve Surgery*

#HHS-NIH-NLM-RDS-10-121-SES Doug Lenat (PI) 9/2010 to 9/2011
Funding Agency: National Library of Medicine
*RECOVERY: Computational Thinking to Support Clinicians and Biomedical Scientists*
Researchers and clinicians alike can draw valuable assistance from both statistical models and causal symbolic models. We propose to investigate this constructively – that is, by building a prototype system that utilizes both sources of power as it functions to assist humans carrying out these activities. In this one-year proposed project, one aim is to demonstrate sufficient performance of a prototype – integrating statistical and biology model-based causal reasoning – to justify NLM pursuing a substantially larger and longer-term program in this area. This could lead to a new genre of multi-paradigm systems using increasingly sophisticated logical reasoning about systems biology and drawing on increasingly large and detailed datasets, to discover increasingly sophisticated, experimentally testabele, new hypotheses.
Role: Consultant

No number assigned A. Marc Gillinov, MD (PI) 8/1/2005 to 12/31/2010
Funding Agency: State of Ohio
*Atrial Fibrillation Innovation Center*

The Cleveland Clinic Foundation, its institutional partners, Case Western Reserve University, the University of Cincinnati, and its Ohio commercial partners, AtriCure, Inc, Philips Medical Systems, Sinus Rhythm Technology, Inc. and Symphony Medical, were awarded $15,500,000 in capital funds to establish the Atrial Fibrillation Innovation Center (AFIC), a Wright Center of Innovation, and $8,000,000 in operational funds over 3 years. AFIC falls under Third Frontier human genetics and biomedical engineering areas and addresses the suffering imposed by atrial fibrillation (AF) while catalyzing an emerging Ohio AF therapeutic industry.
Role: Section head

HHSN26820080026C Eugene H. Blackstone, MD (PI) 9/30/2008 to 9/29/2010
Funding Agency: NIH
*National Heart, Lung & Blood Institute Quantitative Clinical Cardiovascular Epidemiology Projects*
Objectives are to 1) invent innovative analytic methods based on an underlying strategy of using computer learning to distinguish signal from noise and minimize prediction error and package them for free use of other investigators, 2) apply and validate these methods in determining prognostic value of several existing and novel diagnostic measures in heart disease suspected of heart disease, 3) identify new risk factors that have public health implications, and 4) use the resulting analyses to create strategic decision support.

HL-072772-01 Eugene H. Blackstone, MD (PI) 7/1/2004 to 7/1/2008
Funding Agency: NIH
*Logical Analysis of Data*
In this project we developed novel survival analysis methods for analyzing large survival databases. Our application focused on 5 cardiac databases related to various cardiac surgery treatments.

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Robert A. Bonomo** | POSITION TITLE<br>Chief, Medical Service, Director VISN 10 GRECC Cleveland VAMC, Professor, Departments of Medicine (primary), Pharmacology, Molecular Biology and Microbiology, and Center for Proteomics (secondary) |
| eRA COMMONS USER NAME<br>**RBONOMO** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Hamilton College, Clinton, New York | B.A. | May, 1976 | Biology |
| New York University, Basic Medical Sciences | | 1977-1979 | Histology |
| Case Western Reserve University, Cleveland,OH | M.D. | May, 1983 | Medicine |
| University Hospitals of Cleveland, Cleveland, OH | | 1983-1986 | Resident, Medicine |
| University Hospitals of Cleveland, Cleveland, OH | | 1990-1994 | Infectious Diseases |
| University Hospitals of Cleveland, Cleveland, OH | | 1998 | CAQ, Geriatrics |

## A. Positions and Honors

**Positions and Employment:**

1986-1990 Clinical Instructor, CWRU School of Medicine, Cleveland, Ohio Physician, Internal Medicine, Cleveland Neighborhood Health Services, Inc. Staff Physician, Cleveland Neighborhood Health Services
1989-1990 Chief of Medicine, Cleveland Neighborhood Health Services
1994-2001 Assistant Professor of Medicine, CWRU School of Medicine, Cleveland, Ohio
1997- Staff Physician, Division of Geriatrics, Cleveland Veterans Affairs Medical Center
2000-2008 Section Chief, Infectious Diseases, Cleveland Veterans Affairs Medical Center
2000- Secondary appointment, Department of Pharmacology, CWRU School of Medicine
2001 Associate Professor of Medicine, CWRU School of Medicine, Cleveland, Ohio
2002 Award of Tenure, CWRU School of Medicine, Cleveland, Ohio
2003 Committee on Medical Education, CWRU School of Medicine, Cleveland, Ohio
2004 Secondary appointment, Department of Molecular Biology and Microbiology, CWRU SOM
2008 Director VISN 10 GRECC (State of Ohio)
2009 Professor of Medicine, Pharmacology, Molecular Biology and Microbiology CWRU School of Medicine, Cleveland, Ohio
2010 Secondary appointment, Professor, Center for Proteomics
2011- Chief of Medicine, Cleveland Veterans Affairs Medical Center; Vice Chairman for Veterans Affairs, Department of Medicine, University Hopsitals, Case Medical Center

**Other Experience and Professional Memberships:**

2002-2003 National Institutes of Health, Study Section, Indian Health Service
2002-2014 Editorial Board, *Antimicrobial Agents and Chemotherapy*
2011-2014 Editorial Board, *Clinical Microbiology Reviews*
2011-2014 Editorial Board, *Applied and Environmental Microbiology*
2005-2012 Program Committee, Interscience Conference on Antimicrobial Agents and Chemotherapy
2006-2011 Editorial Board, *Biochemical Journal*
2006-2011 Editorial Board, *Journal of Biological Chemistry*

| | |
|---|---|
| 2008-2009 | National Institutes of Health, Special Emphasis Panel, Regional Centers of Excellence for Biodefense; ad hoc member Clinical Research and Field Studies of Infectious Diseases, Infectious Diseases and Microbiology; special emphasis panel. |
| 2010 | Infectious Diseases and Microbiology, Drug Discovery and Mechanisms of Antimicrobial Resistance Study section (2013) |
| 2009 | Editorial Board, *Microbial Drug Resistance* |
| 2010 | Editorial Board, *Pediatric Infectious Diseases, Applied and Environmental Microbiology* |
| 2010-2012 | European Congress of Clinical Microbiology and Infectious Diseases, key note speaker |

**Honors:**

| | |
|---|---|
| 1973 | Curran Prize in Classical Languages, Hamilton College |
| 1983 | The Milton B. Schweid Memorial Award CWRU SOM for Excellence in Cardiovascular Disease |
| 1994 | American College of Physicians, Associate Clinical Vignette Competition, Winner |
| 2004 | Kaiser Permanente Excellence in Teaching Award for Basic Medical Sciences, CWRU SOM |
| 2005 | Alpha Omega Alpha Honor Medical Society |
| 2005 | Award from University Hospitals of Cleveland for Excellence in House Staff Teaching |
| 2008 | Distinguished Educator in Infectious Diseases, University of Pittsburgh |
| 2008 | Gender Equity Award for Excellence in Teaching |
| 2008 | "Master Teacher" CWRU School of Medicine |
| 2009 | Member, WHO Patient Safety Programme: the Global Challenge of Antimicrobial Resistance |
| 2009 | Federal Executive Board, Wings of Excellence Award |
| 2009 | Association of American Physicians (National Society) |
| 2009 | President Division A, Antimicrobial Chemotherapy, American Society for Microbiology |
| 2010 | Visiting Professor, American Society for Microbiology, Japan in 2009; Argentina, Fall 2010 |
| 2011 | American Academy of Microbiology, inductee, 2011 |
| 2012 | Association of Professors of Medicine |

## B. Publications (Chosen from 221 in PubMed)

1. Adams MD, … Russo T, Campagnari AA, Hujer AM, **Bonomo RA**, Gill SR. Comparative genome sequence analysis of multidrug-resistant *Acinetobacter baumannii*. J Bacteriol. 2008 Dec;190(24):8053-64. PMC2593238.
2. Bethel CR, Distler AM, Ruszczycky MW, Carey MP, Carey PR, Hujer AM, Taracila M, Helfand MS, Thomson JM, Kalp M, Anderson VE, Leonard DA, Hujer KM, Abe T, Venkatesan AM, Mansour TS, **Bonomo RA**. Inhibition of *OXA*-1 β-lactamase by penems. Antimicrob Agents Chemother. 2008 Sep;52(9):3135-43. PMC2533510.
3. Adams MD, … Jacobs MR, **Bonomo RA**. Resistance to colistin in *Acinetobacter baumannii* associated with mutations in the PmrAB two-component system. Antimicrob Agents Chemother. 2009 Sep;53(9):3628-34.:PMC2737849.
4. Schneider KD, Karpen ME, **Bonomo RA**, Leonard DA, Powers RA. The 1.4 A crystal structure of the class D β-lactamase *OXA*-1 complexed with doripenem. Biochemistry. 2009 Dec 22;48(50):11840-7. PMC2805451.
5. Adams MD, Chan ER, Molyneaux ND, **Bonomo RA**. Genomewide analysis of divergence of antibiotic resistance determinants in closely related isolates of *Acinetobacter baumannii*. Antimicrob Agents Chemother. 2010;54(9):3569-77. PMC2934971.
6. Drawz SM, Babic M, Bethel CR,. **Bonomo RA**. Inhibition of the class C beta-lactamase from *Acinetobacter* spp.: insights into effective inhibitor design. Biochemistry. 2010;49(2):329-40. PMC2810401.
7. Bou G, Santillana E, Sheri A,. **Bonomo RA**, Romero A, Buynak JD. Design, Synthesis, and Crystal Structures of 6-Alkylidene-2'-Substituted Penicillanic Acid Sulfones as Potent Inhibitors of *Acinetobacter baumannii* OXA-24 Carbapenemase. J Am Chem Soc. 2010 Sep 29;132(38):13320-31. PMC3393087.

8. Drawz SM, Bethel CR, Doppalapudi VR, Sheri A, Pagadala SR, Hujer AM, Skalweit MJ, Anderson VE, Chen SG, Buynak JD, **Bonomo RA**. Penicillin sulfone inhibitors of class D -lactamases. Antimicrob Agents Chemother. 2010 Apr;54(4):1414-24. PMC2849368.
9. Jacobs MR, Bajaksouzian S, Good CE,. **Bonomo RA**. Novel bis-indole agents active against multidrug-resistant *Acinetobacter baumannii*. Diagn Microbiol Infect Dis. 2011Jan;69(1):114-6. PMID21146724.
10. Russo TA, Page MG, Beanan JM,. **Bonomo RA**. In vivo and in vitro activity of the siderophore monosulfactam BAL30072 against *Acinetobacter baumannii*. J Antimicrob Chemother. 2011 Apr;66(4):867-73. PMC3058568.
11. Ramirez MS, Adams MD, **Bonomo RA**, Centrón D, Tolmasky ME. Genomic analysis of *Acinetobacter baumannii* A118 by comparison of optical maps: identification of structures related to its susceptibility phenotype. Antimicrob Agents Chemother. 2011 Apr;55(4):1520-6. PMC3067174.
12. Clemmer KM, **Bonomo RA,** Rather PN. Genetic analysis of surface motility in *Acinetobacter baumannii*. Microbiology. 2011 Sep;157(Pt 9):2534-44. PMC3352170.
13. Tian GB, Adams-Haduch JM, Taracila M, **Bonomo RA**, Wang HN, Doi Y Extended-spectrum AmpC cephalosporinase in Acinetobacter *baumannii*: ADC-56 confers resistance to cefepime. Antimicrob Agents Chemother. 2011 Oct;55(10):4922-5. PMC3186995.
14. Schneider KD, Ortega CJ, Renck NA, **Bonomo RA**, Powers RA, Leonard DA. Structures of the class D carbapenemase OXA-24 from Acinetobacter *baumannii* in complex with doripenem. J Mol Biol. 2011 Mar 4;406(4):583-94. PMC3057435.
15. Saroj SD, Clemmer KM, **Bonomo RA**, Rather PN. Novel mechanism for fluoroquinolone resistance in Acinetobacter *baumannii*. Antimicrob Agents Chemother. 2012 Sep;56(9):4955-7. PMC3421888.
16. Che T, **Bonomo RA**, Shanmugam S, Bethel CR, Pusztai-Carey M, Buynak JD, Carey PR. Carboxylation and Decarboxylation of Active Site Lys 84 Controls the Activity of OXA-24 β-Lactamase of Acinetobacter *baumannii* : Raman Crystallographic and Solution Evidence. J Am Chem Soc. 2012 Jul 11;134(27):11206-15. PMC3404726.

## C. **Research Support**

**ACTIVE**

R01 AI072219 (PI) 8/1/07-7/31/12 2.4 calendar
NIH/NIAID No cost extension until 7/31/13
*Multidrug Resistant Acinetobacter baumannii*
The major goals are to examine cephalosporin resistance by determining the atomic structure of the class C (ADC-type) beta-lactamases and testing novel boronic acid and sulfone transition state inhibitors against this class of cephalosporinases. We will examine carbapenem resistance by random mutagenesis of the class D beta-lactamases, OXA-23 and OXA-58, and will perform mass spectrometry to determine the intermediates of inactivation by beta-lactamase inhibitors. Efflux pumps are a major component of antibiotic resistance. The genetic heterogeneity of the regulatory regions of the adeABC efflux pump will be determined and will be used to develop a novel PCR/ESI-MS method to predict the multidrug resistant phenotype in *Acinetobacter*.

Merit Review (PI) 1/1/09-12/31/12 2.4 calendar
Department of Veterans Affairs $150,000/year
*The Continuing challenge of beta-lactamases: KPC Carbapenemases*
The major goals of this project are to determine the sequence requirements for resistance by investigating the contribution of Ambler positions T237, H274, R220, W105 and S130 to imipenem, cefoxitin, and ceftazidime hydrolysis; to describe the kinetic interactions (*Ki*, *k*cat, *k*inact, *k*inact/*Ki*, timed inactivation) of betalactamase inhibitors against KPC-2 and map the products of inactivation by mass spectrometry; crystallize clavulanic acid, tazobactam, and boronic acid transition state inhibitors in the active site of KPC-2 betalactamase; to assess the expression levels of KPC-type beta-lactamases in different clinical strains of *K. pneumoniae* and determine if the regions 5' to *bla*KPC-2 and *bla*KPC-3 genes influence the amount of enzyme being produced and the minimum inhibitory concentrations (MICs); and to determine the crystal structure of KPC-2 inactivated by BLIP.

R01 AI063517 (PI) 6/1/10-5/31/15 2.4 calendar
NIH/NIAID $250,000/year

*Challenges in beta-Lactamase Mediated Resistance*

We will complete our studies of ES SHV beta-lactamases by testing novel BATSIs possessing unique R1 side chains. We will also define the sequence requirements, molecular, and kinetic interactions that characterize the catalysis and inhibition of PDC-3. To understand the interactions of PDC-3 with cephalosporins, carbapenems, and BATSIs on a deeper level, we will test the role of Thr105Ala, Thr289, Asn343, Asn346 and Arg349 in PDC-3 using site-saturation and Ala replacement mutagenesis and to investigate the properties of PDC-3 that permit the evolution of the ES and carbapenemase profile, we will introduce specific deletion mutations into the R2-loop of PDC-3. We will also determine the apo crystal structure of PDC-3 and the structure of PDC-3 complexed with BATSIs possessing ceftazidime (LP06) and cefotaxime R1 side chains.

R01 AI100560 Bonomo, Spencer & Vila (PIs) 2/7/12-1/31/17 1.2 calendar
NIH/NIAID $383,522/year

*A mechanism based approach to metallo-beta-lactamase inhibition*

Carbapenemases, or carbapenem-hydrolyzing beta-lactamases that potentially inactivate all beta-lactams including carbapenems, can severely limit the treatment of infections caused by Gram-negative bacteria. Among the carbapenemases, metallo-beta-lactamases (MBLs such as NDM-1, VIM-2, IMP-1, and SPM-1) are rapidly emerging world-wide and pose one of the most serious public health threats. We seek to study these clinically relevant MBLs to provide evidence that a common reaction intermediate exists and can be exploited to make an effective inhibitor. To this end we will: 1) characterize the populated reaction intermediates in clinically relevant MBLs (i.e., NDM-1, VIM-2, IMP-1, and SPM-1); 2) identify biochemical features of the mobile loops flanking the active sites of common MBLs that assist in recognizing a broad repertoire of substrates and evaluate these loops as potential pharmacophores for inhibitor development; and 3) design compounds that will mimic the common anionic intermediates to give insight into the mechanism of inhibition.

GRANT10471424 Greenfield & Marcus (Co-PIs); Bonomo (Co-I)
DoD/USAMRAA 9/15/10-9/14/13 0.6 calendar
$10,600/year

I*nhibition of Orthopaedic Implant Infections by Immunomodulatory Effects of Host Defense Peptides*

Over 100,000 orthopaedic infections occur in the U.S. each year and more than 80% are due to *Staphylococcus aureus*. Host defense peptides represent a promising new approach to inhibiting infection. The aims of this grant are to test the hypothesis that soluble host defense peptides reduce infection of orthopaedic implants.

R01 AI090155 Kreiswirth (PI); Bonomo (Co-PI) 5/01/11-3/31/16 1.2 calendar
NIH/NIAID $50,000/year

*The Molecular Basis of Epidemic blaKPC gene Klebsiella*

Our goal is to molecularly characterize *K. pneumoniae* isolates identified by Dr. Kreiswirth and his team. We will PCR screen for the genes encoding ESBLs, AmpCs, carbapenemases, plasmid mediated quinolone resistance (qnrs), and aminoglycoside modifying enzymes. In the carbapenem strains we will also screen for porin mutations and assess levels of KPC expression.

**PENDING**

Merit Review (PI) 10/1/12-9/30/16 2.4 calendar
Dept. of Veterans Affairs $150,000/year

*The Continuing Challenge of Carbapenemases in K. pneumoniae: KPC-2 & NDM-1*

In this grant we will determine the effect of substitutions in the □-loop of KPC □-lactamase at amino acid positions R164, E166, N170, and D179 2 and ascertain how these mutations alter microbiological phenotype, protein stability and catalytic mechanism. We will also study NDM-1 and perform mutagenesis to remove, in a stepwise manner, the "distinctive additional sequence" at amino acid positions 163 to 166 (163-166) and assess the impact of these deletions on resistance (phenotype), hydrolysis of standard □-lactam and carbapenem

substrates, and protein stability. Next, we will use mutagenesis to replace (site-saturation) and to delete F70 (70) in NDM-1, an amino acid at the entrance of the active site and assess the activity of this variant and its role in protein stability and catalysis.

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Boom, W. Henry** | POSITION TITLE<br>Professor and<br>Director, Tuberculosis Research Unit (TBRU) |
| eRA COMMONS USER NAME<br>**henry_boom** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Hengelosch Gymnasium, Hengelo, Netherlands | Eindexamen | 1971 | |
| Institut d'Etudes Politiques, Paris, France | C.E.P. | 1972 | Political Science |
| Amherst College, Amherst, MA | A.B. | 1975 | Biology |
| University of Rochester, Rochester, NY | M.D. | 1979 | Medicine |

## A. Positions and Honors

**Post-Doctoral Training**

1979-83 Intern, Res. and Chief Res. in Medicine, George Washington Univ. Med. Ctr., Washington, DC

1983-88 Clinical/Res. Fellow, Inf. Dis., Mass. Gen. Hosp.('83-'88); Dept. of Trop. Pub. Health, Harvard School of Pub. Health ('84-'87); Dept. of Pathology, Brigham and Women's Hosp. ('87-'88), Boston, MA

**Positions and Employment**

1988-1995 Assistant Professor, Department of Medicine, Case Western Reserve Univ., Cleveland, OH

1995-2000 Associate Professor with tenure, Case Western Reserve University

1999-2011 Vice Chair for Research, Dept. of Medicine, Univ. Hospitals Case Medical Center

1999-present Director, Tuberculosis Research Unit, Case Western Reserve University

2000-present Professor of Medicine, Pathology ('03-present), and Molecular Biology & Microbiology ('08-present), Case Western Reserve University

**Other:**

1991-1999 Associate Editor ('91-'95), Section Editor ('95-'99), Journal of Immunology

2004-2008 Member, NIH Study Section, Host Interactions with Bacterial Pathogens (HIBP) Study Section

2008 Co-Chair, NIH Review for Reg. Ctrs. of Excellence for Bio-defense & Emerging Infect. Diseases

## B. Selected peer-reviewed publications (Selected from 152 peer-reviewed publications/review articles)

1. Noss EH, Sellati TJ, Radolf JD, Belisle J, Golenbock DT, **Boom WH***, Harding CV*. Toll-like receptor 2-dependent inhibition of macrophage class II MHC expression and antigen processing by 19 kD lipoprotein of M. tuberculosis. J Immunology, 167:910-918, 2001. PMID: 11441098 (*Joint Senior Authorship)
2. Gehring AJ, Dobos KM, Belisle KM, Harding CV*, **Boom WH***. *Mycobacterium tuberculosis* LprG (Rv1411c): a novel TLR-2 ligand that inhibits human macrophage MHC-II antigen processing. J Immunol. 173:2660-2668, 2004. PMID: 15294983 (*Joint Senior Authorship)
3. Pecora ND, Gehring AJ, Canaday DH, **Boom WH*,** Harding CV*. *M. tuberculosis* LprA Is a Lipoprotein Agonist of TLR2 That Regulates Innate Immunity and APC Function. J Immunol. 177:422-9, 2006. PMID: 16785538 (*Joint Senior Authorship)
4. Rojas RE, Thomas J, Gehring AJ, Hill P, Belisle J, Harding CV*, **Boom WH***. Phosphatidylinositol mannoside from *M. tuberculosis* binds alpha5beta1 integrin (VLA-5) on CD4+ T cells and induces adhesion to fibronectin. J Immunol. 177:2959-2968, 2006. PMID: 16920931 (*Joint Senior Authorship)
5. Pennini ME, Pai RK, Schultz CS, Hamilton TA, **Boom WH***, Harding CV*. *M. tuberculosis* 19-kDa lipoprotein inhibits IFN-gamma-induced chromatin remodeling of MHC2TA by TLR2 and MAPK signaling. J Immunol. 176:4323-4330, 2006. PMID: 16547269 (*Joint Senior Authorship).

6. Pennini ME, Yang J, Croninger CM, **Boom WH**, Harding CV. CCAAT/enhancer-binding protein beta and delta binding to CIITA promoters is associated with the inhibition of CIITA expression in response to *M. tuberculosis* 19-kDa lipoprotein. J Immunol. 179:6910-6918, 2007. PMC2631233
7. Pecora ND, Fulton SA, Reba SM, Drage MG, Simmons DP, Urankar-Nagy NJ, **Boom WH***, Harding CV*. *M. bovis* BCG decreases MHC-II expression *in vivo* on murine lung macrophages and dendritic cells during aerosol infection. Cell Immunol. 254:94-104, 2009. PMC2653222 (*Joint Senior Authorship)
8. Mahon RN, Rojas RE, Fulton SA, Franko J, Harding CV*, **Boom WH***. *M. tuberculosis* glycolipids directly inhibit CD4+ T cell activation by interfering with TCR signaling. Infect Immun 77:4574-83, 2009. PMC2747961 (*Joint Senior Authorship)
9. Ramachandra L, Qu Y, Wang Y, Lewis CJ, Cobb BA, Takatsu K, **Boom WH**, Dubyak GR, Harding CV. *M. tuberculosis* synergizes with ATP to induce release of microvesicles and exosomes containing MHC-II molecules capable of antigen presentation. Infect Immun. 78:5116-25, 2010. PMC2981298
10. Drage MG, Tsai J, Pecora1 ND, Cheng TY, Arida AR, Shukla S, Rojas RE, Seshadri C, Moody DB, **Boom WH***, Sacchettini JC*, Harding CV*. *Mycobacterium tuberculosis* lipoprotein LprG (Rv1411c) binds triacylated glycolipid agonists of Toll-like receptor 2. Nature Struct Mol Biol. 17:1088-95, 2010. PMC2933325 (*Joint Senior Authorship)
11. Harding CV, **Boom WH**. Regulation of class II MHC antigen processing by *Mycobacterium tuberculosis*: a role for Toll-like receptors. Nature Rev Microbiology, 8:296-30, 2010. PMC3037727
12. Lancioni CL, Li Q, Thomas JJ, Ding X, Thiel B, Drage MG, Pecora ND, Ziady AG, Shank S, Harding CV, **Boom WH**, Rojas RE. *M. tuberculosis* lipoproteins directly regulate human memory CD4+ T cell activation via TLR2/1. Infect Immun. 79:663-73, 2011. PMC3028837
13. Lancioni CL, Mahan CS, Johnson DF, Walusimbi M, Chervenak KA, Nalukwago S, Charlebois E, Havlir D, Mayanja-Kizza H, Whalen CC, **Boom WH**. Effects of antiretroviral therapy on immune function of HIV-infected adults with pulmonary tuberculosis and CD4+ >350 cells/mm3. J Inf Dis. 203:992-1001, 2011. PMC3068037
14. Mahon RN, Sande OJ, **Rojas RE**, Levine AD, Harding CV, **Boom WH**. Mycobacterium tuberculosis ManLAM inhibits T-cell-receptor signaling by interference with ZAP-70, Lck and LAT phosphorylation. Cell Immunol. 2012; .275:98-105. PMC pending.
15. Li Q, Ding X, Thomas JJ, Harding CV, Pecora ND, Ziady AG, Shank S, **Boom WH**, Lancioni CL, Rojas RE. Rv2468c, a novel Mycobacterium tuberculosis protein that co-stimulates human CD4+ T cells through VLA-5. J Leukocyte Biol. 2012; 91:311-20. PMC3290430

## C. Research Support

**Ongoing Research Support as PI**

RO1 (AI027243-years 18-24) Boom (PI) 07/01/07-06/30/13
NIAID
*"Heterogeneity of T-cells in M. tuberculosis infection"*
This project focuses on the human T cell response to MTB with the following aims: 1) To determine the cellular events associated with VLA-5 (alpha5beta1) dependent PIM-induced human CD4+ T cell migration and adhesion to fibronectin, and to compare different PIM families and species in their ability to induce CD4+ T cell adhesion and migration. 2) To determine the identity and mechanism of a novel MTB molecule that co-stimulates human memory CD4+ T cells in the presence of extracellular matrix protein. 3) To determine if human CD8+ T cells, gamma-delta T cells and Tregs are modulated by LprG, PIM and the co-stimulator of Aim 2 to the same degree and manner as CD4+ T cells.

RO1 (HL106798-years 1-4) Boom (PI)/Chance (Co-PI) 09/17/10-08/31/14
NHLBI
*"Proteogenomics of Dysregulated Protein Interaction Networks in MTB infection"*
This proposal combines access to unique clinical specimens (peripheral blood cells, plasma, broncho-alveolar lavage specimens) from epidemiologically well characterized persons with MTB infection in US, Uganda and

South Africa with experts in the use of proteomics, genetic epidemiology and cytokine biology for a multidisciplinary systems biology approach to LTBI and its progression to active TB.

NO1 (AI095383/AI070022-years 13-19) Boom (PI) 05/01/07-04/30/14
NIAID
*"Tuberculosis Research Unit (TBRU)"*
Aims: To conduct epidemiologic, immunologic, microbiologic studies of *M. tuberculosis* infection and to perform clinical trials of new immuno-therapeutic approaches, vaccines, drugs and drug treatment protocols and diagnostic tests for tuberculosis in TB endemic settings in Uganda and S. Africa.

GC6-74 Boom (PI for CWRU) 07/01/05-12/31/12
Gates Foundation
Grand Challenge #6 (GC6-74; Kaufmann, Overall PI): *"Biomarkers of protective immunity against tuberculosis in the context HIV/AIDS in Africa"*
Aim: This Grand Challenge will address surrogate markers of protective immunity to *M. tuberculosis* in field sites in Africa. The subcontract to CWRU supports immunologic and epidemiologic studies in Kampala, Uganda.

NO1 (DAIT-04-39-years 3-10) Boom (PI Sub-Contract) 09/01/06-08/31/14
NIAID
*"Large Scale T Cell Epitope Discovery Program"* (Lewinsohn, Overall PI)
Aim: This initiative supports research on discovery of novel T cell epitopes of *M. tuberculosis*. This subcontract to CWRU supports coordination and conduct of clinical studies in Uganda to test and validate CD8 epitopes.

**Ongoing Research Support as Co-Investigator**

RO1 (AI034343) Harding (PI) 06/1/08-05/31/13
NIAID
"Bacterial and Liposomal Antigen Processing"
Goal is to understand cross-processing MTB for MHC-I restricted CD8+ T cells. Aim 1 addresses basic mechanisms of cross processing of MTB. Aim 2 investigates the cross processing functions of lung APCs. Aim 3 addresses regulation of cross processing by Toll-like receptors, interferons and MTB.

R01 (HL096811) Stein (PI) 08/1/09-07/31/14
NHLBI
*"Pathway analysis of tuberculosis pathogenesis"*
Aims: 1. Fine map novel chromosomal regions and analyze candidate genes in key immune pathways associated with resistance to Mtb infection. 2. Analyze cytokine responses to innate immunity ligands to identify innate immune responses associated with resistance to Mtb infection. 3. Develop a structural equation modeling framework appropriate for analysis of family data. Genetic and immunologic predictors of resistance to Mtb infection will be performed in the context of a long-standing household contact study in Kampala, Uganda.

T32 (AI007024) Kazura (PI)/Boom (Co-PI) 07/01/10-06/30/15
NIAID
*"Training in Geographic Medicine and Infectious Diseases"*
Aim: To provide rigorous training of promising post-doctoral fellows in the application of the tools of immunology and molecular biology to the study of parasitic, bacterial and viral diseases.

**Completed Research Support as PI**

RO1 (HL055967) Boom (PI) 09/15/06-5/31/12
NHLBI
*"M. tuberculosis Infection in the Lung"*

This project focuses on a murine model of pulmonary *M. tuberculosis* infection with the following aims: 1) To determine the ability of lung APC (alveolar macrophages, CD11c+ lung parenchymal macrophages and dendritic cells) to activate naïve and effector MHC-II restricted CD4+ T cells, and the ability of MTB lipoproteins (19 kDa LpqH, 24 kDa LprA, 24 kDa LprG) and TLR-2 to inhibit lung APC function; 2) To determine the molecules and mechanisms used by MTB to directly inhibit activation and function of naïve and effector CD4+ T cell in the lung; 3) To use CD4+ MTB 85B- and ovalbumin-specific TCR transgenic mice to determine during MTB infection the *in vivo* mechanisms for naïve and effector CD4+ T cell activation and the role(s) of lung APC in this activation.

**Pending Research Support as PI**

None

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Calabrese, Joseph R.** | POSITION TITLE<br>Professor of Psychiatry; Director, Mood Disorders Program; Bipolar Disorders Research Chair |
| eRA COMMONS USER NAME jcalabrese | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Xavier University | B.S. | 05/76 | Biology, Summa Cum Laude |
| Ohio State University | M.D. | 06/80 | Medicine |
| Cleveland Clinic Foundation | | 06/84 | Psychiatry |
| National Institute of Mental Health | | 06/86 | Biological Psych. Branch |

**A. Positions and Honors**

**Positions and Employment**

| | | |
|---|---|---|
| Research Fellow (Gold & Post) | National Institute of Mental Health<br>Neuroendocrinology, Biological Psychiatry Branch | 1984-1986 |
| Dir., Mood Disorders Program | University Hospitals Case Medical Center<br>Case Western Reserve Univ. School of Medicine | 1989-Present |
| Professor of Psychiatry/with Tenure | Case Western Reserve Univ. School of Medicine | 1996-Present |
| Principal Investigator | Bipolar Disorder Across the Life Cycle Center for Interventions and Services Research (P20) | 2003-Present |

**Honors**

| | |
|---|---|
| NARSAD Lifetime Achievement Award for Psychiatric Research in Mood Disorder | 2004 |
| Bipolar Disorders Research Chair awarded | 2007 |
| Gerald L Klerman Senior Investigator Award | 2008 |
| Ohio Physician's Psychiatric Association Lifetime Achievement Award | 2012 |
| European Bipolar Alliance Lifetime Achievement Award | 2012 |

**B. Selected peer-reviewed publications (selected from over 350 publications: H Index = 38)**

1. **Calabrese JR**, Delucchi GA: Spectrum of efficacy of divalproex in 55 rapid-cycling manic depressives. Am J Psychiatry 1990 Apr;147(4):431-4. PMID: 2107762
2. Bauer MS, **Calabrese JR**, Dunner DL, Post R, Whybrow PC, Gyulai L, Tay LK, Younkin S, Bynum D, Lavori P, Price A: Multi-Site Data Reanalysis: Validity of rapid cycling as a course modifier for bipolar disorder in DSM-IV. Am J Psychiatry 1994 Apr; 151(4):506-515. PMID: 8147448
3. **Calabrese JR**, Kimmel SE, Woyshville MJ, Rapport DJ, Faust CJ, Thompson PA, Meltzer HY: Clozapine in treatment refractory mania. Am J Psychiatry 1996 Jun; 153(6):759-64. PMID: 8633686.
4. **Calabrese JR**, Bowden CL, McElroy SL, Cookson J, Andersen J, Rhodes L, Keck PE, Bolden-Watson C, Zhou J, Ascher J: Spectrum of activity of lamotrigine in treatment refractory bipolar disorder. Am J Psychiatry. 1999 Jul; 156(7):1019-23. PMID: 10401445
5. **Calabrese JR**, Bowden CL, Sachs G, Yatham L, Behnke K, Mehtonen O-P, Montgomery P, Ascher J, Paska W, Earl NL, DeVeaugh-Geiss J, for the Lamictal 605 Study Group: A placebo-controlled 18-month trial of lamotrigine and lithium maintenance treatment in recently depressed patients with bipolar I disorder. J Clin Psychiatry. 2003 Sept; 64(9):1013-1024. PMID: 14628976
6. **Calabrese JR**, Vieta E, El-Mallakh R, Findling RL, Youngstrom EA, Elhaj O, Gajwani P, Pies R: Mood state at study entry as predictor of risk of relapse and spectrum of efficacy in bipolar maintenance studies. Biol Psychiatry. 2004 Dec 15; 56(12):957-73. PMID: 15601606
7. **Calabrese JR**, Keck PE, Jr., Macfadden W, Minkwitz M, Ketter TA. Weisler RG, Cutler AJ, McCoy R, Wilson

E, Mullen J, for the Bolder Study Group: A randomized, double-blind, placebo-controlled trial of quetiapine, in the treatment of bipolar I or II depression. Am J Psychiatry. 2005 July; 162(7):1351-1360. PMID: 15994719

8. **Calabrese JR**, Shelton MD, Rapport DJ, Youngstrom EA, Jackson K, Bilali S, Ganocy SJ, Findling, RL: A 20-month, double-blind, maintenance trial of lithium vs. divalproex in rapid-cycling bipolar disorder. Am J Psychiatry. 2005 Nov; 162:2152-2161. PMID: 16263857
9. Sachs GS, Nierenberg AA, **Calabrese JR**, Marangell LB, Wisniewski SR, Gyulai L, Friedman E, Bowden C, Fossey M, Ostacher M, Ketter T, Patel J, Hauser P, Rapport D, Martinez J, Allen M, Miklowitz DJ, Otto MW, Dennehy EB, Thase ME: Effectiveness of adjunctive antidepressant treatment for bipolar depression: A double-blind placebo controlled study. N Engl Journal Med. 2007 Apr 26; 356(17):1711-22. PMID: 17392295

## C. Research Support

**Ongoing Research Support**

1R01HS01937-01 Nierenberg (Co-PI) 9/30/10-9/29/13
Recovery Act 2009 Limited Competition: Agency for Healthcare Research & Quality (AHRQ), Clinical and Health Outcomes Initiative in Comparative Effectiveness. Comparative Effectiveness of a Second Generation Antipsychotic or a Mood Stabilizer for Bipolar Disorder
Role: Site PI

1 U01 MH92758-01 Kelsoe (Co-PI) 9/10/10-5/31/2015
Pharmacogenetics Research Network III
*"Pharmacogenomics of Mood Stabilizer Response in Bipolar Disorder"*
Role: Site PI

P30MH086045 Bowden (PI) 9/20/2011-6/30/2016
*Optimizing Outcomes in Bipolar Illness Interventions in Hispanic Communities. "Sequential Multiple Assignment Randomized Treatment (SMART) for Bipolar Disorder"*
A Sequential Multiple Assignment Randomized Treatment (SMART) strategy employs a rule for adding new treatments based on each patient's current illness state and response during the trial, mimicking the adaptive nature of treatment selection which occurs in clinical settings, but in a controlled way which allows application of causal inference.
Role: Site PI

DoD Army RDT&E Defense Research Sciences Calabrese (6 site Co-PI) 2008-2018
W81XWH-07-1-0409: Ohio Army National Guard Mental Health Initiative
The goal of the project is to elucidate short-and long-term predictors of Resilience and Risk Factors Associated With Combat-related Posttraumatic Psychopathology.

**Completed Research Support**

N01MH800001 Neirenberg (PI) 10/1/07-9/30/10
*"Lithium Treatment - Moderate dose Use Study (LiTMUS): A Randomized Controlled Effectiveness* (*trial within Bipolar Trials Network*)."
This study will assess the effectiveness of lithium as a component of treatment as usual (TAU) in a generalizable group of patients with bipolar disorder.
Role: Site PI

P20 – MH066054 Calabrese (PI) 9/1/03-6/30/09
*Bipolar Disorder Across the Life Span*
The goal of this interventions and services research center was the conduct of studies designed to improve clinical outcomes in underserved populations of bipolar disorder across the life cycle.
Role: PI

N01MH800001 Neirenberg (PI) 10/1/05-9/30/11
"Bipolar Trials Network (*extension of Systematic Treatment Enhancement Program for Bipolar Disorder*)"
Role: Site PI

R21 MH-62650 Calabrese (PI) 2/1/02 – 1/31/05
Combination Therapy in Rapid Cycling Bipolar Disorder
Role: PI

R01 MH-50165 (Supplement) Calabrese (PI) 10/1/97-12/1/01
Combination Therapy in Rapid Cycling Bipolar Disorder Accompanied by Alcohol, Cannabis and/or Cocaine
Role: PI

R01 MH-50165 Calabrese (PI) 4/95-12/01
Combination Therapy in Rapid Cycling Bipolar Disorder
The goal of this project was to compare the efficacy of the combination of lithium and divalproex to lithium monotherapy in the prevention of episodes in patients with rapid cycling bipolar disorder.
Role: PI

HRSA 1 C76 HF 00502-01 Calabrese (PI) 8/1/02-8/1/05
Center of Excellence for the Care and Study of Patients with Bipolar Disorder and Other Serious Mental Disorders Accompanied by Alcohol/Drug Abuse in Penal Setting
Role: PI

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Chak, Amitabh** | POSITION TITLE<br>Professor |
| eRA COMMONS USER NAME **AMCHAK** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| Yale University, CT | BS | 1978 | Biophysics/Biochemistry |
| Yale University, CT | MS | 1979 | Biophysics/Biochemistry |
| Columbia Univ. College of Physicians & Surgeons, NY | MD | 1984 | Medicine |

## A. Positions and Honors

**Positions and Employment**

1984-1986 Internal Medicine, Columbia Presbyterian Medical Center, New York, NY
1986-1991 GI Fellowship, Columbia Presbyterian Medical Center, New York, NY
1986-1989 Instructor in Clinical Medicine, Columbia University, New York NY
1988-1991 Attending in Internal Medicine, Columbia Presbyterian University, New York, NY
1989-1991 Assistant Professor of Clinical Medicine, Columbia University, New York, NY
1990-1991 Attending on Gastroenterology Procedures, Columbia Presbyterian University, New York, NY
1991-1998 Assistant Professor of Medicine, Case Western Reserve University, Cleveland, OH
1991- Attending in Gastroenterology, University Hospitals of Cleveland and Wade Park Veterans Affairs Medical Center
1995- Head, Section of Gastrointestinal Endoscopy, University Hospitals of Cleveland, OH
1998-2006 Associate Professor, Medicine-Gastroenterology, Case Western Reserve University, Cleveland, OH
2000- Member, Case Comprehensive Cancer Center, Cleveland, OH
2004- Head of Clinical Research, Division of Gastroenterology, University Hospitals of Cleveland, OH
2006- Professor, Medicine-Gastroenterology and Oncology, Case Western Reserve University, Cleveland, OH

**Honors**

1978 Phi Beta Kappa, Yale University; 1984 Sandoz Award, Columbia University College of Physicians and Surgeons 1986-1991 Physician Scientist Award (NIH), Columbia University College of Physicians and Surgeons; 1992 Markowitz-Blades-Lerner Award, Case Western Reserve University, for training at Indiana University; 1998 Wilson Cook Research Scholar; 1998 Fellow, American College of Physicians; 2002 Fellow, American College of Gastroenterology; 2006 Best Research Mentor, Department of Medicine; 2010 Endoscopic Mentoring Award, ASGE.

## B. Selected Peer-reviewed Publications (Selected from 151 peer-reviewed publications)

Chak A, Faulx A, Kinnard M, Brock W, Willis J, Wiesner GL, Parrado AR, Goddard KA. Identification of Barrett's Esophagus in relatives by endoscopic screening. Am J Gastroenterol 99:2107-2114, 2004.

Das A, Thomas S, Zablotska LB, Neugut AI, Chak A. Association of esophageal adenocarcinoma with other subsequent primary cancers. J Clin Gastroenterol 40:405-411, 2006.

Das A, Chak A, Sivak MV Jr, Payes J, Cooper GS. Endoscopic ultrasonography and prognosis of esophageal cancer. Clin Gastroenterol Hepatol 4:695-700, 2006.

Chak A, Ochs-Balcom H, Falk G, Grady WM, Kinnard M, Willis JE, Elston R, Eng C. Familiality in Barrett's esophagus, adenocarcinoma of the esophagus, and adenocarcinoma of the gastroesophageal junction. Cancer Epidemiol Biomarkers Prev 15:1668-1673, 2006.

Chak A, Faulx A, Eng C, Grady W, Kinnard M, Ochs-Balcom H, Falk G. Gastroesophageal reflux symptoms in patients with adenocarcinoma of the esophagus or cardia. Cancer 107:2160-2166, 2006.

Ochs-Balcom HM, Falk G, Grady WM, Kinnard M, Willis J, Elston R, Eng C, Chak A. Consortium approach to identifying genes for Barrett's esophagus and esophageal adenocarcinoma. Transl Res 150:3-17, 2007.

Atkinson M, Das A, Faulx A, Kinnard M, Falck-Ytter Y, Chak A. Ultrathin esophagoscopy in screening for Barrett's esophagus at a veterans administration hospital: easy access does not lead to referrals. Am J Gastroenterol 103:92-97, 2008.

Thompson CL, Khiani V, Chak A, Berger NA, Li L. Carbohydrate consumption and esophageal cancer: an ecological assessment. Am J Gastroenterol 103:555-561, 2008.

Cooper GS, Kou TD, Chak A. Receipt of previous diagnoses and endoscopy and outcome from esophageal adenocarcinoma: a population-based study with temporal trends. Am J Gastroenterol 104:1356-1362, 2009.

Chak A, Falk G, Grady WM, Kinnard M, Elston R, Mittal S, King JF, Willis JE, Kondru A, Brock W, Barnholtz-Sloan J. Assessment of familiality, obesity, and other risk factors for early age of cancer diagnosis in adenocarcinomas of the esophagus and gastroesophageal junction. Am J Gastroenterol 104:1913-1921, 2009.

Shaheen NJ, Sharma P, Overholt BF, Wolfsen HC, Sampliner RE, Wang KK, Galanko JA, Bronner MP, Goldblum JR, Bennett AE, Jobe BA, Eisen GM, Fennerty MB, Hunter JG, Fleischer DE, Sharma VK, Hawes RH, Hoffman BJ, Rothstein RI, Gordon SR, Mashimo H, Chang KJ, Muthusamy VR, Edmundowicz SA, Spechler SJ, Siddiqui AA, Souza RF, Infantolino A, Falk GW, Kimmey MB, Madanick RD, Chak A, Lightdale CJ. Radiofrequency ablation in Barrett's esophagus with dysplasia. N Engl J Med 360:2277-2288, 2009.

Sun X, Elston R, Barnholtz-Sloan J, Falk G, Grady WM, Kinnard M, Mittal SK, Willis JE, Markowitz S, Brock W, Chak A. A segregation analysis of Barrett's Esophagus and associated adenocarcinomas. Cancer Epidemiol Biomarkers Prev 19:666-674, 2010. PMCID: PMC2838211

Shaheen NJ, Peery AF, Overholt BF, Lightdale CJ, Chak A, Wang KK, Hawes RH, Fleischer DE, Goldblum JR; AIM Dysplasia Investigators. Biopsy depth after radiofrequency ablation of dysplastic Barrett's esophagus. Gastrointest Endosc. 2010 Sep;72(3):490-496.e1. Epub 2010 Jul 3. PMID: 20598302.

Kumon RE, Repaka A, Atkinson M, Faulx AL, Wong RC, Isenberg GA, Hsiao YS, Gudur MS, Deng CX, Chak A. Characterization of the pancreas in vivo using EUS spectrum analysis with electronic array echoendoscopes. Gastrointest Endosc. 2012 Apr 11. [Epub ahead of print] PubMed PMID: 22498178.

Elmunzer BJ, Scheiman JM, Lehman GA, Chak A, Mosler P, Higgins PD, Hayward RA, Romagnuolo J, Elta GH, Sherman S, Waljee AK, Repaka A, Atkinson MR, Cote GA, Kwon RS, McHenry L, Piraka CR, Wamsteker EJ, Watkins JL, Korsnes SJ, Schmidt SE, Turner SM, Nicholson S, Fogel EL; U.S. Cooperative for Outcomes Research in Endoscopy (USCORE). A randomized trial of rectal indomethacin to prevent post-ERCP pancreatitis. N Engl J Med. 2012 Apr 12;366(15):1414-22. PubMed PMID:22494121.

Peery AF, Hoppo T, Garman KS, Dellon ES, Daugherty N, Bream S, Sanz AF, Davison J, Spacek M, Connors D, Faulx AL, Chak A, Luketich JD, Shaheen NJ, Jobe BA; Barrett's Esophagus Risk Consortium. Feasibility, safety, acceptability, and yield of office-based, screening transnasal esophagoscopy (with video). Gastrointest Endosc. 2012 Mar 15. [Epub ahead of print] PubMed PMID: 22425272.

Leidner RS, Ravi L, Leahy P, Chen Y, Bednarchik B, Streppel M, Canto M, Wang JS, Maitra A, Willis J, Markowitz SD, Barnholtz-Sloan J, Adams MD, Chak A, Guda K. The microRNAs, MiR-31 and MiR-375, as candidate markers in Barrett's esophageal carcinogenesis. Genes Chromosomes Cancer. 2012 May;51(5):473-9. Epub 2012 Feb 3. PubMed PMID: 22302717.

## C. Research Support

**Ongoing Research Support**

U54CA163060 09/01/11–08/31/16
NIH (Chak, PI)
BETRnet: Genetic Determinants of Barrett's Esophagus and Esophageal Adenocarcinoma
The overall objectives are to conduct a rigorous, integrated spectrum of transdisciplinary human research in Barrett's esophagus (BE) and esophageal adenocarcinoma (EAC)

1P50CA15096401A1 09/01/11–08/31/16
NIH/NCI SPORE (Markowitz, PI)
Case GI SPORE
This Case GI SPORE proposal provides for a cutting edge Specialized Program of Research Excellence in gastrointestinal malignancies with emphasis on colorectal cancers and with additional attention to adenocarcinoma of the esophagus.
Role: Project Leader

5R21 CA135692-02 (Chak, PI) 07/21/08-06/30/12
NIH/NCI
Insulin/IGF-1 Pathway in Barrett's Esophagus
The central hypothesis is that "hyperinsulinemia and high levels of IGF-1 possibly related to the Western diet in susceptible individuals contribute to genetic and epigenetic changes in the esophageal epithelium that are key to the development of Barrett's esophagus and its subsequent progression to esophageal adenocarcinoma. This research will identify biomarkers that may lead to methods for identifying people with Barrett's esophagus who are at risk for developing cancer and lead to treatments aimed at halting or reversing this process.

5K24 DK002800-09 (Chak, PI) 12/01/99-06/30/12
NIH/NIDDK
Patient Oriented Research in Barrett's Esophagus
The goal of this renewed career award is to develop skills in genetic epidemiology, mentor junior investigators in patient oriented research while investigating familial aggregation of Barrett's Esophagus and its associated cancers.

5R01 DK070863-05 (Chak, PI) 09/30/05-08/31/12
NIH/NIDDK
Familial Barrett's Esophagus
The specific aims of this proposal are: (1) To recruit and screen family members of esophageal adenocarcinoma patients, comparing age of cancer onset between probands classified as familial with those classified as apparently sporadic; (2) To perform endoscopic screening and measure the recurrence risk of Barrett's esophagus in siblings of probands with Barrett's esophagus and esophageal adenocarcinoma; and (3) To bank DNA from families with Barrett's esophagus and esophageal adenocarcinoma. Using the multidisciplinary approach of our collaborative team of investigators, these aims will result in new information regarding a genetic predisposition to the development of Barrett's esophagus and esophageal adenocarcinoma.

1RC4DK090645-01 (Chak, PI) 9/30/10 – 8/31/12
NIH/NIDDK
Transnasal Esophagoscopy Vs. Esophageal Capsule Endoscopy For Barrett's Screening
The specific aims of this proposal are: 1) train physician extenders at a VA in the performance of both procedures; 2) compare acceptability when the two procedures are used for BE screening in primary care clinics at a VA; and 3) measure and compare patient satisfaction with the two procedures. This research will identify which of the two unsedated procedure should be implemented in BE screening.

**Completed Research Support**

5R21DK081161-02 (Blair Jobe, PI; Chak, Co-I) 9/1/09 – 8/31/11
Clinical Risk Factors For Barretts Esophagus In A Primary Care Setting
The specific aims of this proposal are: 1) to determine the prevalence of BE within a representative sample of the Nation's primary care population as a surrogate for the US population; 2) develop a clinical risk factor probability model that predicts the presence of BE; 3) construct and validate a nomogram that incorporates the most potent risk factors as a guide for determining endoscopic screening threshold. This R21 proposal centers on further developing the most optimal methods for subject enrollment, data management, sample size determination, and developing a protocol for multi-center endoscopic screening in primary care patients which will be essential to the eventual success of a large scale trial.

1R13CA144432-01 (Chak, PI) 6/30/10 – 5/31/11
NIH/NCI
Familial Barrett's Esophagus Summit
The specific aims of this proposal are to bring national and international investigators interested in the genetic susceptibility to Barrett's esophagus and esophageal adenocarcinoma together to - 1) determine a common definition of the FBE phenotype/trait; 2) develop mutual transfer agreements for sharing samples; 3) select common genotyping platforms for data sharing; 4) define the most promising joint study designs for identifying susceptibility genes; 5) develop joint collaborative proposals; and 6) identify project managers who will ensure the success of these research teams.

5U54 CA116867-05 (Berger, PI) 09/19/05-08/31/10
NIH/NCI
Case Center for Transdisciplinary Research on Energetics and Cancer at Case Comprehensive Cancer Center
Project 2: Insulin Resistance Syndrome Pathway Factors and Colon Polyps
Goals are defined organizationally and scientifically. Organizationally, we seek 1) to establish a productive, durable program for transdisciplinary research on energetics and cancer at Case University, 2) to provide pilot project support and training opportunities for new and established scientists who can conduct integrative research on energetics, energy balance and their consequences relative to cancer across the continuum-- from cancer causation and prevention through survival, and 3) to establish collaborative relations with investigators throughout our university and at other TREC Centers and universities to maximally and synergistically utilize resources to significantly impact problems associated with obesity and cancer.
Role: Project 2 Co-Investigator

5UL1 RR024989-03 (Davis, PI) 09/17/07-05/31/12
NIH/NCRR
Case Western Reserve University/Cleveland Clinic CTSC
Pilot Project (Basilion, PI): Molecular Imaging of Dysplasia in Barrett’s Esophagus
The CWRU/Cleveland Clinic CTSC coordinates the existing resources relevant to translational and clinical research at CWRU and 3 of its hospital affiliates, Cleveland Clinic, MetroHealth Medical Center, and University Hospitals Case Medical Center, including 3 existing GCRC facilities, a successful multidisciplinary institutional K12 program, technological and statistical core facilities and practice-based research networks, as will as create new resources.
Role: Pilot Project Co-Investigator

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Mark R. Chance** | POSITION TITLE |
| eRA COMMONS USER NAME **Mrchance** | Director and Professor<br>Vice Dean for Research, CWRU School of Medicine |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Wesleyan University, Middletown, CT | B.A. | 1980 | Biology |
| MIT, Boston, MA | | 1980-1984 | Biochemistry |
| University of Pennsylvania, Philadelphia, PA | Ph.D. | 1986 | Biophysics |
| AT&T Bell Labs, Murray Hill, NJ | Post-Doc | 1986-1988 | Biophysics |

## A. Positions and Honors

**Positions and Employment**

1984-1988 Visiting Scientist, AT&T Bell Laboratories, Murray Hill, NJ
1988-1992 Assistant Professor in Chemistry, Georgetown University
1994-2005 Director, Molecular Biophysics Training Program, Albert Einstein College of Medicine (AECOM)
1993-1998 Associate Professor in Physiology & Biophysics and Biochemistry, AECOM
1998-2005 Professor of Physiology & Biophysics and Biochemistry, AECOM
1995- Director, Center for Synchrotron Biosciences, NSLS, Brookhaven Labs (BNL)
2005- Director, Center for Proteomics and Bioinformatics and Cleveland Foundation Center for Proteomic Medicine, Case Western Reserve University, Cleveland OH
2005-2010 Professor of Physiology & Biophysics, Case Western Reserve University
2009- Chief Scientific Officer, NEO Proteomics, Inc. Cleveland, OH
2010- Interim Chair (2010-2012) and Professor (2010-Present), Department of Genetics
2011- Charles W. and Iona A. Mathias Professor of Cancer Research
2011- Vice Dean for Research, CWRU School of Medicine, Cleveland, OH

**National and International Committees**

1995-1998 Scientific Advisory Board, ELETTRA Synchrotron, Trieste, Italy
2000-2001 Chair, NSLS User Executive Committee, Brookhaven National Laboratory
2001 Federation of American Societies of Experimental Biology Consensus Funding Conference, DOE Sub-Panel
2001-2005 Chair, Scientific Advisory Committee, Center for Fluorescence Spectroscopy, University of Maryland
2001-2003 Chair, Biomedical Technology Centers Directors' Organization, National Center for Research Resources
2003- Scientific Advisory Committee, Protein Crystallography Research Resource, BNL, Chair (2007)
2003-2007 Biomedical Research & Training Committee (BRT-A), National Institute for General Medical Sciences
2004 Chair, Special NIDDK Study Section for PAR-040-76: Proteomic and Metabolomic Approaches to Diagnose Diabetes and Pre-diabetes
2007-2009 Experimental Facilities Advisory Committee, National Synchrotron Light Source-II, BNL
2006-2009 Biophysics Proposal Review Panel, Advanced Light Source, Lawrence Berkeley National Lab.
2007 Speaker, NHLBI Systems Medicine Workshop
2007 Panel Member, NIDDK workshop "Clinical Proteomics in Diabetes and its Complications"
2008 Member, NIGMS Systems Biology Center Review Panel
2009- Editorial Board Member, Cancer Genomics and Proteomics
2009- Editorial Board Member, International Journal of Proteomics

| | |
|---|---|
| 2009 | Reviewer, Research Grants Council, Hong Kong, China |
| 2010- | Editorial Board Member, Molecular and Cellular Proteomics |
| 2010- | Editorial Board Member, Journal of Clinical Bioinformatics |
| 2011 | Academic Editor, PLoS Biology |

**Honors**

| | |
|---|---|
| 1980 | Hawk Prize in Biochemistry, Wesleyan University |
| 1980-1984 | NIH Graduate Fellow, Massachusetts Institute of Technology, Department of Biology |
| 1985-1986 | Cardiovascular Fellow, University of Pennsylvania, Department of Biochemistry and Biophysics |
| 1990-1992 | The Upjohn Company New Faculty Research Award |
| 1995-2002 | Joseph & Anne Wunsch Fellow in Biophysical Engineering, Albert Einstein College of Medicine |
| 1996-2001 | Irma T. Hirschl Career Scientist Award |
| 2003 | Dean's Achievement Award, Albert Einstein College of Medicine |
| 2011 | Charles W. and Iona A. Mathias Professor of Cancer Research |

**B. Selected Peer-reviewed Publications (Selected; underlined names represent *pre* or post doctoral trainees)**

**Most relevant to the current application**

1. Amisha Kamal, J.K., Chance, M.R. "Modeling of Protein Binary Complexes Using Structural Mass Spectrometry Data." *Protein Science*, 17(1):79-94, 2008. PMCID: PMC2144602
2. Zheng, X., Wintrode, P.L., Chance, M.R. "Complementary Structural Mass Spectrometry Techniques Reveal Local Dynamics in Functionally Important Regions of a Metastable Serpin." *Structure*, 16(1):38-51, 2008
3. Yohannes, E., Chang, J., Christ, G.J., Davies, K.P., Chance, M.R. "Proteomics Analysis Identifies Molecular Targets Related to Diabetes Mellitus Associated Bladder Dysfunction", *Mol. Cell. Proteomics*, 7(7):1270-85, 2008. PMCID: PMC2493381
4. Bohon, J., Jennings, L.D., Phillips, C.M., Licht, S., Chance, M.R. "Synchrotron Protein Footprinting Supports Substrate Translocation by ClpA via ATP-Induced Movements of the D2 Loop, *Structure*, 16(8):1157-65, 2008.
5. Yohannes, E., Chang, J., Christ, G.J., Davies, K.P., Chance, M.R. "Proteomics Analysis Identifies Molecular Targets Related to Diabetes Mellitus Associated Bladder Dysfunction", *Mol. Cell. Proteomics*, 7(7):1270-85, 2008. PMCID: PMC2493381
6. *Nibbe, R.K.*, Markowitz, S., Myeroff, L., Ewing, R., Chance, M.R. "Discovery and scoring of protein interaction subnetworks discriminative of late stage human colon cancer," *Mol. Cell. Proteomics*, 8(4):827-45, 2009. PMCID: PMC2667362
7. *Nibbe, R.K.*, Chance, M.R. "Approaches to Biomarkers in human colorectal cancer: looking back, to go forward", *Biomarkers in Medicine*, 2009, 3(4): 385-396, 2009. PMCID: PMC2749258
8. *Nibbe, R.K.*, Chance, M.R., Koyuturk, M. "Integrative Proteomics Approaches to Identify Important Sub-networks in Human Colorectal Cancer", *PLoS Comp. Bio.*, 6(1):e1000639. doi:10.1371/journal.pcbi.1000639, 2010. PMCID: PMC2797084
9. Yohannes, E., Chang, J., Tar, M., Davies, K., Chance, M.R. "Molecular Targets for Diabetes Mellitus Associated Erectile Dysfunction", *Mol. Cell. Prot.*, 9(3):565-78, 2010. PMCID: PMC2849705
10. *Patel, V.N.*, Bebek, G., Mariadason, J.M., Wang, D., Augenlicht, L.H., Chance, M.R. "Prediction and Testing of Biological Networks Underlying Intestinal Cancer", *PLoS ONE*, 5(9): e12497. doi:10.1371/journal.pone.0012497, 2010. PMCID: PMC2931697
11. Bebek, G., *Patel, V.*, and Chance, M.R. "PETALS: Proteomic Evaluation and Topological Analysis of a mutated Locus' Signaling", *BMC Bioinformatics*, 11: 596, 2010. doi:10.1186/1471-2105-11-596
12. *Cafasso, J.*, Manjasetty, B.A., Karr, E.A., Sandman, K., Chance, M.R., Reeve, J.N. "Preliminary crystallography confirms that the archaeal DNA-binding and tryptophan-sensing regulator TrpY is a dimer", *Acta Cryst. Sect. F Struct. Biol. Cryst. Commun.* 66(Pt11): 1493-1495, 2010. PMCID: PMC3001657

13. Nibbe, R.K., Chowdhury, S.A., Koyuturk, M., Ewing, R., Chance, M.R. "Protein-protein interaction networks and subnetworks in the biology of disease", *WIRES: Systems Biology and Medicine*, epub ahead of print, 2010.
14. Bebek, G., Koyutürk, M., Chance, M.R., Price, N.D. "INTEGRATIVE -OMICS FOR TRANSLATIONAL SCIENCE - Session Introduction", *Pac Symp Biocomput.*1-3, 2011.
15. Linderman, G., *Patel, V.*, Chance, M.R., Bebek, G. "BiC: a web server for calculating bimodality of coexpression between gene and protein networks", *Bioinformatics*, 407(5):673-86, 2011.
16. Oztug Durer, Z.A., Kamal, J.K., Benchaar, S., Chance, M.R., Reisler, E. "Myosin binding surface on actin probed by hydroxyl radical footprinting and site-directed labels." J Mol Biol 2011 Nov 25;414(2):204-16. Epub 2011 Oct 1 PMCID: PMC3221818
17. Kiselar, JG., Datt, M., Chance, M.R., Weiss, MA. "Structural Analysis of proinsulin hexamer assembly by hydroxyl radical footprinting and computational modeling." *Journal of Biol. Chem.*, 286(51):43710-6, 2011. PMCID: PMC3243561
18. Yohannes, E., Chance, M.R. "Systems immunology and adaptive immune response to HIV infection" *Encyclopedia of Systems Biology*, W. Dubitzky, O. Wolkenhauer, K. Cho & H. Yokota (eds.), DOI 10.1007/978-1-4419-9863-7, 2011.
19. Nibbe, R.K., Chowdhury, S.A., Koyuturk, M., Ewing, R., Chance, M.R. "Protein-protein interaction networks and subnetworks in the biology of disease", *WIRES: Systems Biology and Medicine*, 3(3):357-67, 2011.
20. Patel, V., Chance, M.R., Book Chapter: "Colorectal Cancer and its Molecular Subsystems: Construction*, Interpretation, and* Validation", Wiley-Blackwell, [in press]

## C. Research Support

**Ongoing Research Support**

P30-EB-009998 (Chance) 9/09-8/14
NIH
Case Center for Synchrotron Biosciences
This center assists NIH funded users in accessing structural biology beamlines for their research in crystallography, nucleic acid and protein footprinting, and x-ray spectroscopy.

R01-EB-09688 (Chance) 3/10-2/14
NIH
Radiolytic Footprinting Methods for Structural Mass Spectrometry
This grant is to further develop methods of radiolytic footprinting to probe the structure of rhodopsin and actin.

R01-HL-106798 (Boom/Chance-Multiple -PIs) 9/10-8/14
NIH
Proteogenomics of Dysregulated Protein Interaction Networks in MTB Infection
This grant investigates signatures of TB latency and recurrence using proteomic and genomics data combined in a systems biology framework.

P01-DE-019759 (Weinberg) 3/09-2/14
NIH
Oral Mucosal Immunity in Vulnerable HIV Infected Populations
Mark Chance-PI-Proteomics and Bioinformatics Core
The core assists investigators in carrying out proteomics and systems biology studies.
UL1-RR-024989 (Davis) 9/07-8/17
NIH
Case Western Reserve University/Cleveland Clinic CTSA
Mark Chance - PI of Translational Technology Core

The goal of this core is to facilitate systems biology approaches to understanding the molecular basis of disease, including coordination of human tissue samples and proteomic and genomic analysis.

P30-CA-043703 (Gerson) 7/07-06/13
NIH
Cancer Center Proteomics Core
Mark Chance- PI of Proteomics Core
To provide proteomics services to cancer center investigators.

P01-AI-074286 (Cho) 5/08-04/13
NIH (HIVRAD)
Development of a Subunit Envelope Vaccine
Mark Chance – Co-Investigator- Project 2-Structural Evaluation of Antigens
To solve structures of HIV envelope glycoprotein antigens.

U01-GM-094612 (Handel) 09/10-06/15
NIH
Structure, Dynamics and Activation Mechanisms of Chemokine Receptors
Mark Chance - PI of CWRU Subcontract

P30 AI036219 (Karn) 04/97-04/15
NIH
Center for AIDS Research Proteomics Core

R01LM01124 (Koyutürk) 08/12-07/16
NIH
Enhancing Genome-Wide Association Studies via Integrative Network Analysis"

DBI-1228549 (Chance) 08/12-07/17
NSF
MRI Consortium: Development of a Dampling Wiggler Beamline for X-Ray Footprinting at NSLS-II

**Completed Research Support**

HHSN272500800009C (Dearborn/Chance-Multiple –PIs) 09/10-09/12
NIH-NICHD
Integrated NCS Genomics & Proteomics Core

P41-EB-01979 (Chance) 03/94-05/10
NIH
Center for Synchrotron Biosciences
This project has been replaced by P30-EB-09998.

U54-GM-74945 (Burley) 10/00-6/10
NIH
New York Center for Structural Genomix
Mark Chance - PI of CWRU Sub-contract

P20-DA-026133 (Chance) 4/09-5/12
NIH
Case Center for Proteomics in HIV/AIDS and Drug Abuse

P20-DK-090871 (Daneshgari) 9/10-9/12
NIH
Urological Complications of Obesity and Diabetes
Co-Investigator

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Cooper, Gregory S.** | POSITION TITLE<br>Professor |
| eRA COMMONS USER NAME GCOOPER | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| University of Pennsylvania, Philadelphia, PA | BA | 1982 | Sociology |
| University of Pennsylvania, Philadelphia, PA | MA | 1982 | Sociology |
| University of Pennsylvania, Philadelphia, PA | MD | 1986 | Medicine |

**A. Positions and Honors**

1986-1989 Medical Resident, University Hospitals of Cleveland (UHC), Case Western Reserve University (CWRU), Cleveland, OH
1989-1991 Gastroenterology Fellow, UHC and CWRU, Cleveland, OH
1991-1992 Chief Medical Resident, UHC and CWRU, Cleveland, OH
1992-1993 Clinical Epidemiology and Gastroenterology Fellow, UHC and CWRU, Cleveland, OH
1993-1994 Assistant Professor of Medicine, CWRU and UHC, Cleveland, OH
1994-1996 Assistant Professor of Medicine and General Medical Sciences (Oncology), CWRU and UHC, Cleveland, OH
1994- Member, Case Comprehensive Cancer Center, Cleveland, OH
1996-1999 Assistant Professor, Medicine and Epidemiology & Biostatistics, CWRU and UHC, Cleveland, OH
1999-2005 Associate Professor of Medicine-Gastroenterology, General Medical Sciences (Oncology) and Epidemiology & Biostatistics, CWRU and UHC, Cleveland, OH
2005- Professor of Medicine-Gastroenterology, General Medical Sciences (Oncology) and Epidemiology & Biostatistics, CWRU and UHC, Cleveland, OH
2006- Co-Leader, Cancer Prevention, Control and Population Research Program, Case Comprehensive Cancer Center, Cleveland, OH
2011- Director, Office of Comparative Effectiveness Research, Case Clinical Translational Science Collaborative (CTSC), Cleveland, OH

**Honors and Awards:**
2005 John Peter Minton Hero of Hope Research Medal of Honor from the American Cancer Society, Ohio Division

**Study Sections**
2006- 2012 American Cancer Society: Cancer Control and Prevention: Health Policy and Health Services Research
2009- National Institutes of Health: Health Services Organization and Delivery(HSOD) Study Section, Ad Hoc Reviewer
2009- American College of Gastroenterology : Research Committee

**Advisory Boards**
2012- University of Arizona Cancer Center External Scientific Advisory Board
2012- Columbia University Cancer Center External Scientific Advisory Board

**B. Selected peer-reviewed publications (selected 2000-present)**

Cummings KC 3rd, Xu F, Cummings LC, Cooper GS. A comparison of epidural analgesia and traditional pain management effects on survival and cancer recurrence after colectomy: a population-based study. Anesthesiology 2012; 116:797-806.

Cummings LC, Delaney CP, Cooper GS: Laparosopic versus open colectomy for colon cancer in an older population: a cohort study. World J Surg Oncol 2012: 10:31.

Greer KB, Thompson CL, Brenner L, Bednarchik B, Dawson D, Willis J, Grady WM, Falk GW, Cooper GS, Li L, Chak A. Association of insulin and insulin-like growth factors with Barrett's oesophagus. Gut. 2012; 61:665-72.

Cooper GS, Kou TD, Barnholtz-Sloan JS, Koroukian SM, Schluchter MD: Use of colonoscopy for polyp surveillance in Medicare beneficiaries. Cancer (accepted for publication).

Cooper GS, Kou TD, Rex DK: Complications following colonoscopy with anesthesia assistance: a population-based analysis. JAMA Intern Med (accepted for publication).

**Additional Peer Review Publications Relevant to the Field (10)**

Cooper GS, Kou TD, Reynolds HL Jr. Receipt of guideline-recommended follow-up in older colorectal cancer survivors: a population-based analysis. Cancer 113:2029-2037, 2008.

Cooper GS, Kou TD, Wong RC. Outpatient management of nonvariceal upper gastrointestinal hemorrhage: unexpected mortality in Medicare beneficiaries. Gastroenterology 136:108-114, 2009.

Cooper GS, Kou TD, Chak A: Receipt of previous diagnoses and endoscopy and outcome from esophageal adenocarcinoma: a population-based study with temporal trends. Am J Gastroenterol 2009; 104:1356-62.

Mines D, Gu Y, Kou TD, Cooper GS: Recombinant human bone morphogenic protein-2 and pancreatic cancer: a retrospective cohort study. Pharmacoepid Drug Safety 2011; 20:111-8.

Kouroukian SM, Bakaki P, Beaird H, Earle C, Cooper GS: Cancer stage comparison between dual Medicare-Medicaid eligibles using Medicaid as a supplemental health insurance program and low-income non-duals. J Public Health Manag Pract 2011; 17:479-91.

Flocke SA, Stange KC, Cooper GS, Wunderlich TL, Oja-Tebbe N, Divine G, Lafata JE. Patient-rated importance and receipt of information for colorectal cancer screening. Cancer Epidemiol Biomarkers Prev 20:2168-2173, 2011.

Koroukian SM, Bakaki PM, Owusu C, Earle CC, Cooper GS: Cancer outcomes in low-income elders: Is there an advantage to being on Medicaid? Medicare Care Medicaid Research Review 2012; 2:E1–E22.

Dor A, Koroukian SM, Xu F, Stulberg JJ, Delaney CP, Cooper GS: Pricing of surgeries for colon cancer: patient severity and market factors. Cancer 2012; 118:5741-8.

Cooper GS, Xu F, Barnholtz Sloan JS, Koroukian SM, Schluchter MD: Management of malignant colon polyps: a population-based analysis of colonoscopic polypectomy versus surgery. Cancer 2012; 118:651-9

Cooper GS, Xu F, Barnholtz Sloan JS, Schluchter MD, Koroukian SM: Prevalence and predictors of interval colorectal cancers in Medicare beneficiaries. Cancer 2012, Cancer 2012; 118:3044-52.

**C. Research Support.**

**ACTIVE**

1R01 CA132862-01 (Cooper, PI) 01/01/09-12/31/11 (NCE through 12/31/13)
NIH/NCI
Colonoscopy: Practice Patterns and Limitations
Colorectal cancer, the second most fatal cancer in the U.S., is largely preventable through the removal of polyps. However, there is only limited knowledge about the treatment and outcome of colorectal polyps in routine clinical practice. Using data from a large number of Medicare patients, we will study practice patterns for polyp removal via colonoscopy, evaluate its effectiveness in the treatment of early stage colorectal cancer, and estimate the potential failed detection rate at colonoscopy.

1P50CA150964 (Markowitz, PI; Cooper, Co-Project Leader) 9/1/12-8/31/17
NIH/NCI
Case GI SPORE
Detection of Advanced Adenomas via Stool DNA (sDNA) Methylation Testing
The goal of this project is to evaluate the accuracy of a panel of stool DNA methylation markers in detection of advanced polyps in a screening population, including the management of apparent false positive tests.

RSGI-12-218-01-CPHPS (Cooper, PI) 7/1/12-6/30/14
American Cancer Society
Healthcare Reform and Cancer Screening
The goals of this proposal are to evaluate the use of screening mammography, colonoscopy and PSA testing in Medicare beneficiaries before and after the Affordable Care Act legislation and to determine variation in procedure use according to patient and regional characteristics.

5P30 CA043703-22 (Gerson, PI) 09/30/91-03/31/13
NIH/NCI
Comprehensive Cancer Center Support Grant
The objectives of the Center are: 1) to improve the prevention, diagnosis, and therapy of cancer through research; 2) to stimulate and support innovative, coordinated, interdisciplinary research on cancer diagnosis, treatment, and control; 3) to develop clinical applications of research discoveries and to make these applications available as quickly as possible; and 4) to develop cancer prevention and control activities to contribute to the reduction of cancer morbidity and mortality in Northeast Ohio and the surrounding region and nation. Role: Leader of Cancer Prevention, Control and Population Research Program

1R01 CA129766-01 (Dor, PI) 7/1/09-6/30/12 (NCE through 6/30/13)
NIH/NCI
The Pricing of Major Cancer Surgeries: Impact of Insurance, Outcomes and Severity
The overall aim of this proposal is to investigate price variations for selected cancer surgical treatments and to evaluate the degree to which managed care and other forms of insurance are able to capture discounts from hospitals in the medical marketplace. Role: Site PI

UL1TR000439 (Davis, PI) 6/29/12-5/31/17
NIN/NCATS
Clinical and Translational Science Collaborative of Cleveland
The support will establish the Office of Comparative Effectiveness Research at the Case CTSC and serve as a resource for education and research support.

Research Scholar Grant (Koroukian, PI) 1/1/12-12/31/13
American Cancer Society
Multilevel Evaluation of Breast Cancer Prevention Efforts in Ohio
The study will specifically examine transitions between the Breast and Cervical Cancer Early Detection Program, Medicare and Medicaid, will include surveys of BCCEDP Directors, and will consider both county-specific factors and individual factors on stage of breast cancer diagnosis, treatment received and survival. Role: Co-Investigator

Medtronic, Inc. (Cooper, PI) 10/1/12-9/30/13
Investigator Initiated Research Contract)
Recombinant human Bone Morphogenic Protein- (rhBMP-2) and Cancer Risk: A Retrospective Cohort Study in Medicare Beneficiaries
The aim of this study is to determine cancer risk among patients administered rhBMP-2 at the time of lumbar spinal fusion surgery.

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Kevin D. Cooper** | POSITION TITLE<br>Professor & Chair<br>Department of Dermatology<br>Case Western Reserve University |
| eRA COMMONS USER NAME<br>**KCOOPER** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| University of Florida, Gainesville, FL | B.S. | 1973 | Basic Biological Sciences |
| Univ. of Florida Coll. Of Medicine, Gainesville, FL | M.D. | 1977 | Medicine |
| Dept. of Dermatology, Oregon Health Science Univ. Portland, OR | Residency | 1981 | Dermatology |
| Dermatology, National Cancer Institute, Bethesda, MD | Fellowship | 1985 | Senior Medical Staff Fellow |

**A. Positions and Honors**

**POSITIONS AND EMPLOYMENT**

1985 -- Staff Physician, Veterans Affairs Medical Center, Ann Arbor, MI, and Cleveland, OH
1985-1995 Assistant, Associate, and Full Professor, Dept. of Dermatology, Univ. of Michigan, Ann Arbor, MI
1986-1995 Director, Immunodermatology & Cutaneous Lymphoma Prgms, Univ. of Michigan, Ann Arbor, MI
1995 -- Professor and Chair, Dept. of Dermatology, Case Western Reserve University / University Hospitals of Cleveland, Cleveland, OH
1997-- Director, NIAMS Skin Diseases Research Center, Case Western Reserve University
2006-- Director, Murdough Family Center for Psoriasis, University Hospitals Case Medical Center
2007-- Director, NIAMS Psoriasis Center for Research Translation, Case Western Reserve University

**OTHER EXPERIENCE AND PROFESSIONAL MEMBERSHIPS**

- Med/Scientific Advisory Committees: National Psoriasis Foundation 93-98; Amer Skin Assoc 95-00; Cutaneous Lymphoma Found. 01-present, Natl Eczema Assoc (01-present, Chair, 01-09); CARF (07-present).
- Research Committees, CWRU SOM (95-present) and Case Comprehensive Cancer Center (96)
- Federal Study Sections and Advisories: Special Emphasis Panels Member 96- present, Ad Hoc Study -Sections (i.e. SDRC P30 Review Panel, 08), SBIR/STTR Review Panel Member (MOSS 08), VA Merit Review reviewer, NIAMS Retreat Advisory Group (04), NIAMS Advisory Panels on Psoriasis (07) and Genome Wide Association studies (07) (Chair), T32 Review Panel (10).
- President-Elect, President, and Past President, Society for Investigative Dermatology (03-06).
- Co-Chair, Symposium on the Biology of Skin- Immunocyte-Keratinocyte Interactions (07).
- President, Council of Clinical Chairs, Case SOM & University Hospitals Case Medical Center (07-present).
- Program Chair 2008, American Academy of Dermatology Annual Mtg, San Antonio, TX (Committee 03-08).
- Program Committee Chair, American Dermatologic Association Annual Meeting, UT (09).
- President–Elect and President, Association of Professors of Dermatology, (09-12).
- Brd of Directors, Univ. Hospitals Med. Group (08-present) & Univ. Hospitals Case Medical Center (07-present)

**HONORS**

-Rook Plenary Lectureship & Award, British Association of Dermatologists, (08)
- Marion B. Sulzberger Plenary Lectureship, Amer. Academy of Dermatology, San Francisco, CA (09)
- Dohi Plenary Lectureship & Award, Japanese Dermatologic Association, Fukuoka, Japan (09)
- Farber Lectureship, Society for Investigative Dermatology, (11)

**B. Selected peer-reviewed publications.** (from among over 240 peer-reviewed publications)

**Most Relevant to the current application**

Sugiyama, H., Gyulai, R., Toichi, E., Garaczi, E., Shimada, S., Stevens, S.R., McCormick, T.S., **Cooper, K.D**. Dysfunctional Blood and Target Tissue $CD4^{+}CD25^{high}$ Regulatory T Cells in Psoriasis: Mechanism Underlying Unrestrained Pathogenic Effector T Cell Proliferation. J of Immunology, 174: 164-173, 2005.

McCormick, T., Toichi, E., Lu, K., **Cooper, KD.,** Skin-infiltrating Monocytes/Macrophages Migrate to Draining Lymph Nodes and Produce IL-10 After Contact Sensitizer Exposure to UV-Irradiated Skin. J Invest Dermatol, 128 (11): 2705-15, 2008

Karnik P, Tekeste Z, McCormick TS, Gilliam AC, Price VH, **Cooper KD**, Mirmirani P. Hair Follicle Stem Cell-Specific PPARgamma Deletion Causes Scarring Alopecia. J Invest Dermatol. 129(5):1243- 57, 2009, PMID: 19052558

Goodman WA, Levine AD, Massari JV, Sugiyama H, McCormick TS, **Cooper KD.** IL-6 Signaling in Psoriasis Prevents Immune Suppression by Regulatory T Cells. Journal of Immunology. 183(5):3170-6, 2009, PMID:19648274

Ferenczi K, Ohtola J, Aubert P, Kessler M, Sugiyama H, Somani AK, Gilliam AC, Chen JZ, Yeh I, Matsuyama S, McCormick TS, **Cooper KD**. Malignant T cells in cutaneous T cell lymphoma lesions contain decreased levels of the anti-apoptotic protein Ku70. British Journal of Dermatology Apr 16. 2010 PMID: 20408834

Baron ED, Malbasa CL, Santo-Domingo D, Fu P, Miller JD, Hanneman KK, Hsia AH, Oleinick NL, Colussi VC, **Cooper KD.** Silicon phthalocyanine (Pc 4) photodynamic therapy is a safe modality for cutaneous neoplasms: results of a phase 1 clinical trial. Lasers Surg Med. 2010 Dec;42(10):728-35. PMID 21246576

Goodman WA, Young AB, McCormick TS, **Cooper KD,** Levine AD. Stat3 phosphorylation mediates resistance of primary human T cells to regulatory T cell suppression. J Immunol. 186(6):3336-45. 2011 PMID 21307288

**Additional Recent Publications of Importance to the field - ****

** Bata-Csorgo Z, Hammerberg C, Voorhees JJ, **Cooper KD**: Kinetics and regulation of human keratinocyte stem cell growth in short term primary ex vivo culture; growth factors cooperative with IFN gamma from psoriatic lesional T lymphocytes stimulate proliferation among psoriatic uninvolved, but not normal, stem keratinocytes. J Clin Invest 95:317-327, 1995.

Stevens SR, Shibaki A, Meunier L, **Cooper KD**. Suppressor T cell-activating macrophages in UV-irradiated human skin induce a novel, TGFβ-dependent, form of T cell activation characterized by deficient IL-2Rα expression. J Immunol 155:5601-5607, 1995.

** Hammerberg C, Duraiswamy N, **Cooper KD**: Reversal of Immunosuppression Inducible Through

** Javier AF, Bata-Csorgo Z, Ellis CN, Kang S, Voorhees JJ, **Cooper KD:** Rapamycin (Sirolimus) inhibits proliferating Cell nuclear antigen expression and blocks cell cycle in the $G_1$ phase in human keratinocyte stem cells. J Clin Invest 99(9):2094-2099, 1997.

** Gilliam AC, Kremer IB, Yoshida Y, Stevens SR, Tootell E, Teunissen MBM, Hammerberg C, **Cooper KD**: The human hair follicle: a reservoir of CD40+B7-deficient Langerhans cells which repopulate epidermis after UVB exposure. J Invest Dermatol 110:422-427, 1998.

** Hammerberg C, Katiyar SK, Carroll MC, **Cooper KD**. Activated complement component 3 (C3) is required for ultraviolet induction of immunosuppression and antigenic tolerance. J Exp Med 187(7):1133-1138, 1998.

** Bata-Csorgo Z, **Cooper KD,** Voorhees JJ, Hammerberg C. Fibronectin and □5 integrin regulate keratinocyte stem cell cycling: a mechanism for increased fibronectin potentiation of T cell lymphokine- driven keratinocytic stem cell hyperproliferation in psoriasis. J Clin Invest 101:1509-1518, 1998.

Stevens SR, Hanifin JM, Hamilton T, Tofte SJ, **Cooper KD**: Long-term effectiveness and safety of recombinant human interferon-□ therapy for atopic dermatitis despite unchanged serum IgE levels. Arch Dermatol, 134:799-804, 1998.

Yoshida Y, Kang K, Berger M, Chen G., Gilliam AC, Moser A, Wu L, Hammerberg C, and **Cooper KD**: Monocyte induction of IL-10 and downregulation of IL-12 by iC3b deposited in ultraviolet-exposed human skin. J Immunol 161:5873-5879, 1998.

Szabo SK, Hammerberg C, Yoshida Y, Bata-Csorgo Z, **Cooper KD**: Identification and quantitation of interferon-gamma producing T cells in psoriatic lesions: localization to both $CD4^+$ and $CD8^+$ subsets. J Invest Dermatol 111:1072-1078, 1999.

Kremer IB, Stevens SR, Gould JW, DiCarlo J, Quinby G, and **Cooper KD**: Intradermal GM-CSF alters cutaneous antigen presenting cells and differentially affects local versus distant immunization in humans. Clin Immunol. 96(1):29-37, 2000.

** Selgrade MK, Smith MV, Oberhelman-Bragg LJ, LeVee GJ, Koren HS, **Cooper KD**. Dose response for UV-induced immune suppression in people of color: Differences based on erythemal reactivity rather than skin pigmentation. Photochem and Photobiol, 74(1): 88-95, 2000.

Chen, G, McCormick, TS, Hammerberg, C, Ryder-Diggs, S, Stevens, SR, **Cooper, KD** Basal keratinocytes from uninvolved psoriatic skin exhibit accelerated spreading and focal adhesion kinase (FAK) responsiveness to fibronectin. J. Invest Dermatol 117:1538-1545, 2001.

Stevens SR, Parry EJ, Mark J, Neckel S, **Cooper** KD: Quantitating skin disease burden in cutaneous T-cell lymphoma: The severity weighted assessment tool (SWAT) Arch Dermatol. 138 (1): 42-8, 2002.

** Takahara M, Kang K, Liu L, Yoshida Y, McCormick TS, and **Cooper KD**. iC3b arrests monocytic cell differentiation into CD1c-expressing dendritic cell precursors: A mechanisms for transiently decreased dendritic cells in vivo after human skin injury by ultraviolet B. J Invest Dermatol, 120(5): 802-809, 2003.

** Baron, ED, Fourtanier, A, Compan, D, Medaisko, C, **Cooper, KD** and Stevens, SR: High UVA protection affords greater immune protection confirming that UVA contributes to human immunosuppression. J Invest. Dermatol, 121: 869-875, 2003.

Tang, N, Liu L, Kang K, Mukherjee PK, Takahara M, Chen G, McCormick TS, **Cooper KD**, and Ghannoum M. Inhibition of monobytic interleukin-12 by *Candida albicans* via selective activation of ERK mitogen-activated protein-kinase. Infect Immun, 72(5): 2513-2520, 2004.

Lou X, Liu L, Tang N, Lu KQ, McCormick TS, Kang K, and **Cooper KD**. Inhibition of monocyte-derived dendritic cell differentiation and interleukin-12 production by complement iC3b via mitogen-activated protein kinase signaling pathway. Exp Dermatol, 14(4): 303-310, 2005.

** Toichi E, McCormick TS, Mascelli MA, Kaufmann CL, Aria N, Gottlieb AB, Everitt DE, Frederick B, Pendley CE, and **Cooper KD**. An anti-IL-12p40 antibody downregulates type 1 cytokines, chemokines, and IL-12/IL-23 in psoriasis. J of Immunology, 177: 4917-4926, 2006.

** Oshtory S., Apisarnthanarax N., Gilliam AC., **Cooper KD**., Meyerson HJ., Utility of Flow Cytometry in the Diagnosis of Mycosis Fungoides. Journal of the American Academy of Dermatology, 57 (3): 454 -462, 2007

** Ismail, S, Rujing, H., Sanborn, S., Stevens, S., **Cooper, K.,** Wood, G., Gilliam, A. Immunohistochemical staining for CD45R isoforms in paraffin sections to diagnose mycosis fungoides-type cutaneous T-cell lymphoma. Journal of the American Academy of Dermatology, 56(4): 635-642, 2007

Bordeaux JS, Lu KQ, **Cooper KD.** Melanoma: prevention and early detection. Semin Oncol. Dec;34(6):460-6, 2007.

** Beshad R, Korman N, **Cooper KD**. A retrospective case series review of the peroxisome proliferator-activated receptor ligand rosiglitazone in the treatment of atopic dermatitis. Arch Dermatol, 144 (1): 84-88, 2008.

Bennett, M., Robinson, M., Baron,E., **Cooper, KD**., Skin Immune Systems and Inflammation: Protector of the Skin or Promotor of Aging? J Invest Dermatol, 13 (1): 15-9, 2008

** Somani, A-K., Swick A.R., **Cooper K.D**, McCormick T.S., Severe Dermatomyositis Triggered by Interferon β-1a Therapy and Associated with Enhanced Type I IFN Signaling. Arch. Dermatol, 144 (10): 1341-9, 2008

## C. Research Projects (All as PI)

**Ongoing:**

P30 AR039750, Cooper (PI) 03/01/97 - 08/31/16 1.8 calendar months
NIH/NIAMS $400,000
Skin Diseases Research Center
To generate new knowledge that will have a sustained impact on cutaneous biology that will improve the quality of life of patients with skin disease.

P50 AR055508, Cooper (PI) 09/24/07 – 08/31/13 (NCE) 4.8 calendar months
NIH/NIAMS $784,477
Psoriasis Center of Research Translation
To bring a multidisciplinary team of translational physician scientists, nurses, community clinicians, laity, and basic scientists from different departments and disciplines together to apply the intellectual and scientific resources of the institution to new therapies for psoriasis patients.

T32 AR007569, Cooper (PI) 7/01/91 - 6/30/14 1.2 calendar months
NIH/NIAMS $212,500
Training in investigative and molecular dermatology
Major goal is to provide interdisciplinary training to MD and PhD scientists contemplating a career in academic dermatology

R01 AR051498, Cooper (PI) 8/1/04 - 6/30/15 2.4 calendar months
NIH/NIAMS $225,000
Psoriatic regulatory T cell dysfunction
Identification of immunoregulation abnormalities in psoriasis.

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Daly, Barbara J.** | POSITION TITLE<br>Professor & Director, Clinical Ethics Service |
| eRA COMMONS USER NAME **BJDALY** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| University of Massachusetts, Amherst, MA | BSN | 1969 | Nursing |
| Case Western Reserve University (CWRU), Cleveland, OH | MSN | 1972 | Med-Surgical Nursing |
| Cleveland State University, Cleveland, OH | MA | 1989 | Philosophy |
| Bowling Green State University, Bowling Green, OH | PhD | 1993 | Philosophy |

**A. Positions and Honors**

**Positions and Employment**

1969 Staff Nurse, Valley Hospital, Ridgewood, NJ
1969-1970 Specialty Nurse, Fort Logan Mental Health Center, Denver, CO
1971-1972 Clinical Nurse I, University Hospitals of Cleveland, Cleveland, OH
1972-1976 Clinical Instructor Medical-Surgical Nursing, CWRU, Cleveland, OH
1972-1976 Administrative Nurse Clinician, University Hospitals of Cleveland, Cleveland, OH
1975-1976 Nursing Consultant, Veterans Administration Hospital, Cleveland, OH
1976-pres. Assistant Director of Medical-Surgical Nursing, University Hospitals of Cleveland, OH
1976-1991 Assistant Clinical Professor, Medical-Surgical Nursing, CWRU, Cleveland, OH
1991-pres. Assistant Professor, School of Nursing and School of Medicine, CWRU, Cleveland, OH
1993-pres. Director, Clinical Ethics Service, University Hospitals of Cleveland, Cleveland, OH
1996-2006 Associate Professor, School of Nursing and Biomedical Ethics, CWRU, Cleveland, OH
2006-pres Professor, School of Nursing and Biomedical Ethics, School of Medicine, CWRU, Cleveland, OH

**Other Experience and Professional Memberships**

1974-pres American Nurses Association
1974-pres Ohio Nurses Association
1974-pres Greater Cleveland Nurses Association
1978-pres Society of Critical Care Medicine
1984-pres American Association of Critical Care Nurses
1994-pres Volunteer Guardianship Program/Adult Guardianship Program, Advisory Board
1995-pres American Society for Bioethics and the Humanities
2005-pres Oncology Nursing Society
2006-pres Hospice and Palliative Nurses Association
2006-pres American Academy for Hospice and Palliative Medicine

**Honors**

1971-pres. Sigma Theta Tau, Alpha Mu Chapter
1978 Award for Excellence, FPB School of Nursing Alumni Association
1980-pres. Fellow, American Academy of Nursing
1987 Involved Nurse Award, Greater Cleveland Nurses Association
1993 Outstanding Professional Achievement, FPB Alumni Association
2001 Distinguished Research Lecturer, American Association of Critical Care Nurses

2005 Daniel J. Pesuit Spirit of Renewal" Award, Sigma Theta Tau International
2008 Society of Critical Care Medicine, "Grenvik Family Award for Ethics"
2009 Hospice and Palliative Nurses Association, "Distinguished Career Award"
2009 American Association of Critical Care Nurses, "Pioneering Spirit Award"

**B. Selected Peer-reviewed Publications**

**Most relevant to the current application**

1. Daly, BJ, Rosenfeld, K. (2003). Maximizing benefits and minimizing risks in health services research near the end of life. Journal of Pain & Symptom Management 25 (4): S33-42.
2. Daly, BJ, Douglas SL, Kelley, CG, O'Toole E, Montenegro, HD. (2005) Trial of a disease management program to reduce readmissions of the chronically critically ill. Chest 128: 507-517.
3. Daly BJ, Douglas SL, Foley H, Lipson AR, et al. (2006). Psychosocial registry for persons with cancer and their family caregivers: a method for facilitating quality of life and symptom research. Psycho-Oncology 16: 1-7.
4. Douglas SL, Daly BJ, et al. (2007). Chronically critically ill patients: Health-related quality of life and resource use after a disease management intervention. American Journal of Critical Care 16: 447-457 PMCID: PMC2040111
5. Kelley, C.G., Daly, B.J., Douglas, S.L., & Standing, T. (2008). Racial differences in perceptions held by caregivers of long-term ventilator patients at the end-of-life. International Journal of Palliative Nursing, 13(1), 30-38. PMID: 17353848
6. Mazanec P, Daly BJ, Pitorak EF, Kane D, Wile S, Wolen J. (2009). A new model of palliative care for oncology patients with advanced disease. J Hospice and Palliative Nurs; 11: 324-331.
7. Daly BJ, Douglas SL, Gordon NH, Kelley CG, O'Toole E, Montenegro, H, Higgins P. (2009). Composite outcomes in the chronically critically ill: Survival, location, and cognitive status at four months. American Journal of Critical Care. 18: 456-466. PMCID: PMC2882850
8. Daly BJ, Douglas S, Lipson A, Foley H. (2009). Needs of older caregivers of patients with advanced cancer. Journal of Amer. Gero. Society 57: S293-S295.
9. Hickman RL, Daly BJ, Douglas SL, & Clochesy JM. (2010). Informational coping style and depressive symptoms in family decision makers. American Journal of Critical Care, 19: 410-420. PMCID: PMC3081725
10. Daly BJ, Douglas SL, O'Toole EE, Gordon N, Hejal H, Peerless J, Rowbottom J, Garland A, Lilly C, Wiencek C, Hickman R. (2010). Effectiveness trial of an intensive communication structure for families of long-stay ICU patients. Chest 138; 1340-1348. PMCID: PMC2998207
11. Mazanec PM, Daly BJ, Townsend A. (2010). Hospice utilization and end-of-life care decision making of African Americans. American Journal of Hospice and Palliative Medicine 27: 560-566. PMID: 21071435
12. Mazanec S, Daly BJ, Douglas S, Musil C. (2011). Predictors of psychosocial adjustment during the postradiation treatment transition. Western Journal of Nursing Research 33: 540-559. PMID: 20947795
13. Mattson MR, Demshar RK, Daly BJ. (ePub ahead of print, Jan 30, 2012). Quality of life of young adult survivors of hematologic malignancies. Cancer Nursing, 32. PMID: 22293158
14. Douglas SL, Daly BJ. (in press). The Impact of patient quality of life and spirituality upon caregiver depression for those with advanced cancer. Palliative and Supportive Care.
15. Daly BJ, Douglas SL, Lipson AR, Gunzler D. (2013). Clinical Trial of a Supportive Care Team for Patients with Advanced Cancer. J Pain Symp Mgt (in press)

**C. Research Support**

**Ongoing Research Support**

R01 NR014059-01 Slomka (PI) 09/01/12-08/31/16
NIH/NINR
*Randomized Trial of an HIV Navigation Program for Early Palliative Care*

This study will increase our understanding of persons living with HIV/AIDS (PLWHA) who are at highest risk for need of palliative care services and provide a model for provision of early palliative care support for adult PLWHA with chronic comorbidities.
Role: Co- Investigator

R01 NR013322-02 Daly (PI) 09/27/11 – 07/31/13
NIH/NINR
*Mapping the Complexity of End of Life Transitions in Chronically Critically Ill*
This is a prospective examination of the multiple interacting factors that affect transitions in goals of care and treatment decisions by family surrogates of long-stay ICU patients.

P30 NR011907-02 Daly (PI) 09/30/09 – 01/31/13
NIH/NINR
*Building End-of-life Science through Positive Human Strengths and Traits*
This center grant establishes an itnerdisciplinary center witht he objectives of promoting the discovery and applciation of concepts from positive psychology tot he care of individuals facing life-limiting illnesses, such as cancer. It provides for the recruitment of three junior faculty and support of their pilot projects, in addition to support for the growth of an interdisciplinary faculty collaborative around common research interests.

P30 NR010676-05 Moore (PI) 09/29/07 - 06/30/13
NIH/NINR
*Center of Excellence to Build the Science of Self-Management: A Systems Approach*
The SMART Center will prepare a critical mass of researchers to extend and disseminate knowledge related to self-management, contribute to the development of emerging biobehavioral research methods, focus on critical issues related to health disparities, and incorporate economic considerations as part of their research.
Role: Co-investigator

**Completed Research Support**
T32 NR009761 (Moore, PI) 05/18/06 – 4/30/12
NIH / NINR
*Multiple Morbidities in Vulnerable Populations: Nurse Scientist Training.*
This training grant is designed to prepare nurse scientists at the pre-doctoral and post-doctoral level in program of research focused on populations with identified vulnerabilities related to low birth weight in neonates, chronically illness (including cancer), and critical illness with multiple co-morbidities.
Role: Core faculty

NR018717 (Daly, PI) 08/01/07 – 5/31/11
NIH/NINR
*Improving the Quality of Advanced Cancer Care with Disease Management*
This is a trial of a Disease Management program for patients with advanced GI, lung, and Gyn cancers, focused on the provision of comprehensive, coordinated palliative and psychosocial care within the acute cancer treatment center.

P20 CA 103736 03/31/05 – 12/1/07
Cancer Center P-20 "Aging Cancer Research Program" (CA-103736)
Cancer Center P Award (N. Berger, PI) – Subproject
*Psychosocial Data Registry for Persons with Cancer and Family Caregivers*
This was a pilot project to design and establish the feasibility of a research registry to collect data regarding the psychosocial needs and status of persons undergoing treatment for cancer. The project enrolls all consenting adults at an NCI-designated Comprehensive Cancer Center; data will be available to other researchers.
Role: PI on sub-project

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Neal V. Dawson, M.D.** | POSITION TITLE<br>Professor of Medicine<br>Professor of Epidemiology and Biostatistics |
| eRA COMMONS USER NAME **NDAWSON** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| University of Missouri, Columbia | AB | 1967-1971 | Zoology |
| University of Missouri, Columbia | ---- | 1972 | Physiology |
| University of Missouri, Columbia – School of Medicine | MD | 1972-1976 | Medicine |
| University of Missouri, Columbia – Resident Physician | ---- | 1976-1979 | Medicine |
| University of Missouri, Columbia – Chief Resident | ---- | 1979-1980 | Medicine |
| University of California, San Francisco – Robert Wood Johnson Clinical Scholar | ---- | 1980-1982 | Clinical Epidemiology Decision Sciences |

**A. Positions and Employment**

| | |
|---|---|
| 1976 | Diplomate of the National Board of Medical Examiners |
| 1980 | Diplomate of the American Board of Internal Medicine |
| 1982-90 & 92-93 | Firm Director, Division of General Medicine, MetroHealth Medical Center, Cleveland, OH |
| 1982-90 | Assistant Professor of Medicine, Case Western Reserve University, Cleveland, OH |
| 1984-86 | Research Scholar, Keck Foundation/Health Systems Management Center, Case Western Reserve University |
| 1985-87 | Medical Director, Medical Group Practice Clinics, MetroHealth Medical Center, Cleveland, OH |
| 1990-99 | Associate Professor of Medicine |
| 1996-00 | Associate Professor of Epidemiology and Biostatistics |
| 1998-Present | Associate Editor, Medical Decision Making |
| 1982-2009 | Staff Physician, MetroHealth Medical Center, Cleveland, OH |
| 1999-Present | Professor of Medicine |
| 2000-Present | Professor of Epidemiology and Biostatistics |

**Honors, Service, and Grant Reviews**

| | |
|---|---|
| 1987 | First Prize Award, Blue Cross and Blue Shield of Ohio Annual Competition for Innovation in Health Care Productivity (Representing the Department of Medicine "Firms") |
| 1991 | Henry Christian Award for Excellence in Research (Clinical Epidemiology) from the American Federation for Clinical Research |
| 1992 | Henry Christian Award for Excellence in Research (Clinical Epidemiology/Healthcare Research) from the American Federation for Clinical Research |
| 1992 | Agency for Health Care Policy and Research: Feasibility of a Central Source of Computerized Medical Records for Effectiveness Research |
| 1992 | RAND/Health Care Financing Administration: Standards for Prediction Models |
| 1995 | Centers for Disease Control and Prevention: Establishing Medically Relevant Performance Goals for the Laboratory |
| 2001 | Arthritis Research Campaign Project Grant Reviewer (United Kingdom) |
| 2002-03 | National Science Foundation Proposal Review: Decision Risk and Management Science |
| 2005-10 | Best Doctors in America |
| 2006-07 | Robert Wood Johnson Foundation Proposal Review: Substance Abuse Policy Research Program |

| | |
|---|---|
| 2006 | NIMH, ZMH1 CNFQ, R-13, Small Conference Grant Review |
| 2009 | Netherlands Organisation for Scientific Research (NWO), Vidi grant review, Innovational Research Incentives Scheme, |
| 2009 | Ad Hoc Reviewer, Special Emphasis Panel/Scientific Review Group10 ZRG1 RPHB-A (58) |
| 2011 | Ad Hoc Reviewer, Special Emphasis Panel/Scientific Review Group 2011/10 MID 1 (K-24) |
| 2012 | NIMH, Special Emphasis Panel/Scientific Review Group 2013/01 ZMH –1 ERB-I (01) S |

**B. Selected peer reviewed publications (in chronological order)**

**Most relevant to the current application**

1. **Dawson NV**, Arkes HR. Systematic errors in medical decision making: Judgment limitations. *J Gen Intern Med* 1987;2:183-7.
2. **Dawson NV**, Arkes HR, Siciliano C, Blinkhorn R, Lakshmanan M, Petrelli M. Hindsight bias: An impediment to accurate probability estimation in clinicopathologic conferences. *Med Decis Making* 1988;8:259-64.
3. Speroff T, Connors A, **Dawson N**. Multivariate lens model analysis of physician judgment of hemodynamic status. *Med Decis Making* 1989;9:243-52.
4. **Dawson NV**, Cebul RD. Advances in quantitative techniques for making medical decisions: The last decade. *Eval Health Prof* 1990;13:37-62.
5. Emerman CL, **Dawson N**, Speroff T, Siciliano C, Effron D, Rashad F, Shah Z, Bellon E. Comparison of physician judgment and decision aids for ordering chest radiographs for pneumonia in outpatients. *Ann Emerg Med* 1991;20:1215-9.
6. **Dawson NV**, Dadheech G, Speroff T, Smith RL, Schubert DSP. The effect of patient gender on the prevalence and recognition of alcoholism on a general medicine inpatient service. *J Gen Intern Med* 1992;7:38-45.
7. **Dawson NV**. Physician judgment in clinical settings: Methodologic influences and cognitive performance. *Clin Chem* 1993;39:1468-80.
8. Knaus WA, Harrell FE, Lynn J, Goldman L, Phillips RS, Connors AF, **Dawson NV**, Fulkerson WJ, Califf RM, Desbiens N, Layde P, Oye RK, Bellamy PE, Wagner DP and the SUPPORT Investigators. The SUPPORT prognostic model: Prediction of survival for seriously ill hospitalized adults. *Ann Intern Med* 1995;122:190-202.
9. The SUPPORT Investigators. Impact of an intervention to improve decision making for seriously ill hospitalized patients: The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment (SUPPORT). *JAMA* 1995;274:1591-8.
10. Perzynski AT, Terchek J, Blixon C, **Dawson NV**. Playing the numbers: How hepatitis C patients create meaning and make health care decisions from medical test results. Sociology of Health and Illness 2012 (Epub ahead of print) PMID 23009649

**Other recent publications**

1. Blixen CE, Webster NJ, Hund AJ, Perzynski AT, Kanuch SW, Stoller EP, McCormick RA, **Dawson NV**. Communicating about alcohol consumption in nonharmful drinkers with hepatitis C: Patient and provider perspectives. J Gen Intern Med 2008;23:242-7. PMCID: PMC2359467
2. **Dawson NV**, Singer ME, Lenert L, Patterson MB, Sami SA, Gosenhouser I, Lindstrom HA, Smyth KA, Barber MJ, Whitehouse PJ. Health state valuation in mild to moderate cognitive impairment: Feasibility of computer-based, direct patient utility assessment. *Med Decis Making* 2008;28:220-32. PMID: 18349434
3. Stoller EP, Webster NJ, Blixen CE, McCormick RA, Hund AJ, Perzynski AT, Kanuch SW, Thomas CL, Kercher K, **Dawson NV**. Alcohol consumption decisions among nonabusing drinkers diagnosed with hepatitis C: An exploratory sequential mixed methods study. J Mixed Methods Res 2009;3:65-86. PMCID: PMC2792926
4. Rose JH, Kypriotakis G, Bowman KF, Einstadter D, O'Toole EE, Machekano R, **Dawson NV**. Patterns of adaptation in patients living longer with advanced cancer. Cancer 2009;115(18 suppl):4298-310.

PMID:19731358

5. Perzynski AT, McCormick R, Webster NJ, Blixen CE, Kanuch S. Thomas CL, Mullen K, **Dawson NV**. Psychosocial correlates of alcohol use and reduction for individuals with hepatitis C. Journal of Studies on Alcohol and Drugs 2011;72:787-98. PMCID: PMC3174024

**C. Research Support.**

**Ongoing Research Support**

NIH 1RO1MH085665 Dawson (PI); Sajatovic (PD/PI) 07/01/11 – 05/31/16
Improving Outcomes for Individuals with Serious Mental Illness and Diabetes
Overall goals: A randomized trial of education (diabetes and mental illness) and peer support versus treatment as usual to improve care and outcomes of patients in a safely net system who have both diabetes and serious mental illness (schizophrenia, schizoaffective disorder, bipolar disorder, major depression)
Role: PI

Connors (PI)
Saint Luke's Foundation 03/01/05 – 12/30/15
Buckeye Health Center: Ensuring Accessible HealthCare and Healthy Living
Healthy Weight and Lifestyles Intervention for Adults
Overall goals: In a primary care neighborhood practice serving largely African American adults, to test the feasibility and effectiveness of a program to perform: 1) Annual obesity and related disease screening; 2) Annual low intensity tailored lifestyle intervention 3) Develop and implement an intense lifestyle intervention that is accessible for a low-literacy population to be offered to about 75 obese patients annually.
Role: Director, Evaluation Component

KL2-RR024990 Davis (PI) 9/17/07-05/31/17
NIH
CTSA-KL2-MHMC
Overall goals: Training Program for postdoctoral Clinical Research Scholars and thereby help to transform and strengthen the nation's clinical research enterprise. The program is a partnership among Case/CCLCM of CWRU, UHoC and MHMC
Role: Director, KL2 Scholar Seminar Series; research proposal vetting; mentor; mentor oversight

2 T32 HS00059-11 Rimm (PI) 7/1/08 – 6/30/13
Agency for Healthcare Research and Quality
Training Program in Health Services Research
Role: Faculty and Research Mentor

**Completed Research Support**

RG4103A4/2 (Fox--CCF; Dawson--MHS) 10/1/09-09/30/11
National Multiple Sclerosis Society (NMSS)
Overall goals: This study will assess how patients with multiple sclerosis value a variety of health outcomes and the association of those valuations with treatment preferences.
Role: Co-Investigator

R01 CAH1082828 Rose (PI) 09/19/03 - 06/30/11
NCE
NIH-AHRQ
Aging and Supportive Care in Advanced Cancer
Overall goals: to perform a randomized trial of coping and communication support for adult patients with incurable late stage cancer.

Role: Co-Investigator

RO1AG022459-O1A2 Sudano (PI) 06/01/05-05/31/10
NIH/NIA
Subject/Objective Health Measures by Race/Ethnicity
Overall goals: Examines measurement equivalence between subjective measures of physical functioning and a performance-based index of physical functioning among several diverse racial/ethnic groups.
Role: Co-Investigator

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Dolansky, Mary A.** | POSITION TITLE<br>Associate Professor, School of Nursing |
| eRA COMMONS USER NAME **MDOLANSKY** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| Kent State University, Kent, OH | BSN | 1984 | Nursing |
| Kent State University, Kent, OH | MSN | 1990 | Nursing |
| Case Western Reserve University (CWRU), Cleveland, OH | PhD | 2001 | Nursing |
| CWRU, Cleveland, OH | Post-doctoral Fellowship | 2001-2003 | Gerontology |
| Metro Health Medical Center | Certificate | 2001-2003 | Improvement Science |
| CASE/Cleveland Clinic Multidisciplinary Clinical Research Career Development | Career Development Award | 2005-2008 | Multidisciplinary Clinical Research |

**A. Positions and Honors.**

**Positions and Employment**

1984-1985 Staff R.N., Medical Nursing, University Hospitals of Cleveland, Cleveland, OH
1985-1988 Staff R.N., CCU and ICU, Parma Community General Hospital Parma, OH
1988 -1994 Staff R.N., CCU, Cardiac Step-down, Cardiac Rehabilitation, Fairview General Hospital, Cleveland, OH
1990-1992 Full-time Instructor, Nursing of the Adult, Kent State University Kent, OH
1995-2001 Research Assistant, Frances Payne Bolton School of Nursing (FPB), CWRU, Cleveland, OH
2001-2003 John A. Hartford Scholar, Post Doctoral Fellowship, FPB, CWRU, Cleveland, OH
2001-2003 Faculty Scholar, Quality Improvement, Metrohealth Medical Center, Cleveland, OH
2004-2005 Magnet Coordinator, University Hospitals of Cleveland, Cleveland, OH
2004-2008 Instructor, FPB, CWRU, Cleveland, OH
2005-2008 Post-doctorate, Case/Cleveland Clinic Multidisciplinary Clinical Research Training Program, CWRU, Cleveland, OH
2008 - 2012 Assistant Professor, FPB, CWRU, Cleveland, OH
2012-present Associate Professor, FPB, CWRU, Cleveland, OH

**Other Experience and Professional Memberships**

American Heart Association Council on Cardiovascular Nursing
American Association of Cardiovascular and Pulmonary Rehabilitation
Gerontological Society of America
American Association of Heart Failure Nurses
Preventative Cardiac Nurse Association

**Honors and Awards**

1990 Henderson Award for Academic Excellence, Kent State University, Kent, OH
1992 Outstanding Service Award for outstanding service to Delta Xi Chapter, Sigma Theta Tau International
1992-1998 Willis B. Boyer Memorial Scholarship Fund for Gerontological Nursing
1998 Peg Schlitz Memorial Nursing Research Award, Delta Xi Chapter, Sigma Theta Tau

International

1998 New Investigator Award, Rehabilitation Nursing Foundation of the Association of Rehabilitation Nurses

1999 Ruth Barber Moon Award for Distinguished Graduate Studies, Case Western Reserve University, Cleveland, OH

2000 Second Place, Graduate Student Poster Exchange, 24th Annual Meeting of the Midwest Nursing Research Society, Dearborn, MI

2000 Outstanding Scientific Merit, Poster Presentation, 26th Annual Educational Conference of the Association of Rehabilitation Nurses, Reno NV

2001 The Marie Haug Student Award, Excellence in Aging Studies, Case, Cleveland, OH

2003 Outstanding Dissertation Award, Midwest Nursing Research Society Gerontological Section

2010 Evidenced Based Practice Award, Midwest Nursing Research Society Gerontological Section

2011 Next Generation of Care, Greater Cleveland Nurses Association and the Cleveland Magazine Faces of Care, finalist.

**B. Peer-reviewed publications.** (Chronological order)

1. Dolansky, M. A. & Moore, S. M. (2000). Effect of cardiac rehabilitation on older adults' lower extremity functioning following coronary artery bypass surgery. Circulation (supplement II), 102(18), 822.
2. Moore, S. M. & Dolansky, M. A. (2001). Randomized trial of a home recovery intervention following coronary artery bypass surgery. Research in Nursing and Health, 24, 93-104.
3. Moore, S. M., Dolansky, M. A., Ruland, C. M., Pashkow, F. J., & Blackburn, G. G. (2003). Predictors of women's exercise maintenance following a cardiac rehabilitation program. Journal of Cardiopulmonary Rehabilitation, 23(1), 40-9.
4. Dolansky, M. A. & Moore, S. M (2004). Effect of cardiac rehabilitation on older adults' recovery outcomes following coronary artery bypass surgery. Journal of Cardiopulmonary Rehabilitation. 24(4), 236-244.
5. Dolansky, M. A. & Moore, S. M (2006). Older adults' views of cardiac rehabilitation. Journal of Gerontological Nursing. 32(2) 37-44.
6. Dolansky, M. A. & Hassanein, S. (2007). Cardiac rehabilitation in a skilled nursing facility: Need, feasibility, and current services. Journal of Cardiopulmonary Rehabilitation and Prevention, 27, 5.
7. Dolansky, M. A. & Moore, S. M. (2008). Older adults' early disability following a cardiac event. Western Journal of Nursing Research. 30(2), 163-180.
8. Dolansky, M. A. & Moore, S. M. (2008). Older adults' use of post-acute and cardiac rehabilitation services after hospitalization for a cardiac event. Rehabilitation Nursing, 33(2) 75-83.
9. Seo, Y, Roberts, B.L., Pina, I., & Dolansky, M. (2008). Predictors of motor tasks essential for daily activities among persons with heart failure. Journal of Cardiac Failure. 14(4), 296-302.
10. Dolansky, M.A.; Singh, MK; Neuhauser, D (2009). Quality and safety education: Foreground and background, Quality Management in Health Care, 18(3), 151-157.
11. Dolansky, M. A., Stepanczuk, B. A., Charvat, M.S., Moore, S.M. (2010). Women's and men's Exercise Adherence After a Cardiac Event: Does Age make a Difference? Research in Gerontological Nursing. 3(1), 30-38. PMCID: PMC2897096
12. Zullo, M.; Dolansky, M. A. and Jackson, L.W. (2010). Cardiac Rehabilitation, health behaviors and body mass index following myocardial infarction. Journal of Cardiopulmonary Rehabilitation, 30(1) 28-34.
13. Roberts, B. L., Dolansky, M. A., & Weber, B. A. (2010). Psychometrics for the task self-efficacy scale. Research Theory and Nursing Practice, 24(2) 113-127. PMID 20549917.
14. Dolansky, M. A., Xu, F., Zullo, M., Shishehbor, M., Moore, S. M., Rimm, A.A. (2010). Post-acute care services received by older adults following a cardiac event: A population-based analysis. Journal of Cardiovascular Nursing, 25(4), 342-249. PMID 20539168.
15. Nochomovitz, E., Prince-Paul, M.J., Dolansky, M.A., Singer, M. E., DeGolia, P., Frank, S. H. (2010). State Tested Nursing Aides' Provision of End-of-Life Care in Nursing Homes: Implications for Quality Improvement. Journal of Hospice and Palliative Nursing, 12(4), 255-262.

16. Zullo, M., Dolansky, M. A. and Jackson, L.W. (2011). Metabolic Syndrome: Identification and Management in Cardiac Rehabilitation. Journal of Cardiopulmonary Rehabilitation. 31(2)92-99. PMID 20842044.
17. Boxer, R., Dolansky, M. A., Hitch, J., Pina, I. (2011). The Bridge Project Improving the Transition from Hospital to Home for Patients with Heart Failure through Education and Program Development in Skilled Nursing Facilities. Journal of the American Medical Association.
18. Jones, K., Tullai-McGuinness, S., Dolansky, M. A., Amany, F. (2011). Expanded Adult Day Program as a Transition Option from Hospital to Home" Policy, Politics & Nursing Practice, 12(1), 18-26.
19. Webel, A.R., Dolansky, M., Henry, A. & Salata, R. (2011) Women's Self-Management of HIV: Context, Strategies and Considerations. Journal of the Association of Nurses in AIDS Care. E-pub ahead of print.
20. Dolansky, M. A., Zullo, M., Moore, S. M., Boxer, R.S. (2011). Initial Efficacy of a Cardiac Rehabilitation Transition Program: Cardiac TRUST. Journal of Gerontological Nursing. 37(12), 36-44. PMID 22084960.
21. Zullo, M.D., Jackson, L.W., Whalen, C.C., Dolansky, M. A. (2012). Evaluation of the recommended core components of cardiac rehabilitation practice: an opportunity for quality improvement. Journal of Cardiopulmonary Rehabilitation and Prevention. Jan-Feb 32(1) 32-40.PMID 22193929.
22. Dolansky, M. A., Hussain, S., Zullo, M., Schaefer, J. T., Boxer, R.(2012). Cardiac Rehabilitation during Post-acute Care: A Missed Opportunity. Heart and Lung. 41(2) 115-124.
23. Dolansky, M. A. Hitch, J. A., Piña, I., Boxer, R. S. (accepted). Implementation of a Heart Failure Management Program in Skilled Nursing Facilities: Lessons Learned. Clinical Nursing Research.
24. Dolansky, M.A., Helba, M., Druschel, K., Courtney, K. (2013). Nursing student medication errors: A root cause analysis to develop a fair and just culture. Journal of Professional Nursing. March/April.

## C. Research Support

**Ongoing Research Support**

1R01HL113387-01 Boxer (PI) 5/1/2012-4/30/17
*Efficacy of Skilled Nursing Facility Heart Failure Management, NIH, NHLBI.*
The goal of this RCT is to determine the efficacy of a heart failure disease management program in skilled nursing facilities.
Role: Co-I.

1R01HL096710-01A1 Dolansky (Co-PI); Hughes (Co-PI) 4/5/10-1/31/14
*Cognitive Impairment and Self-management in Adults with Heart Failure*
The goal of this study is to assess the relationship between cognitive impairment, patient self-management, health, and health service use in adults with heart failure.
Role: Co-PI

Veterans Administration Singh & Watts (PI) 3-1-11 to 2-28-16
*VA Office of Academic Affiliations, Center of Excellence in Primary Care Education: Transforming Out-patient Care (TOPC)*
The goal of this project is to integrate interdisciplinary team training into the resident and nurse practicioner training to enhance quality and safety.
Role: Co-Chief Operating Officer

Macy Foundation Underwood & Ornt (PI) 7/1/10 – 6/30/14
*Interprofessional learning Exchange and Development Program (I-Lead)*
The goal of this project is to develop and test a longitudinal interdisciplinary curriculum for nursing and medical students to enhance quality and safety.
Role: Co-I

Robert Wood Johnson Foundation Cronenwett, (PI) 11/15/09-11/14/12
*Veterans Administration Quality Scholars Program, Quality and Safety Education for Nurses: Phase III*

The purpose of this training program mentor pre-and postdoctoral physicians and nurses in the Veterans Administration Quality Scholar Senior Fellow program and to develop and test quality improvement curriculum.
Role: Mentor

**Pending**

1T32NR014213-01 Daly (PI) 7/1/13 - 6/30/18
Symptom Management and Palliative Care Research in Adults with Advanced Disease
The purpose of this training program is to mentor pre and postdoctoral nurses in the application of symptom management and palliative care for persons with heart failure.
Role: Core Faculty

**Completed Research Support**

R03 HS019795-01 Zullo (PI) 9/1/10-8/31/12
AHRQ
*Disability, Illness Burden, and Transitions of Care to Cardiac Rehabilitation*
The purpose of this study is to identify the relationships among disability, illness burden, and transitions of care and cardiac rehabilitation using the Chronic Disease Warehouse database.
Role: Co-I

Robert Wood Johnson Foundation Dolansky (Co-PI); Moore (Co-PI) 10/1/08-9/30/10
*A Measure of Systems Thinking: A Key Component of the Advancement of the Science of CQI*
The goal of this project is to develop and conduct psychometric testing of the Systems Thinking Scale (STS).

1P30NR010676-01 Moore (PI) 9/29/07- 6/30/12
NIH/NINR
*Center of Excellence to Build the Science of Self-Management: A Systems Approach*
The SMART Center will prepare a critical mass of researchers to extend and disseminate knowledge related to self-management, contribute to the development of emerging biobehavioral research methods, focus on critical issues related to health disparities, and incorporate economic considerations as part of their research.
PI of Pilot study: A Skilled Nursing Facility Self-management Cardiac Rehabilitation Intervention.
Role: Pilot Investigator 9/29/07-6/30/10

McGregor Foundation, Cleveland, Ohio Boxer (PI) 12/1/08-12/31/09
*Heart Failure Management and Quality Improvement in the Skilled Nursing Facility*
Role: Co-I

Parma Hospital Foundation Jones(PI) 10-1-08 to 9-30-09
*Parma D.A.Y. Program Evaluation*
Role: Co-I

McGregor Foundation, Cleveland, Ohio Boxer (PI) 7/1/08-12/1/08
*The management of Heart Failure in Long Term Care and in the Skilled Nursing Facility: The Bridge project phase I*
Role: Co-I

1KL2RR024990 (Clinical Research Scholar) 8/15/07-4/1/08
*Feasibility and Safety of a Skilled Nursing Facility Self-management Cardiac Rehabilitation Intervention,*
Case/Cleveland Clinic Multidisciplinary Clinical Research Career Development Award
Role: Principal Investigator, K12/KL2 Pilot Funds

1KL2RR024990 (Clinical Research Scholar) 1/15/07-7/1/07
*Older Adults in a Skilled Nursing Facility following a Cardiac Event: Need and Feasibility of Cardiac Prehab Services*, Case/Cleveland Clinic Multidisciplinary Clinical Research Career Development Award
Role: Principal Investigator, K12/KL2 Pilot Funds

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME John Kevin Donahue, MD | POSITION TITLE<br>Professor of Medicine, Biomedical Engineering, Physiology and Biophysics |
| eRA COMMONS USER NAME: kdonahue | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(S) | FIELD OF STUDY |
|---|---|---|---|
| Washington University, St. Louis, MO | B.A. | 1987 | Chemistry/Michael J. Welch, PhD Education, Biology |
| Washington University, St. Louis, MO | M.D. | 1992 | Medicine/Peter B. Corr, PhD and John P. Atkinson, MD |
| Hospital of the University of Pennsylvania, Philadelphia, PA | Residency | 1994 | Internal Medicine/ Ed Holmes, MD |
| Johns Hopkins University School of Medicine, Baltimore, MD | Clinical Fellowship | 1996 | Cardiology/Ken Baughman, MD |
| Johns Hopkins University School of Medicine, Baltimore, MD | Research Post-doctoral Fellowship | 1998 | Electrophysiology/John Lawrence, MD and Eduardo Marban, MD PhD |
| Johns Hopkins University School of Medicine, Baltimore, MD | Clinical Subspecialty Fellowship | 1999 | Clinical Cardiac Electrophysiology/ Hugh Calkins, MD |

**A. Positions And Appointments:**

1999 - 2005 Active full-time staff, cardiac electrophysiology, Johns Hopkins Hospital.
1999 - 2004 Assistant Professor, Department of Medicine, Johns Hopkins University.
2003 - 2005 Director of Cardiac Genetics, Johns Hopkins University.
2004 - 2005 Associate Professor, Department of Medicine, Johns Hopkins University.
2005 - 2011 Associate Professor, Department of Medicine, Case Western Reserve University.
2005 - Active full-time staff, cardiac electrophysiology, Metrohealth Hospital.
2007 - Adjunct appointments in Biomedical Engineering, and Physiology & Biophysics, CWRU.
2011- Professor (with tenure) of Medicine, Biomedical Engineering, Physiology & Biophysics, CWRU

**Professional Activities:**
**Subspecialty Board:** American Board of Internal Medicine, Test Committee on Clinical Cardiac Electrophysiology 2010-
**Editorial Board:** Circulation Research 1999-2005, Journal of Cardiovascular Electrophysiology 2008-, Journal of Interventional Cardiac Electrophysiology 2011-
**Journal reviewer:** Nature Medicine, JAMA, Circulation, Journal of the American College of Cardiology, Gene Therapy, Journal of Gene Medicine, Molecular Therapy, American Journal of Physiology, Journal of Electrocardiography, Heart Rhythm, PACE, Journal of Molecular and Cellular Cardiology
**Grant reviewer: Standing committees:** NIH ZHL1 special emphasis panel 2007-present, AHA—Mid-Atlantic Affiliate 2002-2005, National Foundation 2006-2009. **Ad hoc:** NIH—BRP, SBIR/STTR, PPG, FDA Orphan Drug Program; US-Israel Binational Science Foundation, Health Research Council of New Zealand, Deutsche Forschungsgemeinschaft.

**Honors And Awards:**
1987 Phi Beta Kappa Honorary Society, 1987 American Chemical Society, Charles D. Coryell Award, 1990 Four Schools Physician-Scientist Training Program, 1996 Astra-Merck, Young Investigator Competition, national finalist, 1998 NASPE, Wilson Greatbatch, Ltd. Travel Award, 1999 Johns Hopkins University, Richard

S. Ross Clinician Scientist Award, 2000 American Heart Association, "Top 10 Research Advances in Cardiovascular Disease", 2001 David H. Bernstein Idea Award, 2009 induction into the American Society for Clinical Investigation.

**B. Peer-Reviewed Publications** [per NIH guidance limit to 15 (out of 51 total)]:

1. Donahue JK, Kikkawa K, Johns D, Marbán E, and Lawrence JH. Ultrarapid, highly efficient viral gene transfer to the heart. *Proceedings of the National Academy of Sciences* 1997;94:4664-4668.
2. Donahue JK, Kikkawa K, Thomas AD, Marbán E, and Lawrence JH. Acceleration of widespread adenoviral gene transfer to intact rabbit hearts by coronary perfusion with low calcium and serotonin. *Gene Therapy* 1998;5:630-634.
3. Donahue JK*, Heldman AH, Fraser H, McDonald AD, Miller JM, Rade JJ, Eschenhagen T and Marbán E. Focal modification of electrical conduction in the heart by viral gene transfer. *Nature Medicine* 2000;6:1395-1398. *first and corresponding author
4. Nagata K, Marbán E, Lawrence JL and Donahue JK. Phosphodiesterase inhibitor-mediated potentiation of adenovirus delivery to myocardium. *J Mol Cell Cardiol* 2001:33:575-580.
5. Bauer A, McDonald AD, Donahue JK. Pathophysiological findings in a model of persistent atrial fibrillation and severe congestive heart failure. *Cardiovasc Research* 2004;61:764-770.
6. Bauer A, McDonald AD, Peller L, Rade JJ, Miller JM, Heldman AW and Donahue JK. Physiologically-relevant heart rate control from gene therapy in persistent atrial fibrillation. *Circulation* 2004;110:3115-3120.
7. Kikuchi K, McDonald AD, Donahue JK. Targeted modification of atrial electrophysiology by homogeneous transmural atrial gene transfer. *Circulation* 2005;111:264-270.
8. Sasano T, Kikuchi K, McDonald A, Donahue JK. Molecular ablation of ventricular tachycardia after myocardial infarction. *Nature Medicine* 2006;12:1256-8.
9. Sasano T, Kikuchi N, McDonald A, Lai S, Donahue JK. Targeted, high efficiency homogeneous gene transfer. *J Mol Cell Cardiol* 2007;42:954-61.
10. Ashikaga H, Sasano T, Dong J, Zviman MM, Evers R, Hopenfeld B, Castro V, Helm RH, Dickfeld T, Nazarian S, Donahue JK, Berger RD, Calkins H, Abraham MR, Marbán E, Lardo AC, McVeigh ER, Halperin HR. Magnetic resonance-based anatomical analysis of scar-related ventricular tachycardia: implications for catheter ablation. *Circ Res* 2007;101:939-47.
11. Sasano T, Kelemen K, Greener ID, and Donahue JK. Ventricular tachycardia from the healed myocardial infarction scar: validation of an animal model and utility of gene therapy. *Heart Rhythm*. 2009;6:S91-7.
12. Amit G, Kikuchi K, Greener ID, Yang L, Novack V and Donahue JK. Selective molecular potassium channel blockade prevents atrial fibrillation. *Circulation.* 2010;121:2263-70.
13. Swaminathan PD, Purohit A, Soni S, Voigt N, Singh MV, Glukhov AV, Gao Z, He BJ, Luczak ED, Joiner ML, Kutschke W, Yang J, Donahue JK, Weiss RM, Grumbach IM, Ogawa M, Chen PS, Efimov I, Dobrev D, Mohler PJ, Hund TJ, Anderson ME. Oxidized CaMKII cuases cardiac sinus node dysfunction in mice. *J Clin Invest* 2011;121:3277-88.
14. Igarashi T, Finet JE, Takeuchi A, Fujino Y, Strom M, Greener ID, Rosenbaum DS, Donahue JK. Connexin gene transfer preserves conduction velocity and prevents atrial fibrillation. *Circulation* 2012;125:216-25.
15. Greener ID, Sasano T, Igarashi T, Strom M, Rosenbaum DS, Donahue JK. Connexin 43 gene transfer improves conduction velocity and reduces ventricular arrhythmia susceptibility. *J Am Coll Cardiol* 2012;60:1103-10.

**Patents**

Gene delivery compositions and methods (US Patents #6376471, #685570)
Methods and compositions for nucleic acid delivery (US Patent #6992070)
Cardiac arrhythmia treatment methods, (US Patent #7034008)
Gene delivery to organs, (pending US application #20050014714)

## C. Research Support:

**Pending:**

R01 HL121384 9/2013-8/2018
Agency: NIH/NHLBI
*"The effect of connexin43 phosphorylation status on ventricular arrhythmia susceptibility"*
This project assesses the relationship between connexin43 phosphorylation and conduction velocity under baseline and stress conditions.
Role: Principal Investigator

DP1 D017193 9/2013-8/2018
Agency: NIH
*"Novel mechanism-based therapies for ventricular arrhythmias after myocardial infarction"*
This project will define the mechanism of ventricular arrhythmias arising from the infarct borderzone and apply that information to develop novel therapies to prevent these arrhythmias.
Role: Principlal Investigator

R21 AG42701 3/2013-2/2015
Agency: NIH/NIA. Direct cost $275,000 total
*"Final preclinical development of gene therapy for post-operative atrial fibrillation"*
This project focuses on completing the FDA-mandated preclinical steps prior to initiation of a gene therapy clinical trial for post-operative atrial fibrillation. The goals are to define dose range and safety.
Role: Principal Investigator

**Active:**

R01 HL093486 7/2008-6/2013
Agency: NIH/NHLBI. Direct cost $250,000/yr
*"Gene transfer approaches to atrial fibrillation"*
This project focuses on expression of connexins and potassium channel mutations in the atria to modify or eliminate atrial fibrillation. The goals of the project are to define safety and efficacy of this gene therapy
Role: Principal Investigator

R01 HL067148 (no-cost extension) 12/2001-7/2012
Agency: NIH/NHLBI Direct cost $280,000/yr
*"Focal modification of electrical conduction in the heart"*
This project focuses on overexpression of $G\alpha_{i2}$ in the cardiac atrioventricular node during chronic atrial fibrillation. The goals are to define the mechanism of AV node suppression after $G\alpha_{i2}$ over expression and to characterize the response of the AV node to this suppression.
Role: Principal Investigator

Agency: Foundation Leducq Transatlantic Networks of Excellence program 10/2008-9/2013
*"Alliance for Calmodulin Kinase Signaling in Heart Disease"* Direct Cost $55,000/yr
Role: Associate Member

**Completed**

R01 EB2846
Agency: NIH/NIBIB 2003-2007
*"Improved methods for myocardial gene transfer"* Direct Cost $180,000/yr
This grant explored the general hypothesis that a systematic exploration of gene delivery variables would lead to development of new tools for successful gene transfer.
Role: Principal Investigator

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Mitchell L. Drumm** | POSITION TITLE<br>Professor |
| eRA COMMONS USER NAME **MDRUMM** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| The Ohio State University, Columbus, OH | BS | 1983 | Genetics |
| The University of Michigan, Ann Arbor, MI | PhD | 1990 | Human Genetics |
| The University of Michigan, Ann Arbor, MI | Postdoc | 1992 | Human Genetics |

**A. Positions and Honors.**

| | |
|---|---|
| 1992 | **Research Investigator**, Department of Internal Medicine, University of Michigan |
| 1992-1999 | **Assistant Professor**, Departments of Pediatrics and Genetics, Case Western Reserve University |
| 1992-2000 | **Assistant Professor**, Department of Genetics, Case Western Reserve University |
| 1999-present | **Associate Professor**, Department of Pediatrics, Case Western Reserve University |
| 2000-2008 | **Associate Professor**, Department of Genetics, Case Western Reserve University |
| 2008-present | **Professor**, Department of Pediatrics, Case Western Reserve University |
| 2008-present | **Professor**, Department of Genetics, Case Western Reserve University |
| 2010-present | **Vice Chair for Research**, Department of Pediatrics, Case Western Reserve University |

| | |
|---|---|
| 2009 | **Bruce Jackson Award** for Undergraduate Mentoring |
| 2010 | **Paul Di Sant'Agnese Scientific Achievement Award** (Cystic Fibrosis Foundation) |

**B. Selected peer-reviewed publications (in chronological order).**

C. Mueller1, S. A. Braag, A. Keeler, C. Hodges, M. Drumm, T. R. Flotte. Lack of Cftr in CD3+ lymphocytes leads to aberrant cytokine secretion and hyperinflammatory adaptive immune responses. AJRCMB, 2011 44(6):922-929

J.E. Pittman, E.H Calloway, M. Kiser, J. Yeatts, S.D. Davis, M.L. Drumm, M. Schechter, M.W. Leigh, M. Emond, A. Van Rie and M.R. Knowles. Age at Pseudomonas aeruginosa acquisition and subsequent severity of cystic fibrosis lung disease. Pediatric Pulmonology, 2010, *Epub Dec 10.*

C. Taylor, C. W. Commander, J. M. Collaco, L. J. Strug, W. Li, F. A. Wright, A. D. Webel R G. Pace, J. R. Stonebraker, K Naughton, R Dorfman, A. Sandford, S. M. Blackman, Y. Berthiaume, P. Paré, M. L. Drumm, J. Zielenski, P. Durie, G R. Cutting, M. R. Knowles, M. Corey. A Novel Lung Disease Phenotype Adjusted for Mortality Attrition for Cystic Fibrosis Genetic Modifier Studies. Pediatric Pulmonology, 2011 *Epub April 5*.

V. Bezzerri, P. d'Adamo, A. Rimessi, C. Lanzara,‡ S. Crovella, E. Nicolis, ATamanini, E. Athanasakis, M Tebon, G. Bisoffi, M. L. Drumm, M. R. Knowles, P. Pinton, P. Gasparini, G. Berton, and G. Cabrini. PLCB3 is a key modulator of IL-8 expression in cystic fibrosis bronchial epithelial cells. J. Immunology, 2011 186: 4946-4958.

F. Wright, L. J. Strug, V. Doshi, C. Commander, S. L. Blackman, L. Sun, Y. Berthiaume, A. Cojocaru, M. Collaco, M. Corey, D. Cutler, R. Dorfman, K. Goddard , D. Green, J. Kent, E. Lange, S. Lee, W. Li, J. Luo, G. Mayhew, K. Naughton, R. Pace, P. Paré, J.Rommens, A. Sandford, J. Stonebraker, W. Sun, C. Taylor, L.Vanscoy, F. Zou, J. Blangero, J. Zielenski, W. O'Neal, M. Drumm, P. Durie, M. Knowles, G. R. Cutting. Genome-wide association and linkage identify modifier loci of lung disease severity in cystic fibrosis at 11p13 and 20q13.2. *Nature Genetics*, 2011, Jun;43(6):539-546.

C.A. Hodges, B.R. Grady, K. Mishra, C. Cotton, M.L. Drumm. Cystic Fibrosis growth retardation is not due to intestinal epithelium dysfunction. *Am. J. Physiol. Gastro*. 2011, 301:G528-G536.

X.L. Guo, R.G. Pace, J.R. Stonebraker, C.W. Commander, A.T. Dang, M.L. Drumm, A. Harris, F. Zou, D.M. Swallow, F.A. Wright, W.K. O'Neal, M.R. Knowles. Mucin Variable Number Tandem Repeat Polymorphisms and Severity of Cystic Fibrosis Lung Disease: Significant Association with *MUC5AC. PLoS One*, 2011; 6(10):e25452.

A. Mitchell, L. Judis, U. Schwarze, Vaynshtok, M.L. Drumm, P. Byers. Characterization of Tissue-Specific and Developmentally Regulated Alternative Splicing of Exon 64 in the COL5A1 Gene. *Connective Tissue Research*, 2012;53(3):267-276.

L.B. Henderson, V.K. Doshi, S.M. Blackman, K.M. Naughton, R.G. Pace, J. Moskovitz, M.R. Knowles, P.R. Durie, M.L. Drumm and G.R. Cutting. Variation in *MSRA* modifies risk of neonatal intestinal obstruction in cystic fibrosis. *PLoS Genetics*, 2012 Mar;8(3):e1002580. Epub 2012 Mar 15.

L. Sun, J.M. Rommens, H. Corvol, W. Li, X. Li, T. Chiang, F. Lin, R. Dorfman, P-F Busson, R.V. Parekh, D. Zelenika, S. Blackman, M. Corey, V. Doshi, L. Henderson, K. Naughton, W. K. O'Neal, R. G. Pace, J. R. Stonebraker, S. D. Wood, F. A. Wright, J. Zielenski, A. Clement, M. L. Drumm, P-Y Boëlle, G. R. Cutting, M. R. Knowles, P. R. Durie and L.J. Strug. The Hypothesis-Driven GWAS identifies 'missing heritability' in modifiers of disease phenotypes: Application to Meconium Ileus in Cystic Fibrosis. *Nature Genetics* 2012; 44(5):562-569. PMID 22466613

I. Bederman, A. Perez, L. Henderson, J. A. Freedman, J. Poleman, D. Guentert, N. Ruhrkraut, M. L. Drumm. Altered *de novo* lipogenesis contributes to low adipose stores in cystic fibrosis mice. American Journal of Physiology, *Gastrointestinal and Liver Physiology, 2012;* 303(4):G507-518. PMID 22679004

T. L. Bonfield, C. A. Hodges, C. U. Cotton, M. L. Drumm. Absence of the Cystic Fibrosis Transmembrane Regulator (*Cftr)* from Myeloid-Derived Cells Slows Resolution of Inflammation and Infection. *Journal of Leukocyte Biology*, 2012 92(5):1111-122. PMID 22859830

A. Cakmak, X. Qi, A. E. Cicek, I. Bederman, L. Henderson, M. Drumm, G. Ozsoyoglu. A New Metabolomics Analysis Technique: Steady-State Metabolic Network Dynamics Analysis" *Journal of Bioinformatics and Computational Biology* 2012, 10(1) 1240003.

A. E. Cicek, I. Bederman, L. Henderson, M. Drumm, G. Ozsoyoglu. ADEMA: An Algorithm to Determine Expected Metabolite Level Changes Using Mutual Information' *PLOS Computational Biology*, 2012 *in press*.

R. J. Darrah, I. R. Bederman, A. L. Mitchell, C. A. Hodges, C. Campanaro, M.L. Drumm, F. Jacono. Ventilatory pattern and energy expenditure are altered in cystic fibrosis mice. *Journal of Cystic Fibrosis*, 2013 *in press*

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Raed A. Dweik, M.D.** | POSITION TITLE<br>PROFESSOR OF MEDICINE<br>DIRECTOR, PULMONARY VASCULAR PROGRAM<br>PULMONARY AND CRITICAL CARE MEDICINE |
| eRA COMMONS USER NAME<br>**RAEDDWEIK** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| Univ. of Jordan School of Medicine, Amman, Jordan | M.B;B.S. | 1982-88 | Medicine and Surgery |
| Jordan University Hospital, Amman, Jordan | | 1988-90 | Internship/Residency |
| Wright State University, Dayton, OH | | 1990-93 | Internal Medicine |
| Cleveland Clinic, Cleveland, OH | | 1993-96 | Pulmonary/Critical Care |

**A. Positions and Honors**

2005 - pres. Director, Pulmonary Vascular Program; Pulmonary, Allergy, and Critical Care Medicine, Cleveland Clinic, Cleveland, OH
2011 - pres. Professor of Medicine, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University
2004 - 2010 Associate Professor of Medicine, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University
2004 - 2008 Assistant Director, General Clinical Research Center (GCRC), Cleveland Clinic
2000 - pres. Staff, Pulmonary & Critical Care Medicine, Cleveland Clinic
1998 - 1999 Associate Staff, Pulmonary & Critical Care Medicine, Cleveland Clinic
1996 - 1997 Clinical Associate, Pulmonary & Critical Care Med., Cleveland Clinic

**Board Certifications**
Internal Medicine (1993, 2003), Royal College of Physicians (Canada) (1995), Pulmonary Disease (1996, 2006), Critical Care Medicine (1997, 2007)

**Honors and Awards**
2011- Ad Hoc Reviewer, Respiratory Integrative Biology and Translational Research (RIBT) Study section, National Heart Lung and Blood Institute (NHLBI)-NIH
2009- pres. Scientific Advisory Board (SAB) Member, Mid-Infrared Technologies for Health and the Environment, A National Science Foundation (NSF) – Engineering Research Center at Princeton University and Partners
2008 - pres. Member / Reviewer, Cardiorenal and Lung Peer Review Committee American Heart Association (AHA)
2005 - pres. Listed in "Best Doctors® in America"
2005 - 2010 Member Study Section: Mentored Clinical Scientist Development Award (K08), National Heart Lung and Blood Institute (NHLBI), National Institutes of Health (NIH)
2004 - 2010 Member Study Section: Mentored Patient Oriented Research Career Development Awards (K18, K23, K24 and K25), National Heart Lung and Blood Institute (NHLBI)
2003 Ad hoc Reviewer, Special Emphasis Panel NRSA Research Training Grants National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health
2002 - 2005 Member, American Thoracic Society (ATS) taskforce to standardize measurement of Nitric Oxide (NO) in exhaled breath
2002 Participant: NIH Beryllium Research Symposium: Basic Mechanisms and Human Health

2001 - 2005 Member, Joint American Thoracic Society (ATS)-European Respiratory Society (ERS) taskforce on Exhaled Breath Condensate (EBC)
2001 American College of Chest Physicians (ACCP) Young Investigator Award
2000 Participant: NIH-NHLBI workshop on Nitric Oxide as a potential therapeutic agent
2000, 03, 04, 06, 07 Distinguished Teacher Award, Cleveland Clinic, Cleveland, OH
1995 Bruce Hubbard Stewart Fellow, Cleveland Clinic, Cleveland, OH
1993 Best Resident Scholarly Paper Award, Wright State Univ. Hospitals, Dayton, OH
1990 Outstanding Postgraduate Level (PGY1) Award, Wright State Univ.
1982 - 1988 Full medical school scholarship, The University of Jordan, Amman, Jordan

**B. Peer- reviewed publications (selected from more than 100 papers and 30 chapters):**

1. **Dweik RA**, Laskowski D, Abu-Soud HM, Kaneko F, Hutte R, Stuehr DJ, Erzurum SC. Nitric oxide synthesis in the lung. Regulation by oxygen through a kinetic mechanism. J Clin Invest. 1998;101(3):660-6. **PMCID: 508610**.
2. Kaneko FT, Arroliga AC, **Dweik RA**, Comhair SA, Laskowski D, Oppedisano R, Thomassen MJ, Erzurum SC. Correlation of nitric oxide reaction products to severity of pulmonary hypertension. Am J Respir Crit Care Med. 1998; 158:917-23.
3. **Dweik RA**. Pulmonary hypertension and the search for the selective pulmonary vasodilator. Lancet. 2002;360(9337):886-7.
4. Xu W, Koeck T, Lara AR, Neumann D, DiFilippo FP, Koo M, Janocha AJ, Masri FA, Arroliga AC, Jennings C, **Dweik RA**, Tuder RM, Stuehr DJ, Erzurum SC. Alterations of cellular bioenergetics in pulmonary artery endothelial cells. Proc Natl Acad Sci U S A. 2007;104(4):1342-7. **PMCID: 1783136**.
5. Aytekin M, Comhair SA, de la Motte C, Bandyopadhyay SK, Farver CF, Hascall VC, Erzurum SC, **Dweik RA.** High levels of hyaluronan in idiopathic pulmonary arterial hypertension. Am J Physiol Lung Cell Mol Physiol. 2008;295(5):L789-99. **PMCID: 2584887**.
6. Heresi GA, **Dweik RA**. Sarcoidosis-associated pulmonary hypertension. One size does not fit all. Chest. 2009;135(6):1410-2. **PMCID: in progress**.
7. Heresi GA, Aytekin M, Newman J, DiDonato J, **Dweik RA.** Plasma levels of high-density lipoprotein cholesterol and outcomes in pulmonary arterial hypertension. Am J Respir Crit Care Med. 2010;182(5):661-8. **PMCID: in progress**.
8. Erzurum S, Rounds SI, Stevens T, Aldred M, Aliotta J, Archer SL, **Dweik RA,** et al. Strategic plan for lung vascular research: An NHLBI-ORDR Workshop Report. Am J Respir Crit Care Med. 2010;182(12):1554-62. **PMCID: in progress**.
9. **Dweik RA**, Boggs PB, Erzurum SC, Irvin CG, Leigh MW, Lundberg JO, et al. An Official ATS Clinical Practice Guideline: Interpretation of Exhaled Nitric Oxide Levels (FENO) for Clinical Applications. Am J Respir Crit Care Med. 2011; 84:602-15. **PMCID: in progress**.
10. Heresi GA, Tang WH, Aytekin M, Hammel J, Hazen SL, **Dweik RA**. Sensitive cardiac troponin I predicts poor outcomes in pulmonary arterial hypertension. Eur Respir J. **2011. PMCID: in progress**.
11. Krowka MJ, Miller DP, Barst RJ, Taichman D, **Dweik RA**, Badesch DB, et al. Portopulmonary Hypertension: A Report From the US-Based REVEAL Registry. Chest. 2012;141:906-15.
12. Aytekin M, Aulak KS, Haserodt S, Chakravarti R, Cody J, Minai OA, **Dweik RA.** Abnormal platelet aggregation in idiopathic pulmonary arterial hypertension: role of nitric oxide. Am J Physiol Lung Cell Mol Physiol. 2012;302:L512-20.
13. Tonelli AR, Plana JC, Heresi GA, **Dweik RA**. Prevalence and Prognostic Value of Left Ventricular Diastolic Dysfunction in Idiopathic and Heritable Pulmonary Arterial Hypertension. Chest. 2012;141:1457-65.
14. Minai OA, Gudavalli R, Mummadi S, Liu X, McCarthy K, **Dweik RA**. Heart rate recovery predicts clinical worsening in patients with pulmonary arterial hypertension. Am J Respir Crit Care Med. 2012;185:400-8.

15. Batal O, Faulx M, Krasuski RA, Khatib OF, Hammel JP, Hussein AA, Minai OA, **Dweik RA**. Effect of Obesity on B-Type Natriuretic Peptide Levels in Patients With Pulmonary Arterial Hypertension. Am J Cardiol. 2012 Jun 7.
16. Tonelli AR, Aytekin M, Feldstein A, **Dweik RA**. Leptin in Pulmonary Hypertension. Pulmonary Circulation. 2012 ; 2:214-9. 146.
17. Tonelli AR, Haserodt S, Aytekin M, **Dweik RA**. Nitric Oxide Deficiency in Pulmonary Hypertension: implications for pathobiology and therapy. Pulmonary Circulation. In Press.
18. **Dweik RA (Chair),** Rounds S, Erzurum SC, Archer S, Fagan K, Hassoun P, Hill N, Humbert M, Kawut SM, Krowka M, Michelakis E, Morrell NW, Stenmark K, Tuder RM, Newman J. Pulmonary Hypertension Phenotypes: An Official Statement of the American Thoracic Society. Submitted.

## C. Research Support

**Active**

Tech 09-003 (Dweik) 06/26/08-06/30/13 1.2 calendar
Sate of Ohio Third Frontier Program $1,177,131 (no cost extension)
*Breath Analysis: Targeted Sensor Development and Commercialization for Health Care Diagnostics*
State of Ohio Third Frontier Research Commercialization Program (RCP)
Role: Principal Investigator

1P01 HL107147-01 (Hascall overall, Dweik project 4) 07/01/11-05/31/18 2.76 calendar
NIH/NHLBI $1,565,101 (Total Program); $245,616 (Project 4)
*Hyaluronan Matrices in Vascular Pathologies*
Project 4: *Hyaluronan in the Lung*
The 5 projects in our PEG will explore the emerging central role that hyaluronan (HA)-based matrices have in vascular development and inflammatory pathologies of the vasculature.
Role: Project Leader, Project 4

1P01 HL103453-01 (Erzurum) 08/02/11-06/30/16 2.4 calendar
NIH $1,715,450
*Asthma Inflammation Research (AIR)*
We propose to: *(1)* Translate our current collaborative and mechanistic research discoveries into innovative clinical approaches that provide the most advanced and reliable diagnostic and monitoring tools and treatments for asthma; and *(2)* Use our clinical research observations to inform our program's basic bench mechanistic investigations so that we are prepared to expand and improve on the clinical approaches for asthma care.
Role: Core Leader, Core B: *Clinical Core*

1U10 HL109250-01 (Gaston) 08/08/11-06/30/17 0.12 calendar
NIH $190,000
*Airway redox biochemistry as a determinant of asthma phenotype during adolescence and adulthood*
We propose to study a new component that is informative for longitudinal assessment of severe asthma phenotypes: gender effects. We aim to develop clinical testing procedures to accurately assign metabolic asthma phenotypes; and to follow patients in each phenotype to uncover clinical longitudinal outcomes.
Role: Co-Investigator

1R21 RR026231-01A1 (Wysocki) 07/01/10-06/30/13 0.42 calendar
NIH $10,000
Laser spectroscopic instrumentation for isotopic sensing of biogenic Nitric Oxide
The research proposed in this project will lead to development of a novel laser spectroscopic sensing instrumentation, which will provide unique capabilities of biogenic NO quantification.
Role: Collaborator

**Research Grants/Projects (Sponsored Active):**

Cotherix, Actelion 2006 -
Registry to EValuate Early And Long-term PAH Disease Management (REVEAL)
Role: Cleveland Clinic Site Principal Investigator

Novartis: QTI571A2301 2009-
A 24-week randomized placebo-controlled, double-blind multi-center clinical trial evaluating the efficacy and safety of oral QTI571 as an add-on therapy in the treatment of severe pulmonary arterial hypertension: Imatinib in Pulmonary arterial hypertension, a Randomized, Efficacy Study (IMPRES)
Role: Cleveland Clinic Site Principal Investigator

Novartis: CAMN107X2201 2010-
A 24 week, randomized, double blind, multicenter, placebo controlled efficacy, safety, tolerability and PK trial of Nilotinib (Tasigna®, AMN107) in Pulmonary Arterial Hypertension (PAH)
Role: Cleveland Clinic Site Principal Investigator

Bayer HealthCare: Protocol, EAS12934/PATENT 2011-
Randomized, double-blind, placebo-controlled, multi-centre, multi-national study to evaluate the efficacy and safety of oral BAY 63-2521 (1 mg, 1.5 mg, 2 mg, or 2.5 mg tid) in patients with symptomatic Pulmonary Arterial Hypertension (PAH)- (PATENT)
Role: Cleveland Clinic Site Co-Investigator (PI: Minai)

Bayer HealthCare: Protocol, EAS 16097 /CHEST 2011-
An open-label phase III b study of Riociguat in patients with in-operable CTEPH, or recurrent or persisting PH post PEA who are not satisfactorily treated and cannot participate in any other CTEPH trial. (CHEST)
Role: Cleveland Clinic Site Co-Investigator (PI: Heresi)

GeNO LLC 2012-
A Phase 2, Open-Label, Dose-Escalation Study in Subjects with Pulmonary Arterial Hypertension, (PAH, WHO Group 1) and Pulmonary Hypertension Secondary to Idiopathic Pulmonary Fibrosis, (PH-IPF WHO Group 3) Using Inhaled NITROsyl™. (PHiano)
Role: Cleveland Clinic Site Co-Investigator (PI: Tonelli)

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Douglas Einstadter** | POSITION TITLE<br>Professor of Medicine |
| eRA COMMONS USER NAME **DEINSTADTER** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| University of Michigan, Ann Arbor, MI | BS (Chem) | 1979 | Chemistry |
| University of Illinois, Chicago, Il | MD | 1986 | |
| University of Washington, Seattle, WA | MPH | 1992 | Epidemiology |

**A. Positions and Honors.**

**Positions and Employment:**

1979-1980 Research Analytical Chemist, Velsicol Chemical Corporation, Ann Arbor, MI
1980-1982 Research Assistant, Department of Biological Chemistry, Univ. of Michigan, Ann Arbor, MI
1986-1989 Intern/Resident, Internal Medicine, MetroHealth Medical Center, Cleveland, OH
1989-1990 Chief Medical Resident, Internal Medicine, MetroHealth Medical Center, Cleveland, OH
1990 -1992 Senior Fellow/Acting Instructor General Internal Medicine, Department of Medicine, Veterans Administration Medical Center, Seattle, WA
1992 - 2000 Assistant Professor, Department of Medicine, Case Western Reserve University, Division of General Internal Medicine, MetroHealth Medical Center, Cleveland, OH
2000 - 2006 Associate Professor, Department of Medicine, Case Western Reserve University, Division of General Internal Medicine, MetroHealth Medical Center, Cleveland, OH
2006 - Professor, Department of Medicine, Case Western Reserve University, Division of General Internal Medicine, MetroHealth Medical Center, Cleveland, OH

**Honors:**

1975 – 79 U of M Club of Ann Arbor Academic Scholarship
1979 Honors in Cellular and Molecular Biology, University of Michigan
1979 Honors in Chemistry, University of Michigan
1983 Top 10% of Class Honors University of Illinois
1985 Alpha Omega Alpha Honor Medical Society
1986 MD with Honors, University of Illinois

**B. Selected peer-reviewed publications (in chronological order).**

**Most relevant to the current application:**

1. Baker DW, Einstadter D, Thomas C, Husak S, Gordon NH, Cebul RD. The effect of publicly reporting hospital performance on market share and risk-adjusted mortality at high-mortality hospitals. Med Care. 2003;41:729-40.
2. Baker DW, Einstadter D, Thomas C, Cebul RD Mortality trends for 23,505 Medicare patients hospitalized with heart failure in Northeast Ohio, 1991 to 1997. Am Heart J. 2003;146:258-64.
3. Baker DW, Einstadter D, Husak SS, and Cebul RD. Trends in postdischarge mortality and readmissions: has length of stay declined too far? Arch Intern Med. 2004 Mar 8;164(5):538-44.
4. Love TE, Cebul RD, Einstadter D, Jain AK, Miller H, Harris CM, Greco PJ, Husak SS, Dawson NV, and for the DIG-IT Investigators. Electronic Medical Record-Assisted Design of a Cluster-Randomized Trial to Improve Diabetes Care and Outcomes. J Gen Intern Med 2008; 23(4):383–91.

**Publications - Journal Articles:**

5. Einstadter D, Cebul RD, and Franta PR. Effect of a Nurse Case-Manager on Post-Discharge Follow-up. J Gen Intern Med 1996;11:684-688.
6. Hoffman RM, Einstadter D, and Kroenke K. A Rational Approach to the Dizzy Patient. J. Clin. Outcomes Med 1997;4:33-41.
7. Yuan Z, Bowlin S, Einstadter D, et. al. Atrial Fibrillation as a Risk Factor for Embolic and Non-Embolic Stroke: A Population-based Cohort Study in the Elderly. Am J Public Health 1998;88:395-400.
8. Yuan Z, Cooper GS, Einstadter D, Cebul RD, Rimm AA. The Association Between Hospital Type and Mortality and Length of Stay. Medical Care 2000;38:231-245
9. Yuan Z, Dawson N, Cooper GS, Einstadter D, Cebul R, Rimm AA. Effect of Alcohol-related Disease on Hip Fracture and Mortality: A Retrospective Cohort Study of 876,337 Hospitalized Medicare Beneficiaries. Am J Public Health 2001;91:1089-1093.
10. Rose JH, O'Toole EE, Einstadter D, Love TE, Shenko CA, and. Dawson NV. Patient Age, Well-being, Perspectives, and Care Practices in the Early Treatment Phase for Late-Stage Cancer. J Gerontol A Biol Sci Med Sci. 2008 Sep;63(9):960-8.
11. Rose JH, Kypriotakis G, Bowman KF, Einstadter D, O'Toole EE, Mechekano R, and Dawson NV. Patterns of Adaptation in Patients Living Long Term With Advanced Cancer. Cancer. 2009 Sep 15;115(18 Suppl):4298-310.
12. Liu CW, Einstadter D, Cebul RD. Care fragmentation and emergency department use among complex patients with diabetes. Am J Manag Care. 2010 Jun;16(6):413-20.
13. Singh MK, Einstadter D, Lawrence R. A structured women's preventive health clinic for residents: a quality improvement project designed to meet training needs and improve cervical cancer screening rates. Qual Saf Health Care. 2010 Oct;19(5):e45. Epub 2010 Aug 10.
14. Avery AK, Toro MD, Einstadter D. Decreasing Missed Opportunities for HIV Testing in Primary Care through Enhanced Utilization of the Electronic Medical Record. J AIDS Clinic Res 2012; S4:006.

**C. Research Support.**

**Ongoing**

1 P30 HS 021648-01 Cebul (PI) 7/01/2012- 6/30/2014
Robert Wood Johnson Foundation
Red Carpet Care for Patients in the Greatest Need: The Greater Cleveland Super-Utilizer Project
Overall goals: In partnership with one commercial and one Medicaid health plan, this study will undertake a two-year health care system-oriented community-based team intervention to reduce avoidable and expensive utilization for 150 complex and "super-utilizing" patients.
Role: Co-Investigator

Cebul (PI)
Robert Wood Johnson Foundation 5/1/11 - 4/30/2013
Better Health *Greater* Cleveland 3.0
Overall goals: Competing renewal of RWJF support for Greater Cleveland's Aligning Forces for Quality initiative that will expand the program's current performance measurement, public reporting, and quality improvement activities to include important utilization metrics and payment reform activities region-wide.
Role: Co-Investigator

RO1MH085665-01A2 Dawson/Sajatovic (PIs) 07/01/2011 - 04/30/2016
NIMH
Improving Outcomes for Individuals with Serious Mental Illness and Diabetes
Overall goals: Conduct a randomized trial of a nurse and peer led behavioral intervention for persons with co-morbid SMI and Diabetes in a safety net, primary care setting.

Role: Co-investigator
Connors (PI)
Saint Luke's Foundation 03/01/05 – 12/30/15
Grant Title: Buckeye Health Center: Ensuring Accessible Health Care and Healthy Living
Project Title: Healthy Weight and Lifestyles Intervention for Adults
Overall goals: In a primary care neighborhood practice serving largely African American adults, to test the feasibility and effectiveness of a program to perform: 1) Annual obesity and related disease screening; 2) Annual low intensity tailored lifestyle intervention 3) Develop and implement an intense lifestyle intervention that is accessible for a low-literacy population to be offered to about 75 obese patients annually.
Role: Co-Investigator

**Recently Completed**
64079 Cebul (PI) 05/01/08 – 04/30/11
The Robert Wood Johnson Foundation
Regional Quality Strategy
Overall goals: For Aligning Forces for Quality (AF4Q) – The Regional Market Project
Role: Co-Investigator

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Elston, Robert C.** | POSITION TITLE<br>Distinguished University Professor |
| eRA COMMONS USER NAME **relston** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Cambridge University, England | BA Hons. | 1955 | Natural Sciences |
| Cambridge University, England | Dip Ag | 1956 | Agriculture |
| Cambridge University, England | MA | 1957 | Natural Sciences |
| Cornell University, Cornell, NY | PhD | 1959 | Animal Breeding |
| University of North Carolina, Chapel Hill, NC | Postdoc | 1960 | Statistics |

## A. Positions and Honors

**Positions and Employment**

1960-1962 Assistant Professor, University of North Carolina (UNC), Chapel Hill, NC
1962-1964 Senior Research Fellow in Biometric Medicine, University of Aberdeen
1964-1969 Associate Professor, UNC, Chapel Hill, NC
1969-1979 Professor & Director of Genetics Laboratory, School of Public Health, UNC, Chapel Hill, NC
1979-1995 Professor and Head, Biometry and Genetics, Louisiana State University Medical Center, New Orleans, LA
1991-1995 Director, Center for Molecular and Human Genetics, Louisiana State University Medical Center
1995- Professor and Director, Division of Genetic and Molecular Epidemiology, Epidemiology & Biostatistics Department, Case Western Reserve University, Cleveland, OH
2004- Co-Leader, Cancer Genetics Program, Case Comprehensive Cancer Center, Cleveland, OH
2008- Chair, Epidemiology & Biostatistics Department, Case Western Reserve University, Cleveland, OH

**Honors**

1955-1956 Coulthurst Scholar
1956-1957 King George VI Memorial Fellow
1956-1959 Cornell Scholar
1973-1974 John Simon Guggenheim Memorial Fellow
1977-1979 NIMH Research Scientist Award
1991-2000 Hoch Award-American Psychopathological Association
1994 Wick R. Williams Memorial Award-Fox Chase Cancer Center
1995 Leadership Award-International Genetic Epidemiology Society
1996 William Allan Award-American Society of Human Genetics
1997 President-International Genetic Epidemiology Society
1998 NIH MERIT Award
2000 Lead invited speaker: Grand Opening of the Sir Henry Wellcome Building of Genomic Medicine, Oxford University
2001 Fellow, Institute of Mathematical Statistics, elected
2003 July-August issue of Human Heredity dedicated to the 30th Anniversary of: Elston RC, Haseman JK.
2004 Bernard G. Greenberg, Distinguished Lecturer, University of North Carolina at Chapel Hill, Department of Biostatistics
2004 Marvin Zelen Leadership Award for Statistical Science from the School of Public Health, Harvard University

2007 John H. Blaffer Visiting Professor Award, University of Texas, MD Anderson Cancer Center
2007 American Society of Human Genetics Award for Excellence in Human Genetics Education

**B. Selected Peer-reviewed Publications** (selected from over 600 publications)

**Most relevant to the current application**

1. Wang X, Elston RC, Zhu X (2011) Statistical Interaction in Human Genetics: How should we model it if we are looking for Biological Interaction?; Nat Rev Genet; 12(1):74; PMID: 21102529.
2. Feng T, Elston RC, Zhu X. (2011) Detecting Rare and Common Variants for Complex Traits: Sibpair and Odds Ratio Weighted Sum Statistics (SPWSS, ORWSS). Genet Epidemiol; Epub. PMID: 21594893.
3. Li M, Ye C, Fu W, Elston RC, Lu Q (2011) Detecting Genetic Interactions for Quantitative Traits with U-Statistics. Genet Epidemiol; ePub doi:1002/gepi.20594. PMID: 21618602.
4. Slavin TP, Feng T, Schnell A, Zhu X, Elston RC. (2011) Two-Marker Association Tests Yield New Disease Associations for Coronary Artery Disease and Hypertension. Hum Genet; ePub doi:10.1007/s00439-011-1009-6. PMID: 21626137.
5. Chen Y, Wang W, Zhou Y, Shields R, Chanda SK, Elston RC, Li J. (2011) In Silico Gene Prioritization by Integrating Multiple Data Sources. PLoS ONE 6(6): e21137. doi:10.1371/journal.pone.0021137. PMID: 21731658.
6. Ye C, Cui Y, Wei C, Elston RC, Zhu J, Lu Q. (2011) A non-parametric method for building predictive genetic tests on high-dimensional data. Hum Hered; 71(3):161-70. PMID: 21778735.
7. Morris, N, Elston RC (2011) A Note on Comparing the Power of Test Statistics at Low Significance Levels American Statistical Association 65(3):164-66
8. Ye, C, Cui, Y, Wei, C, Elston, RC, Zhu, J (2011) A Non-Parametric Method for Building Predictive Genetic Tests on High-Dimensional Data Human Heredity 71: 161-170 PMID: 21778735
9. 8. Wang, X, Morris, N, Schair, D, Elston, RC (2012) Power of Single- vs. Multi-Marker Tests of Association Genetic Epidemiology 36: 480-487 DOI: 10.1002/gepi.21642 PMID: 22648939

**Additional recent publications of importance to the field**

1. Won S, Elston RC (2008). The power of independent types of genetic information to detect association in a case-control study design. Genet Epidemiol; 32(8): 731-756. PMID: 18481783
2. Lou XY, Chen GB, Yan L, Ma JZ, Mangold JE, Zhu J, Elston RC, Li MD (2008). A combinatorial approach to detecting gene-gene and gene-environment interactions in family studies. Am J Hum Genet; 83 (4): 457-467. PMID: 18834969
3. Won S, Kim S, Elston RC (2009). Phase uncertainty in case-control association studies. Genet Epidemiol; 33(6): 463-478. PMID: 19194981 PMCID: PMC2838926.
4. Bochud M, Staessen JA, Maillard M, Mazeko MJ, Kuznetsova T, Woodiwiss A, Richart T, Norton G, Thijs L, Elston R, Burnier M (2009). Ethnic differences in proximal and distal tubular sodium reabsorption are heritable in Black and White populations. J Hypertension; 27(3):606-612. PMID: 19262228.
5. Wan L, Sun K, Ding Q, Cui Y, Li M, Wen Y, Elston RC, Qian M, Fu W (2009). Hybridization modeling of oligonucleotide SNP arrays for accurate DNA copy number estimation. Nucleic Acids Res; July 7: 1-12. PMID: 19586935.
6. Kim S, Abboud H, Pahl M, Tayek J, Snyder S, Tamkin J, Alcorn H, Ipp E, Nast C, Elston RC, Iyengar SK, Adler S (2010). Examination of association with candidate genes for diabetic nephropathy in a Mexican American population. Clin J Am Soc Nephrology: 5(6):1072-8.
7. Schnell, AH, Sun, X, Igo, RP, Elston, RC (2011) Some Capabilities for Model-Based and Model-Free Linkage Analysis using the Program Package S.A.G.E. (Statistical Analysis for Genetic Epidemiology) 72: 237-246 PMID: 22189466

## C. Research Support

**Ongoing Research Support**

R25 CA094186 (Elston, PI) 09/24/07-07/31/12
NIH/NCI
*Training in Computational Genomic Epidemiology of Cancer*
This program provides postdoctoral training in the transdisciplinary area of training at the intersection of cancer research, epidemiology, biostatistics, genetics, and computer science.

P30 CA043703 (Gerson, PI) 04/01/07-03/31/12
NIH/NCI
*Comprehensive Cancer Center Support Grant*
The objectives of the Center are: 1) to improve the prevention, diagnosis, and therapy of cancer through research; 2) to stimulate and support innovative, coordinated, interdisciplinary research on cancer diagnosis, treatment, and control; 3) to develop clinical applications of research discoveries and to make these applications available as quickly as possible; and 4) to develop cancer prevention and control activities to contribute to the reduction of cancer morbidity and mortality in Northeast Ohio and the surrounding region and nation. Role: Co-Leader, Cancer Genetics Program.

R01 DK070863 (Chak, PI) 09/30/05-08/31/12
NIH/NIDDK
*Familial Barrett's Esophagus*
The major goal of this project is to provide new information regarding a familial/genetic predisposition to the development of Barrett's esophagus and esophageal adenocarcinoma. Role: Co-I

2R01HG003054-05A1 (Zhu, PI) 03/15/05-04/30/13
NIH/NHGRI
*Statistical Methods for Analyzing High-Throughput Genotype Data*
This project will 1) develop a unified statistical framework for genetic association analysis of unrelated individuals and family data sampled from admixed populations; 2) develop statistical methods to identify SNPs that can explain an admixture mapping signal; 3) develop statistical methods for association analysis of copy number variations in admixed populations; 4) develop statistical methods for analysis of secondary phenotypes in a case-control GWAS in admixed populations; 5) develop, distribute and support freely available software packages for methods proposed in this application. Role: Co-I

R01-CA144040 (Markowitz, PI) 09/28/09-08/31/14
NIH/NCI
*Identifying Inborn Genetic Susceptibility to Development*
To identify genetic markers of metastasis susceptibility by using the technique of a whole genome association study.

R01-DK083538 (Chelmisky, PI) 07/01/09-05/31/14
NIH/NIDDK
*Neurophysiologic & Autonomic Characterization of Interstitial Cystitis and Painful Bladder Syndrome*
The long-term aim is to define the broad neural, psychological, and endocrine phenotypes that characterize IC/PBS. Role: Co-I

T32 HL-007567-27 (Elston, PI) 09/01/10-08/31/15
NIH/HLBI
*Biometric Genetic Analysis of Cardiopulmonary Disease*
This program provides predoctoral and postdoctoral training in statistical genetics as applied to lung inflammation and infection, sleep and hypoxic response, cardiopulmonary and cardiorenal disease, and hypertension.

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **ENG, Charis, MD, PhD** | POSITION TITLE<br>Hardis/ACS Professor and Chairwoman, Genomic Medicine Institute; Professor of Genetics |
| eRA COMMONS USER NAME **chariseng** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| University of Chicago, IL | BA | 06/82 | Biological Sciences |
| University of Chicago, IL | PhD/MD | 06/86,06/88 | Devel Biol/Medicine |
| Beth Israel Hospital & Harvard Med Sch, Boston | Residency | 06/91 | Internal Medicine |
| Dana-Farber Cancer Institute, Boston | Fellowship | 09/95 | Medical Oncology |
| University of Cambridge, UK | Postdoc | 09/95 | Human Cancer Genetics |

## A. Positions and Honors

**Positions and Employment**

1992-1995 CRC Dana-Farber Fellowship in Human Cancer Genetics, University of Cambridge, UK
1992-1995 Senior Registrar in Clinical Cancer Genetics, University of Cambridge Addenbrooke's Hospital, Cambridge, UK and Royal Marsden Hospital, London, UK
1995-1998 Assistant Professor of Medicine, Dana-Farber Cancer Institute and Harvard Medical School, Boston
1995-1998 Active Staff Physician, Adult Oncology, Dana-Farber Cancer Institute, Boston, MA
1999-2002 Associate Professor (with tenure) of Medicine, The Ohio State University, Columbus, OH
1999-2005 Director, Clinical Cancer Genetics Program, Comprehensive Cancer Center, The Ohio State University
2002-2005 Professor (with Tenure) of Medicine, The Ohio State University
2002-2005 Klotz Endowed Chair in Cancer Research, The Ohio State University
2002-2005 Director, Division of Human Genetics, Department of Internal Medicine, The Ohio State University
2005- Professor and Chair, Genomic Medicine Institute, Cleveland Clinic Lerner College of Medicine, OH
2005- Professor (with Tenure) and Vice Chairman, Dept. of Genetics, Case Western Reserve University School of Medicine, Cleveland
2006- Director, Cancer Genomic Medicine Clinical Fellowship Training Program, Cleveland Clinic
2008- Sondra J & Stephen R Hardis Endowed Chair in Cancer Genomic Medicine, Cleveland Clinic

**Other Experience and Professional Memberships (Selected)**

1996- Member, American Society of Human Genetics (Board of Directors, 2005-09)
1996- Member, American Assoc Cancer Res (Publications Committee, 2004-06)
2000-09 *Cancer Research* (Assoc Editor 2000-03, Senior Editor 2004-09)
2006- Personalized Medicine Coalition, Clinical Science Committee (Chair, 2007-09)
2007- Board of Scientific Councilors, NHGRI
2009-11 US Dept of Health & Human Services' Secretary's Advisory Comm Genetics, Health & Society

**Honors (Selected)**

1982 Phi Beta Kappa; Sigma Xi Associate Membership; 1987 Sigma Xi Promotion to Full Membership
1988 Alpha Omega Alpha
2001 Elected Member, American Society for Clinical Investigation (ASCI)
2002 *Doris Duke Distinguished Clinical Scientist Award (2002-2009)
2003 Elected Fellow, American Association for the Advancement of Science (AAAS)
2004 Elected Member, Association of American Physicians (AAP)

2005 *The Donald V. Unverferth Award for Sustained Scholarly Excellence and Extraordinary Mentorship by a Faculty Member, Department of Internal Medicine, The Ohio State University, Columbus
2005 American Thyroid Association Van Meter Award
2006 Ernst Oppenheimer Award of The Endocrine Society
2006 American Cancer Society JP Minton Hero of Hope Research Medal of Honor (Clinical Research)
2009 *American Cancer Society Clinical Research Professorship (2009- )
2010 Elected Member, Institute of Medicine of the National Academies
2012 *John S. Diekhoff Award for Excellence in Graduate Mentoring, Case Western Reserve University, Cleveland, OH

**Awards/Honors to Trainees (Selected)**

Christopher Alvarez-Breckenridge: AACR-Thomas J. Bardos Undergraduate Scholarship Award, 95th and 96th Annual AACR Meetings, Mar., 2004 and Apr., 2005
Kristin A. Waite, PhD: AACR-Merck Scholar-in-Training Award, 96th Annual AACR Meeting, Apr., 2005
Frank Weber, MD: 2006 Endocrine Society & Pfizer, Inc. International Award for Excellence in Clinical Research for a Paper Published in *J Clin Endocrinol Metab* 2005
Guillaume Assié, MD, PhD: Clinical Research Fellowships, Fondation de France and Féderation des Centres de Lutte Contre le Cancer, 2006-07
Shireen Ganapathi: American Cancer Society Joseph F. Silber Undergraduate Research Fellowship, 2008
Stacy Williams McNair: Undergraduate Summer Research Scholarship for Minority Students Excelling in the Sciences, 2008
Kristi L. Bennett, PhD: AACR-AFLAC, Inc. Scholar-in-Training Award, 100th Annual AACR Meeting, Denver, CO, 2009
Lamis Yehia, MS: Fulbright International Scholarship, 2012-15 (CWRU Dept of Pathology)
Ying Ni, MS: DOD Predoctoral Fellowship, 2009-12, AACR-Women in Cancer Research Award, 103rd Annual AACR Meeting, Chicago, 2012
Yu Wang, PhD: Susan G. Komen Foundation Postdoctoral Fellowship, 2010-13
Emily Pontzer, AB: NIGMS T32 Training Fellowship in Genetics (CWRU), 2010-12 and NCI F30, 2013-15

**B. Selected Peer-reviewed Publications** (Selected from >350 peer-reviewed publications)

**Most relevant to the current application**

(All these first authors are pre- or *postdoctoral* trainees)

McWhinney SR, Pasini B, Stratakis CA, Carney Triad and Carney-Stratakis Dyad Consortium (of which **C Eng** is a member ). Germline mutations in the genes encoding succinate dehydrogenase subunits (*SDHB, SDHC, SDHD*) cause a familial form of gastrointestinal stromal tumors. N Engl J Med 2007; 357:1054-6.

*Patocs A*, Zhang L, Xu Y, Weber F, Caldes T, Mutter GL, Platzer P, **Eng C**. Stromal *TP53* mutation or 5-locus allelic imbalance and nodal metastases in breast cancer. N Engl J Med 2007; 357:2543-51. [with Editorial]

*Assié G*, LaFramboise T, Platzer P, **Eng C**. High frequency of germline genomic homozygosity associated with cancer cases. JAMA 2008; 299:1437-45. [Featured in "This Week in *JAMA*"]

Pezzolesi MG, Platzer P, Waite KA, **Eng C**. Differential expression of *PTEN*-targeting micro-RNAs *miR-19a* and *miR-21* in Cowden syndrome. Am J Hum Genet 2008; 82:1141-9.

Ni Y, Zbuk KM, Sadler T, Patocs A, Lobo G, Edelman E, Platzer P, Orloff MS, Waite KA, **Eng C**. Germline mutations and variants in the succinate dehydrogenase genes in Cowden and Cowden-like syndromes. Am J Hum Genet 2008; 83:261-8.

*Tan MH*, Mester J, Peterson C, Yang Y, Chen JL, Rybicki LA, Milas K, Pederson H, Remzi B, Orloff MS, **Eng C**. A clinical scoring system for selection of patients for *PTEN* mutation testing is proposed on the basis of a prospective study of 3,042 probands. Am J Hum Genet 2011; 88:42-56.

Nizialek (Pontzer) EA, Peterson C, Mester JL, Downes-Kelly E, **Eng C.** Germline and somatic *KLLN* alterations in breast cancer dysregulate G2 arrest. Hum Mol Genet 2013 (in press)

Heald B, Plesec T, Liu X, Pai R, Patil D, Moline J, Sharp RR, Burke CA, Kalady MF, Church J, **Eng C**. Implementation of universal health system-wide microsatellite instability and immunohistochemistry screening for diagnoses of Lynch syndrome in a large academic medical center. J Clin Oncol 2013 (in press)

**Additional recent publications of importance to the field (in chronological order)**

Kurose K, Gilley K, Matsumoto S, Watson PH, Zhou XP, **Eng C**. Frequent somatic mutations in *PTEN* and *TP53* are mutually exclusive in the stroma of breast carcinomas. Nature Genet 2002; 32:355-7

Neumann HPH, Pawlu C, 12 others, Januszewicz A, **Eng C**. Distinct clinical features characterize paraganglioma syndromes associated with *SDHB* and *SDHD* mutations. JAMA 2004; 292:943-51

Weber F, Xu Y, Zhang L, Patocs A, Shen L, Platzer P, **Eng C**. Microenvironmental genomic alterations and clinico-pathologic behavior in head and neck squamous cell carcinomas. JAMA 2007; 297:187-95.

Shen WH, Balajee AS, Wang J, Wu H, **Eng C**, Pandolfi PP, Yin Y. Essential role of PTEN in the maintenance of chromosome integrity. Cell 2007; 128:157-70.

Fukino K, Shen L, Patocs A, Mutter GL, **Eng C**. Genomic instability within tumor stroma and clinicopathologic characteristics of sporadic primary invasive breast carcinomas. JAMA 2007; 297:2103-11.

Bennett KL, Mester J, **Eng C**. Germline epigenetic regulation of *KILLIN* in Cowden and Cowden-like syndromes. JAMA 2010; 304:2724-31.

Orloff MS, Peterson C, He X, Ganapathi S, Heald B, Yang YR, Bebek G, Romigh T, Song JH, Wu W, David S, Cheng Y, Meltzer SJ, **Eng C**. Germline Mutations in *MSR1, ASCC1 and CTHRC1* in individuals with Barrett esophagus and/or esophageal adenocarcinoma. JAMA 2011; 306:410-9.

## C. Research Support

**Ongoing Research Support (Selected)**

1R01 CA118980-01A2 Eng (PI)
NCE
National Cancer Institute
PTEN nuclear-cytoplasmic localization in breast cancer
The goal of this project is to determine the mechanism of PTEN nuclear-cytoplasmic trafficking as it relates to breast carcinogenesis.
Role: PI

BCRF Eng (PI) 10/01/07-9/30/13
Breast Cancer Research Foundation
Genes that affect mitochondrial function as novel mediators of breast cancer susceptibility
The goals of this project is to examine autosomally encoded mitochondrial complex II component genes, *SDHx*, as breast cancer susceptibility genes and as modifiers of cancer risk.
Role: PI

2P01 CA124570-06 Ringel (Program Director); Eng (Project 2 PI) 03/01/13-02/28/18
National Cancer Institute Genetic and signaling pathways in epithelial thyroid carcinogenesis
Project 2 Title: Genetic alterations that initiate follicular thyroid carcinogenesis
The goals of this project are to delineate the genetics of follicular thyroid carcinogenesis through a multidisciplinary translational approach spanning translational human genetics, mouse modeling and in vitro functional interrogation as well as experimental therapeutics.
Role: Project 2 PI

AMF Eng (PI) 01/31/09-01/30/14
The Ambrose Monell Foundation
Cancer Genomic Medicine Fellowship Training Program

The goal of this program is to train MD or MD-PhD clinician-clinical translational investigators in the novel subspecialty of cancer genomic medicine.
Role: PI and Fellowship Program Director

CRP-09-0171-01-CCE Eng (PI) 07/01/09-06/30/14
American Cancer Society
Clinical Research Professorship
Novel susceptibility genes and modifying factors of neoplasia risk in the PTEN hamartoma tumor syndrome
The goal of this Clinical Research Professorship is to provide programmatic support for clinical translational research in genetics- and genomics-based cancer risk assessment and management.

1R01DE021554-01 Eng (PI)
NCE
National Institutes of Health
*Metagenomic profiling of oral polymicrobial flora in head and neck cancers*
The goal is to utilize massively parallel sequencing to profile oral microflora in normal oral mucosa and HNSCC.

1R01CA151532 Kulke and Eng (PIs) 09/16/11-09/15/13
National Cancer Institute
*Molecular and genetic analysis for neuroendocrine cancer risk*
The goal is to analyze the germline, via focused and global genomics approaches, germline variation associated with neuroendocrine tumor risk and response to targeted therapies

WRH2012 (Eng) 01/15/12-01/14/14
William Randolph Hearst Foundations
*Heritable Cancers Research Program*
The goal is to determine if family health history increases the sensitivity of the *PTEN* Cleveland Clinic score

**Completed Research Support (Selected)**
20020346 Eng (PI) 12/15/02-12/14/09
Doris Duke Charitable Foundation
*Genetics of* PTEN *and molecular-based patient care*
This is a Distinguished Clinical Scientist Award to support inter-disciplinary translational research and mentorship activities on the platform of the comprehensive analysis of *PTEN* in cancer as a paradigm for clinical cancer genetics translational research.
Role: PI

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Erzurum, Serpil C, MD** | POSITION TITLE<br>Professor of Medicine |
| eRA COMMONS USER **SERPILERZURUM** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Youngstown State University, Youngstown, OH | B.S. | 1983 | Chemistry/Biology |
| Northeastern Ohio Universities College of Medicine, Rootstown, OH | M.D. | 1983 | Medicine |

## A. Positions and Honors

**Positions and Employment**

1983-1986 Internal Medicine Residency, Baylor College of Medicine, Houston, TX
1987-1990 Pulmonary/Critical Care Fellowship, U Colorado Health Sciences Center, Denver, CO
1990-1992 Senior Staff Fellow, NHLBl, NIH
1992-1993 Assistant Professor, Pulmonary, Allergy, Critical Care Medicine, U Pittsburgh, PA
1993-present Pulmonary, Allergy & Critical Care, and Cancer Center, Cleveland Clinic
2003-present Professor, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University
2004-present Chair, Pathobiology, Cleveland Clinic Lerner Research Institute
2007-present Director, Clinical Research Unit, Clin & Transl Sciences Award (CTSA)

**Board Certifications**

Internal Medicine (1986), Pulmonary (1990, 2000, 2010), Critical Care (1993, 2000)

**Honors and Awards**

Full Academic Gould Honor College Scholarship, Youngstown State University (1977); American Medical Women's Association Award for Excellence in Academics (1983); Alpha Omega Alpha (1983); Henry D. McIntosh Outstanding Resident Award, Baylor College of Medicine (1986); NIH Clinical Investigator Award KO8 (1994-99); NIH Midcareer Award in Patient Oriented Research K24 (2000-05); American Society of Clinical Investigation (ASCI)(elected member 2001); Clinical Research Scientific Achievement Award, Cleveland Clinic (2002); Association of American Physicians (AAP) (Elected Member 2005); Member of Study Sections: NHLBI Research Career Development Award (K) series (2001-02); Lung Biology Pathology Study Section (LBPA, 2003-04); Lung Cellular Molecular Immunology (LCMI, 2004-06); Roland H. Ingram Honorary Lecturer, Emory University (2005); Tom Neff Honorary Lecturer, U Colorado (2006); Hicks Honorary Lecturer, Northwestern (2006); Distinguished Alumni Award, Northeastern Ohio Universities College of Medicine (2006); Advisory Board, Aspen Lung Conference; Elected Fellow, American Association for the Advancement of Science (AAAS)(2006); Member, NHLBI's Board of External Experts; Member, American Board of Internal Medicine Pulmonary Disease Board (2008-13); Paul B. Beeson Visiting Professor, Yale (2009); Chair, Allergy, Immunology and Inflammation of the American Thoracic Society (ATS) (2009-11); NHLBI MERIT award (2009); Member, ATS Board of Directors (2009-11); Deputy Editor, Am J Resp Critical Care Med (2010 -2012)

## B. Selected peer-reviewed publications

1. Dweik RA, Laskowski D, Abu-Soud HM, Kaneko FT, Hutte R, Stuehr DJ, Erzurum SC. Nitric oxide synthesis in the lung: regulation by oxygen through a kinetic mechanism. J CLIN INVEST. 1998; 101:660-666. PMCID: PMC508610.

2. Kaneko FT, Arroliga AC, Dweik RA, Comhair SA, Laskowski D, Oppedisano R, Thomassen MJ, Erzurum SC. Biochemical reaction products of nitric oxide as quantitative markers of primary pulmonary hypertension. AM J RESP CRIT CARE MED. 1998; 158:917-923. PMID: 9731026.
3. Machado RF, Londhe Nerkar MV, Dweik RA, Hammel J, Janocha A, Pyle J, Laskowski D, Jennings C, Arroliga AC, Erzurum SC. Nitric Oxide and Pulmonary Arterial Pressures in Pulmonary Hypertension. FREE RADICAL BIOL &MED. 2004; 37:1010-17. PMID: 15336317.
4. Xu W, Kaneko FT, Zheng S, Comhair SAA, Janocha AJ, Goggans T, Thunnissen FBJM, Farver C, Hazen SL, Jennings C, Dweik RA, Arroliga AC, Erzurum SC. Increased arginase II and decreased NO synthesis in endothelial cells of patients with pulmonary arterial hypertension. FASEB J. 2004 Nov;18(14):1746-8. PMID: 15364894.
5. Hoit BD, Dalton N, Erzurum SC, Laskowski D, Strohl KP, Beal C. Nitric oxide and cardiopulmonary hemodynamics in Tibetan highlanders. JOURNAL OF APPLIED PHYSIOLOGY. 2005; 99(5):1796-801. PMID: 16024527.
6. Xu W, Koeck T, Lara AR, Neumann D, DiFilippo FP, Koo M, Janocha AJ, Masri FA, Arroliga AC, Jennings C, Dweik RA, Tuder RA, Stuehr DJ, Erzurum SC. Alterations of Cellular Bioenergetics in Pulmonary Artery Endothelial Cells. PROC NATL ACAD SCI USA. 2007; 104:1342-1347. PMCID: PMC1783136.
7. Masri FA, Xu W, Comhair SAA, Asosingh K, Koo M, Vasanji A, Drazba J, Anand-Apte B, Erzurum SC. Hyperproliferative apoptosis-resistant endothelial cells in idiopathic pulmonary arterial hypertension. AM J PHYSIOL Lung Cell Mol Physiol. 2007 Sep; 293(3):L548-54. (*selected for Faculty of 1000 Biology) PMID: 17526595.
8. Erzurum SC, Ghosh S, Janocha AJ, Xu W, Bauer S, Bryan NS, Tejero J, Hemann C, Hille R, Stuehr DJ, Feelisch M. Beall CM. Higher blood flow and circulating NO products offset high-altitude hypoxia among Tibetans. PROC NATL ACAD SCI USA. 2007 Nov 6; 104(45):17593-8. PMCID: PMC2077056.
9. Asosingh K, Aldred MA, Vasanji A, Drazba J, Sharp J, Farver C, Comhair SAA, Xu W, Licina L, Tuder RM, Erzurum SC. Circulating Angiogenic Precursors in Idiopathic Pulmonary Arterial Hypertension. AM J PATH. 2008 Mar; 172(3):615-27. PMCID: PMC2258264.
10. Fijalkowska I, Xu W, Comhair SA, Janocha AJ, Mavrakis LA, Krishnamachary B, Zhen L, Mao T, Richter A, Erzurum SC, Tuder RM. Hypoxia inducible-factor 1 alpha regulates the metabolic shift of pulmonary hypertensive endothelial cells. AM J PATHOL. 2010 Mar; 176(3):1130-8. PMCID: PMC2832136.
11. Farha S, Asosingh K, Xu W, Sharp J, George D, Comhair S, Park M, Tang WH, Loyd JE, Theil K, Tubbs R, Hsi E, Lichtin A, Erzurum SC. Hypoxia Inducible Factors in Human Pulmonary Arterial Hypertension: A Link to the Intrinsic Myeloid Abnormalities. BLOOD 2011 117: 3485-3493. PMCID: PMC3072874 [Available on 2012/3/31].
12. Drake KM, Zygmunt D, Mavrakis L, Harbor P, Wang L, Comhair SA, Erzurum SC, Aldred MA. Altered MicroRNA Processing in Heritable Pulmonary Arterial Hypertension: An Important Role for Smad-8. AM J RESPIR CRIT CARE MED. 2011 Dec 15;184(12):1400-8. Epub 2011 Sep 15. PMID: 21920918. PMCID: PMC3262031
13. Comhair, SA, Xu W, Mavrakis L, ALdred MA, Asosingh K, Erzurum SC. Human Primary Lung Endothelial Cells in Culture. Am J Respir Cell Mol Biol. 2012;46(6):723-30. PMCID: PMC3380284
14. Bauer EM, Shapiro R, Zheng H, Ahmad F, Ishizawar D, Comhair SA, Erzurum SC, Billiar TR, Bauer PM. High Mobility group Box-1 Contributes to the Pathogenesis of Experimental Pulmonary Hypertension via Activation of Toll-like Receptor 4. Mol Med. 2012 Dec 20. PMID: 23269975
15. Farha S, Sharp J, Asosingh K, Park M, Comhair SA, Tang WH, Thomas J, Farver C, Hsieh F, Loyd JE, Erzurum SC. Mast cell number, phenotype, and function in human pulmonary arterial hypertension. Pulm Circ. 2012 Apr-Jun;2(2):220-8. PMID: 22837863 PMCID:PMC3401876

## C. Research Support

**Active**

5P01 HL081064-05 (Erzurum) 04/15/06-03/31/13 3.0 calendar
NIH/NHLBI NoCost
Extension
*Pathobiology of Asthma*
Project 1: *Role of Nitric Oxide in Asthma*
Core A: *Administrative Core*
The major goal of this project is to identify the elements that initiate, intensify and modulate the inflammatory response in the asthmatic airway.
Role: Program PI; Project 1 Leader; Core A Leader

2UL1TR000439-06 (Davis) 06/29/12-05/31/17 1.2 calendar
NIH/NCATS $1,453,288
*CTSA of Case Western Reserve University*
The major goal of this program is to provide infrastructure support for patient-oriented research across the collaborating institutions of Case Western Reserve University, University Hospitals, Cleveland Clinic, and MetroHealth Medical Center.

09-0095 (Erzurum) 07/01/09-06/30/13 0 calendar
American Asthma Foundation (AAF) No Cost Extension
*Imaging Inflammation in Asthma*
The major goal of this project is to develop an innovative and scientifically sound noninvasive method for evaluation of regional inflammation in asthma. Inflammation imaging would be a significant advance highly relevant for asthma research and potentially the clinical care of asthmatic patients.
Role: Principal Investigator

Cardiovascular Medical Research and Education Fund (CMREF)
AHA (Comhair) 04/01/11-03/31/14 0 calendar
*Transplant and Preparation Center* $169,644
The major goal of the Center is to participate in the Idiopathic Arterial Hypertension (IPAH) Research Network to harvest lungs for use in research of pulmonary vascular disease.
Role: Co-Principal Investigator

5R37 HL060917-14 (Erzurum) 08/01/09-07/31/15 2.4 calendar
NIH/NHLBI $247,500
*Nitric Oxide in Pulmonary Hypertension*
Overall our goals are to define the pathophysiology of the abnormal vascular growth in PAH, and in so doing, apply the knowledge to improve the care of patients.
Role: Principal Investigator

5U10 HL109250-02 (Gaston, Erzurum & Teague) 08/08/11-06/30/17 0.60 calendar
NIH/NHLBI $225,000
(CCLCM consortium)
*Airway redox biochemistry as a determinant of asthma phenotype during adolescence and adulthood*
The role of the Cleveland Clinic consortium is the enroll patients and perform several of the SARP-wide assays, including urinary bromotyrosine and serum SOD activity.
Role: Co-Principal Investigator

5U01 HL102225-02 (Israel) 09/01/11-05/31/13 0.18 calendar
NIH/NHLBI $51,053
*KIT Inhibition in Asthma (KIA)*
We will study whether imatinib, an inhibitor of mast cell number and function that is licensed for some types of cancers, but is well tolerated, improves the signs and symptoms of asthma while reducing the numbers and function of mast cells in the lung. This study will lay the groundwork for larger clinical studies using this drug, or others, to target mast cells in asthma.
Role: Co-Investigator

5P01 HL103453-02 (Erzurum) 08/02/11-06/30/16 3.0 calendar
NIH/NHLBI $1,715,450
*Asthma Inflammation Research (AIR)*
We propose to: *(1)* Translate our current collaborative and mechanistic research discoveries into innovative clinical approaches that provide the most advanced and reliable diagnostic and monitoring tools and treatments for asthma; and *(2)* Use our clinical research observations to inform our program's basic bench mechanistic investigations so that we are prepared to expand and improve on the clinical approaches for asthma care.
Role: Role: Program PI; Project 1 Leader; Core A Leader

1R01HL115008-01 (Erzurum, Prasad, Tang) 08/15/12-05/31/17 0.60 calendar
NIH/NHLBI $446,066
*Pulmonary Vascular-Right Ventricular Axis Research Program*
The goal of this study is to discover the fundamental mechanisms underlying the development and progression of heart failure so that we can use the knowledge to develop successful strategies for comprehensive treatment of the pulmonary hypertension and heart failure.
Role: Co-Principal Investigator (contact PI)

**Pending**
1R01 HL119163-01 (Comhair, Erzurum) 04/01/13-03/31/17 0.60 calendar
NIH/NHLBI $303,640
*Mechanisms of Secondhand Smoke Effects on Asthma*
The aims of this project are to *(1a)* determine whether SHS exposure in adults with asthma leads to greater loss of lung function (in children lesser gain of lung function), and greater indices of asthma severity over time; (1b) identify if SHS promotes development of a more severe asthma phenotype through mechanisms that include amplification of oxidative stress; and (2) identify if there is an interaction between SHS and common and rare genetic variants resulting in severe asthma.
Role: Co-Principal Investigator

2P01 HL081064-06 (Erzurum) 12/01/13-11/30/18 3.0 calendar
NIH/NHLBI $1,361,638
*Pathobiology of Asthma*
Core A: *Administrative Core*
Project 1: *Airway Epithelial Metabolism in Asthma*
The Pathobiology of Asthma Program aims to test the overall hypothesis that resident epithelial and smooth muscle cells initiate and perpetuate airway inflammation, hyper-reactivity and remodeling. Our long-term goals are to apply the discoveries made in this Program to develop more effective and targeted therapies for asthma patients.
Role: Program Principal Investigator; Core A Leader, Project 1 Leader

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Fiocchi, Claudio** | POSITION TITLE<br>Professor of Molecular Medicine |
| eRA COMMONS USER NAME **CFIOCCHI** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Santa Casa Medical School, Sao Paulo, Brazil | MD | 01/69 | Medicine |
| Cleveland Clinic | | 06/76 | Internal Medicine |
| Cleveland Clinic | | 06/78 | Immunology |
| Cleveland Clinic | | 06/80 | Gastroenterology |

## A. Positions and Honors

**Positions and Employment**

1971-1973 Instructor of Medicine and Parasitology, Santa Casa Medical School, Sao Paulo, Brazil
1974-1976 Resident, Internal Medicine, Cleveland Clinic Foundation, Cleveland, OH
1976-1978 Fellow, Research Immunology, Cleveland Clinic Foundation, Cleveland, OH
1976-1980 Fellow, Gastroenterology, The Cleveland Clinic Foundation, Cleveland, OH
1980-1993 Staff, Gastroenterology and Research Institute, Cleveland Clinic Foundation, Cleveland, OH
1991-1993 Head of Digestive Disease Research, Research Institute, Cleveland Clinic Foundation, Cleveland, OH
1993- present Professor of Medicine and Head of Research, Division of Gastroenterology, Case Western Reserve University School of Medicine and University Hospitals of Cleveland, Cleveland, OH
1994- present Professor of Pathology, Case Western Reserve University School of Medicine, Cleveland, OH
1997- present Professor of Pediatrics, Rainbow Babies & Children's Hospital, Case Western Reserve University
2005-present Staff, Department of Pathobiology, Cleveland Clinic Foundation, Cleveland, OH
2005-present Staff, Department of gastroenterology and Hepatology, Digestive Disease Institute, Cleveland Clinic, OH
2005-present Professor of Molecular Medicine, Cleveland Clinic Lerner College of Medicine, Cleveland Clinic

**Honors**

1989-1993 Member, GMA-2 Study Section, NIDDK, NIH
1991 Premier Physician Award, Crohn's & Colitis Foundation of America
1992-1997 Editorial Board, Gastroenterology
1994-present Associate Editor, Inflammatory Bowel Diseases
1997-present Editorial Board, Digestive and Liver Disease
1998-2002 Member, GMA-2 Study Section, NIDDK, NIH
1999-2009 MERIT Award, NIDDK, NIH
2001-present Associate Editor, Current Opinion in Gastroenterology
2000-2006 Editorial Board, American Journal of Physiology, Gastrointestinal & Liver Physiology
2009-2012 Editorial Board, American Journal of Physiology, Gastrointestinal & Liver Physiology
2007 The Clifford and Jane Anthony Chair for Digestive Disease Research and Education
2010 Foreign member, Brazilian National Academy of Medicine
2010 Henry Janowitz Lifetime Achievement Award in IBD of the Crohn's & Colitis Foundation of America
2011-present Associate Editor, American Journal of Physiology, Gastrointestinal & Liver Physiology
2011 Honorary member, Brazilian Federation of Gastroenterology

**B. Selected Peer-reviewed Publications (Selected from over 100 peer-reviewed publications)**

**Most relevant to the current application**

1. Danese S, Sans, M, de la Motte C, Graziani C, West G, Phillips MH, Pola R, Rivera-Reyes BM, Willis J, Gasbarrini A, **Fiocchi C**. Angiogenesis as a novel component of inflammatory bowel disease pathogenesis. *Gastroenterology*. 2006;130(7):2060-2073. PMID: 17170016
2. Scaldaferri F, Vetrano S, Sans M, Straface G, Arena V, Stigliano E, De la Rue S, Repici A, Pola R, Sturm A, Malesci A, Panes J, Yla-Herttuala S, **Fiocchi C**, Danese S. VEGF-A links angiogenesis and inflammation in inflammatory bowel disease pathogenesis. *Gastroenterology*. 2009;136(2):585-595.e5. Epub 2008 Oct 7.
3. Rieder F, Kessler S, West G, Bhilocha S, de la Motte C, Sadler T, Gopalan B, Stylianou E, **Fiocchi C**. Mucosal inflammation-induced endothelial-to-mesenchymal transition: a novel mechanism of intestinal fibrosis. *Am J Pathol* 2011;179:2660-2673. PMID: 21945322
4. de Souza HS, West GA, Rebert N, de la Motte C, Drazba J, **Fiocchi C**. Increased levels of survivin, via association with heat shock protein 90, in mucosal T cells from patients with Crohn's disease. *Gastroenterology* 2012;143:1017-1026.e9.
5. Schirbel A, Kessler K, Rieder F, West G, Asosingh K, McDonald C, **Fiocchi C**. Pro-angiogenic activity of TLRs and NLRs: a novel link between microbiota and intestinal angiogenesis. *Gastroenterology* 2013 Mar;144(3):613-623.e9. Epub 2012 Nov 10.

**Additional recent publications of importance to the field (in chronological order)**

1. Lawrance IC, Wu F, Willis J, West GA, **Fiocchi C**, Chakravarti S. A murine model of chronic inflammation-induced intestinal fibrosis down-regulated by antisense NF-kappa B. *Gastroenterology*. 2003;125(6):1750-1761. PMID: 14724828
2. Danese S, de la Motte C, Sturm A, West GA, Strong SA, Katz JA, **Fiocchi C.** Platelets trigger a CD40-dependent inflammatory response in the microvasculature of inflammatory bowel disease patients. *Gastroenterology*. 2003;124(5):1249-1264. PMID: 12730866
3. 4. Ina K, Kusugami K, Kawano Y, Nishiwaki T, Wen Z, Musso A, West GA, Ohta M, Goto H, **Fiocchi C**. Intestinal fibroblast-derived IL-10 increases survival of mucosal T cells by inhibiting growth factor deprivation- and Fas-mediated apoptosis. *J Immunol*. 2005;175(3):2000-2009. PMID: 16034145
4. Sans M, Danese S, Rivera-Reyes BM, de la Motte C, West GA, Phillips M, Katz JA, **Fiocchi C**. Enhanced recruitment of CX3CR1+ T-cells by mucosal endothelial cell-derived fractalkine in inflammatory bowel disease. *Gastroenterology*. 2007;132(1):139-153. Epub 2006 Oct 12. PMCID: PMC2194659
5. Danese S, Sans M, Spencer D, Beck I, Doñate F, Plunkett ML, de la Motte C, Redline R**,** Shaw DE, Levine DA, Mazar AP, **Fiocchi C**. Angiogenesis blockade as a new therapeutic approach to experimental colitis. *Gut*. 2007;56(6):855-562. PMCID: PMC1954843
6. Danese S, Scaldaferri F, Vetrano S, Repici A, Ricci R, Staface G, Malesci A, Vecchi M, **Fiocchi C**, Rutella S. Critical role of the CD40/CD40-ligand pathway in regulating mucosal inflammation-driven angiogenesis in inflammatory bowel disease. *Gut*. 2007;56(9):1248-1256. Epub 2007 Feb 22. PMCID: PMC1954974
7. de la Motte C, Nigro J, Vasanji A, Rho H, Kessler S, Bandyopadhyay SK, Danese S, **Fiocchi C**, Stern R. Platelet-derived hyaluronidase 2 cleaves hyaluronan into fragments that trigger monocyte-mediated production of proinflammatory cytokines. *Am J Pathol*. 2009;174(6):2254-2264. Epub 2009 May 14. PMCID: PMC2684190
8. Angulo S, Morales A, Danese S, Llacuna L, Masamunt MC, Pultz N, Cifone MG, De Simone C, Delgado S, Vila J, Panés J, Donskey C, Fernández-Checa JC, **Fiocchi C**, Sans M. Probiotic sonicates selectively induce mucosal immune cells apoptosis through ceramide generation via neutral sphingomyelinase. *PloS One* 2011;6:e16953
9. Pastorelli L, Hoang S, Garg R, Spina L, Mattioli B, Scarpa M, **Fiocchi C**, Vecchi M, Pizarro T. Epithelial-derived IL-33 and its receptor, ST2, are dysregulated in ulcerative colitis and in experimental Th1/Th2 driven enteritis. *Proc Natl Acad Sci U S A*. 2010;107:8017-8022. PMID: 20385815

10. Ma J, Altomare A, Guarino M, Cicala M, Rieder F, **Fiocchi C**, Li D, Cao W, Behar J, Biancani P, Harnett K. HCl-induced and ATP-dependent upregulation of TRPV1 receptor expression and cytokine production by human esophageal epithelial cells. *Am J Physiol Gastrointest Liver Physiol* 2012 Jul 12. [Epub ahead of print]

**C. Research Support**

**Ongoing Research Support**

5R01 DK50984-12 Fiocchi 20% effort
NIH/NIDDK 04/15/2010 - 03/31/2015
*Title: Cell Interactions in the Inflamed Intestinal Mucosa*
Project goal: This study is aimed at the investigation of the interaction between immune and non-immune cells in the pathogenesis of inflammatory bowel disease. Specifically, mesenchymal and endothelial cells from the intestinal mucosa will be assessed for their capacity of modulating the function of mucosal T lymphocytes**.**
Role: PI

2R01 DK069854-06 Fiocchi & Danese 15% effort
NIH/NIDDK 07/01/2011 - 06/30/2015
*Title: The Role of Lymphangiogenesis in IBD Pathogenesis*
Project goal: This proposal focuses on the potential role of new lymphatic vessel formation in the intestinal mucosa on the initiation and maintenance of chronic intestinal inflammation.
Role: Co-PI

1R01 DK093630-01A1 Fiocchi & Stylianou 20% effort
NIH/NIDDK 09/10/2012 - 05/31/2016
*Title: Epithelial cell-derived IL-1α as a novel danger signal in IBD pathogenesis*
Project goal: The central hypothesis is that necrotic epithelial cell-derived IL-1α is major intestinal DAMP and represents a novel component of IBD pathogenesis that contributes to the chronicity of inflammation.
Role: Co-PI

1T32 DK83251-01A1 Fiocchi & Cominelli 0% effort
NIH/NIDDK 07/01/2010 - 06/30/2015 *Title: Combined Training Program in Digestive Disease Sciences*
Project goal: This program is aimed at the training in the broad field of clinical and basic research in academic gastroenterology.
Role: Co-PI

AmTrust Charitable Foundation Fiocchi 0% effort
*Title: Functional Exploration of Genetic Mutations in Crohn's Disease* 04/01/2008 - 02/28/2013
Project goal: This study is aimed at the investigation of the consequences of Crohn's disease associated IL-23R and PTPN2 variants on immune function in patients and animal models of IBD.
Role: PI

**Pending Research Support**

None

**Completed Research Support**

7R01 DK50984-10S1 Fiocchi 09/20/2009 - 08/31/2010
NIH/NIDDK
*Title: Cell Interactions in the Inflamed Intestinal Mucosa*
Project goal: This study is an administrative supplement to R01 DK050984-10.
Role: PI

5R37 DK30399-23 Fiocchi 08/01/1982 - 03/31/2010
NIH/NIDDK
*Title: Mucosal Lymphokines in Inflammatory Bowel Disease*
Project goal: This study is aimed at the investigation of the signal transduction pathways involved in activation, growth and regulation of mucosal T-cells derived from normal and inflammatory bowel disease involved intestine
Role: PI

1T32 DK61917-05 Fiocchi 09/15/2002 - 06/30/2007
NIH/NIDDK
*Title: Training Program in Academic Gastroenterology*
Project goal: This program is aimed at the training in the broad field of clinical, translational and basic research in academic gastroenterology.
Role: PI

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Fitzpatrick, Joyce J.** | POSITION TITLE<br>Elizabeth Brooks Ford Professor of Nursing |
| eRA COMMONS USER NAME | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Georgetown University, Washington, DC | BSN | 05/66 | Nursing |
| The Ohio State University, Columbus, OH | MS | 07/67 | Psychiatric Mental Health Nursing |
| New York University, New York, NY | PhD | 12/75 | Nursing |
| Harvard University, Cambridge, MA | IEM | 05/87 | Institute for Educational Management |
| Weatherhead School of Management, Case Western Reserve University, Cleveland, OH | MBA | 05/92 | Management |

## A. Positions and Honors

**Positions and Employment**

1975 Assistant Professor, New York University, Division of Nursing
1975-1981 Associate Professor, Wayne State University, College of Nursing, Detroit, MI (Tenured-1979)
1976-1977 Chairperson, Department of Nursing Systems, Wayne State University, College of Nursing, Detroit, MI
1979-1981 Director, Center for Health Research, Wayne State University, College of Nursing, Detroit, MI
1981-1982 Professor, Wayne State University, College of Nursing, Detroit, MI
1982-1984 Visiting Professor, Rutgers-The State University, College of Nursing, Newark, NJ
1982-1994 Administrative Associate, University Hospitals of Cleveland, Cleveland, OH
1982-1997 Dean of Nursing, Frances Payne Bolton School of Nursing Case Western Reserve University, Cleveland, OH
1988-Present Elizabeth Brooks Ford Professor, Frances Payne Bolton School of Nursing Case Western Reserve University, Cleveland, OH
2002-Present Adjunct Professor, Geriatrics Mount Sinai School of Medicine, New York, NY
2009-2011 Adjunct Professor, Catherine McAuley School of Nursing, University College Cork,Cork, Ireland

**Other Experience and Professional Memberships**

1998-2002 Senior Scholar, John A. Hartford Foundation Institute for Geriatric Nursing New York University
1998-2002 Visiting Scholar, New York University Division of Nursing
2000- Present Visiting Scholar, The Mount Sinai Hospital, Department of Nursing, New York, NY
2004- Consultant, Dreyfus Health Foundation, Program Development
2009 Grace Tien Visiting Professor, Department of Nursing Studies University of Hong Kong
2009 Seoul Cyber University Chair Professor
2009- Senior Advisor and Chair, Global Advisory Committee Center for Nursing Research and Education, Mount Sinai School of Medicine
2011- Chair, American Nurses Foundation Board of Directors

**Honors**

1983-2006 *American Journal of Nursing* Book of the Year Award for 19 books.
2003 Sigma Theta Tau International Lucie S. Kelly Mentor Award
2005 Sigma Theta Tau International Mary Tolle Wright Founders Award for Leadership

2007-2008 Fulbright Award for University College Cork, Cork, Ireland
2010 Midwest Nursing Research Society Lifetime Achievement Award
2011 Frontier University of Nursing Doctor of Humane Letters, Honora Causa

**B. Selected peer-reviewed publications and books (since 2008, from total of 300 publications)**

Scherer, D., & Fitzpatrick, J. J. (2008). Perceptions of patient safety culture among physicians and RNs in the peri-operative area. AORN Journal, 87(1), 163-175.

Donahue, M., Piazza, I., Quinn Griffin, M., Dykes, P., & Fitzpatrick, J. J. (2008). The relationship between nurses' perceptions of empowerment and patient satisfaction. Applied Nursing Research, 21(1), 2-7.

Salyer, J. L. H., Walusimbi, M., & Fitzpatrick, J. J. (2008). Knowledge and attitudes of Ugandan midwives regarding HIV. Journal of Association of Nurses in AIDS Care, 19(2), 105-113.

Fitzpatrick, J. J. (2008). Meaning in life: Translating nursing concepts to research. Asian Nursing Research, 2(1), 1-4.

Jose, J., Quinn Griffin, M. T., Click, E. R., & Fitzpatrick, J. J. (2008). Demands of immigration of Indian nurses. Asian Nursing Research, 2(1), 46-54.

Ea, E. E., Quinn Griffin, M. T., L'Eplattenier, N., & Fitzpatrick, J. J. (2008). Job satisfaction and acculturation among Filipino Registered Nurses. Journal of Nursing Scholarship, 40(1), 46-51.

Beechinor, L. A. V., & Fitzpatrick, J. J. (2008). Demands of immigration among nurses from Canada and the Philippines. International Journal of Nursing Practice 14(2), 178-187.

Quinn Griffin, M. T., Salman, A., Lee, Y., Seo, Y., & Fitzpatrick, J. J. (2008). A beginning look at the spiritual practices of older adults. Journal of Christian Nursing, 25(2), 100-102.

Neushotz, L. A., & Fitzpatrick, J. J. (2008). Improving substance abuse screening and intervention in a primary care clinic. Archives of Psychiatric Nursing 22(2) 78-86.

Campo, T., McNulty, R. M., Sabatini, M., & Fitzpatrick, J. J. (2008). Nurse practitioners performing procedures with confidence and independence in the emergency care setting. Advanced Emergency Nursing Journal, 30(2), 150-167.

Hunnibell, L., Reed, P., Quinn Griffin, M. T., & Fitzpatrick, J. J. (2008). Self transcendence and burnout in hospice and oncology nurses. Journal of Hospice and Palliative Care Nursing.10(3), 172-179.

Fitzpatrick, J. J. (2008) The importance of temporality for nursing science and professional practice. Nursing Science Quarterly, 21, 223-225.

Thompson, C. W., & Fitzpatrick, J. J. (2008). Positive health practices and temporal perspectives in low income adults. Journal of Clinical Nursing, 17(13), 1708-1717.

Cerra, A., & Fitzpatrick, J. J. (2008). Can in-service education help prepare nurses for spiritual care. Journal of Christian Nursing, 25(4), 204-209.

McLoughlin, K., & Fitzpatrick, J. J. (2008). Self reports of recovery-oriented practices of mental health nurses in state mental health institutes: Development of a measure. Issues in Mental Health Nursing.29(10), 1051-1065.

Garbutt, S., Peltier, J., & Fitzpatrick, J. J. (2008). Evaluation of an instrument to measure nurses' familiarity with emergency preparedness. Military Medicine. 173(11), 1073-77.

McCarthy, G., & Fitzpatrick, J. J. (2008). Research development in a university nursing school in Southern Ireland. International Nursing Review. 55(4), 379-386.

Jones, J. S., Drake, V., & Fitzpatrick, J. J. (2008). Frequency of post-licensure Registered Nurse boundary violations with patients in the State of Ohio: A comparison based on type of pre-licensure Registered Nurse education. Archives of Psychiatric Nursing. 22(5), 356-363.

Layne, V. A., & Fitzpatrick, J. J. (2008). Stretching midlife maladies away: A guide for women. The Nurse Practitioner Journal: The American Journal of Primary Care, 33(12):33-38.

Scarinci, E., Quinn Griffin, M. T., & Fitzpatrick, J. J. (2008). Spiritual well being and spiritual practices among women with HIV. Journal of the Association of Nurses in AIDS Care. 20(1): 69-76.

Donahue, M. O., Brown, J. A., & Fitzpatrick, J. J. (2009). Medication administration process assessment: Applying lessons learned from commercial aviation. Journal of Nursing Administration. 39(2):77-83.

Lee, Y., Salman, A., & Fitzpatrick, J. J. (2009). HIV/AIDS preventive self-efficacy, depressive symptoms, and risky sexual behavior in adolescents: A cross-sectional questionnaire survey. International Journal of Nursing Studies, 46(5), 653-660.

Reilly, J., & Fitzpatrick, J. J. (2009). Stress and sense of belonging in Doctor of Nursing Practice students. Journal of Professional Nursing, 25(2), 81-86.

Zurmehly, J., Martin, P. A., & Fitzpatrick, J. J. (2009). Registered nurse empowerment and intent to leave current position and/or profession. Journal of Nursing Management, 17(3), 383-391.

Lopez, A., McCaffrey, R., Quinn Griffin, M. T., & Fitzpatrick, J. J. (2009). Spirituality among women with gynaecological cancer. Oncology Nursing Forum, 36(3), 300-305.

Guzik, A., Menzel, N., Fitzpatrick, J. J., & McNulty, R. M. (2009). Patient satisfaction with nurse practitioner and physician care in occupational health setting. Journal of the American Association of Occupation Health Nurses, 57(5), 191-197.

Garber, J., Madigan, E. A., Click, E., & Fitzpatrick, J. J. (2009). Attitudes toward collaboration and servant leadership among nurses, physicians, and residents. Journal of Inter-professional Care, 23(4), 331-340.

Fitzpatrick, J. J. (2009). Development of research agendas. NAIRTL. Cork: Ireland: University College Cork.

You, K. S., Lee, H., Fitzpatrick, J. J., Kim, S., Marui, E., Lee, J. S., & Cook, P. (2009) Religiosity, spirituality, depression, and perceived health among Korean elders in the community. Archives of Psychiatric Nursing, 23(4), 309-322.

McCarthy, G., & Fitzpatrick, J. J. (2009). Development of a competency model for nurse managers in Ireland. Journal of Continuing Education in Nursing, 40(8), 346-350.

Tyer-Viola, L., Nicholas, P. K., Corless, I. B., Barry, D. M., Hoyt, P., Fitzpatrick, J. J., Adejuno, O., & Davis, S. M. (2009). Social responsibility of nursing: A global perspective. Policy, Politics and Nursing Practice. 10(2), 110-118.

Rogers, V. L., Quinn Griffin, M. T., Wykle, M. L., & Fitzpatrick, J. J. (2009). Internet versus face-to-face therapy: Emotional self disclosure issues for young adults. Issues in Mental Health Nursing.30(10), 596-602.

Bahadori, A., & Fitzpatrick, J. J. (2009). Level of autonomy of primary care nurse practitioners. Journal of the American Academy of Nurse Practitioners, 21(9), 513-519.

Mintz-Binder, R. D., & Fitzpatrick, J. J. (2009). Exploring social support and job satisfaction within associate degree program directors in California. Nursing Education Perspectives, 30(5), 299-304.

Neushotz, L., Parisien, K., Porter, C., Hoar, P., Holloman, P., & Fitzpatrick, J. J. (2009). Nursing research sheds light on key nursing-care values. American Nurse Today. 4(8): 50-52.

Whelan Gales, M., Quinn Griffin, M. T., Maloni, J., Fitzpatrick, J. J. (2009). Spiritual well being, spiritual practices and depression among hospitalized older adults with heart failure. Geriatric Nursing, 30(5), 312-17.

Twedell, D., Donahue, M., Dykes, P., Smith, L., & Fitzpatrick, J. J. (2009). The EMPOWER Project: An initiative to educate and mentor paraprofessional staff. Journal of Continuing Education in Nursing. 40(11), 487-488.

Jones, T. S., & Fitzpatrick, J. J. (2009). CRNA-physician collaboration in anesthesia. AANA Journal, 77(6), 431-436.

Stewart, J. G., McNulty, R. M., Quinn Griffin, M. T., & Fitzpatrick, J. J. (2010). Psychological empowerment and structural empowerment among nurse practitioners. Journal of the American Academy of Nurse Practitioners, 22(1), 27-34.

Gardenier, D., Andrews, C. M., Thomas, D., Bookhardt-Murray, & Fitzpatrick, J. J. (2010). Social support and adherence: Differences among clients in an AIDS Day Health Care Program. Journal of the Association of Nurses in AIDS Care, 21(1), 75-85.

Fazzino, D., Quinn Griffin, M. T., McNulty, R. M., & Fitzpatrick, J. J. (2010). Energy healing and pain: A review of the literature. Holistic Nursing Practice, 24(2): 79-88.

Sharpnack, P. A., Quinn Griffin, M. T., Bender, A., & Fitzpatrick, J. J. (2010). Spiritual and alternative health practices among the Amish. Holistic Nursing Practice 24(2): 64-72.

Miller, J., & Fitzpatrick, J. J. (2010). Patient education: Piercing: Does health education make a difference? The Nurse Practitioner Journal.35(6): 48-52.

Palmer, B., Quinn Griffin, M. T., Reed, P., & Fitzpatrick, J. J. (2010). Self transcendence and work engagement in acute care staff registered nurses, Critical Care Nurse Quarterly, 33(2): 139-148.
Fitzpatrick, J. J., Campo, T., Graham, G., & Lavandero, R. (2010). Empowerment and intent to leave among a national sample of critical care nurses. American Journal of Critical Care, 19:218-227.
Gerard, S., Quinn Griffin, M. T., & Fitzpatrick, J. J. (2010). Advancing quality diabetes education through evidence and innovation. Journal of Nursing Care Quality. 25(2): 160-167.
Porter, C. A., Kolkaba, K., McNulty, R. M., & Fitzpatrick, J. J. (2010,). The effect of a labor management partnership on nurse satisfaction and turnover. Journal of Nursing Administration. 40(5): 205-210.
Twedell, D., Donahue, M., Smith, L., Dykes, P., & Fitzpatrick, J. J. (2010). Phase 2 of the EMPOWER Project: Enhancing communication for paraprofessionals. Journal of Continuing Education in Nursing, 41(5): 197-198.
Heffernan, M., Quinn Griffin, M. T., McNulty, R. M., & Fitzpatrick, J. J. (2010). Self compassion and emotional intelligence among nurses. International Journal of Nursing Practice, 16(4), 366-373.
Thomas, J., Burton, M., Quinn Griffin, M. T., & Fitzpatrick, J. J. (2010). Self transcendence and spiritual well being among women with breast cancer. Journal of Holistic Nursing. 28(2), 115-122.
Matos, P. A., Neushotz, L. A., Quinn Griffin, M. T., & Fitzpatrick, J. J. (2010). Resilience and job satisfaction among psychiatric nurses. International Journal of Mental Health Nursing, 19(5), 307-312.
Ernst, E. J., Speck, P. M., & Fitzpatrick, J. J. (2010). Photo documentation image quality scoring system in the evaluation of female genital injuries following sexual assault. Advanced Emergency Nursing Journal, 32(3): 272-281.
Ma, A., Quinn Griffin, M. T., Capitulo, K., & Fitzpatrick, J. J. (2010). Demands of immigration among Chinese immigrant nurses. International Journal of Nursing Practice.16(5): 443-453.
Nance, J., Quinn Griffin, M. T., McNulty, R. M., & Fitzpatrick, J. J. Prayer practices of young adults. Holistic Nursing Practice, 24(6): 338-344.
McCarthy, G., Hegarty, J., Savage, E., & Fitzpatrick, J. J. (2010). PhD away day: A component of PhD supervision. International Nursing Review, 57(4):415-418.
Armellino, D. A., Quinn Griffin, M. T., & Fitzpatrick, J. J. (2010). Structural empowerment and patient safety culture among Registered Nurses working in adult critical care units. Journal of Nursing Management, 18(7): 796-803.
Wehmer, M. A., Quinn Griffin, M. T., White, A. H., & Fitzpatrick, J. J. (2010). An exploratory study of spiritual dimensions among nursing students. International Journal of Nursing Education Scholarship, 7(1), Article 40.
Roberti, S. & Fitzpatrick, J. J. (2010). Assessing family satisfaction with care of critically ill patients: A pilot study. Critical Care Nurse 30(6): 18-27.
Ea, E. E., Ehrenfeld, M., & Fitzpatrick, J. J. (2010). Acculturation among immigrant nurses in Israel and the United States. International Nursing Review, 57(4): 443-448.
Hughes, B., & Fitzpatrick, J. J. (2010). Nurse physician collaboration in an acute care community hospital. Journal of Interprofessional Care, 24(6): 625-632.
Murphy, M., & Fitzpatrick, J. J. (2011). Illness intrusiveness of a diagnosis of Hepatitis C virus (HCV) among adults: A pilot study. The Journal for Nurse Practitioners, 7(1): 46-50.
DeMilt, D, Fitzpatrick, J. J., & McNulty, R. M. (2011). Nurse practitioners' job satisfaction and intent to leave current positions, the nursing profession, and the NP role as a direct care provider. Journal of the American Academy of Nurse Practitioners, 23(1): 42-50.
Maylone, M., Ranieri, L., Quinn Griffin, M. T., McNulty, R. M., & Fitzpatrick, J. J. (2011). Autonomy and collaboration among nurse practitioners. Journal of the American Academy of Nurse Practitioners, 23(1): 51-57.
O'Shea, E., Quinn Griffin, M. T., Wallace, M., & Fitzpatrick, J. J. (2011). The effect of an educational session on pediatric nurses' perspectives toward providing spiritual care. Journal of Pediatric Nursing, 26(1): 34-43.
Friedman, I. M., Cooper, A. H., Click, E., & Fitzpatrick, J. J. (2011). Specialized new graduate RN critical care orientation: Retention and financial impact. Nursing Economic$ 29(1): 7-14.
Smith, D., Quinn Griffin, M. T., & Fitzpatrick, J. J. (2011). Exercise and exercise intentions among obese and overweight individuals. Journal of the American Academy of Nurse Practitioners. 23: 92-100.

Hauck, A., Quinn Griffin, M. T., & Fitzpatrick, J. J. (2011). Empowerment among critical care nurses. Journal of Nursing Management, 19:269-276.
Ernst, E. J., Speck, P. M., & Fitzpatrick, J. J. (2011). Usefulness: Forensic photo documentation after sexual assault. Advanced Emergency Nursing Journal, 33:29-38.
Donahue, M., Dykes, P., Smith, L., Miller, M., & Fitzpatrick, J. J. (2011). A leadership initiative to improve communication and enhance safety. American Journal of Medical Quality, 26(3), 206-211.
Rivera, R. R., Boyle, S. M., & Fitzpatrick, J. J. (2011). Closing the RN engagement gap: Which drivers of engagement matter? Journal of Nursing Administration, 41(6): 265-272.
Barden, A. M., Quinn Griffin, M. T., Donahue, M., & Fitzpatrick, J. J. (2011). Shared governance and empowerment in Registered Nurses working in a hospital setting. Nursing Administration Quarterly, 33(3): 212-218.
Slaven-Lee, P. W., Padden, D., Andrews, C. M., & Fitzpatrick, J. J. (2011). Emotional distress and health risk behaviours of mothers of deployed servicemen. International Nursing Review. 58(2):164-170.
Sacco, L. M., Quinn Griffin, M. T., McNulty, R. M., & Fitzpatrick, J. J. (2011). The Serenity Prayer among diabetics: A pilot study. Holistic Nursing Practice, 25(4), 191-197.
Clement-O'Brien, K., Polit, D., & Fitzpatrick, J. J. (2011). Innovativeness of nurse leaders. Journal of Nursing Management.19(4), 431-438.
McCabe, D., Alvarez, C. M., McNulty, R. M., & Fitzpatrick, J. J. (2011). Perceptions of physical restraint use in the elderly among Registered Nurses and nurse assistants in a single acute care hospital. Geriatric Nursing, 32(1): 39-45.
Baker, S., Quinn Griffin, M. T., & Fitzpatrick, J. J. (2011). Empowerment among associate degree nurse faculty. Nursing Education Perspectives, 32(4): 234-239.
Sharpnack, P. A., Quinn Griffin, M. T., Bender, A., & Fitzpatrick, J. J. (2011). Self transcendence and spiritual well being in the Amish. Journal of Holistic Nursing, 29(2): 91-97.
Esposito, E. E., & Fitzpatrick, J. J. (2011). Registered Nurses' beliefs of the benefits of exercise, their exercise behavior, and their patient teaching regarding exercise. International Journal of Nursing Practice, 17:351-356.
Danzey, I. M., Ea, E. E., Fitzpatrick, J. J., Garbutt, S., Rafferty, M., & Zychowitz, M. (2011). The DNP as preparation for nursing education. Journal of Professional Nursing,
Fitzpatrick, J. J., & Donahue, M. (2011). Transitioning hospital-based nurse leaders to professional doctorates. Nurse Leader, 10: 46-47,55.
Green, L., Matos, P., Murillo, I., Neushotz, L., Popeo, D. M., Aloysi, A., Samuel, J., Craig, E. Porter, C., & Fitzpatrick, J. J. (2011). Use of dolls as a therapeutic intervention: Relationship to previous negative behaviors and pro re nata (prn) Haldol use among geropsychiatric inpatients. Archives of Psychiatric Nursing, 25(5): 388-389.
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Fitzpatrick, J. J., Campo, T., & Lavandero, R. (2011). Differences in empowerment and intent to leave current position among certified and non-certified critical care staff nurses. Critical Care Nurse, 31(6): e12-17.
Adorador, A., McNulty, R. M., Hart, D., & Fitzpatrick, J. J. (2011). Perceived barriers to immunizations as identified by Latino mothers. Journal of the American Academy of Nurse Practitioners, 23(9): 301-508.
Nair, D. M., Fitzpatrick, J. J., Click, E. R., McNulty, R. M., & Glembocki, M. (2011). Frequency of nurse-physician collaborative behaviours in an acute hospital. Journal of Interprofessional Care, 26(2): 115-120.
Donahue, M., Kazer, M. W., Smith, L., & Fitzpatrick, J. J. (2011). Effect of a geriatric nurse education program on the knowledge, attitudes, and certification of hospital nurses. Journal of Continuing Education in Nursing. 42(8): 360-4.

McGlynn, K, Quinn Griffin, M. T., Donahue, M., & Fitzpatrick, J. J. (2012). Registered Nurse job satisfaction and satisfaction with the professional practice environment. Journal of Nursing Management, 20(2): 260-265.

Clavelle, J., Drenkerd, K., McGuinnis, S., & Fitzpatrick, J. J. (2012). Transformational leadership practices of chief nursing officers in Magnet® organizations. Journal of Nursing Administration, 42(4): 195-201.

Mikell, P., Fitzpatrick, J., & Quinn-Griffin, M. (2012) Nurse practitioner job satisfaction. JNPA: The Journal, 2(1), 9-15.

Koetting, C., Fitzpatrick, J. J., Lewin, L., & Kilanowski, J. (2012). Nurse practitioner knowledge of sexual abuse among children with cognitive disabilities. Journal of Forensic Nursing. 8(2): 72-80.

Folan, P., DeCain Tarraza, M., Delaney, M., Fardellone, C., Leners, C., Ross, E., & Fitzpatrick, J. J. (2012). Leadership Initiatives to Disseminate the Institute of Medicine Future of Nursing Report. Nursing Policy, Practice and Politics 13(1): 38-44.

Smith, T. D., Capitulo, K. L., Quinn Griffin, M. T., & Fitzpatrick, J. J. (2012). Structural empowerment and anticipated turnover among behavioural health nurses. Journal of Nursing Management, 20(5): 679-84.

Crane, M. J., Quinn Griffin, M. T., Andrews, C. M., & Fitzpatrick, J. J. (2012). The level of importance and level of confidence that midwives in the United States attach to using genetics in practice. Journal of Midwifery and Women's Health, 57(2): 114-9.

Samedy, K., Quinn Griffin, M. T, Capitulo, K. L., & Fitzpatrick, J. J. (2012). Perceptions of structural empowerment: Differences between nationally certified perinatal nurses and perinatal nurses who are not nationally certified, Journal of Continuing Education in Nursing. 43(10): 463-6.

Wang, A, Fitzpatrick, J. J., & Petrini, M. (2012). Comparison of two simulation methods on Chinese BSN students' learning. Clinical Simulation in Nursing, e1-6

Ernst, E. J., Speck, P. M., & Fitzpatrick, J. J. (2012). The element of naturalness when evaluating image quality of digital photo documentation after sexual assault. Advanced Emergency Nursing Journal, 34(3): 250-258.

Fitzpatrick, J. J., & Hoyt-Hudson, P. (2012, in press). Problem solving for better health nursing: Applying lessons learned abroad to the United States. Journal of Professional Nursing.

Devivo, D., Quinn Griffin, M. T., Donahue, M., & Fitzpatrick, J. J. (2012, in press). Perceptions of empowerment among ED nurses, Journal of Emergency Nursing,

Bauce, K., Kridli, R., & Fitzpatrick, J. J. (2012, in press). Perceptions of empowerment and cultural competence among acute care nurses. Online Journal of Cultural Competence in Nursing and Health.

Itzhaki, M., Ea, E. E., Ehrenfeld, M., & Fitzpatrick, J. J. (2012, in press). Job satisfaction of immigrant nurses in Israel and the United States of America. International Nursing Review.

Brennan, M. M., Campo, T., McNulty, R. M., & Fitzpatrick, J. J. (2012, in press). Pediatric resuscitation for nurses working in Ghana. International Nursing Review.

Coffey, A., McCarthy, G., Fitzpatrick, J. J., Weathers, E., Freidman, M. I., Gallo, K., Ehrenfeld, M., Itzhaki, M., Chan, S., Li, W. H. C., Poletti, P., Zanotti, R., Molley, D. W., & McGlade, C. (2012, in press). Advance directives: Nurses' end of life treatment choices in five countries. International Nursing Review.

## C. Research Support

**Ongoing Research Support**

Faculty Seed Grant (CWRU) Fitzpatrick & Quinn Griffin (Co-PIs) 07/01/12-06/30/2013
Initiative on The Advancement of International Health Care Leadership

**Completed Research Support**

Emergency Nurses Association Fitzpatrick (PI) 2011-2012
Differences in empowerment between certified and non-certified emergency department nurses: A national survey.

HRSA 2009-2012
Geriatric Family Centered Care. Role: Consultant

The Donahgue Medical Research Foundation Donahue, (PI) 2008-2010
EMPOWER: Educating and Mentoring Paraprofessionals On Ways to Enhance Reporting of changes in patient status; Patient Safety Research Initiative
Role: Academic Partner and Consultant

American Association of Critical Care Nurses Fitzpatrick (PI) 2007-08
Differences in empowerment between certified and non-certified critical care nurses: A national survey.

Sigma Theta Tau International Workforce Grant J. Zurmehly (PI) 2005-2006
Registered Nurse Empowerment and Intent to Leave Current Position and Profession Role: Co-Investigator

Nursing Care Quality Initiative Fitzpatrick (PI) 03/01/00-06/30/02
Mount Sinai NYU Health and North Shore-Long Island Jewish Health System, New York Health Alliance and Brookdale Foundation

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Gary, Faye Annette** | POSITION TITLE<br>The Medical Mutual of Ohio Kent W. Clapp Chair & Professorship in Nursing |
| eRA COMMONS USER NAME **DRGARY** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Florida A&M University, Tallahassee, FL | BS | 05/62 | Nursing/Sociology |
| Saint Xavier College, Chicago, IL | MS | 05/66 | Psychiatric Nursing |
| University of Florida, Gainesville, FL | EdD | 11/73 | Special Education & Anthropology |

**A. Positions and Honors**

**Positions and Employment**

| | |
|---|---|
| 1962-63 | Charge Nurse, Acute Tuberculosis Clinic Service, Adults/Child, WT Edwards Tuber Hospital, Tallahassee, FL |
| 1963 | Staff Nurse, Intensive Care, Emergency Code Nurse, Upstate Med Center, Syracuse, NY |
| 1964-66 | School Health Nurse (part-time), Saint Xavier College, Chicago, IL |
| 1967-68 | Guest Lecturer, Post Master's Programs SON, University of CA at San Francisco |
| 1967-68 | Coordinator, Multi-discipline Health Team, Chinatown & North Beach, City & County of San Francisco, CA |
| 1968 | Clinical Nurse Specialist, Mentally Ill Adults, Adolescents, & Children, Medical College of Virginia, Richmond, VA |
| 1968-69 | Instructor, Psychiatric Nursing Undergraduate Program, University of Florida, Gainesville |
| 1969-72 | Co-Director, Rehabilitation & Work Evaluation Program, Vocational Rehabilitation of Florida & Santa Fe Community College, Gainesville, FL |
| 1972-75 | Academic Counselor and Faculty Member, Santa Fe Community College, Gainesville, FL |
| 1975-80 | Associate Professor, Graduate Program, Psychiatric/Mental Health Nursing, University of Florida, Gainesville |
| 1978-82 | Graduate Faculty, College of Education, Division of Emotional Disturbances in Children, Department of Special Education, University of Florida, Gainesville |
| 1977-79 | Participating Faculty, Hum. for Health Science Program, College of Medicine, University of Florida, Gainesville |
| 1978-80 | Co-Director, Family & Group Sim & Theo Sem, Department of Psychiatry, College of Medicine, University of Florida, Gainesville |
| 1978-88 | Executive Committee, Women's Study Program, University of Florida, Gainesville |
| 1975-2003 | Joint Appoint, Department of Children & Adolescent Psychiatry, College of Medicine, University of Florida, Gainesville |
| 1975-80 | Associate Professor, College of Nursing, University of Florida, Gainesville |
| 1980-84 | Professor, College of Nursing, University of Florida, Gainesville |
| 1994-2003 | Distinguished Professor, College of Nursing, University of Florida, Gainesville, Department of Psychiatry, College of Medicine |
| 2003-current | Medical Mutual of Ohio Professor for Vulnerable and At-Risk Persons, Frances Payne Bolton School of Nursing, Case Western Reserve University, Cleveland, OH |
| 2010-current | Associate Dean for Minority Affairs and Health Disparities and Interim Associate Dean, Undergraduate Programs, Frances Payne Bolton School of Nursing, Case Western Reserve University, Cleveland, OH |

**Other Experience and Professional Memberships**

2004-10 Member, National Advisory Committee, Substance Abuse & Mental Health Services Administration, Rockville, MD

2004-07 Member, National Advisory Mental Health Council, National Institute of Mental Health, Bethesda, MD

2007 Member, Mental Health America (formerly National Mental Health Association), elected to National Board of Directors, Alexandria, VA

2008-10 Appointed to Expert Advisory Panel, The Joint Commission, Oakbrook Terrace, IL

2009-11 Member, National Quality Forum, National Voluntary Consensus Standards for Patient Outcomes

2010 Member, Board of Directors, National Alliance of the Mentally Ill, Greater Cleveland Chapter, Cleveland, OH

**Honors**

1991 Book of the Year Award, *American Journal of Nursing*, American Nurses Association, "Psychiatric Nursing", Philadelphia: Lippincott. 1-1,050.

1991 Book Award, Ministry of Health, Kingdom of Lesotho, "Primary Health Care in the Kingdom Of Lesotho", Battle Creek, MI: W.K. Kellogg Foundation, 1-317.

2004 Uppity Woman Award: Founding Mother of the Women's Studies Program at the University of Florida, Gainesville, FL

2004 Nurse Researcher of the Year, National Black Nurses Association, San Francisco, CA

2005 Award for Outstanding Contributions to Children, Youth and Families, Department of Juvenile Justice, State of Florida, Governor's Office, Tallahassee, FL

2005 Cultural Competence Award for Diversity, International Society of Psychiatric-Mental Health Nurses (ISPN), Pittsburgh, PA, April 9, 2005

2006 Lifetime Member, National Black Nurses Association, Washington, D.C.

2007 Member, Commission on Graduates of Foreign Nursing Schools (CGFNS), International Appeals Committee, 2007-2010.

2009 Member, NIH Health Disparities Strategic Plan Working Group, subcommittee of National Institutes of Health, 2009-2010.

2008 National Recognition for Advancing Health among Alaska Native and American Indians, National Conference, Cleveland, OH 2007

2008 Lifetime Honorary Member, Alaska Native American Indian Nurses Association

2010 Medical Trailblazer Award, Southern Christian Leadership Conference, Cleveland, OH

2010 Mather Spotlight Award for Excellence in Scholarship and Research, Case Western Reserve University, Case Western Reserve University, Cleveland, OH

**B. Selected peer-reviewed publications**

1. Gary F, Yarandi H, Rivers R (2001). Rural southern African American women's health status, knowledge, and income during menopausal years. *Journal of National Black Nurses Association, 12*(1), 32-40.
2. Gary, F, Scruggs, F, Yarandi, H (2003). Suicide among African Americans: Reflections and a call to action. *Issues in Mental Health Nursing, 24*, 353-375.
3. Gary, F., & Yarandi, H. (2004). Depression among Rural Southern African American Women: A factor analysis of the Beck Depression Inventory. *Nursing Research, 53*(4), 251-259
4. Gary, F. (2005). Barriers to mental illness care among ethnic minorities. *Issues in Mental Health Nursing, 26*(10), 979-999.
5. Gary, F. (2005). Research on the stigma of mental illness among ethnic minority populations in the United States. *Issues in Mental Health Nursing, 26*(10), 971-977.
6. Bussing, R, Koro-Ljungberg, M, Gary, F, Mason, D, Garvan, C (2005). Exploring help-seeking for ADHD: A mixed method approach. *Harvard Review of Psychiatry, 13*(2), 85-101.

7. Mathunjwa, T., & Gary, F. (2006). Women and HIV/AIDS in the Kingdom of Swaziland: Culture and risks. *Journal of National Black Nurses Association, (17)*2, 39-46.
8. Bussing, R, Gary, F., Mills, T., & Garvan, C. (2007). Cultural variations in parental health beliefs, knowledge, and information sources related to Attention-Deficit/Hyperactivity Disorder. *Journal of Family Issues, (28)*3, 291-318.
9. Murrock, C., & Gary, F. (2008). A culturally-specific dance intervention to increase functional capacity in African American women. *Journal of Cultural Diversity, 15*(4), 168-173.
10. Murrock, C., & Gary, F. (2008). Culturally-specific dance to reduce obesity in African American women. *Health Promotion Practice OnlineFirst*, published on December 19, 2008 as doi: 10.1177/1524839908323520.
11. Mathunjwa-Dlamini, T. R., Gary, F. A., & Yarandi, H. (2008).Self-care practices among perimenopausal African-American women. *UNISWA Research Journal of Agriculture, Science and Technology, 11*(1),10-17.
12. Campbell, J., Campbell, D., Gary, F., Nedd, D., Price-Lea, P., Sharps, P., et al (2008). African American women's response to intimate partner violence: An examination of cultural context. *Journal of Aggression, Maltreatment & Trauma, 16(3), #49*.
13. Koro-Lungberg, M., Bussing, R., Wilder, J., Gary, F. (2011).Role of communication in the context of educating children with Attention-Deficit/hyperactivity Disorder: Parents' and teachers' perspective. *Journal of School Public Relations*. Vol. 32, 41-75.

**C. Research Support**

**Ongoing Research Support**

P30 NR010676-05 Moore (PI) 09/29/07-06/30/12
NIH/NINR
Center of Excellence to Build the Science of Self-Management: A Systems Approach
The SMART Center will prepare a critical mass of researchers to extend and disseminate knowledge related to self-management, contribute to the development of emerging biobehavioral research methods, focus on critical issues related to health disparities, and incorporate economic considerations as part of their research.
Role: Committee Member

P20 MD002286-05 Callwood (PI) 09/30/07-06/30/12
NIH/NIMHD
To reduce and eliminate health disparities in the U.S. Virgin Islands.
Subproject: Faye Gary, PI "Health Status and Access to Healthcare Among African American and African Caribbean Women" is a study now in the last phase of data collection which entails convening Focus Groups.
Administrative Supplement: "Protecting Haitian Women and Children: Earthquake Survivors from Violence and Abuse" D. Campbell, G. Callwood, PIs, F. Gary, Investigator. The goal of this project is to decrease the potential for physical, emotional and sexual abuse of women and children survivors of the Haitian Earthquake of January 2010.
Role: Co-I

**Completed Research Support**

R01 MH 057399 Bussing (PI) 08/01/98-04/30/10
Attention Deficit Hyperactivity Disorder (ADHD): Detection and Service Use
To determine health services utilization for children diagnosed with ADHD
Role: Co-I

R03 CA115191 Zhang (PI) 07/17/06-06/30/09
Assessing Depression in African American Cancer Patients
To investigate depressive experiences of African American cancer patients and identify their depressive symptoms in order to develop a culturally sensitive screening tool for depression.
Role: Co-I

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Mahmoud A. Ghannoum** | POSITION TITLE<br>Professor, Dept. of Dermatology<br>Director, Center for Medical Mycology |
| eRA COMMONS USER NAME **mghannoum** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| American University of Beirut, Beirut, Lebanon | B.Sc. | 1973 | Biology/Chemistry |
| Loughborough University of Technology, Loughborough, England | M.Sc. | 1974 | Medicinal Chemistry |
| Loughborough University of Technology, Loughborough, England | Ph.D. | 1978 | Mycology/Microbial Physiology |
| Case Western Reserve University | EMBA | 2004 | Executive Masters of Business Administration |

**A. Positions and Honors**

**PROFESSIONAL EXPERIENCE**

| | |
|---|---|
| 1978 – 1980 | Lecturer, Higher Institute of Technology, Malta |
| 1980 – 1985 | Lecturer, Dept. of Botany & Microbiology, Kuwait University |
| 1985 – 1990 | Assoc. Professor, Dept. of Botany & Microbiology, Kuwait University |
| 1990 – 1991 | Professor, Dept. of Botany & Microbiology, Kuwait University |
| 1991 – 1996 | Professor of Mycology Research, UCLA School of Medicine, Los Angeles, CA |
| 1996 – 1999 | Scientific Director, Center for Medical Mycology, University Hospitals, Cleveland |
| 1996 – 2000 | Assoc. Professor, Department of Dermatology, Case Western Reserve University |
| 1999 – present | Director, Center for Medical Mycology, University Hospitals, Cleveland |
| 2000 - present | Professor of Dermatology, Case Western Reserve University, Cleveland, OH. |

**ACADEMIC HONORS AND PRIZES**

| | |
|---|---|
| 1987 | Abdul Hameed Shoman Prize for Young Arab Scientists in the Field of Biological Sciences |
| 1992 -present | National Committee for Clinical Laboratory Standards (NCCLS)-Subcommittee on Antifungal Susceptibility Testing |
| 1994-present | Fellow of the Infectious Disease Society of America |
| 1998 – 2000 | Department of Veteran Affairs, Merit Review Subcommittee for Infectious Disease |
| 1999 – present | Chairman, Working Group on Antifungal Susceptibility Testing of Dermatophytes |
| 1998 – 2000 | NIH-NIAID, Bacteriology/Mycology II study section, Ad hoc. |
| 2003 | Kuwait Prize in Microbiology, Kuwait Foundation for the Advancement of Science |
| 2004 | Bristol-Myer Squibb “Freedom of Discovery” award in Infectious Diseases, for work accomplished in biofilm area |
| 2004 | NIH, NIDCR, Special Emphasis Panel grant reviewer, multidisciplinary research on oral manifestation of HIV/AIDS |
| 2005 – present | Secondary Appointment, Dept. of Biological Sciences at the School of Dentistry, Case Western Reserve University |
| 2008 – 2009 | Vice-Chair, Antifungal Susceptibility Testing Sub-Committee, Clinical and Laboratory Standards Instt. |
| 2009 – | Chair, Antifungal Susceptibility Testing Sub-Committee, Clinical and Laboratory Standards Instt. |
| 2009 | Billy Cooper Award, Mycological Societies of the Americas |
| 2010 | President Elect- Mycological Societies of the Americas |

**B. Selected peer-reviewed Publications** (Selected from over 180)

1. Sanati H, Ramos CF, Bayer AS, **Ghannoum MA**. Combination therapy with amphotericin B and fluconazole against invasive candidiasis in neutropenic-mouse and infective-endocarditis rabbit models. Antimicrob Agents Chemother. 1997;41(6):1345-8. PMCID: 163912.
2. Jessup C, Reyes G, Fothergill A, McCarthy D, Rinaldi M, Messer S, Pfaller M, **Ghannoum MA** head-on comparison of the in vitro antifungal activity of conventional and lipid-based amphotericin B: a multicenter study. J Chemother. 2000;12(1):22-9.
3. Chandra J, Kuhn DM, Mukherjee PK, Hoyer LL, McCormick T, **Ghannoum MA**. Biofilm formation by the fungal pathogen Candida albicans: development, architecture, and drug resistance. J Bacteriol. 2001;183(18):5385-94. PMCID: 95423.
4. Chandra J, Mukherjee PK, Leidich SD, Faddoul FF, Hoyer LL, Douglas LJ, **Ghannoum MA**. Antifungal resistance of candidal biofilms formed on denture acrylic in vitro. J Dent Res. 2001;80(3):903-8.
5. Kuhn DM, Chandra J, Mukherjee PK, **Ghannoum MA**. Comparison of biofilms formed by Candida albicans and Candida parapsilosis on bioprosthetic surfaces. Infect Immun. 2002;70(2):878-88. PMCID: 127692.
6. Kuhn DM, George T, Chandra J, Mukherjee PK, **Ghannoum MA**. Antifungal susceptibility of Candida biofilms: unique efficacy of amphotericin B lipid formulations and echinocandins. Antimicrob Agents Chemother. 2002;46(6):1773-80. PMCID: 127206.
7. Kuhn DM, **Ghannoum MA**. Indoor mold, toxigenic fungi, and Stachybotrys chartarum: infectious disease perspective. Clin Microbiol Rev. 2003;16(1):144-72. PMCID: 145304.
8. Mukherjee PK, Chandra J, Kuhn DM, **Ghannoum MA**. Mechanism of fluconazole resistance in Candida albicans biofilms: phase-specific role of efflux pumps and membrane sterols. Infect Immun. 2003;71(8):4333-40. PMCID: 165995.
9. **Ghannoum MA**, Hossain MA, Long L, Mohamed S, Reyes G, Mukherjee PK. Evaluation of antifungal efficacy in an optimized animal model of Trichophyton mentagrophytes-dermatophytosis. J Chemother. 2004;16(2):139-44.
10. **Ghannoum MA**, O'Toole GA. Microbial Biofilms. 1st ed. Washington, DC: American Society for Microbiology Press; 2004.
11. Green CB, Cheng G, Chandra J, Mukherjee P, **Ghannoum MA**, Hoyer LL. RT-PCR detection of Candida albicans ALS gene expression in the reconstituted human epithelium (RHE) model of oral candidiasis and in model biofilms. Microbiology. 2004;150(Pt 2):267-75.
12. Kuhn DM, **Ghannoum MA**. Candida biofilms: antifungal resistance and emerging therapeutic options. Curr Opin Investig Drugs. 2004;5(2):186-97.
13. Kuhn DM, Mukherjee PK, Clark TA, Pujol C, Chandra J, Hajjeh RA, Warnock DW, Soil DR, **Ghannoum MA**. Candida parapsilosis characterization in an outbreak setting. Emerg Infect Dis. 2004;10(6):1074-81.
14. Schinabeck MK, Long LA, Hossain MA, Chandra J, Mukherjee PK, Mohamed S, **Ghannoum MA**. Rabbit model of Candida albicans biofilm infection: liposomal amphotericin B antifungal lock therapy. Antimicrob Agents Chemother. 2004;48(5):1727-32. PMCID: 400590.
15. Chandra J, Patel JD, Li J, Zhou G, Mukherjee PK, McCormick TS, Anderson JM, **Ghannoum MA**. Modification of surface properties of biomaterials influences the ability of Candida albicans to form biofilms. Appl Environ Microbiol. 2005;71(12):8795-801. PMCID: 1317330.
16. Chandra J, Zhou G, **Ghannoum MA**. Fungal biofilms and antimycotics. Curr Drug Targets. 2005;6(8):887-94.
17. Mukherjee PK, Zhou G, Munyon R, **Ghannoum MA**. Candida biofilm: a well-designed protected environment. Med Mycol. 2005;43(3):191-208.
18. Mukherjee PK, Mohamed S, Chandra J, Kuhn D, Liu S, Antar OS, Munyon R, Mitchell AP, Andes D, Chance MR, Rouabhia M, **Ghannoum MA**. Alcohol dehydrogenase restricts the ability of the pathogen Candida albicans to form a biofilm on catheter surfaces through an ethanol-based mechanism. Infect Immun. 2006;74(7):3804-16. PMCID: 1489753.
19. Chandra J, McCormick TS, Imamura Y, Mukherjee PK, **Ghannoum MA**. Interaction of Candida albicans

with adherent human peripheral blood mononuclear cells increases C. albicans biofilm formation and results in differential expression of pro- and anti-inflammatory cytokines. Infect Immun. 2007;75(5):2612-20. PMCID: 1865760.

20. Yeater KM, Chandra J, Cheng G, Mukherjee PK, Zhao X, Rodriguez-Zas SL, Kwast KE, **Ghannoum MA**, Hoyer LL. Temporal analysis of Candida albicans gene expression during biofilm development. Microbiology. 2007;153(Pt 8):2373-85.
21. Zumbuehl A, Ferreira L, Kuhn D, Astashkina A, Long L, Yeo Y, Iaconis T, **Ghannoum MA**, Fink GR, Langer R, Kohane DS. Antifungal hydrogels. Proc Natl Acad Sci U S A. 2007;104(32):12994-8. PMCID: 1941801.
22. Hameed S, Prasad T, Banerjee D, Chandra A, Mukhopadhyay CK, Goswami SK, Lattif AA, Chandra J, Mukherjee PK, **Ghannoum MA**, Prasad R. Iron deprivation induces EFG1-mediated hyphal development in Candida albicans without affecting biofilm formation. FEMS Yeast Res. 2008;8(5):744-55.
23. Imamura Y, Chandra J, Mukherjee PK, Lattif AA, Szczotka-Flynn LB, Pearlman E, Lass JH, O'Donnell K, **Ghannoum MA**. Fusarium and Candida albicans biofilms on soft contact lenses: model development, influence of lens type, and susceptibility to lens care solutions. Antimicrob Agents Chemother. 2008;52(1):171-82. PMCID: 2223913.

## C. Ongoing Research Support

**Ongoing**

2 R01 AI035097-09A2 — Ghannoum (PI) — Period: 12/1/2004-11/30/2009
NIH/NIAID
"Mechanism of IL-12 inhibition by *Candida albicans*"
The major goal of this project is to examine the ability of a soluble factor released by *Candida albicans* to inhibit the ability of normal human monocytes to induce the cytokine IL-12. This soluble IL-12 inhibitory factor (SIIF) will be assessed for its ability to alter the response of monocytes to challenge during *Candida* infections.

**AI-U01-68636** — Benson, Constance A. (PI) — Period: 6/29/2006 – 5/31/2013
NIH/NIDCR
Oral HIV/AIDS Research Alliance (OHARA) at Case
The major goal of this project is to establish a network of US and international investigators to conduct multidisciplinary clinical trials to optimize and support clinical management of oral co-morbidities associated with AIDS.

R01 DE017846 — Ghannoum Mahmoud A. (PI) — 12/1/2006 – 11/30/2011
NIH/NIDCR
Identification of early phase *C. albicans* biofilm proteins
The major goal of this project is to identify proteins expressed during early phase of *Candida* biofilm formation, and determine their role in biofilm formation *in vitro* and *in vivo*.

R01 EY018612-01 — Eric Pearlman (PI) — 09/1/2007–08/30/2012
NIH/Natl. Eye Instt.
Pathogenesis of Fungal Keratitis
The major goal of this project is to examine the pathogenesis of Fusarium solani keratitis, a disease usually found in individuals who have exposure to the soil where spore of the etiologic agent exist, but more recently seen in contact lens wearers who used contaminated lens solution..

**Pending Research Support**

None.

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Higgins, Patricia A.** | POSITION TITLE<br>Associate Professor |
| eRA COMMONS USER NAME **PHIGGINS** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| University of Akron, Akron, OH | BSN | 1986 | Nursing |
| Case Western Reserve University (CWRU), Cleveland, | MSN | 1989 | Nursing |
| CWRU, Cleveland, OH | PhD | 1996 | Nursing |

**A. Positions and Honors**

**Positions and Employment**

1971 Charge Nurse, Medical-Surgical Nursing, University Hospitals, Cleveland, OH.
1971-1974 Charge Nurse, Intensive Care Unit, Mt. Auburn Hospital, Cambridge, MA.
1975-1979 Staff Nurse, Critical Care Units, Wooster Community Hospital (P/T), Wooster, OH.
1979-1981 Clinical Supervisor, Wooster Community Hospital (P/T), Wooster, OH.
1981-1982 Staff Nurse, Kidney Transplant Unit, Massachusetts General Hospital, Boston, MA.
1982-1986 Staff Nurse, Critical Care Units, Wooster Community Hospital (P/T), Wooster, OH.
1986-1987 Case Manager, Vesper Home Care, San Leandro, CA.
1987-1992 Research Assistant, School of Nursing, CWRU, Cleveland, OH.
1989 Case Manager/Data Collector, Alzheimer's Respite Program, Benjamin Rose Institute, Cleveland, OH.
1989-1990 Consultant, Home Care Division, Benjamin Rose Institute, Cleveland, OH.
1992-1995 Lecturer (part-time), School of Nursing, CWRU, Cleveland, OH.
1995-1996 Lecturer, School of Nursing, CWRU, Cleveland, OH.
1996-2006 Assistant Professor, School of Nursing, CWRU, Cleveland, OH.
2000-Pres Researcher, VISN 10 Geriatric Research and Educational Clinical Center (GRECC), Louis Stokes Veterans Administration Medical Center (LSVAMC), Cleveland, OH
2006-Pres Associate Professor, School of Nursing, CWRU, Cleveland, OH

**Honors**

1986 Sigma Theta Tau;
1989 Mildred L. Tuttle Scholar, Frances Payne Bolton School of Nursing, CWRU
1989 Rebecca and Samuel H. Elliot Award for Community Service, Frances Payne Bolton School of Nursing, CWRU
1997 "Top Prof " Award-Mortar Board, CWRU
2004 Distinguished Alumni Award, Outstanding Contribution to Nursing Education, Akron University College of Nursing

**B. Selected peer-reviewed publications**

1. Higgins, P. A. (1998). Patient perception of fatigue while undergoing long-term mechanical ventilation: Incidence and associated factors. *Heart & Lung*, *27*(3), 177-83.
2. Higgins, P. A., & Daly, B. J. (1999). Research methodology issues related to interviewing the long-term ventilator patient. *Western Journal of Nursing Research*, *21*, 773-84.
3. Higgins, P. A. & Moore, S. M. (2000). Levels of theoretical thinking in nursing. *Nursing Outlook*, *48*, 179-83.

4. Higgins, P. A., & Daly, B. J. (2002). Knowledge and beliefs of nurse researchers about informed consent principles and regulations. *Journal of Nursing Ethics, 9*(6), 663-71.
5. Higgins, PA & Daly, BJ. (2005). Adult failure to thrive in the older rehabilitation patient. *Rehabilitation Nursing,* 30,152-159.
6. Winkelman, C, Higgins, PA, Chen, Y. (2005). Activity in the chronically critically ill. *Dimensions of Critical Care Nursing, 24*(6), 281-290.
7. Higgins, PA, Daly, BJ, Lipson, AR, Guo S. (2006). Assessing nutritional status in chronically critically ill adult patients. *American Journal of Critical Care, 15*(2),166-177.
8. Higgins, PA & Straub, AJ (2006). Understanding the error of our ways: Mapping the concepts of validity and reliability. *Nursing Outlook,* 54, 23-29.
9. Higgins, PA, Winkelman C, Lipson, AR, Guo, S & Rodgers, J. (January, 2007). Light measurement in the hospital: A comparison of two methods. Research in Nursing and Health, 30, 120-128.
10. Winkelman, C., Higgins, P., Chen, Y., Levine, A. (2007). Cytokines in long-term ventilated ICU patients after activity and rest. Biological Research for Nursing 8, 261-271.
11. Lee, J. & Higgins, PA. (2008). Predicting post-hospital recovery of physical function among older adults following lower extremity surgery in a short-stay skilled nursing facility. Rehabilitation Nursing, 33(4): 170-177.
12. Murrock, C. J., Higgins, P. A., & Killion, C. (2009). Diabetes outcomes in African American women following a dance intervention. Diabetes Educator, Nov-Dec;35(6):995-1003.
13. Higgins P.A., Hornick T.R., Figueiro M.G. (2010). Rest-Activity and Light Exposure Patterns in the Home Setting: A Methodological Case Study. American Journal of Alzheimer's Disease and Other Dementias, Jun;25(4):353-61. PMID: 20237336
14. Johansson AC, Durning SJ, Gruppen LD, Olson ME, Schwartzstein RM, Higgins PA. Perspective: Medical Education Research and the Institutional Review Board: Reexamining the Process. Academic Medicine. 2011 Jul;86(7):809-17. PMID: 21617512
15. Clark; HL, Banks; R, Jones, L, Hornick, TR, Higgins, PA, Burant, C, & Canaday, DH. Characterization of MHC-II antigen presentation by B cells and monocytes from older individuals. Clinical Immunology. 2012 Aug;144(2):172-7. PMID: 22797466

**C. Research Support**

**Ongoing Research Support**

NCATS (Davis, PI) Annual direct costs: $12,471,965 9/2012-5/2017
NIH 1.2 calendar months
*Institutional Clinical and Translational Science Award (CTSA)*
The purpose of this second funding period is to continue coordinating existing resources relevant to clinical research at Case Western Reserve University and three of its hospital affiliates, the Cleveland Clinic, MetroHealth Medical Center, and University Hospitals Case Medical Center. In addition, new resources will be created, including community partnership resources, a new coordinated bioinformatics infrastructure, a new MD/DNP-Ph.D. program in clinical research, and coordinated resources in bioethics and regulatory support.
Role: Co-Chair of Evaluation Committee
There is no budgetary or scientific overlap.

R01 AG034157-01A2 Figueiro (PI) 05/01/10-04/30/14
NIH
*Methodology Issues in a Tailored Light Treatment for Persons with Dementia*
This study will develop field measurement methodologies for obtaining accurate light-dark exposure and activity-rest patterns in individuals with dementia using the "dime-simeter", a portable precisely calibrated device that continuously records circadian (and visual) light as well as activity for several days or weeks; 2) implement and test the efficacy of a practical, but scientifically sophisticated day-night lighting system designed to improve

entrainment to the solar day and thereby improve sleep-wake patterns and quality in persons with ADRD. There is no budgetary or scientific overlap.
Role: Co-Investigator, Clinical site PI.

Cleveland Veterans Affairs Medical Center (T. Hornick & P Higgins, Co-PI's) 6/2010-6/2013
Cleveland VAMC Geriatric Research and Education Center (GRECC)
*Assessing Frailty in the Geriatric Clinic*
There is a growing body of research on frailty. Conceptualization and measurement, however, remain a challenge. There also is little information on how well the reliable and validated research instruments translate into geriatric practice. We are conducting a feasibility and comparison study, administering two instruments (Fried and Gill, both commonly used in research) during regularly scheduled appointments in the VA Geriatrics Clinic. Chart abstraction data provide clinical characteristics and outcome data. There is no budgetary or scientific overlap.

I01 CX000249-02 Canaday (PI) 10/01/09-09/30/12
Veterans Health Administration
*Predictors of Immunologic Failure in Older Adults*
This study will test the hypotheses that age plus a biobehavioral measure of frailty will predict immunologic and vaccination failure in older adults and that frailty will be a stronger predictor than age of immunologic and vaccine failure. There is no budgetary or scientific overlap.
Role: Co-Investigator

P30 NR010676 (S. Moore, PI) 9/29/07-6/30/12
NIH/NINR
*Center of Excellence to Build the Science of Self-Management: A systems approach*
The SMART Center will prepare a critical mass of researchers to extend and disseminate knowledge of self-management science. No-cost extension as of July 1, 2012.
Role: Faculty Mentor; Scholarship and Mentoring Core committee member (9/29/07-5/31/10)
Director, Evaluation Core (6/1/10-6/30/12)

VISN 10 RIP Award Karim (PI) 10/01/11-09/30/12
Veterans Health Administration
***Implementation of the Spaced Retrieval Technique by Caregivers***
This feasibility study will test an innovative teaching/learning strategy designed to promote safer physical functioning in older adults with dementia. The purpose of this study is to 1) investigate the feasibility of teaching a caregiver spaced retrieval methodology and 2) examine their use of spaced retrieval to improve a functional mobility task in persons with dementia. There is no budgetary or scientific overlap. Currently in no-cost extension to complete Center reports.
Role: Co-Investigator & Mentor

**Completed Research Support**
American Society of Pain Management Nurses Bernhofer (PI) 07/12/11-07/11/12
*Light, Sleep, Mood, and Pain in Medical Inpatients*
The goals of this dissertation study are to describe light exposure, sleep-wake disturbances, mood, and pain in hospitalized adult medical patients and to investigate the relationships among these variables. The long-term goal of this program of research is to develop intervention studies involving manipulation of hospital lighting to treat sleep-wake disturbances, mood, and pain.
Role: Co-Investigator & Dissertation Chair

5U54RR024989 (Davis, PI) 9/17/07-5/31/12
NIH Annual direct costs: $12,471,965
***Institutional Clinical and Translational Science Award (CTSA)***
The purpose of this grant is to coordinate existing resources relevant to clinical research at Case Western Reserve University and three of its hospital affiliates, the Cleveland Clinic, MetroHealth Medical Center, and University Hospitals Case Medical Center, including integrating the three existing GCRC facilities, a successful multidisciplinary institutional K12 program, substantial technological and statistical core facilities, and our famous practice-based research networks. In addition, new resources will be created, including community partnership resources, a new coordinated bioinformatics infrastructure, a new M.D-Ph.D. program in clinical research, and coordinated resources in bioethics and regulatory support.
Role: Co-Chair of Evaluation Committee
There is no budgetary or scientific overlap.

T32 NR009761-05 Moore (PI) 05/18/06-04/30/12
NIH
**Multiple Morbidities in Vulnerable Populations: Nurse Scientist Training**
The goal of this pre- and post-doctoral training program, which incorporates complexity science in its conceptual framework, is to provide research training for nurses pursuing research careers focused on vulnerable populations with multiple morbidities.
Role: Core Faculty

Frances Payne Bolton School of Nursing (P. Higgins/T. Hornick, Co-PIs ) 07/01/07-06/30/09
Case Western Reserve University
**Circadian Rhythms and Light Exposure in Caregiving Elders of Persons with Dementia**
Piloted new technology (Daysimeter™) to investigate circadian and photopic light exposure, melatonin, and rest-activity patterns in community-dwelling dyads (an elder with dementia and their caregiver).

NSF 02-121 Singer (PI) 10/01/03-09/30/08
National Science Foundation
**ADVANCE Institutional Transformation Award Cooperative Agreement**
Contributed to the development of a national science and engineering academic workforce that includes the full participation of women at all levels of faculty and academic leadership through the transformation of CWRU's institutional practices, policies, climate and culture.
Role: Evaluation research committee

NINR RO1 Higgins (PI) 09/01/01-06/30/06
NIH
**Adult Failure to Thrive in the Long-term Ventilator Patient**
Contributed to the understanding of adults with chronic critical illness through the investigation of the relationships among Failure to Thrive (FTT) factors of physical function, cognitive impairment, nutritional status, and depressed mood, and FTT factors and clinical outcomes of weaning success and discharge outcomes.

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Ismail-Beigi, Faramarz** | POSITION TITLE<br>Professor of Medicine, Physiology and Biophysics |
| eRA COMMONS USER NAME **FISMAILBEIGI** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Berea College, Berea, Kentucky | B.A. | 05/62 | Chemistry |
| Johns Hopkins University | M.D. | 05/66 | Medicine |
| University of California, San Francisco and Berkeley | Ph.D. | 02/72 | Biophysics |

**A. Positions and Honors**

**Positions and Employment**

1962-66 Part-time work (summers and during medical school) under Sidney P. Colowick at Vanderbilt University (studies on glycolytic enzymes) and subsequently under Dr. Robert Langdon in the Department of Physiological Chemistry at Johns Hopkins University (characterization of adenylate cyclase in rat heart and liver).
1966-68 Intern and resident, Osler Medical Service, Johns Hopkins Hospital.
1968-71 Postdoctoral Research Fellow and Ph.D. Candidate, University of CA, San Francisco and Berkeley, CA.
1971-72 Senior Resident, Osler Medical Service, Johns Hopkins Hospital, Baltimore, MD.
1972-82 Associate Professor and Professor of Medicine and Physiology, Chairman, Department of Internal Medicine, Pahlavi University, Shiraz, Iran.
1984-91 Associate Professor of Medicine, Columbia University, New York.
1989-92 Member, Physiology Study Section, NIH.
1991-93 Professor of Clinical Medicine, Columbia University, NY.
1992-2008 Member, Editorial Board, *American Journal of Physiology (Cell Physiology).*
1993-2007 Professor of Medicine and Chief, Division of Clinical and Molecular Endocrinology, Case Western Reserve University, Cleveland, OH
1997-2008 Member, Board of Trustees, Diabetes Association of Greater Cleveland
1997-2009 Member, Editorial Board, *Archives Biochemistry and Biophysics*
2007-2009 Member, Editorial Board, *Journal of Biological Chemistry*
1993 - Professor of Medicine, Physiology and Biophysics, and Biochemistry, Case Western Reserve University, Cleveland, OH
1993- Staff Physician Cleveland VA
2003-2009 Diabetes PI, BARI-2D Trial, University Hospitals of Cleveland
2001- PI of ACCORD and ACCORDION Trials for the Ohio/Michigan Network

**Honors**

1965 Phi Beta Kappa; Alpha Omega Alpha
1962-66 Beaumont full-tuition scholarship, Johns Hopkins University School of Medicine
1968-71 Bay Area Heart Association Fellowship Award, University of California

**B. Selected Peer-Reviewed Publications (Selected from 169 peer-reviewed publications)**

**Most relevant to the current application**

The ACCORD STUDY GROUP (member of the writing team). Effects of Intensive Glucose Lowering in Type 2 Diabetes. N Engl J Med, 358: 2545-2559 (2008). PMID: 18539917

Ismail-Beigi, F., Craven, T., Banerji, M. A., et al. Effect of Intensive Treatment of Hyperglycemia on Microvascular Complications of Type 2 Diabetes: An Analysis of the ACCORD Randomized Trial. Lancet, 376: 419-430 (2010). PMID: 20594588

Nyalakonda, K., Sharma, T, and Ismail-Beigi, F. Preservation of Beta Cell Function in Type 2 Diabetes. Endocr Practice, 16: 1038-1055 (2010). PMID: 21030360

Ismail-Beigi, F. Action to Control Cardiovascular Risk in Diabetes (ACCORD) Trial: Clinical Implications. Clin Chem, 57: 261-263 (2011). PMID: 20974799

Gerstein, H., et al. (member of the writing team). Long-Term Effects of Intensive Glucose Lowering on Cardiovascular Outcomes. N Engl J Med, 364: 818-828 (2011). PMID: 21366473

Handelsman Y, et al. (member of the writing team). American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Developing a Diabetes Mellitus Comprehensive Care Plan. Endocr Pract, 17:287-302 (2011). PMID: 21474421

Ismail-Beigi, F., Moghissi, E., Tiktin, M., Hirsch, I. B., Inzucchi, S., and Genuth, S. Individualizing Glycemic Targets in Type 2 Diabetes: Implications of Recent Clinical Trials. Ann Intern Med, 154: 554-559 (2011). PMID: 21502652

Ismail-Beigi, F., Craven, T. E., O'Connor, P. J., Karl, D., et al. Combined Intensive Blood Pressure and Glycemic Control Does Not Produce an Additive Benefit on Microvascular Outcomes in Type 2 Diabetic Patients. Kidney International, 81: 586-594 (2012); PMID: 22166848

Coca, S. G., Haq, N., Ismail-Beigi, F., Thompson, A., Krumholz, H. M., Parikh, C. R. Intensive Glucose Control in Type 2 Diabetes and Benefits to the Kidney: Systematic Review and Meta-analysis. Arch Intern Med. 172:761-769 (2012); PMID: 22636820

Ismail-Beigi, F. Glycemic Management of Type 2 Diabetes. N Engl J Med, 366:1319-1327 (2012). PMID: 22475595

**Additional recent publications of importance to the field (in chronological order)**

Behrooz, A., and Ismail-Beigi F. Dual control of GLUT1 glucose transporter gene expression by hypoxia and by inhibition of oxidative phosphorylation. J. Biol. Chem. 272: 5555-5562 (1997) PMID: 9038162 PMID: 9038162

Badr, G.A., Tang, JI, Ismail-Beigi, F., and Kern, T.S. Diabetes down-regulates glucose transporter (Glut1) expression in retina and its microvessels, but not in cerebral cortex or its microvessels. Diabetes 49:1016-1021 (2000) PMID: 10866055

Jing, M. and Ismail-Beigi, F. Role of 5'-AMP-activated protein kinase in the stimulation of glucose transport in response to inhibition of oxidative phosphorylation. Am. J. Physiol. 59: C484-C491 (2006) PMID: 16162657

Ismail-Beigi, F., Catalano, P. M., and Hanson, R. W. Metabolic programming: Fetal origins of obesity and metabolic syndrome in the adult. Am. J. Physiol. 291: E439-E440 (2006) PMID: 16638823

Jing, M., and Ismail-Beigi, F. Stimulation of Glucose Transport in Response to Activation of Distinct AMPK Signaling Pathways. Am. J. Physiol. 295: C1071-1082 (2008) PMID: 16943243

Spring-Robinson, C., Chandramouli, V., Schumann, W. C., Faulhaber, P. F., Wang, Y., WU, C., Ismail-Beigi, F., and Muzic, M. F. Uptake of 18F-labeled 6-Fluoro-6-deoxy-D-glucose by skeletal muscle is responsive to insulin stimulation. J. Nucl. Med. 50: 912-919 (2009). PMID: 19443592

Zhao. M., Wan, Z., Whittaker, L., Xu, B., Phillips, N. B., Katsoyannis, P. G., Ismail Beigi, F., Whittaker, J., and Weiss, M. A. Design of an insulin analog with enhanced receptor binding selectivity: Rationale, structure, and therapeutic implications. J. Biol. Chem. 284: 32178-32187 (2009). PMCID: PMC2797288

Yang, Y., Petkova, A., Huang, K., Xu, B., Hua, Q., Ye, I-J., Chu, Y-C., Hu, S-Q., Phillips, NB., Whittaker, J., Ismail-Beigi, F., Mackin, RB., Katsoyannis, PG., Tycko, R., and Weiss, MA. An Achilles' Heel in an amyloidogenic protein and its repair: Insulin fibrillation and therapeutic design. J. Biol. Chem., 285:10806-10821 (2010). PMCID: PMC2856287

## C. Research Support

**Ongoing Research Support**

ACCORDION Follow-on Study. Ismail-Beigi (PI) 01/01/2011-12/31/2014
NIH/NHLBI
This is a follow-on project of the ACCORD trial. ACCORD is a type 2 diabetes clinical trial with 2 glycemia goals (Hb A1c of <6.0% versus 7.5%), systolic BP of <140 versus 120 mm Hg, and placebo versus fenofibrate with adequate reduction of LDL with simvastatin.
Role: PI of Ohio/Michigan Network and VAMC site

RO1 DK082423 Ismail-Beigi, Muzic (Co-PIs) 07/01/2009-06/30/2013
NIH/NIDDK
Novel PET Imaging of Glucose Transport.
The goal of this project is to develop new probes for non-invasive imaging of glucose transport in humans.
Role: Co-PI

RO1 DK079233 Weiss (PI) 04/10/2008-03/31/2013
NIH
Novel Insulin Analogues.
This proposal creates and tests novel insulins, specifically single-chain insulins.
Role: Co-Investigator

ADA#1-11-IN-31 Whittaker (PI) 01/01/2011-12/31/2012
American Diabetes Association
Novel receptor selective, low mitogenicity insulin analogs. Novel insulin prepared (in collaboration with Dr. M. Weiss) are to be tested for binding to insulin receptors and IGF-1 receptors.
Role: Co-Investigator

SBIR R43DK092041-01 PI: Frank ( F. Ismail-Beigi as Co-Investigator); 09/01/11 – 08/31/12
Optimized Receptor Binding Profile in an Ultra-Stable, Ultra-Rapid-Acting Insulin

R01 DK096549 - 01A1 (PI: Steven G Coca). F. Ismail-Beigi, Co-Investigator; 2012-2017
Novel Serum and Urinary Biomarkers of Diabetic Kidney Disease.

NIDDK 1U01DK098246 John Lachin (PI), F. Ismail-Beigi PI of the Cleveland site. 2012-2019
Selected as a site for the upcoming GRADE trial; a comparative efficacy study of early treatment of type 2 diabetes.

**Completed Research Support**

NIH-HL-HC-99-16 Ismail-Beigi (PI) 09/30/1999-12/31//2010
Action to Control Cardiovascular Risk in Diabetes (ACCORD)
This project is a type 2 diabetes clinical trial with 2 glycemia goals (Hb A1c of <6.0% versus 7.5%), systolic BP of <140 versus 120 mm Hg, and placebo versus fenofibrate with adequate reduction of LDL with simvastatin.

Role: PI

HL-061746 Adler, Ismail-Beigi (PI) 09/01/2000-11/01/2008
NHLBI (NIH)
Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI 2D) Trial.
The goal of this project was to compare insulin sensitizing agents versus insulin or insulin producing agents.
Role: Co-PI.

RO1 DK61994-01A1 (NIH) Ismail-Beigi (PI) 07/01/2003-06/30/2007
Regulation of Glut1 Function (Continuation of RO1-DK45945).
The goal of this project was to identify novel mechanisms of Glut 1 regulation.
Role: Co-PI

RO1-HL03008 Redline (PI) 09/01/2003-09/29/2007
NIH-NIDDK
The effect of sleep apnea treatment on metabolic syndrome.
The project examined whether treatment of sleep apnea improves the insulin-resistant state of obese patients in the pre-diabetic stage.
Role: Co-Investigator

PO1-HL18708 Dubyak (PI) 02/01/2002-01/31/2007
NIH
Cardiac Bioenergetics: Thyroid hormone control of Na,K-ATPase expression.
The goal of this project was to determine the role of thyroid hormone on Na,K-ATPase expression.
Role: PI of Project #2

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Sudha K. Iyengar** | POSITION TITLE<br>Professor, Epidemiology and Biostatistics, Ophthalmology and Genetics |
| eRA COMMONS USER NAME **siyengar** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| University of Bombay, India | BS | 1984 | Life Sciences; Biochemistry |
| University of Bombay, India | Post-BS | 1985 | Biochemistry |
| University of Pittsburgh, PA | MS | 1988 | Genetics |
| University of Pittsburgh, PA | PhD | 1992 | Genetics |

## A. Positions and Honors

**Positions**

1982-1984 Lab Assistant, Life Sciences, University of Bombay, St. Xavier College, Dept of Life Sciences
1985-1986 Research Assistant, Program in Human Genetics, Dept of Biostatistics, University of Pittsburgh
1986-1992 Graduate Student Researcher, Dept of Human Genetics, University of Pittsburgh
1992-1996 Post doctoral fellow, Dept of Genetics, Yale University School of Medicine
1994-1997 Consultant, San Luis Valley Diabetes Study, Dept of Human Genetics, GSPH, University of Pittsburgh
1997- Director of Genotyping Laboratory, Dept of Epidemiology & Biostatistics, Case Western Reserve University
1997-1999 Senior Instructor, Dept of Epidemiology & Biostatistics, Case Western Reserve University
1999- 2003 Assistant Professor, Dept of Epidemiology & Biostatistics, Case Western Reserve University
2003- 2009 Associate Professor, Dept of Epidemiology & Biostatistics, Case Western Reserve University
2003- 2009 Associate Professor, Dept of Ophthalmology, Case Western Reserve University
2005- 2009 Associate Professor, Dept of Genetics, Case Western Reserve University
2009- Professor, Dept of Epidemiology & Biostatistics, Ophthalmology and Genetics, Case Western Reserve University

**Awards/Other Professional Memberships**

1998 Jacobs Award, American Heart Association, Project: Genetic susceptibility to end-stage renal disease among hypertensives
1998-2001 MetroHealth Medical Center IRB Committee

## B. Selected peer-reviewed publications of 100+ (in chronological order since 2008)

1. Arar NH, Freedman BI, Adler SG, **Iyengar SK**, Chew EY, Davis MD, Satko SG, Bowden DW, Duggirala R, Elston RC, Guo X, Hanson RL, Igo RP Jr, Ipp E, Kimmel PL, Knowler WC, Molineros J, Nelson RG, Pahl MV, Quade SR, Rasooly RS, Rotter JI, Saad MF, Scavini M, Schelling JR, Sedor JR, Shah VO, Zager PG, Abboud HE; Family Investigation of Nephropathy and Diabetes Research Group. 2008. Heritability of the severity of diabetic retinopathy: the FIND-Eye study. Invest Ophthalmol Vis Sci. Sep;49(9):3839-45. PMCID: PMC2583147

2. Kao WH, Klag MJ, Meoni LA, Reich D, Berthier-Schaad Y, Li M, Coresh J, Patterson N, Tandon A, Powe NR, Fink NE, Sadler JH, Weir MR, Abboud HE, Adler SG, Divers J, **Iyengar SK**, Freedman BI, Kimmel PL, Knowler WC, Kohn OF, Kramp K, Leehey DJ, Nicholas SB, Pahl MV, Schelling JR, Sedor JR, Thornley-Brown D, Winkler CA, Smith MW, Parekh RS; Family Investigation of Nephropathy and Diabetes

Research Group. 2008. MYH9 is associated with nondiabetic end-stage renal disease in African Americans. Nat Genet. 40(10):1185-92. PMCID: PMC2614692

3. SanGiovanni JP, Arking DE, **Iyengar SK**, Elashoff M, Clemons TE, Reed GF, Henning AK, Sivakumaran TA, Xu X, DeWan A, Agrón E, Rochtchina E, Sue CM, Wang JJ, Mitchell P, Hoh J, Francis PJ, Klein ML, Chew EY, Chakravarti A. 2009. Mitochondrial DNA variants of respiratory complex I that uniquely characterize haplogroup T2 are associated with increased risk of age-related macular degeneration. PLoS One. 4(5):e5508. Epub 2009 May 12. PMCID: PMC2677106

4. Jun G*, Guo H, Klein BE, Klein R, Wang JJ, Mitchell P, Miao H, Lee KE, Joshi T, Buck M, Chugha P, Bardenstein D, Klein AP, Bailey-Wilson JE, Gong X, Spector TD, Andrew T, Hammond CJ, Elston RC, **Iyengar SK**, Wang B. 2009. EPHA2 is associated with age-related cortical cataract in mice and humans**.** PLoS Genet. 5(7):e1000584. Epub 2009 Jul 31.PMCID: PMC2712078

5. Chen W, Stambolian D, Edwards AO, Branham KE, Othman M, Jakobsdottir J, Tosakulwong N, Pericak-Vance MA, Campochiaro PA, Klein ML, Tan PL, Conley YP, Kanda A, Kopplin L, Li Y, Augustaitis KJ, Karoukis AJ, Scott WK, Agarwal A, Kovach JL, Schwartz SG, Postel EA, Brooks M, Baratz KH, Brown WL, Complication of Age-Related Macular Degeneration Prevention Trial Research Group, Brucker AJ, Orlin A, Brown G, Ho A, Regillo C, Donoso L, Tian L, Kaderli B, Hadley D, Hagstrom SA, Peachey NS, Klein R, Klein BE, Gotoh N, Yamashiro K, Ferriss Lii F, Fagerness JA, Reynolds R, Farrer LA, Kim IK, Miller JW, Corton M, Carracedo A, Sanchez-Salorio M, Pugh EW, Doheny KF, Brion M, Deangelis MM, Weeks DE, Zack DJ, Chew EY, Heckenlively JR, Yoshimura N, **Iyengar SK**, Francis PJ, Katsanis N, Seddon JM, Haines JL, Gorin MB, Abecasis GR, Swaroop A. Genetic variants near TIMP3 and high-density lipoprotein-associated loci influence susceptibility to age-related macular degeneration. Proc Natl Acad Sci U S A 2010 Apr 20;107(16):7401-6. PMCID: PMC286722

6. Kopplin LJ*, Igo Jr. PR, Wang Y, Sivakumaran TA, Hagstrom SA, Peachey NS, Francis PJ, Klein ML, SanGiovanni JP, Chew EY, Pauer GJT, Sturgill GM, Joshi T, Tian L, Xi Q, Henning AK, Lee KE, Klein R, Klein BEK, **Iyengar SK.** Genome-wide association identifies SKIV2L and MYRIP as protective factors for age-related macular degeneration. Genes Immun. 2010 Dec;11(8):609-21. Epub 2010 Sep 23. PMCID: PMC3375062

7. Ikram MK, Xueling S, Jensen RA, Cotch MF, Hewitt AW, Ikram MA, Wang JJ, Klein RK, Klein KEK, Breteler MMB, Cheung N, Liew G, Mitchell P, Uitterlinden AG, Rivadeneira F, Hofman A, de Jong PTVM, van Duijn CM, Kao L, Cheung CY, Smith AV, Glazer NL, Lumley T, McKnight B, Psaty BM, Jonasson F, Eiriksdottir G, Aspelund T, Global BPgen Consortium, Harris TB, Launer LJ, Taylor KD, Li X, **Iyengar SK,** Xi Q, Sivakumaran TA, Mackey DA, MacGregor S, Martin NG, Young TL, Bis JC, Wiggins KL, Heckbert SR, Hammond CJ, Andrew T, Fahy S, Attia J, Holliday EG, Scott RJ, Islam FMA, Rotter JI, McAuley AK, Boerwinkle E, Tai ES, Gudnason V, Siscovick DS, Vingerling JR, Wong TY. Four novel loci (19q13, 6q24, 12q24, and 5q14) influence the microcirculation in vivo. PLoS Genet. 2010 Oct 28;6(10):e1001184. PCMID: PMC2965750

8. Louttit MD, Kopplin LJ*, Igo Jr RP, Fondran JR, Tagliaferri A, Bardenstein D, Aldave, AJ, Croasdale CR, Price M, Rosenwasser GO, Lass JH, **Iyengar SK** for the FECD Genetics Multi-Center Study Group. (2010) A Multi-Center Study to Map Genes for Fuchs' Endothelial Corneal Dystrophy: Baseline Characteristics and Heritability. Cornea. 2012 Jan;31(1):26-35; PMID: 22045388

9. Li X, Bykhovskaya Y, Haritunians T, Siscovick D, Aldave A, Szczotka-Flynn L, **Iyengar SK**, Rotter JI, Talyor KD, Rabinowitz Y. A genome-wide association study identifies novel gene loci for keratoconus, one of the commonest causes for corneal transplantation in developed countries. Hum Mol Genet. 2012 Jan 15;21(2):421-9. Epub 2011 Oct 6. PCMID: PMC3276283

10. Kopplin LJ*, Przepyszny K, Schmotzer B, Rudo K, Babineau DC, Patel SV, Verdier DD, Jurkunas U, **Iyengar SK**, Lass JH; Fuchs' Endothelial Corneal Dystrophy Genetics Multi-Center Study Group. Relationship of Fuchs Endothelial Corneal Dystrophy Severity to Central Corneal Thickness. Arch Ophthalmol. 2012 Apr;130(4):433-9. PMID: 22491913

11. Fritsche LG, Chen W, Schu M, Yaspan BL, Yu Y, Thorleifsson G, Zack DJ, Arakawa S, Cipriani V, Ripke S, Igo, Jr., RP, Buitendijk GHS, Sim X, Weeks DE, Guymer RH, Merriam JE, Francis PJ, Hannum G, Agarwal A, Armbrecht AM, Audo I, Aung T, Barile GR, Benchaboune M, Bird AC, Bishop PN, Branham KE, Brooks M, Brucker AJ, Cade WH, Cain MS, Campochiaro PA, Chan CC, Cheng CY, Chew EY, Chin KA, Chowers I, Clayton DJ, Cojocaru R, Conley YP, Cornes BK, Daly MJ, Dhillon B, Edwards AO, Evangelou E, Fagerness J, Ferreyra HA, Friedman JS, Geirsdottir A, George RJ, Gieger C, Gupta N, Hagstrom SA, Harding SP, Haritoglou C, Heckenlively JR, Holz FG, Hughes G, Ioannidis JPA, Ishibashi T, Joseph P, Jun G, Kamatani Y, Katsanis N, Keilhauer CN, Khan JC, Kim IK, Kiyohara Y, Klein BEK, Klein R, Kovach JL, Kozak I, Lee CJ, Lee KE, Lichtner P, Lotery AJ, Meitinger T, Mitchell P, Mohand-Saïd S, Moore AT, Morgan DJ, Morrison MA, Myers CE, Naj AC, Nakamura Y, Okada Y, Orlin A, Ortube MC, Othman MI, Pappas C, Park KH, Pauer GJT, Peachey NS, Poch O, Priya RR, Reynolds R, Richardson AJ, Ripp R, Rudolph G, Ryu E, Sahel JA, Schaumberg DA, Scholl HPN, Schwartz SG, Scott WK, Shahid H, Sigurdsson H, Silvestri G, Sivakumaran TA, Smith RT, Sobrin L, Souied EH, Stambolian DE, Stefansson H, Sturgill-Short GM, Takahashi S, Tosakulwong N, Truitt BJ, Tsironi EE, Uitterlinden AG, van Duijn CM, Vijaya L, Vingerling JR, Vithana EN, Webster AR, Wichmann HE, Winkler TW, Wong TY, Wright AF, Zelenika D, Zhang L, Zhao L, Zhang K, Klein ML, Hageman GS, Lathrop GM, Stefansson K, Allikmets R, Baird PN, Gorin MB, Wang JJ, Klaver CCW, Seddon JM, Pericak-Vance MA, **Iyengar SK**, Yates JRW, Swaroop A, Weber BHF, Kubo M, DeAngelis MM, Léveillard T, Thorsteinsdottir U, Haines JL, Farrer LA, Heid IM, Abecasis G. Seven new loci associated with age-related macular degeneration. Nature Genetics (in press)

12. Verhoeven VJM, Hysi PG, Wojciechowski R, Fan Q, Guggenheim JA, Höhn R, MacGregor S, Hewitt AJ, Nag A, Cheng CY, Yonova-Doing E, Zhou X, Ikram MK, Buitendijk GHS, McMahon G, Kemp JP, St. Pourcain B, Simpson CL, Mäkelä KM, Lehtimäki T, Kähönen M, Paterson AD, Hosseini SM, Wong HS, Xu L, Jonas JB, Pärssinen O, Wedenoja J, Yip SP, Ho DWH, Pang CP, Chen LJ, Burdon KP, Craig JE, Klein BEK, Klein R, Haller T, Metspalu A, Khor CC, Tai ES, Aung T, Vithana E, Tay WT, Barathi VA, CREAM, Chen P, Li R, Liao J, Zheng Y, Ong RT, Döring A, DCCT/EDIC Research Group, Evans DM, Timpson NJ,. Verkerk AJMH, Meitinger T, Raitakari O, Hawthorne F, Spector TD, Karssen LC, Pirastu M, Murgia F, Ang W, WTCCC2, Mishra A, Montgomery GW, Pennell CE, Cumberland PM, Cotlarciuc I, Mitchell P, Wang JJ, Schache M, Janmahasathian S*, Igo Jr, RPI, Lass JH, Chew EY, **Iyengar SK**, the Fuchs' Genetics Multi-Center Study Group, Gorgels TGMF, Rudan I, Hayward C, Wright AF, Polasek O, Vatavuk Z, Wilson JF, Fleck B, Zeller T, Mirshahi A, Müller C, Uitterlinden AG, Rivadeneira F, Vingerling JR, Hofman A, Oostra BA, Amin N, Bergen AAB, Teo YY, Rahi JS, Vitart V, Williams C, Baird PN, Wong TY, Oexle K, Pfeiffer N, Mackey DA, Young TL, van Duijn CM, Saw SM, Bailey-Wilson JE, Stambolian D, Klaver CCW, Hammond CJ. Genome-wide meta-analyses of multi-ethnic cohorts identify multiple new susceptibility loci for refractive error and myopia. Nature Genetics (in press)

## C. Research Support

**<u>Current</u>**

Research Award (Iyengar) 10/01/2012-09/30/2013
The International Retinal Research Foundation
*Refining AMD Causal Variation Using Epigenetics*
The study proposes to identify retina-specific regulatory elements that influence the gene regulation of *ARMS2/HTRA1* by capturing functionally operational enhancer-promoter interactions in retinal pigment epithelial

cells. This study will provide a greater understanding of the role of non-coding regions in the regulation of *ARMS2/HTRA1* loci and will also provide the information about the influence of *ARMS2* on the expression of *HTRA1*.

R01DC01238001 (Iyengar) 09/01/2012-08/31/2017
NIH/NIDCD
*Genetic Causes of Severe Developmental Speech Sound Disorder in Families*
This study aims to perform high-resolution genotyping using the Illumina Omni 2.5-8 chip in families with SSD, sequence the exome of N=145 trios and discover rare exonic variants in children with severe SSD and their founders and prioritize and classify variants and genomic regions by integrating data from high-density genotyping and exome sequencing using novel methods.

1R01EY023196-01 (Iyengar) 03/01/2013-02/28/2016
NIH/ NEI
*Integrative Genetic Analyses in Fuchs Endothelial Corneal Dystrophy*
This study aims to co-ordinate continued activities of the consortium through development of a centralized infrastructure for analysis and data exchange, delineate the genetic architecture of Fuchs Endothelial Corneal Dystrophy by pursuing detailed secondary analysis of our genome-wide association study (GWAS) and to perform robust replication of the genome-wide significant loci via meta-analyses.

U10EY006594-23 (Klein) 09/30/2010-09/29/2013
NIH/NEI
*Epidemiology of Age-related Macular Degeneration and Other Retinal Diseases*
The Beaver Dam Eye Study cohort will have been under observation for 20 years allowing us to capitalize on this resource to determine the cumulative 20 year incidence, regression, progression, ageperiod-cohort models and transitional state models for AMD and other retinal diseases.

R01EY022302 (Sobrin) 09/01/2012-08/31/2013
NIH/NEI
*Multi-ethnic GWAS of diabetic retinopathy: enhanced power using new statistical methods*
This study aims to develop GWAS summary statistics without admixture association, increase power via liability threshold modeling of duration of diabetes and glycemic control and replicate and fine-map significant associations using DR cohorts from additional populations.
Role: Co-Investigator

R01DC000528 (Lewis) 09/19/2008-08/31/2013
NIH/NIDCD
*Familial Study of Severe Phonology Disorders*
The major goals of this project is to determine long-term outcomes of early childhood speech sound disorders and to identify factors related to the variability in outcomes of individuals with SSD.

**Completed**
R01EY016482-05 (Iyengar) 09/30/2005-08/31/2012
NIH/NEI
*Multi-Center Study to Map Genes for Fuchs' Dystrophy*
The major goals of this project is to propose to use the network built by the multi-center Corneal Donor Study (CDS) as the nexus to identify 500 families with Fuchs dystrophy using the consortium model.

U01 DK057292 (Iyengar) 09/30/1999–08/31/2011
NIH/NIDDK

*Linkage Consortium for End-stage Renal Disease*
The goals of this consortium are to acquire sets of families with well-characterized diabetic nephropathy, establish a secure master database, and to perform genetic scans to identify genes involved in diabetic nephropathy.

| BIOGRAPHICAL SKETCH | | | |
|---|---|---|---|
| NAME **Mukesh K. Jain** | POSITION TITLE<br>Ellery Sedgwick Jr. Chair, Professor of Medicine<br>Case Western Reserve University | | |
| eRA COMMONS USER NAME **MJ1234** | | | |
| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
| University of Buffalo | BS | 1987 | Biochemistry |
| University of Buffalo School of Medicine | MD | 1991 | Medicine |

## A. Position and Honors

**Positions**

1991-1994 Intern/resident, Beth Israel Hospital, Dept. of Medicine, Harvard Medical School
1994-1997 Research Fellow, Harvard School of Public Health, Harvard Medical School
1997-1999 Cardiology Fellow, Cardiovascular Division, Brigham&Women's Hospital, Harvard Medical School
1/00-6/04 Instructor, Cardiovascular Division, Brigham&Women's Hospital, Harvard Medical School
7/04-6/06 Assistant Professor, Cardiovascular Division, Brigham &Women's Hospital, Harvard Medical School
7/04-6/06 Director, Program in Cardiovascular Transcriptional Biology, Brigham &Women's Hospital, Harvard Medical School
7/06- Ellery Sedgwick Jr. Chair & Distinguished Scientist, Professor of Medicine, Director-Case Cardiovascular Research Institute and Chief Research Officer Harrington-McLaughlin Heart & Vascular Institute, University Hospitals Case Medical Center, Case Western Reserve University

**Honors/Awards**

1987 Summa Cum Laude Graduate, University of Buffalo
1990 Alpha Omega Alpha Medical Honor Society
1991 Summa Cum Laude Graduate, University of Buffalo School of Medicine
1995 Young Investigator Award, Vascular Biology Meeting, Seattle, Washington
2001 Recipient of the New England Cardiovascular Society Junior Faculty Award
2005 Elected, American Society of Clinical Investigation (ASCI)
2005 Elected, Fellow American Heart Association
2005 Harvard Medical School Mentor Award
2006 Editorial Board, ATVB & JMCC
2006 Standing Member Vascular Cell & Molecular Biology
2007 Editorial Board, Circulation Research
2008 Consulting Editor, Journal of Clinical Investigation
2009 Elected, Association of American Physicians (AAP)
2009 University Hospitals Case Medical Center Agre Mentorship Award
2010 Chair, Vascular Cell & Molecular Biology Study Section, NIH
2011 Elected, Association University Cardiologists (AUC)
2011 Councilor, North American Vascular Biology Organization
2012 Vice-President American Society for Clinical Investigation (ASCI)
2012 AHA Honorary Russell Ross Memorial Lecture

**B. <u>Peer – reviewed Publications (selected from 77 original and 26 reviews/chapters</u>):**

1. SenBanerjee S, Lin Z, Atkins GB, Grief DM, Rao RM, Kumar A, Feinberg MW, Chen Z, Simon DI, Luscinskas FW, Michel TM, Gimbrone MA, Garcia-Cardena G, Jain MK. KLF2 is a novel transcriptional regulator of endothelial proinflammatory activation. *Journal of Experimental Medicine 2004: 199(10):1305-1315.*
2. Kumar A, Lin Z, SenBanerjee S, Jain MK. TNFa mediated reduction of KLF2 is due to inhibition of MEF2 by NF-kB and Histone Deacetylases. *Molecular and Cellular Biol. 2005; 25(14): 5893-903.*
3. SenBanerjee S, Mir S, Lin Z, Hamik A, Atkins GB, Das H, Banerjee P, Kumar A, Jain MK. KLF2 as a novel mediator of statin effects in endothelial cells. *Circulation 2005; 112(5): 720-726.*
4. Das H, Kumar A, Lin Z, Patino W, Hwang P, Feinberg MW, Majumder PK, Jain MK. The Kruppel-llike Factor 2 regulates proinflammatory activation of monocytes. *PNAS*, 2006; 103(17): 6653-6658.
5. Gray S, Wang B, Orihuela Y, Hong EG, Fisch S, Haldar S, Cline GW, Kin JK, Peroni OD, Kahn B, Jain MK. Regulation of gluconeogenesis by Kruppel-like factor 15 (KLF15). *Cell Metabolism 2007; 5(4):305-12.*
6. Fisch S, Gray S, Heymans S, Haldar S, Wang B, Pfister O, Cui L, Kumar A, Lin Z, Senbanerjee S, Das H, Petersen CA, Mende U, Burleigh BA, Zhu Y, Pinto Y, Liao R, Jain MK. Kruppel-like factor 15 is a novel regulator of cardiomyocyte hypertrophy. *Proceedings of the National Academy of Sciences, 2007; 104(17): 7074-9.*
7. Feinberg MW, Wara AK, Cao Z, Lebedeva M, Rosenbauer F, Iwasaki H, Hirai H, Haspel R, Gray S, Akashi K, Segre J, Kaestner K, Tenen DG, Jain MK. The Kruppel-like Factor KLF4 regulates monocytic differentiation. *EMBO J 26(18): 4138-4148.*
8. Atkins GB, Wang Y, Mahabaleshwar GH, Shi H, Gao H, Kawanami D, Natesan V, Lin Z, Simon DI, Jain MK. Hemizygous deficiency of Kruppel-like factor 2 augments experimental atherosclerosis. *Circulation Research 2008, 2008,* 103(7):690-93.
9. Haldar S, Lu Y, Jeyaraj D, Kawanami D, Cui Y, Eapen SJ, Hao C, Li Y, Doughman Y, Watanabe M, Shimizu K, Sadoshima J, Margulis KB, Cappolla TP, Jain MK. Kruppel-like factor 15 deficiency is a molecular link between heart failure and aortic aneurysm formation. *Science –Translational Medicine 2010 7;2(26):26ra26.*
10. Liao X, Sharma N, Zhou G, Mahabaleshwar G, Hamik A, Kim J, Kaestner K, Jain MK. Kruppel-like factor 4 regulates macrophage subset specification. *Journal of Clinical Investigation 2011, 121(7):2736-49.*
11. Mahabaleshwar G, Kawanami D, Sharma N , Takamai Y, Zhou G, Shi H, Nayak L, Jeyaraj D, Grealy R, White M, McManus R, Ryan T, Leahy P, Lin Z, Haldar SM, Atkins GB, Wong HR, Lingrel JB, Jain MK. Myeloid KLF2 Regulates the Host Response to Polymicrobial Infection and Endotoxic Shock. *Immunity 2011, 34(5):715-28.*
12. Jeyaraj D, Haldar SM, Wan X, McCauley D, Rippergr J, Hu K, Lu Y, Eapen B, Sharma N, Cutler MJ, Gulick J, Sanbe A, Robbing J, Shea S, Albrecht U, Wehrens X, Rosenbaum D, Jain MK. Circadian rhythms govern cardiac repolarization and arrhythmias. *Nature* 2012 Feb; 483(7387):96-9
13. Jeyaraj D, Scheer F, Ripperger JA, Haldar SM, Lu Y, Prosdocimo DA, Eapen SJ, Cui Y, Mahabeleshwar GH, Casadesus G, Mintz EM, Sun H, Wang Y, Ramsey KM, Bass J, Shea SA, Albrecht U and Jain MK. Circadian control of mammalian nitrogen homeostasis. *Cell Metabolism* 2012 15(3):311-23.
14. Haldar SM, Prosdocimo DA, Jeyaraj D, Lu Y, Hoppel C, Jain MK. A KLF15-Dependent Pathway Regulates Skeletal Muscle Adaptation to Exercise. *PNAS,* 2012; 109(17):6739-44.
15. Zhou G, Hamik A, Nayak L, Tian H, Shi H, Lu Y, Sharma N, Liao X, Hale A, Boerboom L, Feaver RE, Gao H, Desai A, Schmaier A, Gerson SL, Wang Y, Atkins GB, Blackman BR, Simon DI, Jain MK. Endothelial Kruppel-like Factor 4 protects against Atherothrombosis. *Journal of Clinical Investigation 2012,* 122(12): 4727-31.

## C. Research Support:

**Active:**

R01HL110630-01 (PI: Jain) 07/01/11- 06/30/2016
NIH/NHLBI
KLF4 and myeloid cell biology
The goals of this project are to understand the role of macrophage KLF4 in metabolic syndrome and atherothrombosis.
OVERLAP: None

RO1HL076754 (PI: Jain) 8/01/04-6/30/13
NIH/NHLBI
KLF2 as a regulator of endothelial cell biology
The major goals of this project are to determine the mechanistic basis for KLF2 mediated regulation of eNOS and VCAM-1 in vitro and to determine the effect of KLF2 overexpression on vessel function and inflammation in vivo.
OVERLAP: None

R01HL097593 (PI: Jain) 05/01/10-04/30/14
NIH/NHLBI
KLF4, the endothelium, and vascular inflammation
The major goals of this project are to determine the mechanistic basis for KLF4 in vascular inflammation, injury, thrombosis, and atheorgenesis.
OVERLAP: None

R01HL112486 (PI: Jain) 02/2012-12/2016
NHLBI
KLF15 in vascular disease.
This project examines the role of KLF15 in aortic aneurysm formation.
OVERLAP: None

T32HL105338 (PI: Jain) 09/20/10-08/31/15
NIH/NHLBI
Cardiovascular Research Training Program
The major goals are to train pre-doctoral and post-doctoral candidates in cardiovascular research.
OVERLAP: None

1R01NR012642 (PI: McComsey) 12/01/10-11/30/15
NIH/NINR
Inflammation, Heart, Bone
Role: Co-Investigator

1R01HL109561 (PI: Medof) 08/01/12-06/30/16
NIH
Local Complement Synthesis and Signaling by Endothelial and Inflammatory Cells
The major goals of this project are to understand the role of interconnections of C3aR/C5aR signal transduction with platelet, leukocyte, EC, and SMC responses to EC injury and clarify how modulation of this signal transduction is connected with KLF4.
Role: Co-Investigator

R01HL086548 (PI: Jain) 02/01/2013-01/31/16
NIH/NHLBI
KLF2, monocyte activation, and vascular inflammation
The major goals of this project are to examine the effect of KLF2 overexpression and deficiency on monocyte/macrophage functions in vitro, to explore the molecular basis for KLF2's ability to inhibit key pro-inflammatory pathways, and to explore the effects of sustained KLF2 expression on acute and chronic models of inflammation.
OVERLAP: None.

Established Investigator Award (PI: Jain) 01/01/13-12/31/2017
American Heart Association
Circadian control of CV function
The major goals are to explore the role for the circadian clock in mycoardial infarction and arrhythmogenesis.

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME<br>Kattan, Michael W. | POSITION TITLE<br>Chair, Department of Quantitative Health Sciences<br>Professor of Medicine<br>Professor, Division of General Medical Sciences<br>Professor, Department of Epidemiology and Biostatistics |
| eRA COMMONS USER NAME<br>MICHAELKATTAN | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| University of Arkansas, Fayetteville, Arkansas | B.S. | 1987 | Food Science |
| University of Arkansas, Fayetteville, Arkansas | M.B.A. | 1989 | Computer Information Systems / Quantitative Analysis |
| University of Houston, Houston, Texas | Ph.D. | 1993 | Business Administration, major in Management Information Systems, minor in Statistics |
| University of Houston, Houston, Texas | Postdoctoral Training | 1994 | Medical Informatics |

## A. Positions and Honors

**Employment**

1994 – 1998 Assistant Professor of Urology and Medical Informatics, Scott Department of Urology and the Information Technology Program, Baylor College of Medicine, Houston, Texas
1998 – 2002 Assistant Attending Outcomes Research Scientist, Departments of Urology and Epidemiology and Biostatistics, Memorial Hospital for Cancer and Allied Diseases, New York, NY
1998 – 2002 Assistant Member, Memorial Sloan-Kettering Cancer Center, New York, NY
2003 – 2004 Associate Attending Outcomes Research Scientist, Departments of Urology and Epidemiology and Biostatistics, Memorial Hospital for Cancer and Allied Diseases, New York, NY
2003 – 2004 Associate Member, Memorial Sloan-Kettering Cancer Center, New York, NY
2003 – 2004 Associate Professor of Clinical Public Health, Cornell University, New York, NY
2003 – 2004 Associate Professor of Biostatistics in Urology, Cornell University, New York, NY
2004 Chairman, Department of Quantitative Health Sciences, Cleveland Clinic, Cleveland, OH
2006 Professor of Medicine, Cleveland Clinic Lerner College of Medicine of Case Western Reserve University, Cleveland, Ohio
2006 Professor, Division of General Medical Sciences, Cancer Center, School of Medicine, Case Western Reserve University, Cleveland, Ohio
2007 Professor, Department of Epidemiology and Biostatistics, School of Medicine, Case Western Reserve University, Cleveland, Ohio
1997-2000 Medical Decision Making, Editorial Board
1999-2002 Urologic Oncology, Associate Editor
1996- 2007 Journal of Urology, Board of Consultants

**Other Experiences and Professional Memberships**

2002-Present Clinical Genitourinary Cancer, Section Editor
2003-Present Urologic Oncology: Seminars and Original Investigation, Associate Editor
2005-2008 Medical Decision Making, Editorial Board
2005-Present Nature Clinical Practice Urology, Advisory Board
2006-Present Cancer Investigation, Editorial Board

**B. Selected Peer-reviewed Publications (Selected from over 400 peer-reviewed publications)**

1. **Kattan MW,** Inoue Y, Talpaz M, Ozer H, Giles F, Guilhot F, Zuffa E, Huber SL, Kantarjian HM, Beck JR. Cost-effectiveness of alpha-interferon compared to conventional chemotherapy in chronic myelogenous leukemia. Ann Intern Med 1996;125:541-548.
2. **Kattan MW**, Cowen ME, Miles BJ. A decision analysis for treatment of clinically localized prostate cancer. J Gen Intern Med 1997;12:299-305.
3. Cowen ME, Miles BJ, Cahill DF, Giesler RB, Beck JR, **Kattan MW**. The danger of applying group-level utilities to the treatment of localized prostate cancer in individual patients. Med Decis Making 1998;18(4):376-380.
4. Giesler RB, Cowen M, Miles BJ, **Kattan MW**. Assessing quality of life in men treated for localized prostate cancer: Development of a new instrument for use in multiple settings. Qual Life Res 2000;9(6):645-665.
5. Ross PL, Littenberg B, Fearn P, Scardino PT, Karakiewicz PI, **Kattan MW**. Paper standard gamble: a paper-based measure of standard gamble utility for current health. Int J Technol Assess Health Care 2003;19(1):135-147.
6. Littenberg B, Partilo S, Licata A, **Kattan MW**. Paper Standard Gamble: The reliability of a paper questionnaire to assess utility. Medical Decision Making 2003; 23(6): 480-488.
7. **Kattan MW**. Comparing treatment outcomes using utility assessment for health-related quality of life. Oncology 2003; 17(12): 1687-1693.
8. Elkin EB, Cowen ME, Cahill D, Steffel M, **Kattan MW**. Preference assessment method affects decision analytic recommendations: a prostate cancer treatment example. Med Dec Making. 2004 Sep-Oct;24(5):504-10.
9. Befort CA, Zelefsky MJ, Scardino PT, Borrayo E, Giesler RB, **Kattan MW**. A measure of health-related quality of life among localized prostate cancer patients: result from on-going scale development. Clin Prostate Cancer. 2005 Sept;4(2):100-108.
10. Elkin EB, Vickers AJ, **Kattan MW**. Primer: using decision analysis to improve clinical decision making in urology. Nat Clin Pract Urol. 2006 Aug;3(8):439-448.
11. Sekeres M, **Kattan MW**, Maciejewski J, Kalaycio M, Fu Z, Golshayan A. A decision analysis to determine the appropriate treatment for low-risk myelodysplastic syndromes. Cancer. 2007 Mar 15;109(6):1125-1132.
12. Fu AZ, **Kattan MW**. Utilities should not be multiplied: evidence from the preference-based scores in the United States. Med Care. 2008 Sep;46(9):984-990.
13. Fu AZ, Cantor SB, **Kattan MW**. Use of nomograms for personalized decision-analytic recommendations. Med Decis Making. 2010 Mar/Apr;30(2):267-274.
14. Earnshaw SR, McDade CL, Black LK, Bell CF**, Kattan MW**. Cost-effectiveness of 5-alpha reductase inhibitors for the prevention of prostate cancer in multiple patient populations. PharmacoEconomics. 2010 Jun;28(6):489-505.
15. **Kattan MW**, Earnshaw SR, McDade CL, Black LK, Andriole GL. Cost-effectiveness of chemoprevention for prostate cancer with Dutasteride in a high risk population based on results from the REDUCE clinical trial. Appl Health Econ Health Policy. 2011 Sept1;9(5):305-315.

**C. Research Support**

**<u>Ongoing Research Support</u>**

1RC4LM010959-01 (Kattan) 09/01/2010 - 08/31/2013
NIH/NLM
Refinement and Enhancement of a Web-Based Risk Calculator Deployment System
This project offers a risk calculator authoring toolkit that 1) permits continuous risk estimation to predict specific medical outcomes, 2) is easy to use by both author and clinician, and 3) is freely available, and will provide greater predictive accuracy with greater ease than other currently available methods.

Role: Principal Investigator

1R01CA154356-01A1 (Ting) 09/01/2011 - 07/31/2016
NIH/NCI
Characterizing the DNA methylomes of indolent and aggressive prostate cancers
The objective of this study is to map genome-wide DNA methylation patterns of low grade and high grade prostate cancers and to identify unique DNA methylation profiles for each type of cancer. This project does not overlap with the current proposal.
Role: Co-Investigator

**Completed Research Projects**

1UL1RR024989-05 (Davis) 09/17/2007 - 05/31/2012
NIH/NCRR
Clinical and Translational Science Award
"Translational Methodologies" Case Western Reserve University, in partnership with the Cleveland Clinic, University Hospitals and MetroHealth Medical Center formed the Clinical & Translational Science Collaborative (CTSC) in September 2007. The National Institutes of Health (NIH) awarded the partners $64 million to become part of a national consortium designed to transform how clinical and translational research is conducted, ultimately enabling researchers to provide new treatments more efficiently and quickly to patients. The consortium, funded through NIH's Clinical and Translational Science Awards, was formed in 2006 with an initial 12 academic health centers located nationwide.
Role: Co-Director

W81XWH-06-2-0033 (Weil) 01/01/2006 - 05/31/2011
Department of Defense/ Center of Excellence
Studies for Eradication of Brain Metastasis from Breast Cancer
The major goal of this project is to use translational clinical research design to understand, treat and prevent brain metastasis from breast cancer.
Role: Co-Investigator

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **James W. Kazura** | POSITION TITLE<br>Professor of International Health, Medicine, and Pathology |
| eRA COMMONS USER NAME **JWKAZURA** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| Washington University, St. Louis, MO | A.B. | 1968 | Biology |
| University of Chicago Pritzker School of Medicine, Chicago, IL | | 1968-69 | Medicine |
| Ohio State University College of Medicine, Columbus, OH | M.D. | 1972 | Medicine |

## A. Positions and Honors

**Employment**

| | |
|---|---|
| 2002-present | Director, Center for Global Health and Diseases, Case Western Reserve University School of Medicine |
| 1997-2002 | Director, Center for International Health, Case Western Reserve University School of Medicine |
| 1989-present | Professor of Medicine and International Health, Division of Geographic Medicine, CWRU |
| 1988-2002 | Chief, Division of Geographic Medicine, Department of Medicine, Case Western Reserve University |
| 1996 | Sabbatical, Walter and Eliza Hall Institute, Laboratory of Mammalian Genetics with Dr. S. Foote, Melbourne, Australia |
| 1983-1987 | Associate Professor of Medicine, Division of Geographic Medicine, Case Western Reserve University and University Hospitals of Cleveland |
| 1978-1983 | Assistant Professor of Medicine, Division of Geographic Medicine, Case Western Reserve University and University Hospitals of Cleveland |

**Other Experience and Professional Memberships**

| | |
|---|---|
| 1972-1976 | Medical residency, University Hospitals of Cleveland (Internal Medicine boards, 1975) |
| 1975-1977 | Hematology fellowship, Hospital of the University of Pennsylvania (Hematology boards, 1978) |
| 2006-present | Section editor, PLoS Pathogens |
| 2004-2007 | Section editor, International J Parasitology |
| 2003-present | American Association of Physicians |
| 2001-2004 | Member, Tropical Medicine and Parasitology Study Section, NIAID |
| 2004-2006 | Chair, Clinical Research and Field Studies Study Section, NIAID |
| 2009-present | Member, Immunity and Host Defense Study Section, NIAID |
| 2012 | President, American Society of Tropical Medicine & Hygiene |
| 1998-2011 | Editor-in-Chief, American Journal of Tropical Medicine and Hygiene |
| 1998-2000 | Associate Editor, Infection and Immunity |
| 1998-2000 | Member, Vaccine Study Section B, NIAID |
| 1997 | Indo-U.S. Panel of Vaccine Action Programs in Malaria |
| 1995-present | Associate Editor, Experimental Parasitology |
| 1998-present | Chairman, U.S-Japan Joint Panel on Parasitic Diseases, NIAID, NIH |
| 1992-present | International Centers for Infectious Disease Research Executive Committee, NIAID, NIH |
| 1991-present | Associate Editor, Microbial Pathogenesis |
| 1993-1997 | USAID expert committee Schistosomiasis Research Project in Egypt |
| 1990-1994 | Member, Tropical Medicine and Parasitology Study Section, NIAID |

1987-present American Society of Clinical Investigation
1984. 1993, 2000, 2004-present WHO Consultant and Expert Committees on microbial genomics, lymphatic filariasis

**B. Selected peer-reviewed publications (selected from malaria papers).** * indicates current or previous trainee

1. Zimmerman PA, *Woolley I, *Masinde GL, Miller SM, McNamara DT, Hazlett F, Mgone CS, Alpers MP, Genton B, Boatin BA, **Kazura JW**. Emergence of FY*A(null) in a Plasmodium vivax-endemic region of Papua New Guinea. Proc Natl Acad Sci U S A. 1999 Nov 23;96(24):13973-7. PMCID: PMC24175.
2. *Patel SS, Mehlotra RK, Kastens W, Mgone CS, **Kazura JW**, Zimmerman PA. The association of the glycophorin C exon 3 deletion with ovalocytosis and malaria susceptibility in the Wosera, Papua New Guinea. Blood. 2001 Dec 1;98(12):3489-91.
3. Maier AG, Duraisingh MT, Reeder JC, *Patel SS, **Kazura JW**, Zimmerman PA, Cowman AF. Plasmodium falciparum erythrocyte invasion through glycophorin C and selection for Gerbich negativity in human populations. Nat Med. 2003 Jan;9(1):87-92. Epub 2002 Dec 9.
4. *John CC, O'Donnell RA, Sumba PO, Moormann AM, de Koning-Ward TF, King CL, **Kazura JW**, Crabb BS. Evidence that invasion-inhibitory antibodies specific for the 19-kDa fragment of merozoite surface protein-1 (MSP-1 19) can play a protective role against blood-stage Plasmodium falciparum infection in individuals in a malaria endemic area of Africa. J Immunol. 2004 Jul 1;173(1):666-72.
5. *Dent A, Malhotra I, Mungai P, Muchiri E, Crabb BS, **Kazura JW**, King CL. Prenatal malaria immune experience affects acquisition of Plasmodium falciparum merozoite surface protein-1 invasion inhibitory antibodies during infancy. J Immunol. 2006 Nov 15;177(10):7139-45.
6. *Moormann AM, Chelimo K, Sumba PO, Tisch DJ, Rochford R, **Kazura JW**. Exposure to holoendemic malaria results in suppression of Epstein-Barr virus-specific T cell immunosurveillance in Kenyan children. J Infect Dis. 2007 Mar 15;195(6):799-808. Epub 2007 Feb 6.
7. *John CC, Tande AJ, Moormann AM, Sumba PO, Lanar DE, Min XM, **Kazura JW**. Antibodies to pre-erythrocytic Plasmodium falciparum antigens and risk of clinical malaria in Kenyan children. J Infect Dis. 2008 Feb 15;197(4):519-26.
8. Noland GS, Hendel-Paterson B, Min XM, *Moormann AM, Vulule JM, Narum DL, Lanar DE, **Kazura JW**, John CC. Low prevalence of antibodies to preerythrocytic but not blood-stage Plasmodium falciparum antigens in an area of unstable malaria transmission compared to prevalence in an area of stable malaria transmission. Infect Immun. 2008 Dec;76(12):5721-8. Epub 2008 Sep 22. PMCID: PMC2583556.
9. *Greene JA, Moormann AM, Vulule J, Bockarie MJ, Zimmerman PA**, Kazura JW**. Toll-like receptor polymorphisms in malaria-endemic populations. Malar J. 2009 Mar 24;8(1):50. [Epub ahead of print].
10. *Dent AE, Chelimo K, Sumba PO, Spring MD, Crabb BS, Moormann AM, Tisch DJ**, Kazura JW**. Temporal stability of naturally acquired immunity to Merozoite Surface Protein-1 in Kenyan adults. Malar J. 2009 Jul 16;8(1):162. PMCID: PMC2719655.
11. *Moormann AM, Sumba PO, Tisch DJ, Embury P, King CH, **Kazura JW**, John CC. Stability of interferon-gamma and interleukin-10 responses to Plasmodium falciparum liver stage antigen 1 and thrombospondin-related adhesive protein immunodominant epitopes in a highland population from Western Kenya. Am J Trop Med Hyg. 2009 Sep;81(3):489-95.
12. Sam-Agudu NA, *Greene JA, Opoka RO, **Kazura JW**, Boivin MJ, Zimmerman PA, Riedesel MA, Bergemann TL, Schimmenti LA, John CC. TLR9 polymorphisms are associated with altered IFN-gamma levels in children with cerebral malaria. Am J Trop Med Hyg. 2010 Apr;82(4):548-55.]
13. Mehlotra RK, Gray LR, Blood-Zikursh MJ, Kloos Z, Henry-Halldin CN, Tisch DJ, Thomsen E, Reimer L, Kastens W, Baea M, Baea K, Baisor M, Tarongka N, **Kazura JW**, Zimmerman PA. Molecular-Based Assay for Simultaneous Detection of Four Plasmodium spp. and Wuchereria bancrofti Infections. Am J Trop Med Hyg. 2010 Jun;82(6):1030-3. PMCID: PMC2877407 [Available on 2011/6/1].

14. *Greene JA, Sam-Agudu N, John CC, Opoka RO, Zimmerman PA, **Kazura JW**. Toll-like receptor polymorphisms and cerebral malaria: TLR2 Δ22 polymorphism is associated with protection from cerebral malaria in a case control study. Malar J. 2012 Feb 15;11:47. PMCID: PMC3306729.
15. Ramesh A, *Small ST, Kloos ZA, **Kazura JW**, Nutman TB, Serre D, Zimmerman PA. The complete mitochondrial genome sequence of the filarial nematode Wuchereria bancrofti from three geographic isolates provides evidence of complex demographic history. Mol Biochem Parasitol. 2012 May;183(1):32-41. Epub 2012 Feb 1.

## C. Research Support-Ongoing

NIAID 1 U19 AI089686-03 7/1/10-6/30/17
Overall Program Director and Project Leader Core A: International Centers for Excellence for Malaria Research: "Research to control and eliminate malaria in SE Asia and SW Pacific"
The overall objective of this ICEMR is to advance knowledge of how national and regional programs to control and eliminate malaria in Papua New Guinea (PNG) and Solomon Islands affect the epidemiology, transmission and pathogenesis/immunity of *Plasmodium falciparum* and *P. vivax* infection and morbidity in 2 distinct endemic settings which represent a wide spectrum of malaria endemicity (holoendemic in mainland PNG, meso/hypoendemic in Western Province, Solomon Islands). A related goal is to build local capacity and infrastructure to monitor, evaluate and guide ongoing and future malaria interventions used by national health authorities in the region.

NIAID 1R01 AI095192-02 7/1/11-6/30/16
PI: Naturally Acquired Immunity to Malaria during the Epidemiologic Transition in Kenya
This research will advance understanding of how decreasing malaria transmission in Africa impacts the strength and durability of acquired immunity that has historically resulted in protection against malaria morbidity by late childhood and credential novel merozoite proteins as potential vaccine targets.

NIAID U54AI057160-10 4/9/09-2/28/14
PI: "Midwest Center for Excellence in Biodefense and Emerging Infectious Diseases Research" (PI: Virgin, H; Washington University in St. Louis) "Innate Immunity to Rift Valley Fever Virus" Project
The goals of this sub project on this multiple project grant are to define host factors contributing to clinical disease from infection with Rift Valley fever virus in Kenya.

Washington University in St. Louis/Bill and Melinda Gates Foundation 11/26/09-10/31/14
"Optimization of Chemotherapy for Control and Elimination of Onchocerciasis and Lymphatic Filariasis" (Weil, G, Wash U PI)
Project Champion for Objective B " Clinical trials to identify new regimens and dosing schedules for therapies for onchocerciasis and filariasis in Africa and Papua New Guinea"

NIAID 1R01 AI098511-01 7/1/12-6/30/16
Co-Investigator: "B cell immunity in HIV exposed uninfected infants in Kenya" (PI A. Dent).
Results of this study will advance our understanding of how in utero infection exposure, particularly HIV, affects fetal/infant B cell ontogeny and responses to vaccines of public health importance in resource-limited countries.

NIAID R01 AI097262-01 8/7/12-7/31/16
Co-Investigator: "Lymphatic Filariasis transmission and elimination in PNG" (D Tisch, PI).
This project will determine how to accurately measure lymphatic filariasis elimination program goals using available diagnostic/monitoring tools.

FIC 2 D43 TW007377-07 8/1/11-7/31/16
Co-Program Director "CASE-PNG Infectious Disease Research Training Program: Global Infectious Disease Research Training Program" (P Zimmerman, P Siba)
"CASE-PNG Infectious Disease Research Training Program: Global Infectious Disease Research Training Program"
This GIDRTP addresses the needs for training and expertise in Epidemiology/Biostatistics and Entomology in public health practice and scientific research on infectious diseases in Papua New Guinea. This will be accomplished through linkage of the PNG Institute of Medical Research and academic partners with graduate degree programs at Case Western Reserve University and Michigan State University.

**Completed Research Support**

CWRU-Provost's Investment Fund 1/1/10-12/31/11
PI: "The Alliance for Global Health"
Alliance members from the participating Schools and the College. Based on our collective earlier experience with students who have been supported by the existing NIH Fogarty-supported Framework for Global Health

NIAID 1U19AI065717-05 8/15/05-4/30/11
Program Director: International Collaboration in Infectious Disease Research (ICIDR) "Mass drug treatment and vector control of filariasis". PI: Core A & Project 1: "Impact of MDA and insecticide treated mosquito nets (ITN) on human infection and disease".
The long-term goals of this multi-project ICIDR application are to advance knowledge of human, parasite and mosquito variables and related implementation and policy issues that will inform and enhance success of controlling disease morbidity and permanently stopping transmission of the filarial parasite *Wuchereria bancrofti* in Papua New Guinea, and by extension, other areas where lymphatic filariasis is endemic.

FIC 1 D43 TW007377-05 7/26/05-3/31/11
Co-Investigator "CASE-PNG Infectious Disease Research Training Program: Global Infectious Disease Research Training Program" (P Zimmerman, Program Director)
This application represents a new effort to develop a collaborative training program in infectious disease research between Case Western Reserve University and the Papua New Guinea Institute of Medical Research.

FIC/NIH 1R25 TW07735-03 9/15/06-8/31/10
Co-Investigator: Framework Programs in Global Health: "Integrated Programs & Curricula for Global Health Education" (R. Blanton, Program Director)
The overall goal of this program is to interest and retain undergraduate, graduate and professional students in international health related careers by expanding the perception of potential relevant fields, facilitating interdisciplinary study and providing opportunities for applied experiences.

FIC/NIH D43 TW006576-05 9/5/03-3/31/09
Co-Investigator: "Global Infectious Disease Research Training Program Award: CWRU-Kenya Infectious Disease Research Training Program" (CH King, Program Director) This program provides a continuing program of education and collaborative research projects between CWRU and the Kenya Ministry of Health.

FIC/NIH 5 D43 TW00920-05 9/20/97-7/31/04
Program Director: "International Training and Research in Emerging Infectious Diseases; Research training for ERID in Kenya and Papua New Guinea". The long term goal of this project is to train laboratory scientists, epidemiologists, clinicians, and public health workers in Kenya and Papua New Guinea so that they will respond more effectively to emerging and re-emerging infectious diseases (ERID) in Africa and the Pacific.

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Ruth A. Keri** | POSITION TITLE<br>Associate Professor, Depts. Pharmacology, Genetics, and Division of General Medical Sciences—Oncology<br>Vice Chair, Department of Pharmacology<br>Associate Director for Basic Research, Case Comprehensive Cancer Center |
| eRA COMMONS USER NAME **RAKERI** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Edinboro Univ. of Pennsylvania, Edinboro, PA | B.A. | 1985 | Chemistry |
| Case Western Reserve Univ., Cleveland, OH | Ph.D. | 1992 | Pharmacology |

**A. Positions and Honors**

**Positions and Employment:**

2011- Associate Director for Basic Research, Case Comprehensive Cancer Center
2010- Vice Chair, Dept. Pharmacology, Case Western Reserve University, Cleveland, OH
2010-12 Co-Director, Molecular Therapeutics Training Program, Department of Pharmacology, Case Western Reserve University, Cleveland, OH
2009- Associate Professor, Dept. Genetics, Case Western Reserve University, Cleveland, OH
2008- Associate Professor (with tenure), Depts. Pharmacology and Oncology, Case Western Reserve University, Cleveland, OH
1999-2008 Assistant Professor, Oncology, Division of General Medical Sciences, Case Western Reserve University, Cleveland, OH
1998-2008 Assistant Professor, Dept. of Pharmacology, Case Western Reserve University, Cleveland, OH
2000-03 Director, CWRU Transgenic Core Facility
1996-1997 Senior Instructor, Dept. of Pharmacology, Case Western Reserve University, Cleveland, OH
1992-1996 Research Associate, Dept. of Pharmacology, Case Western Reserve University, Cleveland

**Other Professional Experience:**

2012-13 AACR Program Committee
2012- Research Affairs Core Committee, The Endocrine Society
2010 Co-Chair, Program Committee, Annual Meeting of the Society for the Study of Reproduction (~1,000 attendees)
2004-10 Faculty for *Frontiers in Reproduction*, "Web-based bioinformatics laboratory for molecular endocrinology" Wood's Hole Marine Biological Laboratory
2005- Faculty of 1000—Medicine, Women's Health, transitioned to Oncology Agents in 2008

**Peer Review Panels:**

2012 NIH/NCI, SEP, SPORES in Breast, Endometrial, and Skin Cancer
2011- NIH, Tumor Cell Biology Study Section, charter member, Co-chair, June, 2012
1997-2001/2009— Editorial Board, Biology of Reproduction
2011- Editorial Board, Frontiers in Cancer Genetics
2011 University of Nebraska, External Review Panel, UNL Life Sciences Competitive Grants Program
2010 NIH/NIEHS, SEP, Breast Cancer and the Environment Research Center Program (BCERP)
2010 NIH/NCI, Oncological Sciences Fellowship Panel (F09), *Ad hoc* member, two panels in 2010
2009 NIH/NIEHS, SEP, Children's Environmental Health and Disease Prevention Research Centers (CEHC)

| | |
|---|---|
| 2009 | NIH, Integrative and Clinical Endocrinology and Reproduction (ICER) Study Section, *Ad hoc* Member |
| 2009, 10 | NIH, Tumor Cell Biology Study Section (TCB), *ad hoc* member |
| 2007 | Breast Cancer Campaign, United Kingdom, Research Grant Referee |
| 2005-06 | Program Project Review Panel, National Cancer Institute of Canada |
| 2005 | Concept Review Panel, USAMRMC Breast Cancer Research Program, Clinical and Experimental Therapeutics #1 |
| 2004-05 | Scientific Review Panel, USAMRMC Breast Cancer Research Program, Clinical and Experimental Therapeutics #1 |
| 2004, 06, 08 | Concept Grants Review Panel, USAMRMC Breast Cancer Research Program, Cell Biology #3 |
| 2003 | Scientific Review Panel, USAMRMC Breast Cancer Research Program, Pathobiology #4 |
| 2003 | Peer Review Panel, USDA National Research Initiative Competitive Grants Program, Animal Reproduction Program |
| 2001-04 | Scientific Review Panel, USAMRMC Prostate Cancer Research Program, Clinical and Experimental Therapeutics #1/3 |
| 2001 | NIH, Biochemical Endocrinology (BCE) Study Section, *ad hoc* member |

**National Advisory Panels:**

| | |
|---|---|
| 2006 | NIEHS Expert Panel, Bisphenol A: An Examination of the Relevance of Ecological, *In Vitro* and Laboratory Animal Studies for Assessing Risks to Human Health, Invited Panel Participant |
| 2006 | National Toxicology Program Workshop, NIEHS, Hormonally Induced Reproductive Tumors: Relevance of Rodent Bioassays, Invited Panel Participant |

**Honors:**

| | |
|---|---|
| 2008 | Mather Spotlight Series Prize for Women's Scholarship, CWRU |
| 2005— | Faculty of 1000—Medicine, Women's Health, transitioned to Oncology Agents in 2008 |
| 2002 | Excellence in Research Award, Department of Pharmacology, CWRU |
| 2001 | "Top Prof" Award, CWRU Mortar Board |
| 1999 | President's Research Initiative Award, CWRU |
| 1998 | Excellence in Teaching Award, Department of Pharmacology, CWRU |
| 1998 | Travel Award to Attend the 80th Annual Meeting of The Endocrine Society |
| 1996 | Mara E. Lieberman Travel Award for Most Promising Young Woman Investigator to the 78th Annual Meeting of The Endocrine Society |
| 1990-1991 | Cellular and Molecular Biological Sciences Training Grant, GM08056 |
| 1987-1990 | Pharmacological Sciences Training Grant, GM07382 |
| 1985 | American Institute of Chemists-Senior in Chemistry Award |
| 1985 | Beta Beta Beta-Biological Sciences Honor Society |
| 1984-85 | Alpha Chi-All College Honor Society |
| 1985 | Graduated Magna cum laude |

**B. Selected Peer-reviewed Publications (from a total of 51):**

1. Landis, MD, Seachrist, DD, Montanez-Wiscovich, ME, Danielpour, D, and **Keri, RA**. 2005. Gene expression profiling reveals that mammary tumors induced by erbb2/neu in transgenic mice have undergone alterations in the TGF-β pathway. *Oncogene*, **24**:5173-5190. PMC1431507
2. Milliken, E.L., Zhang, X.-X., Flask, C., Duerk, J.L., MacDonald, P.N., and **Keri, R.A.** 2005. EB1089, a vitamin D receptor agonist, reduces proliferation and decreases tumor growth rate in a mouse model of hormone-induced mammary cancer. *Cancer Lett.*, **229**:205-215.
3. Landis, M.D., Seachrist, D.D., Abdul-Karim, F., and **Keri, R.A.** 2006. Sustained trophism of the mammary gland is sufficient to accelerate and synchronize development of ErbB2/Neu-induced tumors. *Oncogene*, **25**:3325-3334. PMC1602057

4. Mosley, JD, Poirier, JT, Seachrist, DD, Landis, MD, and **Keri, RA**. 2007. Rapamycin inhibits multiple stages of c-Neu/ErbB2-induced tumor progression in a transgenic mouse model of HER2-positive breast cancer. *Mol. Cancer Ther.* **6**:2188-2197. PMC17699716
5. Mosley, JD and **Keri, RA.** 2008. Cell cycle correlated genes dictate the prognostic power of breast cancer gene lists. *BMC Med. Genomics*. **1**:11. PMC23961706
6. Milliken, EL, Lozada, KL, Johnson, E, Landis, MD, Seachrist, DD, Whitten, I, Sutton, ALM, Abdul-Karim, FW, and **Keri, RA**. 2008. Ovarian hyperstimulation induces centrosome amplification and aneuploid mammary tumors independently of alterations in p53 in a transgenic mouse model of breast cancer. *Oncogene*, **27**:1759-1766. PMC2464908
7. Montanez-Wiscovich, ME, Seachrist, DD, Landis, MD, Visvader, J, Andersen, B, and **Keri, RA**., 2009. LMO4 is an essential mediator of ErbB2/HER2/Neu-induced breast cancer cell cycle progression. *Oncogene*,**15**:3608-3618. PMC2762490
8. Mosley, JD and **Keri, RA**. 2009. Intrinsic bias in breast cancer gene expression data sets. *BMC Cancer*, **9**:214. PMC2711113
9. Bernardo, G, Lozada, KL, Mosley, JD, Miedler, JD, Harburg, G, Asselin-Labat, M-L, Hewitt, SC, Godwin, AK, Korach, KS, Visvader, JE, Kaestner, KH, Abdul-Karim, FW, and **Keri, RA**. 2010. FoxA1 is an essential determinant of ERα expression and mammary ductal morphogenesis. *Development*, **137**:2045-2054, PMC2875844, f*eatured on cover.*
10. Johnson E, Seachrist DD, Deleon-Rodriguez CM, Lozada KL, Miedler J, Abdul-Karim FW, Keri RA. HER2/ErbB2-induced breast cancer cell migration and invasion requires p120 catenin activation of Rac1 and Cdc42. 2010. *J. Biol. Chem.* **285**:29491-29501. PMC2937981, *featured by F1000***.**
11. Yori, JL, Johnson, E, Zhou, G, Jain, MK, and **Keri, RA**. 2010. Krüppel-like Factor 4 inhibits epithelial-to-mesenchymal transition through regulation of E-cadherin gene expression. *J. Biol. Chem.*, **285**:16854-16863. PMC2878056
12. Montañez-Wiscovich ME, Shelton MD, Seachrist DD, Lozada KL, Johnson E, Miedler JD, Abdul-Karim FW, Visvader JE, Keri RA. 2010. Aberrant expression of LMO4 induces centrosome amplification and mitotic spindle abnormalities in breast cancer cells. *J. Pathol.* **222**:271-281.
13. Beach, JR, Hussey, GS, Miller, TE, Chaudhury, A, Patel, P, Monslow, J, Zheng, Q, **Keri, RA**, Reizes, O, Bresnick, AR, Howe, PH, and Egelhoff, TT. 2011. Myosin II Isoform switching mediates invasiveness following TGFβ-induced epithelial-mesenchymal transition. *Proc. Natl. Acad. Sci.*, **108**: 17991-17996. PMC3207690
14. Yori JL, Seachrist DD, Johnson E, Lozada KL, Abdul-Karim FW, Chodosh LA, Schiemann WP, **Keri RA.** Krüppel-like factor 4 inhibits tumorigenic progression and metastasis in a mouse model of breast cancer. *Neoplasia*, **13**:601-10. 2011. PMC3132846, *featured on cover.*
15. Weber Lozada K, Keri RA. Bisphenol A increases mammary cancer risk in two distinct mouse models of breast cancer. *Biol. Reprod.*, **85**:490-497. 2011. PMC3159535, *featured by F1000 Medicine***.**
16. Sizemore, ST, **Keri, RA**. 2012. The forkhead box transcription factor FOXC1 promotes breast cancer invasion by inducing matrix metalloprotease 7 (MMP7) Expression. *J. Biol. Chem.*, **287**:24631-40. PMC3397891
17. Seachrist, DD, Johnson, E, Magee, C, Clay, CM, Graham, JK, Veeramachaneni, DN, **Keri RA**. 2012. Overexpression of follistatin in the mouse epididymis disrupts fluid resorption and sperm transit in testicular excurrent ducts. *Biol. Reprod.*, **87**:41. PMC3431426
18. Bernardo, G., and **Keri, R.A.** 2012. FOXA1: a transcription factor with paralleling functions in development and cancer. *Biosci. Rep*., **32**: 113-30.
19. Peiris, P., Toy, R., Doolittle, E., Panksy, J., Abramowshi, A., Tam, M., Vicente, P., Tran, E., Hayden, E., Camann, A., Erokwu, B., Berman, Z., Wilson, D., Baskaran, H., Flask, C., **Keri, R.A**, Karanthanasis, E. 2012. Imaging metastasis using an integrin-targeting chain-shaped nanoparticle. *ACS Nano*, **6**:8783-8795. PMC3487383
20. Bernardo, GM, Bebek, G, Ginther, CL, Sizemore, ST, Lozada, KL, Miedler, JD, Anderson, LA, Godwin, AK, Abdul-Karim, FW, Slamon, DJ, and **Keri, RA**. 2013. FOXA1 represses the molecular phenotype of basal breast cancer cells. *Oncogene*, **32:**554-563. PMC3371315

21. Asrani, K, **Keri, RA**, Galisteo, R, Brown, SA, Morgan, SJ, Ghosh, A, Tran, NL, Winkles, JA. 2013. The HER2- and Heregulin β1 (HRG)-inducible TNFR superfamily member Fn14 promotes HRG-driven cell migration, invasion, and MMP9 expression. *in press.*

**C. Current Research Support**

1RO1CA154384-01A1 (Keri, PI) 7/1/2011-4/30/16
NIH/NCI "KLF4 regulation of epithelial/mesenchymal transition in breast cancer"
This project focuses on determining if the transcription factor, KLF4, can modulate epithelial and mesenchymal phenotype in breast cancer cells and whether such modulation controls metastatic progression.

NIH 5P30 CA043703-21 (Gerson, PI; Keri, Associate Director for Basic Research) 09/30/91-03/31/13
"Comprehensive Cancer Center Support Grant"
This is the core grant that supports the Case Comprehensive Cancer Center.

**BIOGRAPHICAL SKETCH**

| NAME **Killion, Cheryl M.** | POSITION TITLE<br>Associate Professor |
|---|---|
| eRA COMMONS USER NAME **CKILLION** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| Southern Illinois University, Edwardsville, IL | BS | 1970 | Nursing |
| University of Colorado, Denver, CO | MS | 1973 | Nursing |
| University of California, Los Angeles, CA | MA | 1978 | Anthropology |
| University of California, Los Angeles, CA | PhD | 1986 | Anthropology |

**A. Positions and Honors**

**Positions and Employment**

1973 – 1976 Assistant Clinical Professor, University of California, Los Angeles, CA
1976 – 1978 Research Assistant, University of California, Neuropsychiatric Institute, School of Medicine, Los Angeles, CA
1978 – 1979 Research Assistant, Charles Drew Postgraduate Medical School, Fanon Research & Development Center, Los Angeles, CA
1980 – 1981 Instructor/Coordinator, Cedars Sinai Medical Center, Dept. of Nursing Education, Los Angeles, CA
1982 – 1983 Clinical Research Nurse, University of Southern California Medical Center, Dept. of Nursing Research, Los Angeles, CA
1984 – 1986 Nurse Clinician, Kaiser Permanente Medical Center, Los Angeles, CA
1990 – 1991 Mentor, South African Career Development Program, sponsored by the University of California, Los Angeles, Educational Opportunities
1986– 1992 Lecturer, University of California, Los Angeles, CA
1991– 1992 Nurse Clinician, St. Joseph's Medical Center, Burbank, CA
1992 Lecturer, Mount St, Mary's College, Los Angeles, CA
1992 – 2001 Assistant Professor, School of Nursing, University of Michigan, Ann Arbor, MI
2001 – 2005 Research Associate Professor, School of Nursing, Hampton University, Hampton, VA
2002 – 2005 Director, Center for Minority Health, Hampton University, Hampton, VA
2006 – Present Associate Professor/FPB School of Nursing, Case Western Reserve University, Cleveland, OH

Honors

1976 – 1983 American Nurses Association, Registered Nurse Fellowship for Ethnic Minorities
1989 Afro-American Studies Program for Interdisciplinary Research (ASPIR) Associate Program Scholar (UCLA)
1990 - Present Member, American Anthropological Association
1992 - Present Member, American Nurses' Association
1994 – 1998 Mentor – Undergraduate Research Opportunity Program (UROP) University of Michigan
1995 – 1996 Consultant, Women's Life Center, St. Vincent's Medical Center, Toledo, OH
1993 - 1997 Faculty Award for Research and Creative Projects, Office of the Associate Provost of Academic Affairs, University of Michigan
1997 National Spokesperson for Nurses (Maternal-Child Health) Nurses of America
1997 Convener/Program Coordinator, "Indigenous Healing: "Alive and Well?" Symposium, University of Michigan

| | |
|---|---|
| 1998 | Consultant, University of Puerto Rico/Pan American World Health Organization |
| 2000 | Scholar, Resource Centers for Minority Aging Research, University of Michigan |
| 1998 – 2000 | Member, Detroit/Wayne County Homeless Action Network and Coordinator (Michigan), |
| 2000 | Coordinator, (Michigan) Belize Hurricane Relief |
| 1998 – 2001 | Member, Advisory Board, Complementary and Alternative Medical Research Center, School of Medicine, University of Michigan |
| 1999 – 2001 | Member, Committee for a Multicultural University, U-M Senate for Assembly Committee of University Affairs, University of Michigan |
| 2001 | Gilbert Whitaker Fund for the Improvement of Teaching Award, University of Michigan. Introducing Complementary Therapies and Alternative Healing into the University of Michigan Curriculum (with Dr. Jeanne Raiser) |
| 2002 - Present | Member, Sigma Xi Research Society |
| 2004 - Present | Reviewer, Special Emphasis Panel, National Institute on Minority Health and Health Disparities |
| 2004 – 2006 | Fellow Leadership Enhanced and Development Project – Project Lead Kellogg, Foundation |
| 2006 | Awardee, Researcher of the Year, National Black Nurses Association |
| 2004 – 2008 | Appointed Member, Minority Health Advisory Committee, US Dept. of Health and Human Services |
| 2008 - 2011 | Board of Governors, National League for Nursing |
| 2009 - Present | Reviewer, Loan Repayment Plan, National Institute on Minority Health and Health Disparities |
| 2010 | Fellow, University Center for Innovative Teaching and Excellence, Case Western Reserve University. |
| 2010 - Present | Fellow, American Academy of Nursing |

**B. Selected Peer-reviewed Publications**

1. Killion, C. (1998). Poverty and procreation among women: An anthropological study with implications for healthcare providers. *Journal of Nurse Midwifery*, 43, 273-279.
2. Killion, C. (2000). Extending the extended family for homeless and marginally housed African American women. *Public Health Nursing*, 17, 346-354
3. Killion, C. & Wang, C. (2000). Linking marginally housed African American mothers across life stage and station through photovoice. *Journal of Health Care for the Poor and Undeserved*,11, 310-325.
4. Killion. C. (2001). Understanding cultural aspects of health and illness through photography, *Nursing Outlook* 49, 50-54.
5. Seng, J., Oakley, D., Sampselle, C., Killion, C., Graham-Bermann, S., Liberzon, I. (2001). Post traumatic stress disorder is associated with complications of pregnancy. *Obstetrics and Gynecology*, 97, 17-22.
6. Seng, J.S., Sparbel, K.D., Low, L.K., & Killion, C.M. (2002). Abuse-related post-traumatic Stress and Desired Maternity Care Practices: Women's Perspectives. *Journal of Midwifery and Women's Health* 47, 360-370
7. Seng, J.S., Low, L.K., Sparbel, K.D., & Killion, C.M. (2004). Abuse related post-traumatic during the childbearing year. *Journal of Advances in Nursing*, 46, 604-613.
8. Hurst, C., Montgomery, A., Davis, B., Killion, C., & Baker, S. (2005). The relationship between social support, self-care agency and self care practices of African American women who are HIV Positive. *The Journal of Multicultural Nursing and Health*, 11, (3), 21-24.
9. Killion, C.M. (2007). Patient-centered culturally sensitive care: Trend or major thrust in health care delivery? The *Counseling Psychologist*, 35, 726-734.
10. Killion C.M., Cayetano C. (2009). Making mental health a priority in Belize. (2009) *Archives of Psychiatric Nursing*, 23, 157-165.

11. Killion, C.M., (2010). Mother wit and self-health management: Learning from African American elders. In M. Wykle & S. Gueldner (Eds.). *Healthy Aging: Gerontological Education for Nurses and Other Health Care Professionals.* Boston: Jones & Bartlett.
12. VanHofwegen, L. & Killion, C. (2010). Uncertain lives, uncertain health for children of Latino Day laborers, *Journal of Community Health Nursing*, 28, 1-13.
13. Killion, C. M. Reilly, J., Gallagher-Lepak, S. (2010). Becoming an onliner: Students 'perceptions of moving from traditional to virtual learning. *Online Journal of Nursing Informatics*, 28, 1-10.
14. Bates, M.D. Quinn Griffin, M.T., Killion, C. M. & Fitzpatrick, J.J. (2011). African American males' knowledge and attitudes toward genetic testing and willingness to participate in genetic testing: a pilot study. The *Journal of the National Black Nurses Association*, 22,1-7.
15. Kruska, B. Lindell, D., Killion, C. Criss, S. (2012). "It's like pay or don't have it and now I'm doing without": The voice of transitional uninsured former foster youth. *Policy, Politics and Nursing Practice*, 13, 27-37. (doi: 10.1177/1527154412447012).

**C. Research Support**

**Ongoing Research Support**

U01 HL103622-03 Cutter, L., Moore, S., Borawski, E. (Co-PIs) 08/17/10-04/30/17
NIH/NHLBI
Targeting Obesity and Blood Pressure in Urban Youth
This 3-group randomized clinical trial will test the effect of a multi-level intervention (community, school, and family) on blood pressure and BMI in children in grades 6-8 in the Cleveland Metropolitan School District.
Role: Co-Investigator (Qualitative Methodology**)**

K23 DK091363-02 Jolly (PI) 07/01/11-06/30/16
NIH/NIDDK
Chronic Kidney Disease Knowledge and Awareness Among American Indians
This study will test this inventive modality in a pilot interventional trial with the aim of increasing chronic kidney disease knowledge and awareness and chronic kidney disease protective behaviors among American Indians, as well as assessing feasibility acceptability, and effect size.
Role: Mentor (Qualitative Methodology)

P30 NR010676-05 Moore (PI) 09/29/07 – 06/30/13
NIH/NINR
Center of Excellence to Build the Science of Self-Management Research and Translation (SMART)
The SMART Center prepares researchers to extend and disseminate knowledge related to self-management, contribute to the development of emerging bio-behavioral research methods, focus on critical issues related to health disparities, and incorporate economic considerations as part of their research.
Role: Consultant (Qualitative Methodology)

P20 MD002286-05S1 Callwood, G. & Campbell, D. (Co-PIs) 09/30/07-06/30/13
Caribbean Exploratory Research Center
National Institute for Minority Health and Health Disparities,
Protecting Haitian Women and Children Earthquake Survivors from Violence and Abuse
From this community based study an intervention will be developed to enhance the safety and quality of life of Haitian women and children earthquake survivors.
Role: Consultant (Qualitative Methodology)

**Completed Research Support**

U.S. Department of Education Zauszniewski, J. (PI) 2006-2011
Graduate Assistance in Areas of National Need Fellowship Program
This program provided comprehensive support for doctoral students committed to serve in designated areas of need.
Role: Investigator/Faculty, 5% contribution

American Nurses Foundation Kilanowski, J. (PI) 9/01/08 - 8/31/10
Preferred Methods of Nutrition Education Instruction among Migrant Farm Worker Parents
This study sought to uncover the most strategic and effective means of offering nutrition education to migrant farm worker families. Culturally specific educational materials will be developed based on the preferences of the study population.
Role: Co-Investigator (Methodology)

Ohio Board of Regents Killion, C. (PI) 2006-2008
Research Infrastructure Grant
Complementary and alternative healing Practices among Elderly, Urban Dwelling African Americans
This study provided a description of culturally specific, self- management strategies of older African Americans. It provided evidence of an integrated approach to health and illness.
Role: Principal Investigator, 12.5% contribution

5 R24MD000192-03 Killion, C. (PI) 2002-2005
NIMHD
Hampton University Health Disparities Reduction Project
This research program combined the investigative efforts of nurses and pharmacists to develop studies focusing on eliminating health inequities.
Role: Principal Investigator

**BIOGRAPHICAL SKETCH**

| NAME **Charles H. King** | POSITION TITLE<br>Professor of International Health |
|---|---|
| eRA COMMONS USER NAME **CHARLESKING** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Massachusetts Institute of Technology, Cambridge, MA | B.S. | 02/74 | Biology |
| State University of NY, Downstate Medical Center, NY, NY | M.D. | 05/78 | Medicine |
| University of Michigan, Ann Arbor, MI | M.S. | 04/01 | Biostatistics |

**A. Positions and Honors**

1981-1983 Fellow, Geographic Medicine/Infectious Disease, Department of Medicine, Case Western Reserve University and University Hospitals of Cleveland, Ohio
1983-1990 Assistant Professor of Medicine, Case Western Reserve University, Cleveland, OH.
1990-93 Associate Professor of Medicine and International Health, Case Western Reserve University, and University Hospitals of Cleveland, Cleveland, OH.
1993-98 Associate Clinical Professor of Medicine and International Health, Case Western Reserve University, and Attending Physician, University Hospitals of Cleveland, Cleveland, OH.
1998-2006 Associate Professor of International Health, Medicine, and Epidemiology & Biostatistics, CWRU
2006-present Professor of International Health, Medicine, and Epidemiology & Biostatistics, Center for Global Health & Diseases, Case Western Reserve University, and University Hospitals of Cleveland, Cleveland, OH.
2009-present Senior Scientist, Schistosomiasis Consortium for Operational Research and Elimination (SCORE), University of Georgia, Athens, Ga.
2010-present Medical Director, Cuyahoga County Board of Health

**Other Experience and Professional Memberships**

1984-1987 Assistant Epidemiologist, University Hospitals of Cleveland, Cleveland, Ohio
1991/2/3, 2002/4/5/8/9/11 Temporary Advisor, World Health Organization, Geneva, Switzerland
1998 Post-graduate training in mathematical modeling, Wellcome Trust Center for Epidemiology of Infectious Diseases, Oxford, UK.
1999-2001 Graduate training in clinical research design and statistical analysis, University of Michigan School of Public Health, Ann Arbor, MI
1999-present Director, W.H.O. Collaborating Centre for Basic and Applied Research on Schistosomiasis at Case Western Reserve University
2003-present CWRU Center for Statistics and Geospatial Data (CSGD) Advisory Council
2004, 2008 NSF Ecology of Infectious Diseases Review Panel
2004-present Consultant on Travel Medicine, Cuyahoga County Board of Health
2005, 2007 NIH PTHE Study section, NIAID (ad hoc)
2005 WHO Scientific Working Group for Schistosomiasis
2006-present Deputy Editor, PLOS Neglected Tropical Diseases
2006-present Co-Chair, DMID Data Safety Monitoring Board 06-0039, NIH
2007-2011 Populations and Public Health Funding Committee, Wellcome Trust
2009 MIDAS Centers of Excellence Study Section, NIH ZGM1 CBCB-5 (MI)
2009-2013 Regular member, International and Cooperative Projects Study Section (ICP1), NIH
2009 WHO Informal working group on genital schistosomiasis and HIV transmission

2011 WHO Informal Consultation of Schistosomiasis Control
2012-present WHO Expert Advisory Panel on Parasitic Diseases

Fellow, American College of Physicians
Fellow, Royal Society of Tropical Medicine and Hygiene
Member, American Society for Tropical Medicine and Hygiene
Member, Infectious Disease Society of America
Member, Society of Vector Ecology
Member, Ohio Mosquito Control Association

**B. 15 Selected peer-reviewed publications**

1. Muchiri EM, Ouma JH, **King CH**. Dynamics and control of *Schistosoma haematobium* transmission in Kenya: an overview of the Msambweni Project. Am J Trop Med Hyg. 1996 Nov;55(5 Suppl):127-34.
2. Kariuki HC, Clennon JA, Brady MS, Kitron U, Sturrock RF, Ouma JH, Ndzovu ST, Mungai P, Hoffman O, Hamburger J, Pellegrini C, Muchiri EM, **King CH**. Distribution patterns and cercarial shedding of *Bulinus nasutus* and other snails in the Msambweni area, Coast Province, Kenya. Am J Trop Med Hyg. 2004 Apr;70(4):449-56.
3. Ouma JH, **King CH**, Muchiri EM, Mungai P, Koech DK, Ireri E, Magak P, Kadzo H. Late benefits 10-18 years after drug therapy for infection with *Schistosoma haematobium* in Kwale District, Coast Province, Kenya. Am J Trop Med Hyg. 2005 Aug;73(2):359-64.
4. Satayathum SA, Muchiri EM, Ouma JH, Whalen CC, **King CH.** Factors affecting infection or reinfection with *Schistosoma haematobium* in coastal Kenya: survival analysis during a nine-year, school-based treatment program. Am J Trop Med Hyg. 2006 Jul;75(1):83-92.
5. Clennon JA, Mungai PL, Muchiri EM, King CH, Kitron U. Spatial and temporal variations in local transmission of *Schistosoma haematobium* in Msambweni, Kenya. Am J Trop Med Hyg. 2006 Dec;75(6):1034-41.
6. Gurarie D, **King CH**, Wang X. A new approach to modelling schistosomiasis transmission based on stratified worm burden. Parasitology. 2010 Jul 13:1951-1965. PMCID:PMC3271124
7. Jia T-W, Utzinger J, Deng Y, Yang K, Li Y-Y, Zhu J-H, **King CH,** Zhou X-N, Quantifying quality of life and disability of patients with advanced schistosomiasis japonica, PLoS Neglected Tropical Diseases, 2011 5:e966. doi:10.1371/journal.pntd.0000966 PMCID:PMC3039691
8. Gurarie D, Wang X, Bustinduy AL, **King CH**, Estimating the potential for catch-up growth with different drug treatment regimens promoted for the control of endemic schistosomiasis, American Journal of Tropical Medicine and Hygiene 84:773-781, 2011. PMCID: PMC3083746
9. Bustinduy AL, Thomas CL, Fiutem JJ, Parraga IM, Mungai PL, Muchiri EM, Mutuku F, Kitron U, **King CH**, Measuring fitness in Kenyan children with polyparasitic infections using the 20-meter shuttle run test as a morbidity metric, PLoS Neglected Tropical Diseases, 5(7): e1213. doi:10.1371/journal.pntd.0001213, 2011. PMCID:PMC3130006
10. Mutuku, F, Bustinduy AL, **King CH**, Mungai PL, Muchiri EM, Kitron U. Impact of drought on the spatial pattern of transmission of *Schistosoma haematobium* in coastal Kenya. American Journal of Tropical Medicine and Hygiene 85:1065-1070, 2011. PMCID:PMC3225153
11. Abbasi I, Hamburger J, Kariuki C, Mungai PL, Muchiri EM, **King CH**, Differing *Schistosoma haematobium* from related animal schistosomes by PCR amplifying inter-repeat sequences flanking newly selected repeated sequences. Am J Trop Med Hyg, 1059-64, 2012. [PMCID in progress]
12. Wang, X, Gurarie D, Mungai PL, Muchiri EM, Kitron U, **King CH**. Projecting the long-term impact of school- or community-based mass-treatment interventions for control of *Schistosoma* infection, PLoS Neglected Tropical Diseases, 6(11): e1903. doi:10.1371/journal.pntd.0001903, 2012. PMCID: PMC3499404
13. Florey LS, **King CH**, Van Dyke MK, Muchiri EM, Mungai PL, Zimmerman PA, Wilson ML. Partnering parasites: Evidence of synergism between heavy *Schistosoma haematobium* and *Plasmodium* species

infections in Kenyan children, PLoS Neglected Tropical Diseases, 6(7): e1723. doi:10.1371/journal.pntd.0001723, 2012. PMCID:PMC3404100

14. Fairley J, Bisanzio D, **King CH**, Kitron U, Mungai P, Muchiri M, King CL, Malhotra I. Birthweight in offspring of mothers with high prevalence of helminth and malaria infection in coastal Kenya. American Journal of Tropical Medicine and Hygiene, 88:48-53, 2103. [PMCID in progress]
15. Terer CC, Bustinduy AL, Magtanong RV, Muhoho N, Mungai PL, Muchiri EM, Kitron U, **King CH**, Mutuku FM. Evaluation of the health-related quality of life of children in *Schistosoma haematobium*-endemic communities in Kenya: a cross-sectional study. PLoS Neglected Tropical Diseases, (in press) 2013.

## C. Research Support

**Ongoing**

Bill and Melinda Gates Foundation OPP1066865 11/9/12-10/31/16
PI: "Enhancing Infant Immunity: Effect of Early Maternal Treatment for Parasitic Infections"
This project seeks to improve infant vaccine responses and early childhood development by identifying the mechanisms of and solutions to the detrimental impact of maternal parasitic infection.

FIC/NIH 1R01TW008067-03 9/20/07-7/31/13
PI: "Eco-epidemiology of schistosomiasis, malaria and polyparasitism in Kenya" EID Program
This multi-disciplinary project examines the transmission dynamics of multiple parasite species and their interactive effect on human populations in developing areas of coastal Kenya.

NIAID U54AI057160-06 6/1/09-5/31/14
Co-Investigator: "Midwest Center for Excellence in Biodefense and Emerging Infectious Diseases Research" (PI: Stanley, S)
The goals of this sub Project are to define host factors contributing to clinical disease from infection with Rift Valley fever virus.

FIC/NIH D43TW000011-22 6/1/09-5/31/13
Co-PI: " HIV/AIDS International Training Program (AITRP)" (C Whalen, Program Director)
Ongoing training grant to support the goal of meeting the public health and scientific challenges of the evolving HIV epidemic in Africa by developing scientific leadership in the field of HIV prevention and treatment.

**Completed Support**

FIC/NIH 1R01TW007872-03 9/15/06-7/31/12
Co-PI: "Changing dynamics of anopheline transmission of malaria" (P Zimmerman, PI)
This study proposes to provide insight into the fine- and medium-scale factors that contribute to village-by-village risk differences for mosquito-borne parasite transmission. It will also include refinement of strategies for monitoring and implementing control of mosquito-borne transmission of malaria and filaria in Papua New Guinea.

NIAID 1R21AI076672-02 6/15/08-5/31/11
PI: "Molecular tools to monitor eradication of *Schistosoma haematobium* transmission"
In accord with the R21 program's developmental focus, this project will create and validate new technologies that can significantly advance knowledge of the environmental features of schistosome transmission and will materially contribute to health-related implementation research for improved schistosomiasis control.

FIC/NIH 1R25 TW07735-03 9/15/06-8/31/10
Co-Investigator: Framework Programs in Global Health: "Integrated Programs & Curricula for Global Health Education" The overall goal of this program is to interest and retain undergraduate, graduate and professional

students in international health related careers by expanding the perception of potential relevant fields, facilitating interdisciplinary study and providing opportunities for applied experiences.

NIH/Fogarty 1 D43 TW06576-05 9/5/03-3/31/09
PI: "Global Infectious Disease Research Training Program Award: CWRU-Kenya Infectious Disease Research Training Program" Coordinated training program for the study of emerging infectious diseases in Africa.
The long term goal of this project is to train laboratory scientists, epidemiologists, clinicians, and public health workers of the Division of Vector Borne Diseases, Ministry of Health, Kenya to augment their response to emerging and re-emerging infectious diseases in East Africa.

NIH 5 U01 AI45473-05 9/1/99-6/30/07
PI: "Urinary Schistosomiasis Determinants of Infection and Disease."
This single project center examines underlying host immune mechanisms and genetic differences responsible for variable disease penetration in populations infected with the parasite *Schistosoma haematobium.* The international center for infectious disease research (ICIDR) is a collaborative project with investigators in Kenya based at the Ministry of Health and Kenya Medical Research Institute.

NIH/NIAID 5 U01 AI045473-05 7/1/03-6/30/07
PI: ICIDR Biodefense Supplement: "Transmission of Rift Valley Fever in Kenya"
This two-year project utilizes sero-epidemiology and remote sensing/spatial analysis to identify and study the landscape features favoring transmission of the biodefense pathogen Rift Valley Fever in Kenya. Predictive models are developed based on climate, weather patterns and land use, and validated through ground-truthing surveys in the Ijara District of NE Province.

NIH 1 R01 TW01543-05 10/1/00-7/31/06
PI: "Human population growth impact on *S. haematobium*."
The long-term goal of this project is to define means for effective interruption of parasite transmission from intermediate host *Bulinus* snails to definitive human hosts. The specific aims of the project are: 1) to determine the impact of human population growth and climate variation on patterns of *S. haematobium* transmission in an endemic region over a multi-year period (1984-2005); 2) To establish molecular PCR monitoring systems for more precise measurement of human/snail/human dynamics of *S. haematobium* transmission at field sites; 3) To develop and test mathematical models of *S. haematobium* transmission, in both small- and large-scale settings, which can be used to define optimal targets for control intervention; and 4) To train scientists from *S. haematobium*-endemic areas in the use of PCR detection techniques, GIS analysis, and remote sensing techniques for the design and implementation of focused parasite control programs.

NIAID (Opportunity Pool) AI33061 4/1/05-3/31/06
PI/Course Director: "Workshop on Spatial Analysis of GIS Data-Applied Statistics for Public Health"
This application is for supplemental opportunity/NASA ICIDR funding to support the development and implementation of a 2005 training workshop on the advanced analysis of spatial data.

FIC/NIH 1D43 TW00920 9/20/97-7/31/04
Co-Investigator: International Training and Research in Emerging Infectious Diseases; Research training for ERID in Kenya and Papua New Guinea (PI: James Kazura).

NIH/NIAID 1RO1 AI41680 9/30/97-8/31/02
Co-Investigator: The genetics of severe hepatic fibrosis in schistosomiasis mansoni. (PI: Ronald Blanton)
Nord Foundation 7/1/99-6/30/00
Principal Investigator: Expanding Access to Learning in International Health

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Li Li** | POSITION TITLE<br>Associate Professor of Family Medicine, Epidemiology and Biostatistics, and Oncology |
| eRA COMMONS USER NAME **LiLiCase** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Tongji Medical University, Wuhan, P.R. China | M.D. | 06/86 | Medicine |
| Tongji Medical University, Wuhan, P.R. China | M.P.H. | 09/89 | Public Health |
| University of Southern California, LA, CA | M.S. | 05/95 | Biometry |
| University of Southern California, LA, CA | Ph.D. | 05/96 | Preventive Medicine |
| National Cancer Institute, Bethesda, MD | Visiting Fellow | 07/97 | Cancer Epidemiology |

## A. Positions and Honors

**Professional Experience**

1989-1990 Lecturer, Tongji Medical University, Institute of Social Medicine, Wuhan, Hubei, P.R.China
1990-1995 Research Assistant, University of Southern California, Institute for Prevention Research, Los Angeles, CA
1997-2000 Medical Resident, Department of Family Practice, University of Kentucky, Lexington, KY
2000- Assistant Professor of Family Medicine, CWRU, Cleveland, OH
2000- Assistant Professor of Epidemiology & Biostatistics, CWRU, Cleveland, OH
2002- Assistant Professor of Oncology, CWRU, Cleveland, OH
2001- Board Certification: American Board of Family Practice
2003- Associate Editor, *Chinese Journal of General Medicine*
2003- Visiting Assistant Professor, Cleveland Clinic Foundation, Department of Cancer Biology, Cleveland, OH
2005- Associate Director, Case Computational Genomic Epidemiology of Cancer Training Program
2007- Acting Associate Director, Cancer Prevention and Control, Case Comprehensive Cancer Center
2008- Associate Professor (with Tenure) of Family Medicine, CWRU
2008- Associate Director, Cancer Prevention and Control, Case Comprehensive Cancer Center

Honors and Awards

2001-2006 Damon Runyon-Lilly Clinical Investigator Award, Damon Runyon Cancer Research Foundation
2007 Nominee, "Professor of the Year", Department of Epidemiology and Biostatistics
2011 Finalist, "Annual Crain's Cleveland Business Health Care Heroes Awards".

**Committees/Professional Associations**

Member, Junior Member Organizing Committee (2002-2004), American Society of Preventive Oncology
Member, ASPO Program Committee (2004-2006), American Society of Preventive Oncology
Member, American Society of Preventive Oncology
Member, International Genetic Epidemiology Society
Member, American Society of Human Genetics
Ad hoc member, National Cancer Institute AARC Review Committee (2009)
Ad hoc member, Department of Defense Ovarian Cancer Study Section (2009)
Ad hoc member, National Cancer Institute EPIC Study Section (Feb and June 2010)

Member, External Advisory Board, Markey Cancer Center, University of Kentucky, Lexington (2001-)
Chair, American Society of Preventive Oncology Annual Meeting 2012 Abstract Review Committee

**B. Selected Peer-reviewed Publications**

1. Carroll RJ, Freedman LS, Kipnis V, **Li L**. A new class of measurement-error models, with applications to dietary data. *Can J Stat*, 1998; 26:467-78.
2. Kipnis V, Carroll R, Freedman LS, **Li L**. Implication of a new dietary measurement error model for estimation of relative risk: Application to four calibration studies. *Am J Epidemiol*, 1999;150:642-51.
3. **Li L**, Yu H, Schumacher F, Casey G, Witte JS. Relation of serum insulin-like growth factor-I (IGF-I) and IGF binding protein-3 to risk of prostate cancer. *Cancer Causes Control*, 2003:721-26.
4. Zhao Z, Xiao Y, Elson P, Tan H, Plummer SJ, Berk M, Aung PA, Lavery IC, Achkar JP, **Li L**, Casey G, Xu Y. Plasma lysophosphatidylcholine levels: potential biomarkers for colon cancer. *J Clin Oncol.* 2007;25:2696-2701.
5. **Li L***, Thompson CL, Plummer SJ, Merkulova A, Acheson L, Tucker TC, Casey G. A common 8q24 genetic variant and the risk of colon cancer: a population based case-control study. *Cancer Epidemiol Biomarkers Prev*. 2008;17:339-342.
6. **Li L***, Thompson CL, Plummer SJ, Tucker TC, Casey G. Association between phosphatidylinositol 3-kinase regulatory subunit p85alpha Met326Ile genetic polymorphism and colon cancer risk. *Clin Cancer Res.* 2008;14:633-637.
7. Nock NL, Thompson CL, Tucker TC, Berger BA, **Li L***. Association between obesity and changes in adult BMI over time and colon cancer risk. *Obesity (Silver Spring)*. 2008;16:1099-1104.
8. Ochs-Balcom HM, Cicek MS, Plummer S, Thompson CL, Tucker TC, Elston RC, Casey G, **Li L***. Association of vitamin D receptor variants, adiposity and colon cancer. *Carcinogenesis* 2008; 29:1788-1793. PMID: 2722851.
9. Nock NL, **Li L**, Elston RC. Modeling genetic and environmental factors in biological systems using structural equation modeling: an application to energy balance. *Proc Ohio Collab Conf Bioinform. 2009;17:3-8.* PMID: in process.
10. Thompson CL, Plummer SJ, Tucker TC, Casey G, **Li L***. Interleukin-22 genetic polymorphisms and risk of colon cancer. *Cancer Causes and Control*. 2010;21(8): 1165-1170. PMCID: in process.
11. Thompson CL, Larkin EK, Patel SR, Redline S, Berger NA, **Li L***. Short duration of sleep increases risk of colon adenomas. *Cancer*. 2011;117:841-7. PMCID: in process.
12. Nock NL*, Thompson CL, Huang H, Kirwan J, **Li L***. Higher bone mineral density is associated with a decreased risk of colon adenoma. *Int J Cancer* 2011;129:956-64. PMCID: in process.
13. Nock NL*, Plummer SJ, Thompson CL, Casey G, **Li L***. FTO polymorphisms are associated with adult body index (BMI) and colorectal adenomas in African-Americans. *Carcinogenesis* 2011;32:748-56. PMID: in process.
14. Ortiz AP, Thompson CL, Chak A, Berger NA, **Li L***. Insulin resistance, central obesity and risk of colorectal adenoma. *Cancer* 2012;118:1774-1781. PMCID: 3262947.
15. Greer KB, Thompson Cl. Brenner L. Bednarchik B, Dawson D, Willis J, Grady WM, Falk GW, Cooper GS, **Li L**, Chak A. Association of insulin and insulin-like growth factors with Barrett's esophagus. *Gut.* 2012; 61:665-672. PMID: 21930730

**C. Research Support**

**<u>Ongoing Research Support</u>**
5P30 CA043703-16 (Stan Gerson) 08/01/07-07/31/18
National Cancer Institute
"Comprehensive Cancer Center Support Grant"
The major goal is to support the Cancer Center Program at CWRU and UHC.
Role: Associate Director for Cancer Prevention and Control

2 R25 CA094186-06 (Robert Elston) 08/01/07-07/31/17
National Cancer Institute
"Training in Computational Genomic Epidemiology of Cancer (CoGEC)"
This R25 training grant continues our previous success to develop new investigators in computational genomic epidemiology of cancer.
Role: Co-Investigator and Associate Director

R01CA136726 (Li Li) 09/01/09-08/30/14
National Cancer Institute
"Obesity-Related Insulin Resistance Signaling Pathway Factors and Colon Cancer"
The major goal of this project is to investigate the relationship between colon cancer with obesity and genes in the critical insulin-related signaling pathways
Role: Principal Investigator

R03CA143917 (PI: Li Li 01/01/11-12/31/12 (no-cost extension)
National Cancer Institute
"Integrating Longitudinal Changes in Mammographic Density into Risk Prediction"
The major goal of this project is to develop a breast cancer risk prediction model that integrates trajectories of longitudinal changes in mammographic density.
Role: Principal Investigator

P50CA50964 Case Western Reserve University GI SPORE (Markowitz SD) 09/01/2011 – 08/31/2016
National Cancer Institute
Project 2: "Detection of Advanced Colon Adenoma via Stool DAN (sDNA) Methylation Testing"
This project in the Case GI SPORE application evaluates methylated vimentin gene and 3 novel methylation markers in stool DNA in the detection of advanced colon adenomas.
Role: Project 2 Co-Leader (Li L, Cooper G)

2 U01CA86400-11 (Brenner DE) 09/01/2011 – 08/31/2016
National Cancer Institute
"Validation and Comparison of Biomarkers for the Early Detection of Colorectal Adenocarcinoma: Great Lakes New England Clinical Validation Center/NCI Early Detection Research Network"
The goal of this NCI Early Detection Research Network-based study is to evaluate the sensitivity and specificity of stool DNA biomarkers, serum galectin-3 ligand, and fecal immunochemical testing for early detection of colorectal neoplasia.
Role: site Co-PI (Li L, Cooper G)

**Completed Research Support**

1 K22 CA120545-01 (Li Li) 09/1/06-08/30/09
National Cancer Institute
"Genetic Epidemiology of Insulin Resistance Pathway Factors and Colon Cancer"
This Transitional Career Development builds on an ongoing population-based case-control study of colon cancer to examine genetic, dietary and lifestyle factors in several insulin resistance syndrome pathways in relation to colon cancer.
Role: Principal Investigator

Damon Runyon-Lilly Clinical Investigator Award (CI-8, Li Li) 07/01/01-12/30/06
Damon Runyon Cancer Research Foundation
"Diet and Novel Susceptibility Genes in the Carcinogenesis of Colon Neoplasia"

This physician-scientist career development award provides support for research on a colon neoplasia genetic epidemiology proposal to investigate the interaction of diet and colorectal neoplasia candidate genes emerging from a genome scan of sib-pairs in the CWRU Colon Neoplasia Sibling Study (CNSS).
Role: Principal Investigator

1 U54 CA-116867-01(Nathan Berger) 09/1/05-08/31/11
National Cancer Institute
"CASE Center for Transdisciplinary Research on Energetics and Cancer"
Project II: "Insulin Resistance Syndrome Pathway Factors and Colon Polyps"
This project comprehensively examines the relation of colon polyps and insulin resistance syndrome, associated gene polymorphisms, haplotypes, diet, and biomarkers in an incident case-control study.
Role: Principal Investigator (Project II)

| BIOGRAPHICAL SKETCH | |
|---|---|
| Lederman, Michael M. | POSITION TITLE<br>Scott R. Inkley Professor of Medicine, Professor of Molecular Biology/Microbiology, Pathology and Biomedical Ethics |
| eRA COMMONS USER NAME (credential, e.g., agency login) | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Brandeis University | B.A. | 1970 | Biology |
| Mt. Sinai School of Medicine | M.D. | 1974 | Medicine |

**A. Positions and Honors**

| | |
|---|---|
| 1974-1978 | Residency, Chief Residency in Medicine, University Hospitals of Cleveland, Cleveland VA Medical Center, Cleveland, OH |
| 1978-1980 | Fellow in Infectious Diseases, University Hospitals of Cleveland, Cleveland VA Medical Center, Cleveland, OH |
| 1980-1988 | Assistant Professor, Department of Medicine, Case Western Reserve University School of Medicine, Assistant Physician, University Hospitals of Cleveland, Cleveland, OH |
| 1988-1996 | Associate Professor, Department of Medicine, Case Western Reserve University School of Medicine, University Hospitals of Cleveland, Cleveland, OH |
| 1996 | Professor, Department of Medicine, Case Western Reserve University School of Medicine, University Hospitals of Cleveland, Cleveland, OH |
| 2002 | Scott R. Inkley Professor of Medicine, Case Western Reserve University School of Medicine, University Hospitals of Cleveland |

**Other Experience and Professional Memberships**

Fellow, American Association for the Advancement of Science
Fellow, Infectious Diseases Society of America
American Association of Immunologists
Association of American Physicians
Clinical Immunology Society
Fellow, American Association of Microbiology
HIV Medicine Association
International AIDS Society
Ugandan Research Society

**Honors**

| | |
|---|---|
| 1979 | Elton Hoyt II Research Award |
| 1982 | N.I.H. New Investigator Research Award |
| 1982 | Sigma Xi Faculty Research Award |
| 1989 | Alpha Omega Alpha - CWRU Chapter Fall Lecturer |
| 1999 | Voice against silence – AIDS Taskforce of Greater Cleveland |
| 2000 | Ohio AIDS Service Award |
| 2001 | Pfizer Visiting Professor, UC Davis Nov |
| 2002 | Scott R. Inkley Endowed Chair in Medicine, Case Western Reserve University |
| 2005 | University of Pittsburgh, Alan Winkelstein Memorial Lecture |
| 2006 | Case Western Reserve University, George Naff Lecture |
| 2006 | Melbourne Infectious Disease Group – Forbes Fellow |

2008 Cleveland Clinic Foundation – R. J. Fasenmeyer Lecturer in Clinical Immunology
2009 Visiting Professor, University of Western Australia
2010 Mt. Sinai Foundation, Maurice Saltzman Award

**B. Ten Peer-reviewed Publications** (from more than 300; trainees and former trainees in **bold**).

1. **Funderburg, N. T., E. Mayne, S. F. Sieg, R. Asaad, W. Jiang**, M. Kalinowska, **A. A. Luciano**, W. Stevens, **B. Rodriguez,** J. M. Brenchley, D. C. Douek, and M. M. Lederman. 2010. Increased tissue factor expression on circulating monocytes in chronic HIV infection: relationship to in vivo coagulation and immune activation. *Blood* 115:161-167. PMC. 19828697.
2. Grant, R. M., D. Hamer, T. Hope, R. Johnston, J. Lange, M. M. Lederman, J. Lieberman, C. J. Miller, J. P. Moore, D. E. Mosier, D. D. Richman, R. T. Schooley, M. S. Springer, R. S. Veazey, and M. A. Wainberg. 2008. Whither or wither microbicides? *Science (New York, N.Y* 321:532-534. PMC. 18653884.
3. Silvestri, G., M. Paiardini, I. Pandrea, M. M. Lederman, and D. L. Sodora. 2007. Understanding the benign nature of SIV infection in natural hosts. *The Journal of clinical investigation* 117:3148-3154. PMC. 17975656.
4. Lederman, M. M., and **S. F. Sieg**. 2007. CCR5 and its ligands: a new axis of evil? *Nature immunology* 8:1283-1285. PMC. 18026077.
5. **Funderburg, N**., M. M. Lederman, Z. Feng, M. G. Drage, J. Jadlowsky, C. V. Harding, A. Weinberg, and **S. F. Sieg.** 2007. Human -defensin-3 activates professional antigen-presenting cells via Toll-like receptors 1 and 2. *Proceedings of the National Academy of Sciences of the United States of America* 104:18631-18635. PMC. 18006661.
6. **Rodriguez, B.**, A. K. Sethi, V. K. Cheruvu, W. Mackay, R. J. Bosch, M. Kitahata, S. L. Boswell, W. C. Mathews, D. R. Bangsberg, J. Martin, C. C. Whalen, **S. Sieg,** S. Yadavalli, S. G. Deeks, and M. M. Lederman. 2006. Predictive value of plasma HIV RNA level on rate of CD4 T-cell decline in untreated HIV infection. *Jama* 296:1498-1506. PMC. 17003398.
7. Lederman, M. M., R. E. Offord, and O. Hartley. 2006. Microbicides and other topical strategies to prevent vaginal transmission of HIV. *Nature reviews* 6:371-382. PMC. 16639430.
8. Brenchley, J. M., D. A. Price, T. W. Schacker, T. E. Asher, G. Silvestri, S. Rao, Z. Kazzaz, E. Bornstein, O. Lambotte, D. Altmann, B. R. Blazar, **B. Rodriguez, L. Teixeira-Johnson**, A. Landay, J. N. Martin, F. M. Hecht, L. J. Picker, M. M. Lederman, S. G. Deeks, and D. C. Douek. 2006. Microbial translocation is a cause of systemic immune activation in chronic HIV infection. *Nature medicine* 12:1365-1371. PMC. 17115046.
9. **Salkowitz, J. R., S. F. Sieg**, C. V. Harding, and M. M. Lederman. 2004. In vitro human memory CD8 T cell expansion in response to cytomegalovirus requires CD4+ T cell help. *The Journal of infectious diseases* 189:971-983. PMC. 14999599.
10. Lederman, M. M., R. S. Veazey, R. Offord, D. E. Mosier, J. Dufour, M. Mefford, M. Piatak, Jr., J. D. Lifson, **J. R. Salkowitz, B. Rodriguez**, A. Blauvelt, and O. Hartley. 2004. Prevention of vaginal SHIV transmission in rhesus macaques through inhibition of CCR5. *Science (New York, N.Y* 306:485-487. PMC. 15486300.

**C. Research Support**

**<u>Current External Funding</u>**
AI-36219 (Karn) 04/01/2010 – 03/31/2014
NIH
Center for AIDS Research (CFAR)
Promote increased collaboration between basic and clinical researchers through a central administrative structure, development of appropriate forums for sharing and exchange of ideas and pilot funding for interdisciplinary research. Also to enhance the depth and breadth of AIDS research by coordinated development of core activities and recruitment of new investigators.

Role: Associate Director

AI-68636 07/26/2006 - 05/31/13
NIH
AACTG Support Laboratory Solicitation (ISL)
Adult AIDS Clinical Trials Group advanced technology laboratory to monitor the immunologic determinants of disease progression among clinical trials participants.
Role: Principal Investigator

AI-069501 10/01/1987 – 11/30/2013
NIH/NIAID
Case Clinical Trials Unit
Develop, implement, and analyze results of clinical treatment trials for HIV infection and its complications
Role: Principal Investigator

1 P01 AI 076174 08/01/2008-07/31/2013
NIH/NIAID
Defining the Pathogenesis of Immune Deficiency in Chronic HIV Infection
This program project application is submitted by the members of the Cleveland Immunopathogenesis Consortium (CLIC) a group of investigators representing 10 academic and research institutions in the United States and Canada who have been engaged in productive collaborations for the past three years. This group of experienced, outstanding investigators capitalizes on complementary research skills and resources and proposes an interdisciplinary program comprising 4 projects and 2 cores in a coordinated research effort aimed at unraveling the mechanisms whereby HIV infection results in progressive immune deficiency.
Role: Principal Investigator

Richard J. Fasenmyer Foundation Award 05/01/2011-05/31/2014
$500,000/year
Cleveland HIV Immunity Project (CHIP)
Role: Principal Investigator

1P01DE019759 (Weinberg) 03/02/2009 – 04/30/2014
NIH/NIDCR
Interdisciplinary on Oral Manifestations of HIV/AIDS in Vulnerable Populations
The central hypothesis of this Program Project is that alterations in innate defense mechanisms determine susceptibility to oral complications following HIV infection. Human beta defensins (hBDs) have been the focus of our group's research in HIV for more than seven years. We have discovered that oral epithelial cell-derived beta defensins can: 1) be induced by HIV; 2) inhibit the ability of the virus to infect immunocompetent cells; and 3) interact with specific chemokine and toll-like receptors resulting in regulation of adaptive immune cells. Moreover, chronic HIV infection and/or highly active antiretroviral therapy (HAART) predisposes the oral mucosae to both cellular and innate immune impairment. Interestingly, amongst the repertoire of innate immune molecules, hBDs are unique, as copy number variations have only been reported for the beta defensin gene cluster; possibly explaining the interpersonal variability in hBD expression levels.
Role: Investigator

UM1 A068636 (Social, Sci Sys) 06/01/2012 – 05/31/2013
NIH via SSS
Salary support for being Chair of the End Organ Disease/Inflammation Transformative Science Groups
Role: Chair

AI69918 (Moore) 7/01/06 - 6/30/14
NIH/NIAID
The North American AIDS Cohort Collaboration on Research and Design (NA-ACCORD)
Establish a collaboration of North American HIV/AIDS cohorts and a data center for compilation of data to address HIV/AIDS research questions that cannot be accomplished through smaller cohorts;
address scientific aims that focus on the failure of highly-active antiretroviral therapy (HAART);
address additional scientific aims related to events that cannot be as well-studied in smaller cohorts; to develop and apply novel statistical and epidemiological methodology that is applicable to these scientific research initiatives.
Role: Investigator

RFA-AI-09-0940 (Goldstein) 08/1/12 – 7/31/13
NIH
Determinants of protection in high risk HIV seronegative men having sex with men.
Role: Investigator

AI105937 (Lederman) 4/1/13 – 3/31/18
NIH/NIAID
Effects of IL6 blockade in treated HIV infection.
The overall objective of this interventional study is to establish the position of heightened IL-6 exposure on the pathways of pathogenesis and morbidity in treated HIV-1 infected persons with immune failure by examining the effects of IL-6 inhibition on the pathogenesis of immune failure and inflammation in treated HIV infection, examining the effect of systemic IL-6 mediated inhibition on indices of cardiovascular disease risk in treated HIV-1 infection and examining the effects of systemic IL-6 inhibition on the inflammatory transcriptome and plasma metabolomes in treated HIV-1 infection
Role: Principal Investigator

1RO1HL117713 (Hsue) 9/26/12-6/30/16
NHLBI
Effect of Low Dose Methotrexate on endothelial Function and Inflammation in HIV
Estimate the effects of LDMTX on cardiovascular inflammatory markers related to cardiovascular disease (CVD) risk, inflammation, and coagulation, including hsCRP, IL-6, sCD163, and D-dimer and also on levels of markers of microbial translocation such as lipopolysaccharide, soluble CD14, markers of HIV immune activation, immune senescence, macrophage markers, monocyte subpopulations, expression of CX3CR1, and coagulation markers such as tissue factor.
Role: Investigator

**BIOGRAPHICAL SKETCH**

| NAME **Ludington, Susan M.** | POSITION TITLE<br>Professor |
|---|---|
| eRA COMMONS USER NAME **SLUDINGTON** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| University of California at Santa Barbara, CA | BS | 1969 | Cell Biology |
| University of California at San Francisco, CA | BS | 1972 | Nursing |
| University of California at San Francisco, CA | MS | 1973 | Maternal-Child Health Nursing/Child Development/ |
| Texas Woman's University, Denton, TX | PhD | 1977 | Psychology |
| State University of New York, Downstate Medical Center, New York, NY | CNM | 1979 | *Nurse-Midwife* |
| Edentec Corporation | CNP | 1992 | Certified Neonatal Pneumographer |

**A. Positions and Honors**

**Positions and Employment**

| | |
|---|---|
| 1972 | Clinical Supervisor, BSN Program, Maternal Child Health, San Francisco Com Coll, CA |
| 1974-1975 | Instructor, University of Illinois School of Nursing, IL |
| 1975-1977 | Assistant Professor of Nursing, Baylor University School of Nursing, TX |
| 1976-1977 | Chair, Maternal Child Health, Baylor University School of Nursing, TX |
| 1978-1979 | Assist Professor, Maternal Child Health Nursing, Imperial Med Cntr Of Tehran, IRAN |
| 1979-1981 | Assist Professor of Nurse-Midwifery, Georgetown University, Washington DC |
| 1980-1981 | Adjunct Associate Professor of Nursing, American University, Washington, DC |
| 1981-1982 | Adjunct Associate Professor of Nursing, George Mason University, Fairfax, VA |
| 1981-1988 | Assist Professor, Maternal Child Health, University of California at Los Angeles (UCLA) |
| 1981-1992 | Founder and President, Infant Development Education Association of America |
| 1983-1987 | Chair, Maternal-Child Health, UCLA School of Nursing, Los Angeles, CA |
| 1989-1996 | Assoc Professor, Maternal Child Health, UCLA School of Nursing, Los Angeles, CA |
| 1992-1996 | Director, Nurse Midwifery Educational Program, UCLA/UCI Los Angeles & Irvine, CA |
| 1992-1996 | Assoc Clin Professor OB/GYN, College of Med, University of California Irvine |
| 1993-1995 | Vice-Chair, Maternal-Child Health, UCLA School of Nursing, Los Angeles, CA |
| 1996-2001 | Full Professor and Senior Researcher, University of Maryland School of Nursing, MD |
| 1998-2000 | Coordinator, Women's Health Specialties, University of Maryland, Baltimore, MD |
| 1998-2001 | Program Director, Nurse-Midwifery Education Prog, University of Maryland, MD |
| 2001-present | Carl W. & Margaret Davis Walter Professor of Pediatric Nursing & Full Professor Frances Payne Bolton School of Nursing, Case Western Reserve University, Cleveland, OH |
| 2007-present | Faculty Associate of Schubert Center for Child Studies, Case Western Reserve University, Cleveland, OH |

**Other Positions (Select)**

| | |
|---|---|
| 2010 | Abstract Reviewer - Council of Advanced Nursing Science 2010 |
| 2009-2011 | Member, Awards Committee, Midwest Nursing Research Society |
| 2009-2012 | Member, International Advisory Board, Swedish Association of Midwives and Sexual and Reproductive HealthCare Journal. |
| 2009 | Member, US AID & SAVE THE CHILDREN Advisory Groups on Kangaroo Care |
| 2007+ | Association of Women's Health, Obstetric, and Neonatal Nurses "Expert Source" |

2006-2008 Chair, National Association of Neonatal Nurses Task Force on Kangaroo Care
2006+ Member, National Association of Neonatal Nurses Research Committee
2006-2008 Member, Midwest Nursing Research Society Research Committee (Invited)
2006 International Federation of Scientists –Participant in Global Emergencies Consensus Conference, Erice, Sicily
2004-2005 Reviewer, NIH Genetics and Sleep Study Section
2004-2006 Chair, Steering Committee, International Network of Kangaroo Mother Care
2004-2006 Member, American Academy of Nursing Fellow Selection Committee
2004 Member , Johnson & Johnson Pediatric Institute's Global Speakers Bureau
2000-2004 Member, Advisory Board, Academy of Neonatal Nurses
2000-2002 Chair, Research Committee, Sigma Theta Tau Pi Chapter
2000-2002 Member, Am. Assoc. Critical Care Nurses Neonatal Advisory Team
2000 Member, World Health Organization Maternal Child Health Bureau, Kangaroo Care Consensus Conference, Erice, SICILY

**Honors (Select)**

2011 March of Dimes Margaret Comerford Freda "Saving Babies, Together" Award
2010 Nurse Researcher Hall of Fame, Inaugural inductee, Sigma Theta Tau, International
2009 Audrey Hepburn Award for Excellence in Contributions to Children's Health, Sigma Theta Tau International, Nov. 2, 2009
2009 First Place Abstract Award 15th Annual Meeting of Society of Pediatric Nurses, Orlando, FL
2009 Research Mentorship Award, Midwest Nursing Research Society
2008 Certificate of Appreciation from the National Association of Neonatal Nurses
2008 Distinguished Scientist Recognition Award. Midwest Nursing Research Society
2007 Excellence in Research Award. Association of Women's Health, Obstetric, & Neonatal Nurses
2007 3rd Place Award for National Medical Computing for Interactive CD on "The Effects and Process of Birth Kangaroo Care" by Phillips Corporation
2007 Woman of Excellence in Research and Scholarship Award. Case Western Res. University

**B. Selected Peer - Reviewed Publications (Selected from peer-reviewed publications)**

1. Ludington-Hoe, SM. Kangaroo care is developmental care. In Kenner C & McGrath J (Eds.) *Developmental Care for Newborns and Infants*. 2nd Ed. (2010). Glenview, IL: National Association of Neonatal Nurses Publication, Pp. 349-388.
2. Martin,JB. & **Ludington-Hoe, SM.** (2010). Near infrared spectroscopy measure of brain activation inpremature infants in an incubator and during Kangaroo Care. *Advances in Neonatal Care, 19*(4), 214—215.
3. Scher M, **Ludington-Hoe, SM,** Kaffashi, F, Johnson, M, Holditch-Davis, D, & Loparo KA. (2009). Neurophysiologic assessment of brain maturation after an eight-week trial of skin-to-skin contact on preterm infants. *Clinical Neurophysiology*, 120(10), 1812- 1818.
4. Ludington-Hoe, SM., Johnson, Morgan, K., Lewis, T., Gutman, J., Wilson, D., & Scher, M. S. (2006). Neurophysiologic assessment of neonatal sleep organization: results of a randomized controlled trial of skin contact with preterm infants. *Pediatrics*. 117(5), e909-e923.
5. Ludington-Hoe, SM, Morgan, K., Abouelfettoh, A. (2008). National clinical guidelines for implementation of Kangaroo Care with premature infants $\geq$ 30 weeks postmenstrual age. National Association of Neonatal Nurses Initiative on Kangaroo Care. *Advances in Neonatal Care,* 8(3S,Suppl), S3-S23.
6. Ludington-Hoe, S. M., Anderson, G. C., Swinth, J. Y., Thompson, C., Hadeed, A. J. (2004). Randomized controlled trial of Kangaroo Care: Cardiorespiratory and thermal effects on healthy preterm infants. *Neonatal Network, 23*(3), 39-48. Won writing award.

**Additional Recent Publications of Importance to the Field (in Chronological Order)**

1. Jarrell, JR., **Ludington-Hoe, SM.,** & Abouelfettoh, A. (2009). Kangaroo Care with Twins: A Case Study in Which One Infant Did Not Respond As Expected. *Neonatal Network 28*(3),157-63.
2. Cong, X, **Ludington-Hoe, SM,** McCain, G, & Fu, P. (2009). Kangaroo care modifies preterm infant heart rate variability in response to heel stick pain. *Early Human Development, 85*,561-567.
3. Ludington-Hoe, S. M., Evidence-Based Review of Physiologic Effects of Kangaroo Care. (2011) *Current Womens' Health Reviews*, 7(4), 200-211.
4. Cong, X. & **Ludington-Hoe, SM**. (2011). Effect of Kangaroo Care on pain scores and cortisol: Randomized cross-over trial. Biologic Research for Nursing, 13(2), 204-216. DOI: 10.1177/1099800410385839.
5. Abouelfettoh, A., **Ludington-Hoe, S.M.,** Visscher, M., Burant, C.J., & Cartner, T. (2011). Effect of skin-to-skin contact on preterm infant skin barrier function and hospital-acquired infection. *J. Clinical Medicine Research, 3*(1). 36-46.

## C. Research Support

**Ongoing Research Support**

AWHONN Ludington (PI) 6/30/2011-6/30/2012
Evaluation of infant neonatal abstinence scores and maternal activation scores when conducting 4 hour sessions of KC per day for 4 consecutive days. Sleep quality is one of the abstinence score items.

Foundation for Neonatal Research Ludington (PI) 10/1/2010-9/30/2011
Descriptive evaluation of 4 days of Kangaroo Care to reduce neonatal abstinence syndrome severity in 58 infants exposed prenatally to buprenorphine. Sleep quality is one of the severity criteria.

Presidential Research Initiative Ludington (PI) 7/1/2008-6/30/2010
Development and testing of personalized chest device to simulate Kangaroo Care. The chest device has been built and is being tested with premature infants to determine safety and physiologic and sleep effects of the device by comparing responses in an incubator to responses in Kangaroo Care.
Role: PI

**Completed Research Support**

NIH 1P20-NR008992 Harrison (PI) 2/1/2009-1/30/2011
This randomized controlled trial is determining the effect of skin-to-skin contact (kangaroo care) on physiologic regulation in infants with congenital heart defects.
Role: Consultant

R15NR009797-01 Damato (PI) 7/1/2007-6/30/2009
*Sleep Patterns in Mothers and Fathers of Twins*
This pilot correlational study determined the relationship between maternal level of sleep and fatigue and depression in mothers of multiple births during the postpartum period.
Role: Co-investigator

RG701 Foundation for Neonatal Research Abouelfettoh (PI) 7/1/2007-6/30/2009
*Dermal Neurobiology of Premature Infant Skin During and After Kangaroo Care*
This evaluative study measured the effects of Kangaroo Care on preterm infant skin hydration, transepidermal water loss, and number of nosocomial infections.
Role: Co-investigator

1R15NR008869-01A1 Dowling (PI) 8/31/2005 - 8/31/2007
*High Risk Black Infants Need Their Mother's Milk*
This randomized controlled trial determined Kangaroo Care effects on preterm infant breastfeeding incidence, duration and performance in high risk black mother-infant dyads.
Role: Co-Investigator

R03-NR-008587 Ludington (PI) 7/1/2003-6/30/2005
*Kangaroo Care to Blunt Pain in Premature Infants*
The randomized cross-over trial pilot tested the heart rate, respiratory rate, oxygen saturation, heart rate variability, cortisol, and premature infant pain profile responses to heel stick after 80 minutes of Kangaroo Care or 80 minutes of incubator care.
Role: PI

1R01-NR-04926-01A1 Ludington (PI) 2/1/2002-1/30/2006
*Effect of Skin Contact on Electrophysiologic Sleep in Preterm Infants*
This randomized controlled trial evaluated the effect of one 3-hour session of Kangaroo Care on electrophysiologic-based sleep organization.
Role: PI

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Madigan, Elizabeth A.** | POSITION TITLE<br>Professor of Nursing |
| eRA COMMONS USER NAME **EMADIGAN** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| Wright State University, Dayton, OH | BSN | 1979 | Nursing |
| Ohio State University, Columbus, OH | MSN | 1988 | Nursing |
| Case Western Reserve University (CWRU), Cleveland, OH | PhD | 1996 | Nursing |

**A. Positions and Honors**

**Positions and Employment**

| | |
|---|---|
| 1980-1981 | Pediatric Staff Nurse, Lima Memorial Hospital, Lima, OH |
| 1981-1983 | Home Care and Hospice Staff Nurse, Van Wert Area VNA, Van Wert, OH |
| 1983-1984 | Clinical Coordinator, Starr Commonwealth School for Boys, Van Wert, OH |
| 1984-1987 | Home Care Staff Nurse, St. Ann's Hospital Home Care Services, Westerville, OH |
| 1987-1989 | Contingent Home Care Staff Nurse, First Choice Home Care, Columbus, OH |
| 1989-1990 | Director of Home Care, Park Medical Center, Columbus, OH |
| 1990-1991 | Director of Inpatient & Home Care Services, Park Med Center, Columbus, OH |
| 1991-1992 | Director of Home Care, Park Medical Center, Columbus, OH |
| 1993-1994 | Graduate Research Assistant, CWRU, Cleveland, OH |
| 1994-1996 | Data Analyst, CWRU, Cleveland, OH |
| 1996-2001 | Assistant Professor, Frances Payne Bolton School of Nursing, CWRU, Cleveland, OH |
| 2000-2001 | Director, Center for Research & Scholarship, Frances Payne Bolton School of Nursing, CWRU, Cleveland, OH |
| 2001 | Visiting Professor, Catholic University, Santiago, Chile |
| 2001-2006 | Assistant/Associate Dean for International Health & Director of the WHO Collaborating Center, Frances Payne Bolton School of Nursing (FPB), CWRU, Cleveland, OH |
| 2001-present | Consultant, Evidence-based nursing practice, World Health Organization (WHO) |
| 2001-2009 | Associate Professor, Frances Payne Bolton School of Nursing, CWRU, Cleveland, OH (Tenured 2005) |
| 2009-present | Professor of Nursing, Frances Payne Bolton School of Nursing, CWRU, Cleveland, OH |
| 2012-present | Associate Dean for Academic Affairs, Frances Payne Bolton School of Nursing, CWRU, Cleveland, OH |

**Honors (selected)**

| | |
|---|---|
| 1994 -1996 | Pre-doctoral fellow, National Research Service Award, NIH/NINR |
| 1994-present | Sigma Theta Tau International, Nursing Honor Society |
| 1995-present | Association for Health Services Research |
| 1996-present | Home Healthcare Nurses Association |
| 2001 | Panel Member, Agency for Healthcare Research and Quality, Special Emphasis Panel, The Effects of Health Care Working Conditions On Quality of Care, NIH |
| 2003 | Midwest Nursing Research Society, Public Health, Community Health, Nurse Managed Center Research Section New Investigator Award |
| 2003 | Excellence in Nursing Research, Ohio Nurses Association |
| 2002-2005 | Permanent Panel Member, Agency for Healthcare Research and Quality Health Care Research and Training Study Section |
| 2006 | Fellow, American Academy of Nursing |

2007 Daniel J. Pesut Spirit of Renewal Award, Sigma Theta Tau International
2010 Distinguished Scientist Recognition Award, Midwest Nursing Research Society

**B. Selected Peer Reviewed Publications (in chronological order):**

1. Fortinsky, R.H., Madigan, E.A., & Tullai-McGuinness, S. (2000). Resource use and patient outcomes in Medicare home care. *Caring, 19*(11), 20-22.
2. Madigan, E. A., Schott, D., & Matthews, C. (2001). Rehospitalization among home health care patients: Results of a prospective study. *Home Healthcare Nurse, 19*(5), 298-305.
3. Fortinsky R. H., Garcia R. I., Joseph Sheehan, T., Madigan E. A., & Tullai-McGuinness, S. (2003).Measuring disability in Medicare home care patients: Application of Rasch modeling to the outcome and assessment information set. *Medical Care, 41*, 601-615.
4. Madigan, E. A., Tullai-McGuinness, S., & Fortinsky, R. H. (2003). Accuracy in the Outcomes and Assessment Information Set (OASIS): Results of a video simulation. *Research in Nursing and Health, 26*, 273-283.
5. Madigan, E. A., & Fortinsky, R. H. (2004). Interrater reliability of the Outcomes and Assessment Information Set: Results from the field. *The Gerontologist, 44*, 689-692.
6. Koroukian, S. M., Murray, P. K., & Madigan, E. A. (2006). Comorbidity, disability, and geriatric syndromes in elderly cancer patients receiving home health care. *Journal of Clinical Oncology, 24*, 2304-2310.
7. Fortinsky, R. H., Madigan, E. A., Sheehan, T. J., Fenster, J. R., & Tullai-McGuinness, S. (2006). Risk factors for hospitalization among Medicare home care patients. *Western Journal of Nursing Research*, 28, 902-917.
8. Scharpf, T. P., Colabianchi, N. Madigan, E. A., Neuhauser, D., Peng, T., Feldman, P. H. & Bridges, J. F. P. (2006). Functional status decline as a measure of adverse events in home health care: an observational study. *BMC Health Services Research*, 6, 162. PMC1774572.
9. Rogers, J., Perlic, M. & Madigan, E. A. (2007). The effect of frontloading visits on patient outcomes. *Home Healthcare Nurse*, 25, 103-109. PMID: 17285038.
10. Madigan, E. A. (2008). People with heart failure and home health care resource use and outcomes. *Journal of Clinical Nursing*, 17, 253.259. PMID: 18578801.
11. Tullai-McGuinness, S., Madigan, E. A., & Fortinsky, R. H. (2009). Validity Testing the Outcome and Assessment Information Set (OASIS). *Home Health Care Services Quarterly, 28*, 45-57. PMC3070156.
12. Deitz, D., Dowell, R. N., Madigan, E. A., & Richard, A. (2010). OASIS-C: Development, testing and release. An overview for home healthcare clinicians, administrators and policy makers. *Home Healthcare Nurse, 28*, 353-362. PMID: 20389254.
13. Madigan EA, Gordon N, Fortinsky RH, Koroukian SM, Piña I, Riggs JS. (2012). Predictors of functional capacity changes in a US population of Medicare home health care (HHC) patients with heart failure (HF). *Arch Gerontol Geriatr*.. 54(3):e300-6. Epub 2011. Sep 6. PMCID: PMC323625.
14. Koroukian, S. M, Scharpf, T., Bakaki P. M. & **Madigan, E. A**. (2011). Identifying comorbidities in home health care patients: does the Outcome and Assessment Information Set have incremental value to Medicare claims data? Home Health Care Services Quarterly, 30, 1-9. (PMC id in process)
15. Madigan EA, Gordon NH, Fortinsky RH, Koroukian SM, Piña I, Riggs JS. (2012). Rehospitalization in a National Population of Home Health Care Patients with Heart Failure. *Health Serv* Res. doi: 10.1111/j.1475-6773..01416.x. [Epub ahead of print]. PMID: 22524242.

**C. Research Support**

**<u>Ongoing Research Support</u>**

P30 NR010676-04 Moore (PI) 09/29/07–06/30/13
NIH/NINR
Center of Excellence to Build the Science of Self-Management: A Systems Approach

The SMART Center will prepare a critical mass of researchers to extend and disseminate knowledge related to self-management, contribute to the development of emerging biobehavioral research methods, focus on critical issues related to health disparities, and incorporate economic considerations as part of their research.
Role: Co-Investigator and Director, Methods and Statistical Core

University Center on Aging & Health President's Initiative/The McGregor Foundation
(Madigan, Co-PI; Boxer, Co-PI) 11/01/09-12/31/13
Supporting Self-management with Telehealth for Patients with Multiple Morbidity
Pilot study evaluating health related outcomes for home health care patients who have co-occurring heart failure, diabetes and chronic pulmonary disease combined with depressive symptoms, anxiety, and cognitive impairment.

**Completed Research Support**

RFD-OD-10-007 R24 Madigan (PI) 09/15/10-08/30/12
NIH-Fogarty International Center (FIC)
GhREAT: Global health Research Expanding Advanced Training
The aims of this project are to accelerate the development of postdoctoral trainees in global health research, taking advantage of existing research programs and the Framework program at Case Western Reserve University (CWRU) and expanding existing relationships and collaborations.

Pan American Health and Education Foundation Madigan (PI) 12/18/09–07/31/12
Health Aging in the Caribbean
The present project is designed to enhance health system approaches to healthy aging in three countries in the Caribbean (St. Lucia, Jamaica, and Barbados) by providing tailored interprofessional training programs for health care workers, based on their identified needs.

T32 NR009761-05 Moore (PI) 04/1/06 - 04/30/12
NIH/NINR
Multiple Morbidities in Vulnerable Populations: Nurse Scientist Training
The predoctoral and postdoctoral training program provides research training for nurses pursuing research careers focused on vulnerable populations with multiple morbidities.
Role: Core Faculty

R01 HL085725 Madigan (PI) 04/1/07 - 02/28/12
NIH/NHLBI
Effects of Home Care Agency Providers and Visits on Heart Failure Patient Outcomes
This study will examine rehospitalization and functional status decline in home health care patients with heart failure using individual, provider and market factors for a national population of home health care patients from 2005.

CWRU-Provost's Investment Fund Kazura (PI) 01/01/2010-12/31/11
The Alliance for Global Health
Alliance members are from the 8 participating Schools and the College. Based on our collective earlier experience with students who have been supported by the existing NIH Fogarty-supported Framework for Global Health, we will continue to support the global health certificate program and field experiences for undergraduate and graduate students across the university.
Role: Co-Investigator

P30 NR010676-03S1 Moore (PI) 9/18/09-08/31/11
NIH/NINR
Full Inclusion of Persons with Disabilities in Self-Management Research

The FIND Lab in the SMART Center of Excellence provides a set of resources and services to researchers about the use of Universal Design principles to design interventions and their delivery and data collection methods to support fuller inclusion of people with disabilities in research.
Role: Co-Investigator

CMS-06-017 Goldberg( PI)
ABT Associates-(Subcontract with Case Western Reserve University) 09/27/06-03/31/10
Centers for Medicare & Medicaid Services
Home Health Quality measures and Data Analysis
Role: PI of Cleveland Site

R25 TW007735A Blanton (PI) 09/15/06-08/31/09
Fogarty International Center
Framework Program for Global Health
The overall objective of the Case Framework Program for Global Health is to interest and retain undergraduate, graduate and professional students in global health related careers by enhancing the perception and profile of relevant fields and courses within the university, facilitating interdisciplinary study and providing opportunities for applied experiences.
Role: Collaborating Faculty

R01 NR005081 Fortinsky (PI) 08/15/04 - 07/31/09
NIH/NINR - Parent (Subcontract from University of Connecticut)
Resource Use and Patient Outcomes in Medicare Home Care
Specific aims were to determine, accounting for potential effects of home care agency factors and county-level market factors: (1) the most important patient-level risk factors for ending an episode of Medicare home care due to hospitalization (2) the most important patient-level risk factors for greater functional disability and clinical symptoms; (3) how staff-specific resource use measures are associated with functional disability and clinical symptoms and (4) patterns and predictors of hospitalization, functional and clinical outcomes, and staff-specific resource use
Role: Co-Investigator

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Markowitz, Sanford D.** | POSITION TITLE<br>Professor |
| eRA COMMONS USER NAME **SMARKOWITZ** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| Harvard College, Cambridge, MA | AB (Summa Cum Laude) | 7/74 | Chemistry/Physics |
| Yale University, New Haven, CT | MD;PhD | 9/80; 6/80 | Medicine/Cell Biology |
| Yale University, New Haven, CT | Postdoctoral | 6/81 | Infectious Diseases |
| University of Chicago | Residency | 6/84 | Internal Medicine |
| National Cancer Institute | Fellowship | 6/87 | Medical Oncology |

**A. Positions and Honors.**

**Positions**

1977-1980 Graduate student with Dr. V. T. Marchesi, Yale University, New Haven, CT
1981-1984 Resident in Internal Medicine, University of Chicago Hospitals & Clinics
1984-1987 Fellow, Clinical Oncology Program, National Cancer Institute & Postdoctoral research, Molecular Biology Laboratory, NCI-Navy-M.O.B., Dr. John Minna, Branch Chief
1987-1997 Assistant/Associate Professor, Medicine-Hematology/Oncology, Case Western Reserve University and University Hospitals of Cleveland, OH
1995- Co-Leader, Cancer Genetics Program, Case Comprehensive Cancer Center, Cleveland, OH
1997- Ingalls Professor of Cancer Genetics, Medicine-Hematology/Oncology, Case Western Reserve University and University Hospitals of Cleveland, OH
1998-2010 Investigator, Howard Hughes Medical Institute

**Selected Honors and Awards:**

1994 Recipient ACS Faculty Research Salary Award;
1995 American Society Clinical Investigation;
1998 and 2007 Invited Lecturer of Princess Takamatsu Cancer Research Fund, Tokyo, Japan;
2000 Petros Palandjian Visiting Professor Harvard Medical School;
2005 American Association Physicians;
2008 Hero of Hope Research Medal, American Cancer Society-Ohio Division
2009 Baldini Visiting Professor, Beth Israel Deaconess Medical Center, Harvard Medical School
2009 Wadler Visiting Professor, Weill Cornell Medical College

**Selected Committees**

National Cancer Institute: Board of Scientific Counselors-Clinical Sciences and Epidemiology;
CALGB: Co-Chair GI Correlative Sciences Committee

**Selected Inventions**

1999, Cancer diagnosis, prognosis and therapy based on mutations in TGF-ß receptors. US Patent 5,866,323;
2009, Methods and Compositions for Detecting Colon Cancers, U.S. Patent 7485420 (commercialized as "ColoSure" test by LabCorp).

**B. Selected Peer-reviewed Publications (Chronological Order)**

**Most relevant to the current application (5)**


1. Yan M, Rerko RM, Platzer P, Dawson D, Willis J, Tong M, Lawrence E, Lutterbaugh J, Lu S, Willson JK, Luo G, Hensold J, Tai HH, Wilson K, Markowitz SD. 15-Hydroxyprostaglandin dehydrogenase, a COX-2 oncogene antagonist, is a TGF-beta-induced suppressor of human gastrointestinal cancers. Proc Natl Acad Sci USA 101:17468-17473, 2004. PMCID: PMC536023
   Parsons DW, Wang TL, Samuels Y, Bardelli A, Cummins JM, DeLong
2. Myung SJ, Rerko RM, Yan M, Platzer P, Guda K, Dotson A, Lawrence E, Dannenberg AJ, Lovgren AK, Luo G, Pretlow TP, Newman RA, Willis J, Dawson D, Markowitz SD. 15-Hydroxyprostaglandin dehydrogenase is an *in vivo* suppressor of colon tumorigenesis. Proc Natl Acad Sci USA 103:12098-12102, 2006. PMCID: PMC1567703
3. Yan M, Myung SJ, Fink SP, Lawrence E, Lutterbaugh J, Yang P, Zhou X, Liu D, Rerko RM, Willis J, Dawson D, Tai HH, Barnholtz-Sloan JS, Newman RA, Bertagnolli MM, Markowitz SD. 15-Hydroxyprostaglandin dehydrogenase inactivation as a mechanism of resistance to celecoxib chemoprevention of colon tumors. Proc Natl Acad Sci U S A 106:9409-9413, 2009. PMCID: PMC2695050
4. Huang G, Eisenberg R, Yan M, Monti S, Lawrence E, Fu P, Walbroehl J, Löwenberg E, Golub T, Merchan J, Tenen DG, Markowitz SD, Halmos B. 15-Hydroxyprostaglandin dehydrogenase is a target of hepatocyte nuclear factor 3beta and a tumor suppressor in lung cancer. Cancer Res 68:5040-5048, 2008. PMCID: PMC2762106
5. Markowitz SD. Aspirin and colon cancer--targeting prevention? N Engl J Med 356:2195-2198, 2007. http://content.nejm.org/cgi/content/full/356/21/2195-a


**Additional recent publications of importance to the field (in chronological order) (10)**


1. Grady W, Willis J, Guilford P, Dunbier A, Toro T, Lynch H, Wiesner G, Ferguson K, Eng C, Park JG, Kim SJ, Markowitz, S: Methylation of the CDH1 promoter as the second genetic hit in hereditary diffuse gastric cancer. Nature Genet 26:16-17, 2000. http://www.nature.com/ng/journal/v26/n1/full/ng0900_16.html
2. 2. Wiesner G, Daley D, Lewis S, Ticknor C, Platzer P, Lutterbaugh J, MacMillen M, Baliner B, Willis J, Elston R.C, Markowitz SD. A subset of familial colorectal neoplasia kindreds linked to chromosome 9q22.2-31.2 Proc Natl Acad Sci U S A 100: 12961-65, 2003. PMCID: PMC240727
3. Chen WD, Han ZJ, Skoletsky J, Olson J, Sah J, Myeroff L, Platzer P, Lu S, Dawson D, Willis J, Pretlow TP, Lutterbaugh J, Kasturi L, Willson JK, Rao JS, Shuber A, Markowitz SD. Detection in fecal DNA of colon cancer-specific methylation of the nonexpressed vimentin gene. J Natl Cancer Inst 97:1124-1132, 2005. http://jnci.oxfordjournals.org/cgi/content/full/97/15/1124, 314:268-274, 2006. http://www.sciencemag.org/cgi/content/full/314/5797/268
4. Wood LD, Parsons D, Jones S, Lin J, Sjoblom T, Leary RJ, Shen D, Boca SM, Barber T, Ptak J, Silliman N, Szabo S, Dezso Z, Ustyanksky V, Nikolskaya T, Nikolsky Y, Karchin R, Wilson PA, Kaminker J, Zhang Z, Croshaw R, Willis J, Dawson D, Shipitsin M, Willson JK, Sukumar S, Polyak K, Park BH, Pethiyagoda C, Pant P, Ballinger D, Sparks A, Hartigan J, Smith DR, Suh E, Papadopoulos N, Buckhaults P, Markowitz SD, Parmigiani G, Kinzler K, Velculescu VE, Vogelstein B. The genomic landscapes of human breast and colorectal cancers. Science 318:1108-1113, 2007. http://www.sciencemag.org/cgi/content/full/318/5853/1108
5. Jones S, Chen WD, Parmigiani G, Diehl F, Beerenwinkel N, Antal T, Traulsen A, Nowak MA, Siegel C, Velculescu VE, Kinzler KW, Vogelstein B, Willis J, Markowitz SD. Comparative lesion sequencing provides insights into tumor evolution. Proc Natl Acad Sci USA 105:4283-4288, 2008. PMCID: PMC2393770
6. Guda K, Moinova H, He J, Jamison O, Ravi L, Natale L, Lutterbaugh J, Lawrence E, Lewis S, Willson JK, Lowe JB, Wiesner GL, Parmigiani G, Barnholtz-Sloan J, Dawson D, Velculescu VE, Kinzler KW, Papadopoulos N, Vogelstein B, Willis J, Gerken TA, Markowitz SD. Inactivating germ-line and somatic mutations in polypeptide N-acetylgalactosaminyltransferase 12 in human colon cancers. Proc Natl Acad Sci U S A 106:12921-129215, 2009. PMCID: PMC2722285
7. Markowitz, SD; Bertagnolli, MM. Molecular basis of colorectal cancer. N Engl J Med 361:2449-60, 2009. http://content.nejm.org/cgi/reprint/361/25/2449.pdf

8. Li M, Chen WD, Papadopoulos N, Goodman SN, Bjerregaard NC, Laurberg S, Levin B, Juhl H, Arber N, Moinova H, Durkee K, Schmidt K, He Y, Diehl F, Velculescu VE, Zhou S, Diaz LA Jr, Kinzler KW, Markowitz SD*, Vogelstein B. Sensitive digital quantification of DNA methylation in clinical samples. Nat Biotechnol. 27:858-63, 2009. http://www.nature.com/nbt/journal/v27/n9/full/nbt.1559.html. *SDM corresponding author.
9. 14.Moinova HR, Leidner RS, Ravi L, Lutterbaugh J, Barnholtz-Sloan JS, Chen Y, Chak A, Markowitz SD*, Willis JE. Aberrant vimentin methylation is characteristic of upper gastrointestinal pathologies. Cancer Epidemiol Biomarkers Prev. 2012 Apr;21(4):594-600. Epub 2012 Feb 7. Cover Article. http://cebp.aacrjournals.org/content/21/4/594.full#sec-1 . *SDM corresponding author.
10. Akhtar-Zaidi B, Cowper-Sal-Iari R, Corradin O, Saiakhove A, Bartels C, Balasubramanian D, Myeroff L, Lutterbaugh J, Jarrar A, Kalady M, Willis J, Moore J, Tesar P, Laframboise T, Markowitz SD, Lupien M, Scacheri P. Epigenomic enhancer profiling defines a signature of colon cancer. Science. 2012 Apr 12. *doi:* 10.1126/science.1217277. http://www.sciencemag.org/content/early/2012/04/11/science.1217277.full

**C. Research Support: Ongoing and Recently Completed Grant Support**

5R01 CA127306-03 (Markowitz, PI) 05/01/07-03/31/12
NIH/NCI
15-PGDH, a Novel in Vivo Suppressor of Colon Neoplasia in Mouse and Man
The goals of this project are to delineate the biological mechanism of 15-PGDH tumor suppression mouse models and to determine the particular importance of regulation of cyclin D1.

5R01 CA130901-02 (Markowitz, PI) 07/25/08-05/31/12
NIH/NCI
New Familial Colon Cancer Gene Discovery Via Combined Linkage and SNP Association
The goal of this project is to identifiy a colon cancer susceptibilty gene within the 9q22.2-31.2 candidate linkage region.

1R01 OD005734-01 (Markowitz, PI) 09/01/09-08/31/14
NIH/Roadmap Transformative R01 Program
Identifying Inborn Genetic Susceptibility to Development of Cancer Metastasis
The goal of this project is to identify genetic markers of metastasis susceptibility by using the technique of a whole genome association study.

1U01 CA152756-01 (Markowitz and Grady, Multi-PI) 08/25/10-06/30/15
NIH/NCI Early Detection Research Network (EDRN)
Identify and Validate Novel Epigenetic Markers for Colorectal Neoplasm
The goal of this project is to identify novel methylated DNA markers of human gastrointestinal cancers and to develop assays of these markers for early detection of human GI cancers pre-cancerous lesions.

1P50CA15096401A1 09/01/2011 – 08/31/2016
NIH/NCI SPORE (Markowitz, PI)
Case GI SPORE
This Case GI SPORE proposal provides for a cutting edge Specialized Program of Research Excellence in gastrointestinal malignancies with emphasis on colorectal cancers and with additional attention to adenocarcinoma of the esophagus

1R01CA160356-01 (Scacheri, Markowitz, Tesar, Multi-PI) 04/31/12-03/31/17
NIH/NCI
Role of Gene Enhancer Elements in Colon Cancer

The goal of this proposal is to characterize a new mechanism for gene dysregulation in human colon cancer, that being alterations of the H3K4me1 mark at gene enhancer elements.

U54CA163060 09/01/2011 – 08/31/2016
NIH (Multiple PI's: Chak,A, Markowitz SD, Berger N, Elston RC, Grady WM, , Shaheen NJ)
Barrett's Esophagus Translational Research Network (BETRNet)
Genetic Determinants of Barrett's Esophagus and Esophageal Adenocarcinoma
The overall objectives are to conduct a rigorous, integrated spectrum of transdisciplinary human research in Barrett's esophagus (BE) and esophageal adenocarcinoma (EAC)

1R21CA149349-01A1 09/09/2011-08/31/2013
NIH (Willis, J PI)
Identification of Significant Race Associated Colon Cancer Drive Gene Mutations
Test the hypothesis that patterns of CAN gene mutations differ among colon cancers arising in individuals of different race, reflecting at the molecular level differences in disease epidemiology, lifestyle, and environmental exposures among these groups. Role: Co-Investigator

NIH 2U01CA08640011 (Brenner PI) 03/01/2011-06/30/2015
Regents of the University of Michigan
Subcontract with Great Lakes New England Clinical and Epidemiology Center of the Early Detection Research Network (EDRN)
The purpose of this subcontract is to provide support for scientific collaboration with the Great Lakes New England Clinical Validation Center (GLNE CVC). Collaborators will participate in the design of research protocols, serve on Committees, plan, attend and participate in once yearly meetings, attend Steering Committee Meetings.

5R01 CA120237-04 (Markowitz, PI) 08/11/06-07/31/11
NIH/NCI
Novel Molecular Markers of Human Colon Neoplasia
The goal of this proposal is to develop noninvasive tests for early detection of colon cancers and precancerous advanced colon adenomas.

5P30 CA043703-22 (Gerson, PI) 09/30/91-03/31/13
NIH/NCI
Comprehensive Cancer Center Support Grant
The objectives of the Center are: 1) to improve the prevention, diagnosis, and therapy of cancer through research; 2) to stimulate and support innovative, coordinated, interdisciplinary research on cancer diagnosis, treatment, and control; 3) to develop clinical applications of research discoveries and to make these applications available as quickly as possible; and 4) to develop cancer prevention and control activities to contribute to the reduction of cancer morbidity and mortality in Northeast Ohio and the surrounding region and nation. Role: Cancer Genetics Program Co-Leader

5U54 CA116867-05 (Berger, PI) 09/19/05-08/31/11
NIH/NCI
Case Center for Transdisciplinary Research on Energetics and Cancer at Case Comprehensive Cancer Center
Project: Obesity and Dietary Pathways Leading to Colon Cancer
The goals of this project are to demonstrate that increased colon cancer risk is associated with obesity per se, and not with increased dietary fat intake, to elucidate the role of increased IGF1 signaling as a mediator of the obesity associated increased colon cancer risk, and to further identify key genes whose expression within the human colon is altered by obesity and by altered IGF1 signaling. Role: Project Leader

N01CN-43302 (Lipkin, PI, Weill Cornell Medical College) 07/01/09-04/29/11
WA#20: CWRU Subcontract (Markowitz, PI)
Selection of Individuals for NSAIDS (Celecoxib) Chemoprevention of Colon Tumors
This project will: i) demonstrate that in animal models that resistance to colon tumor chemoprevention induced by low colonic 15-PGDH can be overcome by use of sulindac instead of celecoxib; and ii) confirm in human material that individuals with low colonic 15-PGDH levels are resistant to colon neoplasia prevention by celecoxib.

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Richard J. Martin** | POSITION TITLE<br>Professor |
| eRA COMMONS USER NAME **RICHARDJMARTIN** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| University of Sydney School of Medicine | M.B., B.S. | 1970 | Medicine |
| Royal North Shore Hosp of Sydney, Sydney, Aust | | 1970-1972 | Jr/Sr Res Med Officer |
| University of Missouri Med Center, Columbia, MO | | 1972-1974 | Pediatric Res/Chief Res |
| Rainbow Babies & Children's Hospital, Cleve, OH | | 1974-1976 | Neonatal Fellow |

## A. Positions and Honors

**Positions**

1976-1977 Senior Instructor, Case Western Reserve Univ School of Medicine, Cleveland, OH
1977-1983 Assistant Professor, Pediatrics, CWRU School of Medicine, Cleveland, OH
1983-1990 Associate Professor, Pediatrics, CWRU School of Medicine, Cleveland, OH
1984-1990 Associate Professor, Reproductive Biology, CWRU School of Medicine, Cleveland, OH
1985-1998 Co-Director, Div of Neonatology, Rainbow Babies & Children's Hospital, Cleve, OH
1986-present Award of Tenure, Case Western Reserve University School of Medicine, Cleve, OH
1990-present Professor, Pediatrics, CWRU School of Medicine, Cleveland, OH
1990-present Professor, Reproductive Biology, CWRU School of Medicine, Cleveland, OH
1998-2011 Director, Division of Neonatology, Rainbow Babies & Children's Hospital, Cleve, OH
1999-present Professor, Physiology & Biophysics, CWRU School of Medicine, Cleveland, OH
2006-present Drusinsky/Fanaroff Endowed Chair, First Holder, University Hospitals of Cleveland, Cleve, OH

**Honors/Awards/Service/Memberships**

1994-present The Best Doctors in America, and America's Top Doctors
1982-present Senior Editor, Neonatal/Perinatal Medicine, Elsevier, Philadelphia, PA [9th ed, 2011]
1984-1990 Editorial Board, *Journal of Pediatrics*
1999-2003 Permanent Member, HED Study Section [1], Center for Scientific Review, NIH
1999-2007 Editorial Board, *Journal of Applied Physiology*
2000 Golden Stethoscope Award, Rainbow Babies & Children's Hospital's Peds Clin Faculty
2002 Member, Clinical Investigation Grants Committee, Canadian Inst of Hlth Res [CIHR]
2003-2010 Chair, Appointments, Promotions & Tenure Committee, Dept Pediatrics
2004-present Editorial Board, *Neonatology*
2004-2010 Member, Sub-Board, Neonatal/Perinatal Medicine, American Board of Pediatrics
2006-present Editorial Board, *Acta Pædiatrica*
2008-2010 Chair, Sub-Board, Neonatal/Perinatal Medicine, American Board of Pediatrics
2010-present Editorial Board, *Journal of Neonatal & Perinatal Medicine*
2010-present Chair, Monitoring Board, NHLBI Prematurity and Respiratory Outcomes Study Group [PROP]
2011-present Chair, Appointments, Promotion & Tenure Committee, CWRU School of Medicine
2012-present Editorial Board, *American journal of Physiology-Lung, Cellular and Molecular Physiology*

## B. SELECTED PEER-REVIEWED PUBLICATIONS [selections from 162 peer-reviewed scientific publications, 22 editorials/commentaries, and 82 chapters/invited reviews]

Ballard RA, Truog WE, Cnaan A, Martin RJ, Ballard PL, Merrill JD, Walsh MC, Durand DJ, Mayock DE, Eichenwald EC, Null DR, Hudak ML, Puri AR, Golombek SG, Courtney SE, Steward DL, Welty SE, Phibbs RH, Hibbs AM, Luan X, Wadlinger SR, Asselin JM, Coburn CE for th NO CLD Study Group: Inhaled nitric oxide in preterm infants undergoing mechanical ventilation. N Engl J Med 355:343-353, 2006.

Smith PG, Dreshaj A, Chaudhuri S, Onder BM, Mhanna MJ, Martin RJ: Hyperoxic conditions inhibit airway smooth muscle myosin phosphatase in rat pups. Am J Physiol Lung Cell Mol Physiol 292:L68-L73, 2007.

Di Fiore JM, Hibbs AM, Zadell AE, Merrill JD, Eichenwald EC, Puri AR, Mayock DE, Courtney SE, Ballard RA, Martin RJ: The effect of inhaled nitric oxide on pulmonary function in preterm infants. J Perinatol 27:766-771, 2007.

Sopi RB, Martin RJ, Haxhiu MA, Dreshaj IA, Yao Q, Jafri A, Zaidi SIA: Role of brain-derived neurotrophic factor in hyperoxia-induced enhancement of contractility and impairment of relaxation in lung parenchyma. Am J Physiol Lung Cell Mol Physiol 295:L348-L355, 2008. [PMID: 18515408].

Kohn AZ, Hoxha Z, Balan K, Martin RJ, Haxhiu MA, Wilson C, Mayer C, Kc P: Developmental changes in brainstem neurons regulating lower airway caliber. Pediatr Res 65:509-13, 2009.

Di Fiore JM, Arko M, Churbock K, Hibbs AM, Martin RJ: Technical limitations in detection of gastroesophageal reflux (GER) in neonates. J Pediatr Gastroenterol Nutr 49(2):177-82, 2009.

Walsh MC, Hibbs AM, Martin CR, Cnaan A, Keller RL, Vittinghoff E, Martin RJ, Truog WE, Ballard PL, Zadell A, Wadlinger SR, Coburn CE, Ballard RA; NO CLD Study Group. Two-year neurodevelopmental outcomes of ventilated preterm infants treated with inhaled nitric oxide. J Pediatr 2010; 156(4):556-561. PMID: 20138299

Di Fiore JM, Bloom JN, Orge F, Schutt A, Schluchter M, Cheruvu VK, Walsh M, Finer N, Martin RJ: A higher incidence of intermittent hypoxemic episodes is associated with severe retinopathy of prematurity. J Pediatr 157:69-73, 2010.

Balan KV, Kc P, Hoxha Z, Mayer CA, Wilson CG, Martin RJ: Vagal afferents modulate cytokine-mediated respiratory control at the neonatal medulla oblongata. Resp Physiol Neurobiol 178:458-464, 2011.

Meuchel LW, Stewart A, Smelter DF, Abcejo AJ, Thompson MA, Zaidi SIA, Martin RJ, Prakash YS: Neurokinin-neurotrophic interactions in airway smooth muscle. Am J Physiol Cell Mol Physiol 301:L91-L98, 2011.

Martin RJ, Wang K, Köro□lu Ö, Di Fiore J, Kc P: Intermittent hypoxic episodes in preterm infants: Do they matter? Neonatology 100:303-310, 2011.

Ali NKM, Jafri A, Sopi RB, Prakash YS, Martin RJ, Zaidi SIA: Role of arginase in impairing relaxation of lung parenchyma of hyperoxia-exposed neonatal rats. Neonatology 101:106-15, 2012.

Di Fiore JM, Kaffashi F, Loparo K, Sattar A, Schluchter M, Foglyano R, Martin RJ, Wilson CG: The relationship between patterns of intermittent hypoxia and retinopathy of prematurity in preterm infants. Pediatr Res 72(6):606-612, 2012.

Di Fiore JM, Walsh M, Wrage L, Rich W, Finer N, Carlo WA, Martin RJ, on behalf of the SUPPORT Study Group of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development Neonatal Research Network: Low oxygen saturation target range is associated with increased incidence of intermittent hypoxemia. J Pediatr 161:1047-1052, 2012.

Pozo ME, Cave A, Köroğlu Ö, Litvin DG, Martin RJ, Di Fiore J, Kc P: Effect of postnatal intermittent hypoxia on growth and cardiovascular regulation of rat pups. Neonatology 102:107-113, 2012.

## C. RESEARCH SUPPORT

**Ongoing Research**

R01 HL056470 2012-2017
[YS Prakash, Mayo Clinic site PI; RJ Martin, Case site PI]
Proposal Title: Neonatal Modulation of Airway Contractility

The purpose of this grant is to characterize physiologic and biologic mechanisms that regulate airway contractile responses in response to hyperoxic exposure in early life.

T32 HD060537-01 [Martin, PI] 2009-2014
Proposal Title: Training in Neonatal Research
In this proposal we seek to offer neonatal fellowship trainees expertise in respiratory neurobiology, brain development and neurodevelopmental outcome with a focus on inflammation. This will enable neonatal fellowship trainees to address the broad spectrum of neonatal morbidities.

**PENDING RESEARCH**

NEI Grant [R01] [Martin, PI] 2013-2017
Project Title: Predictive Patterns of Intermittent Neonatal Hypoxia and Retinopathy of Prematurity
To develop and test a model of intermittent hypoxic episodes as a risk factor and predictor of developing retinopathy of prematurity.

NHLBI Grant [RFA] [Martin, PI] 2013-2016
Project Title: S-Nitrosylation Therapy for Preserving Lung Function in Preterm Infants
This project is a Phase II clinical trial to investigate the ability of inhaled ethyl nitrite to improve respiratory function in preterm infants at risk for neonatal lung injury.

**COMPLETED RESEARCH** [Recent]

R01 HL56470 [Martin, PI] 1996-2007
Proposal Title: Maturation of Airway Relaxant Responses
The project seeks to characterize signaling pathways that mediate airway relaxant responses induced by nitric oxide and prostaglandins under normoxic and hyperoxic conditions.

R01 HL62527 [Martin, PI] 1999-2009
Proposal Title: Developmental Regulation of Hypercapnic Responses
The major goal of this project is characterization of central neurochemical pathways that contribute to impaired hypercapnic ventilatory responses during early postnatal life.

5R01HL 50527-12 Martin [PI] 2005-2009
Proposal Title: Airway-Central Nervous System Control
The purpose of the project is to define the structural organization and functional roles of GABA, NA, and 5-HT inhibitory projections to the airway-related vagal preganglionic neurons in the regulation of cholinergic outflow to the airways.

R23 HL098628 [Martin, PI] 2010-2012
Proposal Title: Cytokines and Neonatal Respiratory Control
The goal of this project is to characterize the role of cytokines in developmental respiratory control by employing an endotoxin-exposed rat pup model.

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **McComsey, Grace A** | POSITION TITLE **Professor** |
| eRA COMMONS USER NAME **Gmccomsey** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| Mont La Salle College, Ain Saade, Lebanon | B.A. | 1979-1982 | Mathematics |
| St. Joseph University, Beirut, Lebanon | M.D. | 1982-1987 | Medicine |
| St. Joseph University and Medical Center, New Jersey | | 1990-1991 | Medicine / Pediatrics |
| Case Western Reserve University | | 1991-1994 | Residency in Medicine |
| Case Western Reserve University | | 1994-1998 | Fellowship in Pediatrics and Adult Infectious Diseases |

**A. Positions and Honors**

**Positions and Employment**

2004-- Chief, Pediatric Infectious Diseases, Rheumatology and Global Health, Rainbow Babies and Children's Hospital
2008-- Professor of Pediatrics and Medicine, Case Western Reserve University, Cleveland, Ohio
1999-- Fellowship Director, Pediatric Infectious Diseases, Rainbow Babies Children, Cleveland OH
2004-2008 Associate Professor of Pediatrics and Medicine, Case, Cleveland, Ohio
1998-2004 Assistant Professor of Pediatrics and Medicine, Case, Cleveland, Ohio
2008-- Permanent Member, ACE Study section, NIH
2008-- Chair, Bone Research Focus Group, AIDS Clinical Trials Group
2008-- CTSA National Pediatrics Oversight Committee
2004-- Expert consultant for NIAID and NIDDK on metabolic/cardiovascular complications of HIV
2006-2007 Member, Optimization of management of HIV disease (OPMAN) committee, ACTG
2003-2007 Member of the Women's Health Committee of the AIDS Clinical Trials Group
2004-2006 Vice-Chair of the Metabolic Complications Committee of the ACTG
2002-2006 Member of the Complication Research Agenda Committee of the ACTG
2003-2005 Member of the Cardiovascular Disease Focus Group of the Adult Clinical Trials Group
2003-2006 Member of the Metabolic Complications Committee of the AIDS Clinical Trials Group

**Honors**

Research paper voted One *of 6 best Basic Science Papers* for "Best of AIDS 2003"
Women Faculty of the CWRU School of Medicine Mid-Career Faculty Development Award; May 2006
Advanced to fellow in Infectious Diseases Society of America, July 2006
HIVMA Leader in HIV Research Award, 2007
Award recipient, Mather Spotlight Series Prize for Women's Scholarship, 2009
"America's Top Physicians", "Best Doctors" 2009-2012
"Woman of the year in Healthcare", "Best Doctors, Cleveland", 2010-2012

**B. Selected peer-reviewed publications**

1. Ross AC, Armentrout R, O'Riordan MA, Storer N, Rizk N, Harrill D, El Bejjani D, McComsey GA. Endothelial Activation Markers are Linked to HIV Status and are Independent of Antiretroviral Therapy and Lipoatrophy. JAIDS 2008; 49:499–506 PMCID:PMC2778267

2. Brown TT, McComsey GA, King MS, Qaqish RB, Bernstein BM, da Silva BA. Loss of Bone Mineral Density after Antiretroviral Therapy Initiation, Independent of Antiretroviral Regimen. J Acquir Immune Defic Syndr 2009;51(5):554-561
3. Ross AC, Rizk N, O'Riordan MA, Dogra V, El-Bejjani D, Storer N, Harrill D, Tungsiripat M, Adell J, McComsey GA. Relationship between Inflammatory Markers, Endothelial Activation and Carotid Intima-Media Thickness in HIV-infected Patients. Clin Infect Dis. 2009;49(7):1119-27
4. Brown TT and McComsey GA. Association between initiation of antiretroviral therapy with efavirenz and decreases in 25-hydroxyvitamin D. Antivir Ther. 2010;15(3):425-9.
5. Ross AC, Storer N, O'Riordan MA, Dogra V, McComsey GA. Longitudinal changes in carotid intima-media thickness and cardiovascular risk factors in human immunodeficiency virus-infected children and young adults compared with healthy controls. Pediatr Infect Dis J. 2010 Jul;29(7):634-8.
6. Hileman CO, Carman TL, Gripshover BM, O'Riordan MA, Storer NJ, Harrill DE, White CA and McComsey GA. Salsalate is poorly tolerated and fails to improve endothelial function in virologically-suppressed HIV-infected adults. AIDS. 2010 Jul 31;24(12):1958-61
7. Ross Allison, O'Riordan MaryAnn, McComsey Grace A. Heightened Inflammation is Linked to Carotid Intima-Media Thickness and Endothelial Activation in HIV-Infected Children. Atherosclerosis. 2010 Aug;211(2):492-8. Epub 2010 Apr 24.PMID: 20471650
8. Tungsiripat Marisa, El Bejjani Dalia, Rizk Nesrine, O'Riordan Mary Ann, Ross Allison C, Hileman Corrilynn, Storer Norma, Harrill Danielle, McComsey Grace A. Rosiglitazone Improves Lipoatrophy in Patients Receiving Thymidine-Sparing Regimens. AIDS. 2010 Jun 1;24(9):1291-8. PMCID:PMC2895409
9. Grace A McComsey, Pablo Tebas, Elizabeth Shane, et al. Bone disease in HIV: A practical review and recommendations for HIV providers. Clin Infect Dis. 2010 Oct 15;51(8):937-946. PMCID:PMC3105903
10. Brown Todd T, Tassiopoulos Katherine, Bosch Ronald J, Shikuma Cecilia, McComsey Grace A. Association between Systemic Inflammation and Incident Diabetes Mellitus in HIV-infected Patients after Initiation of Antiretroviral Therapy. Diabetes Care. 2010 Oct;33(10):2244-9. Epub 2010 Jul 27. PMCID: PMC2945167
11. Grace A McComsey, Douglas Kitch, Eric S Daar, et al. Bone mineral density and fractures in antiretroviral-naïve subjects randomized to abacavir/lamivudine or tenofovir disoproxil fumarate /emtricitabine along with efavirenz or atazanavir/ritonavir: AIDS Clinical Trials Group A5224s, a substudy of ACTG A5202. The Journal of Infectious Diseases 2011;203:1791–801 PMCID:PMC3100514
12. Grace A McComsey, Douglas Kitch, Paul E Sax, Pablo Tebas, Camlin Tierney, Nasreen C Jahed, Laurie Myers, Kathleen Melbourne, Belinda Ha, and Eric S Daar. Peripheral and central fat Changes in Subjects Randomized to Abacavir/Lamivudine or Tenofovir/Emtricitabine with Atazanavir/Ritonavir or Efavirenz: ACTG study A5224s. Clinical Infectious Diseases 2011;53: 185-196. PMCID:PMC3165963
13. Ross Allison C, Tangpricha Vin, Judd Suzanne, Kumari Meena, Hileman Corrilynn, Storer Norma, Harrill Danielle, McComsey Grace A. Vitamin D is linked to carotid intima-media thickness, inflammation, and immune reconstitution in HIV-infected individuals. Antiviral Therapy 2011;16(4):555-63.

**C. Research Support**

Ongoing Research Support

R01 HD070490-01 McComsey (PI) 08/01/11-07/30/16
Vitamin D, drug metabolism, and cardiovascular complications in pediatric HIV
Understand the effect of HIV and its therapy on alterations in vitamin D metabolism and the implications of such alterations on immuneactivation, inflammation and cardiovascular complications in HIV youth and matched healthy youth

R01 NR012642-02 McComsey (PI) 09/28/10-06/30/15
Inflammation, Heart and Bone
Understanding the role of inflammation in two common co-morbidities in HIV: cardiovascular risk and osteoporosis

T32 AI052067-09 McComsey (PI) 07/01/02 - 06/30/13
NIH / NIAID
"Research Training in Pediatric Infectious Diseases"
Train and mentor infectious diseases fellows and post-graduate candidates for a career in infectious diseases

R01HL095132 (Currier, PI) 09/25/08-06/30/13
NIH/NIAID
Prospective evaluation of antiviral therapy and cardiac health
Co-investigator

AI-069501 (PI, Lederman) 10/01/87 – 11/30/13
NIH/NIAID
Case AIDS Clinical Trials Unit
Develop, implement, and analyze results of clinical treatment trials for HIV infection and its complications
Co-investigator; McComsey is currently the Study Chair of two trials sponsored by the ACTG; ACTG 5229 (A Phase II/III, Randomized, Double-Blind, Placebo-Controlled Trial of Uridine Supplementation in HIV Lipoatrophy), and ACTG 5224 (Long-term metabolic assessments in subjects treated with ABC/3TC or TDF/FTC along with either efavirenz or ATV/RTV)

Completed Research Support
Bristol Myers Squibb Co (PI McComsey) 2007-2011
Can metabolically-friendly antiretroviral regimen slow down the rate of progression in carotid artery intima-medial thickness in adults with HIV?

GlaxoSmithKline (PI McComsey) 2006-2011
Placebo-controlled trial of rosiglitazone for HIV lipoatrophy in the absence of thymidine NRTIs: effects on fat, cardiovascular endpoints and bone health

Emory ECRC Seed Grant (PI Ross) 2010-2011
Vitamin D and cardiovascular biomarkers in HIV-infected children and young adults. This pilot study evaluates the relationship between vitamin D levels and cardiovascular biomarkers in HIV-infected children and young adults from 1-25 years of age.
Co-investigator/mentor

Emory CFAR03 Grant (PI Ross) 2010-2011
Vitamin D and cardiovascular biomarkers in HIV-infected children and young adults.
This pilot study evaluates the relationship between vitamin D levels and cardiovascular biomarkers in HIV-infected children and young adults from 1-25 years of age.
Co-investigator/mentor

R01 AI065348 (PI, McComsey) 1/1/06-12/31/11
NIH / NIAID
"Metabolic consequences of thymidine-sparing regimens"
Assessment of the effect of thymidine sparing antiretroviral regimens on mitochondrial and metabolic indices

Campbell Foundation (McComsey PI) 2009-2010
Pilot study of omega-3 fatty acids in HIV cardiovascular risk and endothelial dysfunction

GlaxoSmithKline (PI McComsey) 2005-2010
Underlying atherosclerosis and metabolic syndrome in HIV infected children. Longitudinal assessment of inflammatory markers and carotid IMT in HIV infected children and matched healthy children

R01 AI060484 (PI McComsey) 3/15/05-3/14/10
Role of Mitochondria in HIV Lipoatrophy
Assess the role of mitochondrial dysfunction in the generation and reversal of lipoatrophy. Includes several interventional studies aimed at improving mitochondrial dysfunction and lipoatrophy

R21 AT003111 (PI McComsey) 9/15/05- 6/30/09
Uridine supplementation in HIV lipoatrophy
Assess the efficacy and safety of uridine supplementation in HIV lipoatrophy

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Meropol, Neal J.** | POSITION TITLE<br>Associate Director for Clinical Research, Case CCC;<br>Professor of Medicine<br>Chief, Division of Hematology and Oncology |
| eRA COMMONS USER NAME<br>NMEROPOL | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Princeton University, Princeton, NJ | AB | 1981 | Philosophy |
| Vanderbilt University, Nashville, TN | MD | 1985 | Medicine |

## A. Positions and Honors

**Positions and Employment**

1985-1988 Internship and Residency, Internal Medicine, Case Western Reserve University, Cleveland, OH
1988-1992 Fellow, Hematology and Medical Oncology, University of Pennsylvania, Philadelphia, PA
1992-1998 Assistant Professor, Department of Medicine, State University of New York at Buffalo, Roswell Park Cancer Institute, Buffalo, NY
1998-2009 Fox Chase Cancer Center, Philadelphia, PA, Director, Gastrointestinal Cancer Program, Member 1998-2004, Senior Member 2004-2009
2005-2009 Professor of Medicine, Temple University, Philadelphia, PA
2007-2008 Visiting Scholar, Leonard Davis Institute of Health Economics, University of Pennsylvania, Philadelphia, PA
2008-2009 Adjunct Senior Fellow, Leonard Davis Institute of Health Economics; Senior Fellow, Center for Bioethics, University of Pennsylvania, Philadelphia, PA
2009- Professor of Medicine; Chief, Division of Hematology and Oncology (2010-), University Hospitals Case Medical Center and Case Western Reserve University; Associate Director for Clinical Research, Case Comprehensive Cancer Center; Associate Director for Clinical Programs, University Hospitals Case Medical Center Seidman Cancer Center, Cleveland, OH
2009- Dr. Lester E. Coleman, Jr. Professor of Cancer Research and Therapeutics

**Other Experience and Memberships**

**Certification:** 1988 American Board of Internal Medicine: Internal Medicine; 1990 Hematology; 1991, 2001, 2011 Medical Oncology

**National Committees, Study Sections, and Professional Activities (selected):**

NCI Cooperative Groups: Member, Cancer and Leukemia Group B, GI and Pharmacology and Experimental Therapeutics (PET) Cores (1994-1998); Vice Chair, Cancer and Leukemia Group B, (PET) Core (1996-1998); Member, Eastern Cooperative Oncology Group (ECOG) GI Core Committee (1999-Present); Chair, ECOG Developmental Therapeutics Committee (2003–2010); Member, ECOG Foundation Board (2009-2012); Member, NCI Colon Cancer Task Force (1998-2011, Chair 2006-2011); co-Chair NCI Gastrointestinal Cancer Steering Committee (2011-Present)

American Society of Clinical Oncology: Program Committee, Clinical Pharmacology (1997); Education Committee, Health Services Research, (2004–2006); Program Committee, Gastrointestinal Cancer (2004); Chemoprotectant Guidelines Committee (1997-present); Cancer Research Committee (2006-2011, Chair 2010); Cost of Cancer Care Task Force (2007-present); Chair, Comparative Effectiveness Task Force (2009-2011); Cancer Communication Committee (2012-present); ASCO Board of Directors (2013-2017)

NIH Study Sections: "Informed consent in research involving human participants" (1997); "Ethical, legal and social implications of genetic research (ELSI)" (1998); Cancer Center Support Grant, Subcommittee A (2001,

2010); Pancreas SPORE (2003); Clinical Trials Subcommittee H (Cooperative Groups Review) (2001-2004); Gastrointestinal SPORE (2006)
Editorial Boards: J Clin Oncol (1999-2001); Cancer Biol Ther (2001-Present); Int J Gastrointestinal Cancer (2001-2010); The Oncologist (2008-Present)
Other: National Comprehensive Cancer Center Network (NCCN) Gastric and Esophageal Cancer Guidelines Committee (1997-2009); Colorectal Cancer Technical Panel, National Quality Forum (2004)

**Honors**
1986 Case Western Reserve University Department of Medicine, Outstanding Performance Award for an Intern; 2000 Fox Chase Cancer Center, Award for Excellence in Teaching; 2005 Eastern Cooperative Oncology Group, Young Investigator Award; 2009 Cancer Control Award, PA Division, Southeast Region

**B. Selected Peer-reviewed Publications (from > 200)**

Meropol NJ, Weinfurt KP, Burnett CB, Balshem A, Benson AB III, Castel L, Corbett S, Deifenbach M, Gaskin D, Li Y, Manne S, Marshall J, Slater E, Sulmasy DP, Rowland JH, Van Echo D, Washington S, Schulman KA. Perceptions of patients and physicians regarding phase I cancer clinical trials: implications for physician-patient communication. J Clin Oncol 21:2589-2596, 2003.

Meropol NJ, Gold PJ, Diasio RB, Andria M. Dhami M, Godfrey T, Kovatich AJ, Lund KA, Mitchell E, Schwarting R. Thymidine phosphorylase expression is associated with response to capecitabine plus irinotecan in patients with metastatic colorectal cancer. J Clin Oncol 24:4069-4077, 2006.

Meropol NJ, Buzaglo JS, Millard J, Damjanov N, Miller SM, Ridgway C, Ross EA, Sprandio JD, Watts P. Barriers to clinical trial participation as perceived by oncologists and patients. J Natl Compr Canc Netw 5:655-664, 2007.

Meropol NJ, Niedzwiecki D, Shank B, Colacchio T, Ellerton J, Valone F, Budinger S, Day JM, Hopkins J, Tepper J, Goldberg RM, Mayer RJ for the Cancer and Leukemia Group B. Induction therapy for poor prognosis anal canal carcinoma: a phase II study of the Cancer and Leukemia Group B (C9281). J Clin Oncol 26:3229-3234, 2008.

Cohen SJ, Punt CJ, Iannotti N, Saidman BH, Sabbath KD, Gabrail NY, Picus J, Morse M, Mitchell E, Miller MC, Doyle GV, Tissing H, Terstappen LW, Meropol NJ. Relationship of circulating tumor cells to tumor response, progression-free survival, and overall survival in patients with metastatic colorectal cancer. J Clin Oncol 26:3213-3221, 2008.

Weinfurt KP, Seils DM, Tzeng JP, Compton KL, Sulmasy DP, Astrow AB, Solarino NA, Schulman KA, Meropol NJ. Expectations of benefit in early-phase clinical trials: implications for assessing the adequacy of informed consent. Med Decis Making 28:575-581, 2008. PMCID: PMC2630499

Meropol NJ, Egleston BL, Buzaglo JS, Benson AB 3rd, Cegala DJ, Diefenbach MA, Fleisher L, Miller SM, Sulmasy DP, Weinfurt KP; CONNECT Study Research Group. Cancer patient preferences for quality and length of life. Cancer 113:3459-3466, 2008. PMCID: PMC2606934

Stitzenberg KB, Sigurdson ER, Egleston BL, Starkey RB, Meropol NJ. Centralization of cancer surgery: implications for patient access to optimal care. J Clin Oncol 27:4671-4678, 2009. PMCID: PMC3039919

Wong YN, Hamilton O, Egleston B, Salador K, Murphy C, Meropol NJ. Understanding how out-of-pocket expenses, treatment value, and patient characteristics influence treatment choices. Oncologist 15:566-576, 2010. PMCID: PMC2892556

Hall MJ, Manne SL, Winkel G, Chung DS, Weinberg DS, Meropol NJ. Effects of a decision support intervention on decisional conflict associated with microsatellite instability testing. Cancer Epidemiol Biomarkers Prev 20:249-254, 2011. PMCID: PMC3076798

Blanke CD, Goldberg RM, Grothey A, Mooney M, Roach N, Saltz LB, Welch JJ, Wood WA, Meropol NJ; on behalf of the NCI GI Steering Committee Colon Cancer Task Force. KRAS and colorectal cancer: ethical and pragmatic issues in effecting real-time change in oncology clinical trials and practice. Oncologist 16:1061-1068, 2011.

Miller SM, Hudson SV, Egleston BL, Manne S, Buzaglo JS, Devarajan K, Fleisher L, Millard J, Solarino N, Trinastic J, Meropol NJ. The relationships among knowledge, self-efficacy, preparedness, decisional conflict, and decisions to participate in a cancer clinical trial. Psychooncology doi: 10.1002/pon.3043, 2012. PMCID: PMC3374030

Meropol NJ. Comparative effectiveness research to inform medical decisions: the need for common language. J Clin Oncol 30:4192-3, 2012.

Weinfurt KP, Seils DM, Lin L, Sulmasy DP, Astrow AB, Hurwitz HI, Cohen RB, Meropol NJ. Research participants' high expectations of benefit in early-phase oncology trials: are we asking the right question? J Clin Oncol. In press, 2012.

Meropol NJ, Egleston BL, Buzaglo JS, Balshem A, Benson AB, Cegala DJ, Cohen RB, Collins M, Diefenbach MA, Miller SM, Fleisher L, Millard JL, Ross EA, Schulman KA, Silver A, Slater E, Solarino N, Sulmasy DP, Trinastic J, Weinfurt KP. A web-based communication aid for patients with cancer: the CONNECT™ study. Cancer. In press, 2012.

## C. Research Support

**Ongoing**

5R01 CA127655-05 (Meropol, PI) 04/14/08-02/28/14
NIH/NCI
Preparatory Aid to Improve Decision Making about Cancer Clinical Trials
The major goals of this project are: 1) To develop and pilot test a tailored interactive preparatory aid (PRE-ACT) to promote informed cancer treatment decision making by addressing barriers to considering clinical trials as a treatment option; 2) To evaluate the efficacy of PRE-ACT in improving preparation for considering participation in clinical trials; 3) To investigate relevant background and psychosocial variables that are associated with preparedness, barriers, and treatment outcomes; and 4) To investigate the impact of PRE-ACT on patient decisional conflict, satisfaction with information received, satisfaction with discussion about clinical trials with the physician, satisfaction with the treatment decision, clinical trials discussion, clinical trials participation, and quality of informed consent.

3P30 CA043703-22S3 (Gerson, PI) 09/30/91-03/31/13
NIH/NCI
Case Comprehensive Cancer Center Support Grant
The objectives of the Center are: 1) to improve the prevention, diagnosis, and therapy of cancer through research; 2) to stimulate and support innovative, coordinated, interdisciplinary research on cancer diagnosis, treatment, and control; 3) to develop clinical applications of research discoveries and to make these applications available as quickly as possible; and 4) to develop cancer prevention and control activities to contribute to the reduction of cancer morbidity and mortality in Northeast Ohio and the surrounding region and nation. Role: Associate Director for Clinical Research

5K07 CA136995-04 (Wong, PI) 09/26/08-08/31/13
NIH/NCI
Clinical and Social Implications of Cost Sharing for Cancer Drugs
This Career Development Award supports a multidisciplinary research program to understand the impact of insurance design on cancer drug utilization and clinical outcomes. This Career Development Award will provide the means to take two important steps towards accomplishing this goal. First, it will allow for additional intensive mentored education and training in public policy research, health economics, and advanced statistical methods that will augment the candidate's previous rigorous training in epidemiology, biostatistics, and clinical medicine. Second, it will support the development of an original clinical research program using rigorous epidemiologic, econometric and survey methods to examine the impact of prescription drug insurance coverage on cancer outcomes. Role: Mentor

HHSN261201100070C (Villalona) 09/23/11-09/30/13
NIH/NCI
Early Therapeutics Development with Phase II Emphasis (N01 contract)
The objectives of this contract are to conduct Phase 2 and early clinical trials of NCI-sponsored agents, to evaluate biologic effects of these agents on their molecular targets, to evaluate other relevant biologic effects and to determine clinically relevant outcomes/correlates. Case CCC is a member of the OSU consortium. Dr. Meropol is the PI for Case CCC.

**Pending**

1R25 CA177574-01 (Meropol/Daly, MPIs) 07/01/13–06/30/18
NIH/NCI
Oncology Nurse IMPACT: Improving Communication with Patients about Clinical Trials
The overall goal of this project is to increase oncology nurse discussions about clinical trials with cancer patients in routine clinical settings by providing a tailored, interactive, web-based educational program. This program uses a web-based application to deliver video information about clinical trials to oncology nurses to help them become more comfortable discussing clinical trials as an option with their patients.

2K12 CA076917-16 (Gerson, PI) 09/30/97-06/30/18
NIH/NCI
Clinical Oncology Research Career Development Program (CORP)
The overall goal of the Clinical Oncology Research Career Development Program is to support the intent of the Paul Calabresi Award for Clinical Oncology (K12). The Program fosters interdisciplinary training in clinical and translational oncology therapeutic research for physicians in one of a number of oncology disciplines, including medical, surgical, dermatologic, pediatric, radiation and pathology. Role: Co-Director

**Completed**

5U10 CA021115-35 (Comis, PI FSTRF) 09/01/92-04/30/11
NIH/NCI
Eastern Cooperative Oncology Group's Operations Office
Support to Dr. Meropol as Chair of the ECOG Developmental Therapeutics Committee.

5R01CA100771-06 (Meropol/Weinfurt, MPI) 04/01/03-09/30/11
NIH/NCI-Duke University
Understanding Patient Expectations of Treatment Outcomes
Some patients in Phase I cancer clinical trials report very high expectations that they will receive significant clinical benefit from their participation. Clinicians and bioethicists are concerned that these patients may experience greater depression, anxiety, and other negative reactions when patients' clinical outcomes are poorer than expected. Data from the proposed study will help guide clinicians and researchers in their interactions with patients in phase I trials who express high expectations of benefit.

7R01 CA082085-09 (Meropol, PI) 09/30/98-09/30/11
NIH/NCI
Facilitating Decision Making in Advanced Cancer Patients
Major goals are to: 1) determine the impact of a web-based communication aid on satisfaction with physician-patient communication and decisional conflict; 2) determine the impact of the communication aid on patient expectations regarding potential benefits and adverse reactions associated with treatment options; and 3) determine the influence of the communication aid on the content of the physician-patient consultation.

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Moore, Shirley M.** | POSITION TITLE<br>Edward J. and Louise Mellen Professor of Nursing and Associate Dean for Research |
| eRA COMMONS USER NAME **SMOORE** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| Kent State University, OH | BSN | 1974 | Nursing |
| Case Western Reserve University, OH | MSEd | 1979 | Education |
| Case Western Reserve University, OH | MSN | 1990 | Nursing |
| Case Western Reserve University, OH | PhD | 1993 | Nursing |

## A. Position and Honors

**Positions and Employment**

1969-1971 Staff Nurse, Coronary and Cardiac Intensive Care, The Mt. Sinai Hospital of Cleveland, Cleveland, OH
1971-1972 Head Nurse, Coronary and Cardiac Intensive Care, The Mt. Sinai Hospital of Cleveland
1976-1981 Director, Continuing Education Department, The Mt. Sinai Hospital of Cleveland
1982-1984 Director, Nursing Education, The Cleveland Clinic Foundation, Cleveland, OH
1984-1987 Director, Nursing Resources, The Cleveland Clinic Foundation, Cleveland, OH
1987-1990 Research Assistant, Case Western Reserve University, Cleveland, OH
1990-1992 Grant Project Director, Case Western Reserve University, Cleveland, OH
1992-1996 Assistant Professor, School of Nursing, Case Western Reserve University, Cleveland, OH
1996-2004 Associate Professor, School of Nursing, Case Western Reserve University, Cleveland, OH
2001-present Associate Dean for Research, School of Nursing, Case Western Reserve University
2003-present Faculty Associate, Center for Health Promotion Research, Case Western Reserve University
2004-present Professor, School of Nursing, Case Western Reserve University

**Honors**

1997 Finalist, New Investigator Award, American Heart Association, Council on Cardiovascular Nursing
1997 Fellow, National Academy of Practice in Nursing, National Academies of Practice
1998 Fellow, American Heart Association, Council on Cardiovascular Nursing
2000 Risk Prevention and Health Behavior Review Panel, NIH, Reviewer, Initial Review Group Study Section
2002 Distinguished Contribution to Nursing Research, Acute Care Nursing Section, Midwest Nursing Research Society
2002 Fellow, American Academy of Nursing
2005 Crain's Cleveland Business' Who's Who in Technology for 2005
2006 Edward J. and Louise Mellen Endowed Professorship
2007 Ada Sue Hinshaw Award, Friends of the National Institute of Nursing Research
2008 Competence in Aging Award, American Heart Association Council on Cardiovascular Nursing
2009 John A. Hartford/MNRS Award for Leadership in Geriatric Nursing Research, Midwest Nursing Research Society
2010 Inaugural Inductee, International Nurse Researcher Hall of Fame
2011 Nominee, John S. Diekhoff Award for Excellence in Graduate Mentoring, Case Western Reserve University
2011 Mather Spotlight Prize Women of Excellence Award, Case Western Reserve University

2011 Best Abstract Award, Scientific Sessions, American Heart Association Cardiovascular Nursing Council

**B. Publications (selected from 110)**

**Most relevant to the current application.**

1. Moore, S.M. & Dolansky, M.A. (2001). Randomized trial of a home recovery intervention following coronary artery bypass surgery. Research in Nursing and Health, 24 (2), 93-104.
2. Landers, S.H., Gunn, P.W., Flocke, S.A., Moore, S.M., Kikano, G.E., & Stange, K.C. (2005). Trends in house calls to Medicare beneficiaries. Journal of the American Medical Association, 294(19), 2435-2436.
3. Moore, S.M., Charvat, J.M., Gordon, N.H., Pashkow, F., Ribisl, P., Roberts, B.L., & Rocco, M. (2006). Effects of a CHANGE intervention to increase exercise maintenance following cardiac events. Annals of Behavioral Medicine, 31(1), 53-62.
4. Moore, S.M. & Charvat, J.M. (2007). Promoting health behavior change using Appreciative Inquiry: Moving from deficit models to affirmation models of care. Family and Community Health, Supplement 30(1), S64-S74.
5. Dolansky, M. A. & Moore, S. M. (2008). Older adults' early disability following a cardiac event. Western Journal of Nursing Research. 30(2), 163-180.
6. Dolansky, M.A., Xu, F., Zullo, M., Shishehbor, M, Moore, S.M., & Rimm, A.A. (2010). Post-acute care services received by older adults following a cardiac event: A population-based analysis. Journal of Cardiovascular Nursing, 25(4), 342-349. PMCID: PMC2885047.
7. Miller, DM, Fox, R., Atreja, A., Moore, S., Lee, J-C, Fu, A.Z., Jain, A., Saupe, W., Chakraborty, Stadtler, M., Rudick, R.A. (2010). Using an Automated Recruitment Process to Generate an Unbiased Study Sample of Multiple Sclerosis Patients. Telemedicine and e-Health,16 (1): 63-68. PMCID: PMC2998972

**Additional recent publications of importance to the field (in chronological order)**

1. Murray, M. E., Brennan, P.F., Moore, S. M. (2003). A model for economic analysis. Nursing Economics, 21 (6), 280-287.
2. Dolansky, M.A., Moore, S.M. (2003). Disability and rehabilitation services in older adults following cardiac events. Journal of Cardiopulmonary Rehabilitation, 23, 380.
3. Thanavaro, J. L., Moore, S.M., Anthony, M., Narsavage, G. & Delicath, T. (2006). Predictors of health promotion behaviors in women without prior history of coronary heart disease. Applied Nursing Research, 19(3), 149-155.
4. Conn, V.S., Hafdahl, A.R., Moore, S.M., Mehr, D. & Nielsen, P.J. (2009). Meta-analysis of interventions to increase physical activity among cardiac subjects. International Journal of Cardiology, 133, 307-320. PMCID: PMC2702092
5. Miller, D. M.., Moore, S.M., Fox, R..J., Atreja, A., Fu, A.Z., Lee J.-C., Saupe, W., Stadtler,S, Chakraborty,. Harris, C.M., Rudick, R.A. (2011). Web-based self-management for patients with multiple sclerosis: a practical, randomized trial. Telemedine and e-Health, 17(1), 5-13. PMCID:PMC3064874
6. Williams, A. & Moore, S.M.(2011). Universal Design of Research: Inclusion of Persons with Disabilities in Mainstream Biomedical Studies. Sci Transl Med. 2011 May 11;3(82):82cm12.
7. Moore, S.M. (2012). Scientific reasons for including persons with disabilities in clinical and translational diabetes research. Journal of Diabetes Science and Technology. 6(2), 36-41.

**C. Research Support**

**Ongoing Research Support**

U01 HL103622-03 Moore/Borawski/Cuttler (Co-PI's) 08/17/10-04/30/17
NIH/NHLBI
*Targeting Obesity and Blood Pressure in Urban Youth*

This 3-group randomized clinical trial will test the effect of a multi-level intervention (community, school, and family) on blood pressure and BMI in children in grades 6-8 using a family systems change approach.

UL1TR000439-06 Davis (PI) 09/17/07-05/31/17
NIH/NCATS
*Clinical and Translational Science Collaborative of Cleveland*
The purpose of this grant is to coordinate existing resources relevant to clinical research at Case Western Reserve University and three of its hospital affiliates, the Cleveland Clinic, MetroHealth Medical Center, and University Hospitals Case Medical Center, including three existing GCRC facilities and a multidisciplinary institutional KL2 program.
Role: Co-Director, Education Core; Mentor

R25OD010992-02 Cuttler/Davillier (Co-PI) 05/15/11- 04/30/16
NIH/OD Annual direct costs: $278,648
*BioMed Tech: Students Translating and Exploring Medicine*
This STEM project is a collaboration with the Cleveland Metropolitan School District, the Great Lakes Science Center and Case Western Reserve University to develop an exhibit on obesity of the science museum.
Role: Co-Investigator.

R21 NR013001-01A1 Sajatovic (PI) 05/01/12-04/30/14
NIH/NINR
*Targeted Management Intervention for African-American Men with TIA or Stroke.*
The purpose of the project is to refine and pilot test a self-management intervention for African American Men with TIA or Stroke.
Role: Co-Investigator

R01 HL096710-03 Hughes/Dolansky (Co-PIs) 04/5/10-01/31/14
NIH/NHLB
*Self-management and Cognitive Impairment in Adults with Heart Failure*
Assess the relationship between cognitive impairment and self-management in patients with heart failure.
Role: Co-Investigator

R21NR12513-02 Williams (PI) 07/15/11 - 06/30/13
NIH
*Nonvisual Foot Examination for People with Diabetes and Visual Impairment*
The purpose of this pilot study is to compare the effects of teaching two different methods of foot examination to people who have diabetes and visual impairment: Multi-SAFE, a method for nonvisual foot examination that uses the senses of touch and smell, and usual care, which is to have a sighted person look at the feet.
Role: Co-Investigator

P30 NR010676-05 Moore (PI) 09/29/07-06/30/13
NIH/NINR
*Center of Excellence to Build the Science of Self-Management: A Systems Approach*
The SMART Center provides research infrastructure support to extend and disseminate knowledge related to self-management of health.

BGIA7710003 Plow (PI) 07/01/11-06/30/13
American Heart Association, Beginning Grant-in-Aid (Greater Rivers Affiliate)
*Developing and Testing a SystemCHANGE Intervention in Stroke Survivors*

The purpose of this study is to adapt and test a SystemCHANGE Intervention in stroke survivors to improve quality of life and community integration.
Role: Co-Investigator

R01CA127493-04 Zhang (PI) 01/01/09-11/30/12
NIH/NCI
*Improving Urinary Continence and Quality of Life in Prostate Cancer Patients*
The objective of this study is to test the intervention effect of biofeedback trained Pelvic Floor Muscle Exercises (PFME) combined with support groups on urinary incontinence and health related quality of life in men with prostate cancer.
Role: Co-Investigator

**Completed Research Support**

T32 NR009761-05 (Moore, PI) 05/18/06-04/30/12
NIH/NINR
*Multiple Morbidities in Vulnerable Populations: Nurse Scientist Training*
The proposed predoctoral and postdoctoral training program provides research training for nurses pursuing research careers focused on vulnerable populations with multiple morbidities.

P30NR010676-03S1 Moore (PI) 09/18/09-08/31/11
NIH/NINR
*Full Inclusion of Persons with Disabilities in Self-Management Research*
The FIND Lab in the SMART Center of Excellence provides a set of resources and services to researchers about the use of Universal Design principles to design interventions and their delivery and data collection methods to support fuller inclusion of people with disabilities in research.

R01 HL084767 Moore (PI) 07/10/06-03/31/11
NIH/HLBI
*Improving Long-term Exercise in Older Cardiac Patients*
A head-to-head evaluation of the effects of two theoretically different interventions (SystemCHANGE and CHANGE+) on lifestyle exercise following a cardiac event.

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Musil, Carol Marie** | POSITION TITLE<br>Professor of Nursing |
| eRA COMMONS USER NAME **CMMUSIL** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| University of Cincinnati, Cincinnati, OH | BSN | 05/76 | Nursing |
| Case Western Reserve University (CWRU), Cleveland, OH | MSN | 12/79 | Nursing |
| CWRU, Cleveland, OH, CWRU | PhD, Postdoc | 08/91<br>1992-93 | Nursing<br>Geriatric Mental Health |

**A. Positions and Honors**

**Positions and Employment**

| | |
|---|---|
| 1976-1977 | Staff Nurse, Psychiatric Unit, Jewish Hospital of Cincinnati, Cincinnati, OH |
| 1977-1978 | Staff Nurse, Psychiatric Unit, St. Luke's Hospital, Cleveland, OH |
| 1979 | Psychiatric Nurse, Lake County Mental Health Center, Mentor, OH |
| 1979-1980 | Psychiatric Clinical Specialist, Lakewood Hospital, Lakewood, OH |
| 1980-1990 | Psychiatric Liaison Clinical Nurse Specialist, University Hospitals of Cleveland, Cleveland, OH |
| 1990-1992 | Project Manager, RWJ/Pew Grant, University Hospitals of Cleveland, Cleveland, OH |
| 1992-1993 | NIMH Postdoctoral Fellow, Geriatric Mental Health Nursing, CWRU |
| 1993-1994 | Project Director, *Stresses, Strains, and Elder's Physical Health*, CWRU, Cleveland, OH |
| 1994-2000 | Assistant Professor, School of Nursing, CWRU, Cleveland, OH |
| 2000-2008 | Associate Professor, School of Nursing, CWRU, Cleveland, OH |
| 2002 | Award of tenure, CWRU, Cleveland, OH |
| 2004-Present | University Memory and Aging Center Investigator, University Hospitals of Cleveland/CWRU |
| 2008-Present | Professor, School of Nursing, CWRU, Cleveland, OH |

**Other Experience, Professional Memberships and Contributions**

| | |
|---|---|
| 1991-2012 | Midwest Nursing Research Society; Senior Scientist Award 2008 |
| 1994-2012 | Gerontological Society of America |
| 2001-2012 | American Nurses' Association |
| 2000-2001 | Glennan Fellow, CWRU, Cleveland, OH |
| 2002-2013 | Grant Reviewer, NIH/NIGMS Minority Biomedical Research Support (ad hoc reviewer; permanent member 2006-2012; chaired behavioral subpanels 2007-12); SEP NIEHS-NIA-NCI Center Grants 2003; NIMH B/START Aug 2005; CHLP January 2013 |
| 2005-2008 | Chair, CWRU Faculty Senate Committee on Research |
| 2000-2013 | Faculty Associate at CWRU Centers: University Center on Aging and Health; Schubert Center for Child Development; Center for Health Disparities; Prevention Research Center |
| 2008-2011 | Chair-elect, Chair, Past-Chair, CWRU Faculty Senate |
| 2012 | Guest Lecturer, University of Sao Paulo, Brazil: Stress, caregiving and health |

**Honors**

| | |
|---|---|
| 1979 | Sigma Theta Tau International Honor Society of Nursing, Alpha Mu Chapter |
| 1996-1997 | Virginia S. Kelley Scholar, American Nurses' Foundation |
| 2002 | Stress and Coping Research Section Award, Midwest Nursing Research Society |
| 2004 | The Hartford Institute/MNRS Award for Leadership in Geriatric Nursing Research |
| 2005 | Fellow, American Academy of Nursing |
| 2007 | Fellow, Gerontological Society of America, Behavioral and Social Sciences |
| 2012 | Presentation of Distinction, Council for the Advancement of Nursing Science |

**B. Relevant peer-reviewed publications (in chronological order)**

1. Musil C., & Ahmad, M. (2002). Health of grandmothers: A comparison by caregiver status. Journal of Aging and Health, 14(1), 96-121.
2. Musil, C., Youngblut, J. M., Ahn, S., & Curry, V. (2002). Parenting stress: A comparison of grandmother caretakers and mothers. Journal of Mental Health and Aging, 8(3), 197-210.
3. Musil, C., Warner, C., Yobas, P. K., & Jones, S. (2002). A comparison of imputation techniques for handling missing data. Western Journal of Nursing Research, 24(5), 815-829.
4. Musil, C., Morris, D., Warner, C., & Saied, H. (2003). Issues in caregivers' stress and providers' support. Research on Aging, 25(5), 505-526.
5. Ahmad, M., Musil, C., Zauszniewski, J., Morris, D., & Resnik, M. (2005). Stress, appraisal, coping and health in prostate cancer patients. Journal of Gerontological Nursing, 31(10), 34-43.
6. Musil, C., Warner, C., Jeanblanc, A., Zauszniewski, J., Kercher, K. (2006). Grandmothers, caregiving and family functioning, Journals of Gerontology, Social Sciences, 61B,2, S89-98.
7. Musil, C. M., Warner, C.B., Standing, T., Zauszniewski, J.A., & Wykle, M.L. (2009). Grandmother caregiving, family stress and strain, and depressive symptoms. Western Journal of Nursing Research. 31: 389-408. PMCID: PMC2883890.
8. Muliira JK, Musil CM. (2010). Relationship between methods of coping, social support and receipt of preventive care procedures by primary grandmother caregivers. J Community Health;35(5):479-86.
9. Bigbee, J., Musil, C., & Kanski, D. (2011). The Health of Caregiving Grandmothers: A Rural-Urban Comparison. Journal of Rural Health. 27 (3), 286-296.
10. Musil CM, Gordon NL, Warner CB, Zauszniewski JA, Standing T, Wykle. (2011). Grandmothers and Caregiving to Grandchildren: Continuity, Change, and Outcomes Over 24 Months. The Gerontologist, 51(1):86-100. PMCID: PMC3018867
11. Toly, V., Musil, C., & Carl, JC. (2012). Families with children who are technology-dependent: Normalization and family functioning. Western Journal of Nursing Research. 34, 52-71. PMCID: PMC3271785
12. Toly, V. B., Musil, C. M., & Carl, J. C. (2012). A longitudinal study of families with technology-dependent children. Research in Nursing & Health, 35, 40-54. PMCID:PMC3309461
13. Zauszniewski, J.A., Au, T.Y., & Musil, C.M. (2012). Resourcefulness training for grandmothers raising grandchildren: Is there a need? Issues in Mental Health Nursing, 33(10), 680-686.
14. Zauszniewski, J.A., Au, T.Y., & Musil, C.M. (2013, in press). Biofeedback in grandmothers raising grandchildren: Effects on stress, emotions, and cognitions. Biofeedback.
15. Zauszniewski, J.A., Musil, C.M., & Au, T.Y. (2013, in press). Resourcefulness training for grandmothers raising grandchildren: Acceptability and feasibility of two methods. Issues in Mental Health Nursing.

**C. Research Support**

**Ongoing Research Support**

T32 DE019773-03 Nelson (PI) 08/01/09 – 07/31/14
NIDCR
DMD and Master's in Clinical Research Training (DMD-MCRT)

The goal of this T32 grant is to train DMD students for dual degree to increase the academic work force of qualified clinician scholars.
Role: Faculty

P30 NR010676-05 Moore (PI) 09/29/07-06/30/13
NIH/NINR
Center of Excellence to Build the Science of Self-Management: A Systems Approach
The SMART Center will prepare a critical mass of researchers to extend and disseminate knowledge related to self-management, contribute to the development of emerging biobehavioral research methods, focus on critical issues related to health disparities, and incorporate economic considerations as part of their research.
Role: Co-Investigator

**Completed Research Support**

Musil (PI) 06/01/11-9/31/12
FPB School of Nursing Pilot Funds
Web-based Resourcefulness Training: A Pilot
This pilot project is a test of a web-based recruitment and data collection of the resourcefulness intervention. We are evaluating feasibility, acceptability, safety, and fidelity of the web-based version and comparing these results with non-web-based intervention.

UL1 RR024989-05 Davis (PI) 09/17/07-05/31/12
NIH
Institutional Clinical and Translational Science Award (CTSA)
The purpose of this grant is to coordinate existing resources relevant to clinical research at Case Western Reserve University and three of its hospital affiliates.
Role: Faculty

T32 NR009761-05 Moore (PI) 05/18/06 – 04/30/12
NIH/NINR
Multiple Morbidities in Vulnerable Populations: Nurse Scientist Training
The proposed predoctoral and postdoctoral training program provides research training for nurses pursuing research careers focused on vulnerable populations with multiple morbidities.
Role: Core Training Faculty

R01 NR005067 Musil (PI) 09/05/06 – 12/31/10
NIH/NINR
Grandmothers, Caregiving, Families, and Transitions (Continuation of Intergenerational Caregiving to Youth At-Risk 2001-2006)
The purposes of this continuation are to: 1) extend the evaluation of the grandmother caregiving experience across time, incorporating caregiving transitions; 2) evaluate grandchildren's perceptions of family functioning, support and depressive symptoms and correlate these data with that of the grandmother, and 3) examine the effects of caregiving transitions on grandchildren, and 4) identify perceived needs for interventions.

R21 NR010581 Zauszniewski (PI) 09/13/07-05/31/10
NIH/NINR
Promoting Resourcefulness in Grandmothers Raising Grandchildren
The goal of this R21 exploratory research grant is to pilot test and refine an adapted intervention that teaches personal and social resourcefulness skills to grandmothers raising grandchildren.
Role: Co-Investigator

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Suchitra Shirley Nelson** | POSITION TITLE<br>Professor, Community Dentistry |
| eRA COMMONS USER NAME **SNELSON** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| University of Madras, India | B.Sc. | 05/79 | Nutrition & Diet |
| University of Madras, India | M.Sc. | 05/81 | Nutrition & Diet |
| Case Western Reserve University, Cleveland, OH | M.S. | 05/84 | Nutrition |
| Case Western Reserve University, Cleveland, OH | M.S. | 05/88 | Epidemiology |
| Case Western Reserve University, Cleveland, OH | Ph.D. | 05/92 | Epidemiology |

**A. Positions and Honors**

**Positions and Employment**

1991-1995 Research Associate, Post Doctoral Fellow – Case Western Reserve University, Bolton-Brush Growth Study Center and Department of Orthodontics, Cleveland, OH
1995-1996 Visiting Assistant Professor – Case Western Reserve University (CWRU), School of Dentistry, Department of Community Dentistry, Cleveland, OH
1996-2006 Assistant Professor – CWRU, School of Dental Medicine, Community Dentistry, Cleveland, OH
2006-2010 Associate Professor - CWRU, School of Dental Medicine, Community Dentistry, Cleveland, OH
2010-Present Professor – CWRU, School of Dental Medicine, Community Dentistry, Cleveland, OH

Other Experience and Professional Memberships

2005 National Institute of Dental and Craniofacial Research (NIDCR), Special Emphasis Panel, Grant Reviewer
2006 Agency for Healthcare Research and Quality (AHRQ), Grant Reviewer for R03
2007 NIDCR, Special Emphasis Panel, Grant Reviewer for R21
2007-2010 HRSA, MCHB Research grant reviewer
2008 NIDCR, Special Emphasis Panel, Grant Reviewer for R21 and U54 (Center grants
2009-Present NIDCR Standing Study Section for R03, F, and K grants

**Honors**

1994 B.F. Dewell Honorary Research Award.American Association of Orthodontics Foundation
2008 Presidential Early Career Award for Scientists and Engineers (PECASE), White House Office of Science and Technology Policy

**B. Selected Peer-reviewed Publications (Selected from 53 publications)**

**Most relevant to the current application**

1. Nelson S, Albert JA, Lombardi G, Wishnek S, Asaad G, Kirchner HL, Singer LT. Dental Caries and Enamel Defects in Very Low Birth Weight adolescents. Caries Res 2010;44:509-518 PMID: 20975268.
2. Albert JA, Nelson S. Generalized Causal Mediation Analysis. Biometrics. 2011 Sep;67(3):1028-38. PMID:21306353
3. Nelson S, Lee W, Albert JA, Singer L. Early maternal psychosocial factors predict adolescent caries. J Dental Res 2012; 91(9):859-864. PMID: 22821239
4. Chen Y, Lee W, Ferretti G, Slayton R, Nelson S. Agreement between photographic and clinical examination in detecting development defects of enamel in infants. J Public Health Dentistry 2013 Accepted

5. Nelson S, Albert JM, Geng C, Curtan S, Lang K, Miadich S, Heima M, Malik A, Ferretti G, Eggertsson H, Slayton RL, Milgrom P. Increased enamel hypoplasia in a birth cohort study of VLBW Infants. J Dental Res 2013 In Revision

**Additional recent publications of importance to the field (in chronological order)**

1. Nelson S. Epidemiology for the Practicing Orthodontists. Seminars in Orthodontics. 1999;5(2):77-84. PMID# 10530281.
2. Nelson S, Hans MG, Broadbent BH , Dean D. The Brush Inquiry - An Opportunity to Investigate Health outcomes in a Well Characterized Cohort. Am J Hum Biol 2000; 12:1-9. PMID# 11533998.
3. Nelson S, Kulnis R. Snoring and sleep disturbance among children from an orthodontic setting. Sleep and Breathing 2001; 5(2):63-70. PMID# 11868143.
4. Nelson S, Cakirer B, Lai Y. Longitudinal changes in craniofacial factors among snoring and non-snoring Bolton-Brush subjects. Am J Orthod Dentofac Orthop. 2003;123:338-44. PMID# 12637906
5. Nelson S, Lerner E, Needlman R, Salvator A, Singer L. Cocaine, Anemia, and Neurodevelopmental outcomes in children: A longitudinal study. J Dev. Behav. Peds. 2004;25(1):1-9. PMID# 14767350.
6. Nelson S, Armogan V, Abei Y, Broadbent BH, Hans M. Disparity in orthodontic utilization and treatment need among high school students. J Public Health Dent. 2004;64(1):26-30. PMID# 15078058.
7. Nelson S, Milgrom P. Recruitment of Minority School Children into a Randomized Clinical Trial of Tooth Decay Prevention. Contemp Clin Trials. 2011 Oct 1. PMID: 21986390
8. Nelson S, Eggertsson H, Powell B, Mandaleris J, Ntragatakis M, Richardson T, Ferretti G. Calibration of dental examiners in the ICDAS criteria for a caries prevention community trial. Community Dent Health. 2011 Sep;28(3):238-42. PMID: 21916361
9. Albert JM, Wang W, Nelson S. Estimating overall exposure effects for zero-inflated regression models with application to dental caries. Stat Methods Med Res. 2011 Sep 8. PMID:21908419
10. Nelson S, Mandelaris J, Heima M, Ferretti G, Spiekerman C, Milgrom P. School screening and parental reminders in increasing dental care for children in need: a retrospective cohort study. J Public Health Dent. 2012 Winter;72(1):45-52. PMID:22316214

**C. Research Support**

**Ongoing Research Support**

R01 DE017947-03 Nelson (PI) 07/01/07 – 12/31/13
Longitudinal Study of Dental Caries in VLBW Infants
The goal of this study is to investigate the relationship between birth weight and Early Childhood Caries, and to study the relationship looking at enamel defects and socio-behavioral variables in VLBW and NBW infants.
Role: PI

T32DE019773-01 Nelson (PI) 08/1/09 – 05/31/14
DMD and Master's in Clinical Research Training (DMD-MCRT)
The goal of this T32 grant is to train DMD students for dual degree to increase the academic work force of qualified clinician scholars.
Role: PI

R34 DE022262 Nelson (PI) 09/01/11 – 08/31/13
"Family Intervention with caregivers of children with urgent dental needs
Role: PI

NIH-NIDCR Albert (PI) 10/01/11 – 09/30/16
"Generalized Causal Mediation Analysis for Social Environment and Health Research"
Role: Co-Investigator

**Completed Research Support**

R01 DE017947-04 Nelson (PI) 08/01/10 – 07/31/12
Longitudinal Study of Dental Caries in VLBW Infants – Genetic supplement
The goal of this study is to collect saliva from parent and infants, then isolate and extract DNA for future candidate gene analysis.
Role: PI

R01 DE017947-03 Nelson (PI) 10/01/09 – 09/30/12
Longitudinal Study of Dental Caries in VLBW Infants – Administrative supplement
The goal of this study is to recruit/retain additional subjects and training of examiners for the parent study
Role: PI

R40 MC07838-04 Nelson (PI) 01/01/07 - 12/31/11
Xylitol for Caries Prevention in Inner City Children
The goal of this clinical trial is aimed at investigating the short and long term effectiveness of xylitol intervention on preventing dental caries in Kindergarten school children followed until second grade.
Role: PI

R21 DE016469 Nelson (PI) 09/01/04 – 06/30/07
Oral Health Problems of BPD and VLBW adolescents
The purpose of this study is to investigate the relationship between BPD, VLBW and dental caries in the permanent dentition of adolescents, and to explore the mechanisms underlying this relationship by looking at enamel defects, oral health behavior, and synergistic effects of these two factors.
Role: PI

R03 DE 018391 Albert (PI) 04/01/09 – 03/31/11
Causal mediation analysis of dental caries in VLBW and BPD adolescents
The goal of this study is to develop statistical models to test for mediation effects.
Role: Co-Investigator

**BIOGRAPHICAL SKETCH**

| NAME **Ransohoff, Richard, M.** | POSITION TITLE<br>Director, Neuroinflammation Research Center & Staff Neurologist |
|---|---|
| eRA COMMONS USER NAME **Ransohr** | |

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| Bard College | B.A. | 1964-1968 | Literature |
| Hunter College | - | 1969-1974 | Pre-med |
| CWRU School of Medicine (SOM) | M.D. | 1974-1978 | Medicine |

## A. Positions and Honors

**Professional Experience**

2005- Director, Neuroinflammation Research Center, Dept of Neurosciences, LRI
2003- Professor, Dept of Molecular Medicine (primary) and Pathology (secondary), CCLCM/CWRU
1994- Staff Scientist, Dept of Neuroscience, Lerner Research Institute (LRI), CCF
1993- Staff Neurologist, CCF (Mellen Center for MS Treatment and Research)
1989-1994 Assistant Staff, Research Institute, CCF
1984-1988 Post-doctoral Fellow, Dept of Molecular Biology and Microbiology, CWRU-SOM
1984-1993 Associate Staff, Department of Neurology, CCF
1981-1984 Resident, Department of Neurology, Cleveland Clinic Foundation (CCF)
1978-1981 Resident, Department of Internal Medicine, Mount Sinai Medical Center
1969-1974 Evening Administrator, Bellevue Hospital Center, New York, NY

**Honors, other professional activities, editorial boards, peer review (selected)**

2012 John J. Dystel Prize for MS Research
2009 F.E. Bennett Lectureship, ANA Annual Meeting, Baltimore, MD
2009-2012 MAB, Guthy Jackson Charitable Foundation for NMO Research
2009 Sam and Maria Miller Scientific Achievement Award in Basic Science, CCF
2008 ANA/John N. Whitaker Visiting Professor, U. of California, Irvine
2008-date SAB, Gladstone Institute for Neurological Disease, UCSF
2008-date SAB, Vertex Pharmaceuticals, Cambridge, MA
2007 Fellow, American Association for the Advancement of Science (AAAS)
2006 Member, Association of American Physicians (AAP)
2004-2008 Member, EAB, Meharry Medical College Neuroscience Research Program
2004-2008 Co-Director, MBL Course: "Pathogenesis of neuroimmunological disease"
2003-2012 Steering Committee, NIH Therapeutics Program for Spinal Muscular Atrophy
2003-2008 EAB, MS Lesion Project (National MS Society RG 3185)
2003-2008 Chair, Scientific Review Panel B, National Multiple Sclerosis Society
2002 Samuel and John Bard Award for Science and Medicine
2001-date EAB, Program Project on Alexander's Disease (NS 42803)
2000-date Scientific Advisory Board (SAB), Chemocentryx, Mountain View, CA
1996-date Member, Medical Advisory Board, National Multiple Sclerosis Society
1995-1998 Member, NIH Neurology C Study Section
1988-1993 Clinical Investigator Development Award, NIH, NINDS (KO8-01265)
1987-1992 Harry Weaver Neuroscience Scholar, National Multiple Sclerosis Society
1985 Diplomate, American Board of Psychiatry and Neurology (Neurology)
1981 Diplomate, American Board of Internal Medicine
1978 Alpha Omega Alpha, Case Western Reserve University School of Medicine

2010-2016 Member, CMBG (Cellular and Molecular Biology of Glia) Study Section
2009-2012 Member, Scientific Program Committee, American Neurological Association

2006-date Associate Editor, *Neurology*
2005-2011 Highlights Advisory Board, *Nature Reviews Immunology*
2003-date Advisory Editorial Board, *Trends in Immunology*
2002-2005 Section Editor, *Journal of Immunology*

**B. Publications (from >335 PubMed listings):**

1. PubMed listings:
http://www.ncbi.nlm.nih.gov/sites/myncbi/collections/public/1vMw3LCXayTzILplmsD0lDbQJ/?sort=date&direction=descending

2. Google scholar Citation indices (January, 2013):

| | All | Since 2008 |
|---|---|---|
| Citations | 24007 | 11443 |
| h-index | 80 | 50 |
| i10-index | 259 | 195 |

**C. Research Support**

**Active**
*Chemokines in CNS Inflammation*
Annual Direct Cost: $196,875
Total Direct Costs: $984,975
In this project, we evaluate how chemokine receptor CXCR2 regulates demyelination and remyelination using the cuprizone model.

K24NS51400 PI: Richard M. Ransohoff 02/01/06-01/31/16 3.84 cal. mths (32%)
NIH K24
*Mentored Research: Chemokine Regulation of CNS Inflammation in MS*
Annual Direct Cost: $157,100
Total Direct Cost: $ 859,942
This award supports *in vitro* blood brain barrier studies, with a specific focus on mentoring clinician-investigators.

R21NS074820 PI: Richard M. Ransohoff 03/01/11-02/28/13 0.6 cal. mths (5%)
NIH R21
*Modulating Chemokine Receptors at the Blood-Brain Barrier under Flow*
Annual Direct Cost: $150,000
Total Direct Cost: $ 275,000
The goal of this research proposal is to establish how crossing the blood-brain barrier (BBB) regulates chemokine receptor expression on peripheral blood mononuclear cells (PBMC) including T cells, B cells and monocytes.

RG4550 PI: Richard M. Ransohoff 09/30/11-08/31/14 0.9 cal. mths (7.5%; NS)
NMSS Research Grant
*Monocytes and Microglia in EAE*
Annual Direct Costs: $134,099
Total Costs: $434,167

The goal of this project is to address for the first time how monocytes and microglia, each in their own way, cause tissue damage and tissue repair during EAE. We will study molecules which are also present in MS tissues and we anticipate that our research will lead directly to effective new therapeutic approaches to MS.

PP1800 PI: Richard M. Ransohoff 06/01/12-05/31/13 0.3 cal. mths (2.5%; NS)
NMSS Pilot Award
*Roles of CXCL12 and its receptors in myelin repair by neural stem cell progeny*
Total Direct Costs: $44,000
The goal of this research is to determine if modulating the availability of CXCL12 within the neural stem cell niche affects repair of a focal demyelinating lesion.

WGVJ1209RR PI: Richard M. Ransohoff 09/01/12-08/31/13 0.36 cal. mths (3%; NS)
Guthy Jackson Foundation Cure Grant
*Effects of AQP4 antibodies in NMO-IgG on BBB function*
Total Costs: $100,824
In this proposal we aim to define how AQP4 antibodies in NMO-IgG elicit responses when placed on the luminal (apical) aspect of the endothelium or when placed in direct contact with AQP4 on astrocytes. The model is a unique human brain microvascular endothelial cell/ human astrocyte co-culture exposed to shear forces. We will determine whether exposure to AQP4 antibodies (or control IgG) increases expression of specific leukocyte trafficking determinants on endothelial cells.

R01NS074804 RM Ransohoff/BT Lamb, co-PIs 02/15/09-01/31/14 0.9 cal. mths (7.5%)
NIH R01
*The Role of Fractalkine Signaling in Neurodegenerative Disease*
Annual Direct Cost: $218,751
Total Direct Cost: $1,093,755
This study examines whether soluble CX3CL1 released from neurons signals to CX3CR1 within microglia and plays a unique role in AD phenotypes via blocking phagocytic removal of Aβ by microglia and reducing phosphorylation and aggregation of MAPT within neurons via mechanisms that involve IL1.

AA MCPG PI: Bruce T. Lamb 07/30/11-06/30/14 0.6 cal. mths (5%)
Alzheimer's Association Multi Center Project Grant (Ransohoff, Project 2 leader)
*Genetic Tagging of Mononuclear Phagocytes in Alzheimer's Mouse Models (Project 2)*
Annual Direct Costs: $72,727
Total Costs: $218,181
In this project, we propose to establish a permanent method for selective genetic labeling of peripheral inflammatory monocytes (which can invade the CNS) or resident microglia, to enable distinguishing them in tissues of AD-model mice (either amyloid deposition or tau pathology).

W81XWH12-1-0629 PI: Bruce T. Lamb 10/01/12-09/30/14 0.24 cal. mths (2%)
US DOD Research Grant
*Novel Genetic Models to Study the Role of Inflammation in Injury-induced AD*
Annual Direct Cost: $250,000
Total Costs: $500,000
The overall goal of this application is to examine the effects of traumatic brain injury on Alzheimer's disease (AD) pathologies at both early (3 DPI) and late (120 DPI) timepoints. First, the effects of TBI on extracellular amyloid pathology will be examined in a genomic-based mouse model of AD. Second the effects of TBI on intracellular tau aggregation will be examined in a genomic-based mouse model of AD. Finally, the effects of

TBI on the infiltration of monocytes and microglia will be examined at both the early (3DPI) and late (120 DPI) timepoints.

1P50NS38667 PI : Bruce D. Trapp 12/01/09-11/30/14 0.6 cal. mths (5%)
NIH P50
*Project 1: Chemokines and Chemokine Receptors in MS (Role, Project 1 Leader)*
Annual Direct Cost: $202,621
Total Direct Costs: $1,013,105
The goal of Project 1 is to define in detail how individual chemokine receptors are implicated in early cortical demyelination in MS, by correlating results from MS tissue staining with data obtained in a novel in-vitro model of the blood-brain barrier, under flow conditions.

R01NS071996 PI: Xiaoxia Li 04/01/11-03/31/16 0.6 cal. Mths (5%)
NIH R01
*Molecular and Cellular Mechanisms of IL17 Signaling*
Annual Direct Cost: $245,839
Total Direct Cost: $ 1,229,195
This project will test whether IL-17-induced Act1-mediated signaling in different CNS resident cells coordinately mediate leukocyte recruitment, demyelination and neurodegeneration during autoimmune-induced inflammation of the CNS.

2R01NS049577-04 PI: Claudia Lucchinetti 05/01/09-04/30/14 0.24 cal. mths (2%; NS)
Mayo Clinic-Subcontract
*Mechanisms of Multiple Sclerosis Tissue Pathology*
Annual Direct Cost: $17,000
The overall goal of this project is to examine cortical pathology early in the course of multiple sclerosis, using immunohistochemical methods and a unique resource of biopsy tissues.

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Jeremy N. Rich** | POSITION TITLE<br>Chair and Staff, Department of Stem Cell Biology & Regenerative Medicine |
| eRA COMMONS USER NAME **rich0001** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| Washington University, St. Louis, MO | B.S. | 1989 | Electrical Engineering |
| Duke University School of Medicine, Durham, NC | M.D. | 1993 | Medicine |
| The Johns Hopkins Hospital, Baltimore, MD | Internship | 1993-4 | Internal Medicine |
| The Johns Hopkins Hospital, Baltimore, MD | Residency | 1994-7 | Neurology |
| Duke University Medical Center, Durham, NC | Fellowship | 1997-8 | Neuro-Oncology |
| Duke University School of Medicine, Durham, NC | M.H.Sc. | 2005-9 | Clinical Research |

**A. Research and Professional Experience**

**Positions and Employment**

1998-1999 Associate, Department of Medicine, Duke University Medical Center
2000-2005 Assistant Professor, Dept of Medicine, Duke University Medical Center
2003-2006 Assistant Professor, Dept of Neurobiology, Duke University Medical Center
2005-2007 Associate Professor, Dept of Medicine, Duke University Medical Center
2006-2008 Associate Professor, Dept of Pharmacology & Cancer Biology, Duke University
2007-present Associate Professor with Tenure, Department of Medicine, Duke University
2008-present Chair and Staff, Dept. Stem Cell Biology and Regenerative Med., Cleveland Clinic
2008-present Staff, Dept. of Neurology, Taussig Cancer Center, & Brain Tumor Center, CCF
2008-present Co-Director, The Center for Stem Cell and Regenerative Medicine, NCRM
2009-present Professor, Cleveland Clinic Lerner College of Medicine at Case Western

**Academic Awards**

National Merit Scholar (1985), Alexander S. Langsdorf Fellow (1985), Antoinette Frances Dames Award (1987), Russell R. Pfeiffer Award (1988), Allison Prize (1989), Eta Kappa Nu Electrical Engineering Honorary Society (1989), College Dean's List, (eight times) (1985-1989), Tau Beta Pi Engineering Honorary Society (1989), Summa Cum Laude (1989), Howard Hughes Medical Institute Medical Student Fellow (1991-1992), Alpha Omega Alpha (1992), Hewlett-Packard Award for Outstanding Medical Student (1993), American Academy of Neurology Resident Recognition Award (1997), Howard Hughes Medical Institute Physician Postdoctoral Research Fellow, declined (1998), Frances Goodrich and Albert Hackett/American Brain Tumor Association Fellowship (1998-1999), NINDS K08 recipient (1998-2003), Sidney Kimmel Foundation for Cancer Research Translational Science Fellow (2004-2006), Damon Runyon-Lilly Clinical Investigator (2004-2009), NINDS K02 recipient (2004-9), Elected to the American Neurological Association (2005), American Academy of Neurology Preuss Award in Clinical Neuro-Oncology (2006), Society of Neuro-Oncology Award for Excellence in Basic Research (2006), Invited Speaker/Chair for ASCO and AACR Annual Meetings, Keystone Symposia, International Congress for Radiation Research, and Gordon Research Conferences, Elected to The American Society for Clinical Investigation (ASCI) (2007), Cleveland Clinic Lerner Research Institute Award for Outstanding Science (2010), Elected to Association of American Physicians (AAP) (2012)

**Academic Services**

NIH P01 Review Committee Member (2004, June 2009), NIH U54 TMEN Review Committee Member (2006), NIH TME Review Ad hoc Committee Member (2006-2009) and Permanent member (2009-present), NIH MONC Study Section ad hoc (June 2007), NIH Cancer Stem Cell RFA Review Member (2008), Editorial Board Member

for Neuro-Oncology (2011-present), Scientific Research Advisor (American Brain Tumor Association), Senior Editor for Clinical Cancer Research (2012-present), Editorial Board Member for PLoS Biology (2012-present), Board of Scientific Counselors, NCI (2012-present).

**B. Selected peer-reviewed publications (relevant to this application, SELECTED FROM A TOTAL OF 143)**

1. Bao S, Wu Q, Sathornsumetee S, Hao Y, Li Z, Hjelmeland AB, Shi Q, McLendon RE, Bigner DD, and **Rich JN**. Stem cell-like glioblastoma cells promote tumor angiogenesis through vascular endothelial growth factor. Cancer Res. 2006;66(16):7843-8.
2. Bao S, Wu Q, McLendon RE, Hao Y, Shi Q, Hjelmeland AB, Dewhirst MW, Bigner DD, **Rich JN**. Glioma stem cells promote radioresistance by preferential activation of the DNA damage response. Nature 2006;444(7120):756-60.
3. Sathornsumetee S, Cao Y, Marcello JE, Herndon JE 2nd, McLendon RE, Desjardins A, Friedman HS, Dewhirst MW, Vredenburgh JJ, **Rich JN**. Tumor angiogenic and hypoxic profiles predict radiographic response and survival in malignant astrocytoma patients treated with bevacizumab and irinotecan. J Clin Oncol. 2008;26(2):271-8.
4. Li Z, Bao S, Wu Q, Wang H, Eyler CE, Sathornsumetee S, Shi Q, Cao Y, Lathia J, McLendon RE, Hjelmeland AB, **Rich JN**. Hypoxia-Inducible Factors Regulate Tumorigenic Capacity of Glioma Stem Cells. Cancer Cell 2009;15:1-13. PMCID 2693960
5. Wang H, Lathia JD, Wu Q, Wang J, Li Z, Heddleston JM, Eyler CE, Elderbroom J, Gallagher J, Schuschu J, Macswords J, Cao Y, McLendon RE, Wang XF, Hjelmeland AB, **Rich JN**. Targeting Interleukin 6 Signaling Suppresses Glioma Stem Cell Survival and Tumor Growth. Stem Cells 2009;(10):2393-404. PMCID 2825688
6. Hjelmeland AB, Wu Q, Wickman S, Eyler C E, Heddleston J, Shi Q, Lathia JD, MacSwords J, Lee J, McLendon RE, **Rich JN**. Targeting A20 decreases glioma stem cell survival and tumor growth. PLoS Biol**.** 2010;8(2):e1000319. PMCID 2826371
7. Lathia JD, Gallagher J, Heddleston JM, Wang J, Eyler CE, MacSwords J, Wu Q, Vasanji A, McLendon RE, Hjelmeland AB, **Rich JN**. Integrin alpha 6 regulates glioblastoma stem cells. Cell Stem Cell 2010;6(5):421-32. PMCID 2884275
8. Hjelmeland AB, Wu Q, Heddleston J, Choudhardy G, MacSwords J, Lathia J, McLendon R, Lindner D, Sloan A, **Rich JN.** Acidic stress promotes a glioma stem cell phenotype. Cell Death Differ. 2011 May;18(5):829-40. PMCID 3095828
9. Guryanova OA, Wu Q, Cheng L, Lathia JD, Huang Z, Yang J, MacSwords J, Eyler CE, McLendon RE, Heddleston JM, Shou W, Hambardzumyan D, Lee J, Hjelmeland AB, Sloan AE, Bredel M, Stark GR, **Rich JN**[+], Bao S[+]. Non-receptor tyrosine kinase BMX/ETK maintains tumorigenic potential of glioblastoma stem cells by activating stat3. Cancer Cell 2011;19(4):498-511, [+]denotes corresponding author. PMCID 30767106
10. Eyler CE, Wu Q, Yan K, Macswords JM, Chandler-Militello D, Misuraca KL, Lathia JD, Forrester MT, Lee J, Stamler JS, Goldman SA, Bredel M, McLendon RE, Sloan AE, Hjelmeland AB, **Rich JN**. Glioma stem cell proliferation and tumor growth are promoted by nitric oxide synthase-2. Cell 2011;146(1):53-66. PMCID 3144745
11. Lathia JD, Hitomi M, Gallagher J, Gadani SP, Adkins J, Vasanji A, Liu L, Eyler CE, Heddleston JM, Wu Q, Soeda A, Hoeppner DJ, Ravin R, McKay RDG, McLendon RE, Corbeil D, Chenn A, Hjelmeland AB, Park DM, **Rich JN**. Distribution of CD133 reveals glioma stem cell self-renew through symmetric and asymmetric cell divisions. Cell Death Dis. 2011 Sep 1;2:e200. PMCID 3186899
12. Lathia JD, Gallagher J, Myers JT, Vasanji A, McLendon RE, Hjelmeland AB, Huang AY, **Rich JN**. Direct in vivo evidence for tumor propagation by cancer stem cells. PLoS ONE 2011;6(9): e24807. PMCID 3178553
13. Hjelmeland AB, Lathia JD, Sathornsumetee S, **Rich JN**. Twisted tango: brain tumor neurovascular interactions. Nat Neurosci. 2011;14(11):1375-81.
14. Hamerlik P, Lathia JD, Rasmussen R, Wu Q, Bartkova J, Lee M, Moudry P, Bartek J Jr, Fischer W, Lukas J, **Rich JN***, Bartek J*. Autocrine VEGF-VEGFR2-Neuropilin-1 signaling promotes glioma stem-like cell viability and tumor growth. J Exp Med. 2012;209(3):507-20. *, co-corresponding authors. PMCID 3302235

15. Kim Y, Kim E, Wu Q, Guryanova O, Hitomi H, Lathia JD, Serwanski D, Sloan AE, Weil R, Lee J, Nishiyama A, Bao S, Hjelmeland AB, **Rich JN**. Platelet Derived Growth Factor Receptors Differentially Inform Intertumoral and Intratumoral Heterogeneity. Genes Dev. 2012 Jun 1;26(11):1247-62. PMCID 3371412

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Nancy J. Roizen, M.D., F.A.A.P.** | POSITION TITLE<br>Professor |
| eRA COMMONS USER NAME | Chief, Division of Developmental-Behavioral Pediatrics & Psychology |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| Tufts University | 1968 | B.S. | Biology (cum laude) |
| Tufts University | 1972 | MD | |
| Massachusetts General Hospital, Boston, MA | 1972-1973 | Internship | |
| John Hopkins Hospital, Baltimore, MD | 1974-1975 | Fellow | Developmental Pediatrics |
| University of CA San Francisco | 1975-1976 | Fellow | Behavioral Pediatrics |

**A. Positions and Honors.**

| | |
|---|---|
| 2007-present | Professor, Case Western Reserve University School of Med, Dept of Pediatrics |
| 2001-2005 | Professor, SUNY Upstate Medical University, Depts. of Peds & Psychiatry |
| 1995-2001 | Associate Professor, University of Chicago, Depts. of Peds & Psychiatry |
| 1985-1995 | Assistant Professor of Clinical Pediatrics, University of Chicago, Depts. of Pediatrics and Psychology |

**Administrative**

| | |
|---|---|
| 2007-present | Director, Division of Developmental/Behavioral Pediatrics and Psychology, Rainbow Babies and Children's Hospital, Cleveland, OH |
| 2005-2007 | Medical Staff Chair, The Cleveland Clinic Children's Hospital for Rehabilitation, Shaker Campus, Division of Pediatrics |
| 2005-2007 | Department Chair of Developmental and Rehabilitation Pediatrics, The Cleveland Clinic Children's Hospital for Rehab, Division of Pediatrics |
| 2001-2005 | Vice-Chair Education, SUNY Upstate Medical University, Dept Pediatrics |
| 1990-2001 | Chief Section, Univ of Chicago Dept of Peds, Dev & Behavioral Pediatrics |

**B. Selected peer-reviewed publications (in chronological order).**


Roizen NJ, Blondis TA, Irwin M, & Stein M. Adaptive functioning in children with Attention Deficit Hyperactivity Disorder. *Archives of Child and Adolescent Medicine*. 1994; 148: 1137-1142.

Stein MA, Szumowski M, Blondis TA, & Roizen NJ. Adaptive skills dysfunction in ADD and ADHD children: a research note. *Journal of Child Psychology and Psychiatry*. 1995; 36: 663-670.

Roizen NJ, Blondis TA, Irwin M, Rubinoff a, Kieffer J, & Stein MA. Psychiatric and developmental disorders in families of children with ADHD: Utility of parent report. *Archives of Child and Adolescent Medicine*. 1996; 148: 1137-1142.

Stein MA, Blondis TA, Schnitzler ER, O'Brien T, Fishkin J, Blackwell B, Szumowski E, & Roizen NJ. Methylphenidate dosing: b.i.d. versus t.i.d. *Pediatrics*. 1996; 98: 748-756.

Roizen NJ, Patterson D. Down's Syndrome. *The Lancet*. 2003; 361: 1281-1289.

Olson BG, Rosenbaum PF, Dosa NP, Roizen NJ. Improving guideline adherence for the diagnosis of ADHD in an ambulatory pediatric setting. *Ambulatory Pediatrics*. 2005; 5: 138-142.

Antshel KM, Fremont W, Roizen NJ, Shprintzen R, Higgins AM, Dhamoon A, Kates WR. ADHD, major depressive disorder, and simple phobias are prevalent psychiatric conditions in youth with velocardiofacial syndrome. *Journal of the Academy of Child and Adolescent Psychiatry*. 2006; 45 (5): 596-603.

Roizen N, Antshel KM, Fremont W, AQbdulSabur N, Higgins AM, Shprintzen RJ, Kates WR. 22q11.2DS Deletion Syndrome: Developmental milestones in infants and toddlers. *Journal of Developmental and Behavioral Pediatrics*. 2007;28:119-124

Fremont WP, Nastasi R, Newman N, Roizen NJ. Comfort level of pediatricians and family medicine physicians in diagnosing and treating child and adolescent psychiatric disorders. *Medicine in Psychiatry*. 2008. 38(2): 153-168.

Roizen NJ, Higgins AM, Antshel KM, Fremont W, Shprintzen R, Kates WR. 22q11.2 deletion syndrome: Are motor deficits more than expected for IQ level? *Journal of Pediatrics*. 2010; 157:658-661.

Roizen, NJ. Overview of health issues among persons with Down syndrome. International Review of Research in Mental Retardation 2010; 39:3-33.

Jamieson SE, Peixoto-Rangel AL, Hargrave AC, de Roubaix L-A, Mui EJ, Coulter NR, Miller EN, Fuller SJ, Wiley JD, Castellucci L, Boyer K, Peixe RE, Kirists MJ, deSouza EL, Coyne JJ, Correa-Oliveira R, Sautter M, Smith NC, Lees MP, Swisher CN, Heydemann P, Noble AG, Patel D, Bardo D, Burrowes D, McLone D, Roizen N, Wihters S, Bahia-Oliveria LMG, McLeod R, Blackwell JM. 2010. Evidence for associations between purginergic receptor P2X7 (P2RX7) and toxoplasmosis. 2010;11:374-383.

Steingass K, Chicoine B, McGuire D, Roizen NJ. Developmental Disabilities Grown-up: Down Syndrome. *Journal of Developmental and Behavioral Pediatrics*. 2011;32:548-558.

Roizen NJ, Kuschner ES, Sulkes SB, Hyman SL, Diehl A, Magyar C, van Wijngaarden E, Rodgers L, Cruschel C. A population-based study of medical problems in 440 Children with Down syndrome. (submitted)

**Books**

Batshaw ML, Roizen NJ, Lotrecciano G . *Children with Disabilities*. 7th Ed. Paul H. Brookes, Baltimore, MD, (in press).

Roizen JF, Oz M, Spiker T, Rome E, Wynette G, Oz L, Kahn L, Roizen NJ. *You Raising a Child The Owners Manuel for 1st Breathe to 1st Grade.* Free Press, NY, NY, 2010.

**C. Research Support.**

HRSA (T77MC00004BO), Developmental-Behavioral Pediatrics Fellowship Training Program.
Role: PI. Role: Ultimate and main responsibility for training fellows in Developmental-Behavioral Pediatrics and increasing the local capacity to screen for and evaluate children for autism spectrum disorders.
July 1, 2008-June 30, 2013

**Completed projects**

AUCD-NCBDDD, Behavioral and Medical Disorders in Children with Down Syndrome in New York: Prevalence and Phenotype. Consultant Collaborator. Role: Provided expertise on Down syndrome.
September 10, 2005-September 9, 2008.

NIMH (R01 MH 64824), Biomarkers for Psychosis in Velo-Cardio-Facial Syndrome Co-Investigator. Role: Provided expertise on developmental disabilities and evaluated the children for social adaptive skills and motor skills.
February 19, 2002-January 31, 2007.

**BIOGRAPHICAL SKETCH**

| NAME<br>Rudick, Richard A. | POSITION TITLE<br>Vice Chairman, Research & Development<br>Neurological Institute<br>Director, Mellen Center, Cleveland Clinic<br>Professor, Department of Medicine, CWRU |
|---|---|
| eRA COMMONS USER NAME<br>RICHARDRUDICK | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Ohio University, Athens, Ohio | B.S. | 09/68-06/71 | Zoology |
| Case Western Reserve University School of Medicine, Cleveland, Ohio | M.D. | 09/71-06/75 | Medicine |
| University of Connecticut, School of Medicine, Farmington, CT | | 07/75-06/77 | Medicine Resident |
| Strong Memorial Hospital, University of Rochester, Rochester, NY | | 07/77-06/80 | Neurology Resident and Chief Resident |

**A. Positions and Honors**

**Positions and Employment**

| | |
|---|---|
| 1980 - 1986 | Assistant Professor Neurology, University of Rochester School of Medicine |
| 1982 - | Assistant Editor, Archives of Neurology |
| 1986 - 1987 | Associate Professor Neurology, University of Rochester School of Medicine |
| 1987 - | Adjunct Associate Professor Neurology, University of Rochester School of Medicine |
| 1987 - | Director, Mellen Center for Multiple Sclerosis, Cleveland Clinic Foundation |
| 1993 - | Associate Professor of Neurology, Ohio State University |
| 1996 - | Hazel Prior Hostetler Professor of Neurology, Cleveland Clinic Foundation |
| 2000 - 2007 | Chairman, Division of Clinical Research, Cleveland Clinic Foundation |
| 2003 - | Professor of Medicine, Cleveland Clinic Lerner College of Medicine |
| 2003- | Professor, Center for Clinical Investigation, Case School of Medicine |
| 2007 - | Vice Chairman, Research and Development in the Neurological Institute |

**Other Experience and Professional Memberships**

| | |
|---|---|
| 1974 | Alpha Omega Alpha Honorary Medical Society |
| 1981 | American Academy of Neurology, Fellow |
| 1983 | New York Academy of Sciences, Member |
| 1990 | Society for Experimental Neuropathology, Member |
| 1992 | American College of Physicians, Fellow |
| 1992 | American Neurological Association, Member |
| 1993 | American Society of Neurorehabilitation, Certified Member |
| 1998 | American Society for Experimental Neurotherapeutics (ASENT, Member |
| 2001 | American Association for Advancement of Science, Member |
| 2006 | American Association for Advancement of Science, Fellow |
| 2007 | Association of American Physicians, Member |
| 2009 | Society for Clinical and Translational Science, Member |
| 1982-1996 | *Archives of Neurology*. Assistant Editor |
| 1983-1996 | *Archives of Neurology*, Member, Editorial Board |
| 1985 | *Seminars in Neurology*, Guest Editor, Disorders of Myelin |
| 1992-1997 | *Cleveland Clinic Neuroscience Pathways*, newsletter, Medical Editor |

| | |
|---|---|
| 1986-Present | *Annals of Neurology, JAMA, Archives of Neurology, The Lancet, New England Journal of Medicine, neurology, Journal of Neuroimmunology*, Ad-Hoc Reviewer |
| 2004-Present | Lancet Neurology, Editorial Board |
| 2008 | *Therapy*, published by Future Medicine, U.S. Guest Editor, Multiple Sclerosis Special Focus Issue |
| 2010-Present | *New Frontiers in Multiple Sclerosis: Impact of Disease-Modifying Therapies on Nontraditional Measures of Disease Activity;* Guest Editor and Author, Neurology Supplement |
| 2010-Present | *Neurotherapeutics*, Editorial Board |

**Honors**

| | |
|---|---|
| 1968 | Valedictorian, The Rayen School, Ranked 1/273 |
| 1969 | Borden Freshman Prize for The Outstanding Student, Ohio University, Athens, Ohio |
| 1971 | Josephus Tucker Ullom Premedic Award (Outstanding Premed Student, Ohio University) |
| 1968-1971 | Honors College, Ohio University |
| 1974 | Alpha Omega Alpha Honors Medical Society, CWRU School of Medicine (Elected as Junior Student) |
| 1983-1988 | teacher-Investigator Development Award (K07NS00791) NINCDS "Humoral Immunity in MS" |
| 1994 | Outstanding Alumnus of the Year Award, Ohio University College of Arts and Sciences |
| 1995 | Bruce Hubbard Stewart Award for Humanistic Medicine, Cleveland Clinic Foundation |
| 1996 | Hazel Prior Hostetler Professor Neurology, Cleveland Clinic Foundation |
| 1998 | Alumnus of the Year Award, Department of Neurology, University of Rochester |
| 2000 | Innovation Award for Brain Parenchymal Fraction Software from Enterprise Development, Inc. |
| 2002 | Arnold and Geri King Lifetime Achievement Award from National Multiple Sclerosis Society |
| 2003 | Health Care Professional Hall of Fame Award from National Multiple Sclerosis Society |
| 2010 | Distinguished Alumnus Award, Case Western Reserve University |
| 2011 | Excellence in Health Science Innovation Award, Case Western Reserve University (first recipient) |
| 2012 | 32nd TS Srinivasan Oration Award, TS Srinivasan Centre for Clinical Neurosciences-VHS Hospital, Chennai, India |

**B. Selected Peer-reviewed Publications (from 216 peer-reviewed publications)**

1. Jacobs LD, Cookfair DL, Rudick RA, et al. Intramuscular interferon beta-1a for disease progression in relapsing multiple sclerosis. Ann Neurol, 1996;39:285-294.
2. Rudick RA, Goodkin DE, Jacobs LD, Cookfair DL, Herndon RM, Richert JR, et al. Impact of interferon beta-1a on neurologic disability in relapsing multiple sclerosis. Neurology, 2001;57:S25-30.
3. Rudick RA, Antel J, Confavreux C, Cutter G, Ellison G, Fischer J, et al. Recommendations from the clinical outcomes assessment task force of the National Multiple Sclerosis Society. Ann Neurol, 1997;42:379-382.
4. Rudick RA, Ransohoff RM, Peppler R, VanderBrug Medendorp S, Lehmann P, Alam, J. Interferon beta induces interleukin-10 expression: Relevance to multiple sclerosis. Ann Neurol, 1996;40:618-627.
5. Rudick RA, Simonian NA, Alam JA, Campion M, Scaramucci JO, Jones W, et al. Incidence and significance of neutralizing antibodies to interferon beta-1a in multiple sclerosis. Neurology, 1998;50:1266-1273.
6. Chang A, Tourtellotte WW, Rudick RA, Trapp BD. Premyelinating oligodendrocytes in chronic lesions of multiple sclerosis. N Engl J Med, 2002;346(3):165-73.
7. Rudick RA, Fisher E, Lee JC, Simon J, Jacobs L. Use of the brain parenchymal fraction to measure whole brain atrophy in relapsing-remitting multiple sclerosis. Multiple Sclerosis Collaborative Research Group. Neurology, 1999;53:1698-1704.
8. Rudick RA, Lee J-C, Simon J, Ransohoff RM Fisher E. Defining Interferon Beta Response Status in Multiple Sclerosis Patients. Ann Neurol, 2004 Oct;56:548-55.

9. Rudick RA, Stuart WH, Calabresi PA, Confavreux C, Galetta SL, Radue EW, Lublin FD, Weinstock-Guttman B, Wynn DR, Lynn F, Panzara MA and Sandrock AW. Natalizumab plus interferon beta-1a for relapsing multiple sclerosis. N Engl J Med, 2006 Mar 2;354(9):911-23.
10. Rudick RA, Miller D, Hass S, Hutchinson M, Calabresi PA, Confavreux C, Galetta S, Giovannoni g, Havrdova E, Kappos L, Lublin FD, Miller DH, O'Connor PW, Phillips JT, Polman CH, Radue EW, Stuart WH, Wajgt A, Weinstock-Guttman B, Wynn DR, Lynn F, Panzara MA. Health-related quality of life in multiple sclerosis: effects of Natalizumab. Ann Neurol 2007 Oct; 62(4):335-346.

## C. Research Support

**Ongoing Research Support**

2P50NS038667-11 (Trapp) 12/01/2009 – 11/30/2014
NIH
Gray Matter Atrophy in Multiple Sclerosis (Co-Investigator; Elizabeth Fisher, PhD, PI)
The overall goal of this Center Proposal (Bruce D. Trapp, PI) is to analyze gray matter involvement in MS. Project 3 will investigate MRI-defined gray matter pathology in a cohort of patients studied longitudinally for 15 years, and in autopsy material from well-characterized MS patients.

2UL1TR000439-06 (Davis) 09/17/2007 – 05/31/2017
2KL2TR000440-06 (Davis)
2TL1TR000441-06 (Davis)

NIH/NCATS
Case Western Reserve University/Cleveland Clinic Clinical Translational Science Award (CTSA)

**Completed Research Projects in the last 3 years (selected)**

1UL1RR024989-01 (Davis) 09/17/2007 – 05/31/2012
1KL2RR024990-01 (Davis)
1TL1RR024991-01 (Davis)
NIH/NCRR
Case Western Reserve University/Cleveland Clinic Clinical Translational Science Award (CTSA)
I am the Co-PI on these grants, and program director for the education / training components (1KL2RR024990-01; and 1TL1RR024881). These are institutional grants to support translational and clinical research infrastructure. The CTSA will provide resources for patient-based research that includes support for technology-intensive studies, clinical investigator career development and the community. The CTSA is linked administratively to the Predoctoral Research Training (T32 training) and the Mentored Career Development Program (K12 mechanism).

1P01 NS 38667 (Ransohoff) Project Director, Project 4 12/01/2004 – 11/30/2009
NIH
Biomarkers of the therapeutic response to Interferon in MS (Project 4)
The overall goal of the Program Project (Richard M. Ransohoff, PI) is to analyze inflammation and tissue injury in MS. Project 4 will test the hypothesis that specific aspects of the primary molecular response to exogenously administered interferon will determine the therapeutic response to the drug and to adverse effects.

RG 3604A6/1(Ransohoff), Co-Investigator 04/01/2005 - 03/31/2008
NMSS
Biomarkers of the therapeutic response to Interferon in MS
The overall goal of this grant is to determine novel genes induced by interferon beta that may explain therapeutic effects of interferon in multiple sclerosis.

K23 NS 47211-01 (Fox) 08/01/2004 - 07/31/2009
NIH
Brain Atrophy and Diffusion Tensor Studies in Multiple Sclerosis
The goals of this award are to allow Dr. Fox dedicated time to apply advanced MR techniques to clinical interventions under the mentorship of Drs. Rudick and Phillips.

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Salata, Robert A.** | POSITION TITLE<br>Professor of Medicine |
| eRA COMMONS USER NAME **rasalata** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| University of Notre Dame | B.A. | 12/1974 | Pre-professional Studies and Psychology |
| Case Western Reserve University | M.D. | 05/1979 | Medicine |

## A. Positions and Honors

**Positions and Employment**

1979-1982 Intern and Assistant Resident in Internal Medicine, Univ. Hospitals of Cleveland, Cleveland, OH
1982-1985 Fellow, Divisions of Infectious Diseases and Geographic Medicine, Univ. Hospital of Virginia, University of Virginia School of Medicine, Charlottesville, VA
1985-1986 Instructor, Department of Medicine, Chief Medical Resident, University Hospitals of Cleveland, Cleveland, OH
1986-1990 Assistant Professor of Medicine, Department of Medicine, Division of Geographic Medicine, Case Western Reserve University, Cleveland, OH
1990-1991 Assistant Professor of Medicine and International Health, Department of Medicine, Divisions of Geographic Medicine, Infectious Diseases, and General Medical Sciences, Case Western Reserve, University School of Medicine, Cleveland, OH
1991-1994 Assistant Professor of Medicine and International Health, Associate Chief and Clinical Director, Division of Infectious Diseases, Case Western Reserve, University School of Medicine, Department of Medicine, Cleveland, OH
1994-1998 Associate Professor of Medicine, International Health, Epidemiology & Biostatistics, Division Chief and Clinical Program Director, Division of Infectious Diseases, Case Western Reserve, University School of Medicine, Department of Medicine, Cleveland, OH
1998-present Professor of Medicine, International Health, Epidemiology & Biostatistics, Division Chief, Division of Infectious Diseases and HIV Medicine, Case Western Reserve, School of Medicine, Department of Medicine, Cleveland, OH
1999-2008 Vice-Chair for International Affairs, Department of Medicine, University Hospitals Case Medical Center, Cleveland, OH
2008-present Executive Vice-Chair, Department of Medicine, University Hospitals Case Medical Center

**Other Experience and Professional Memberships**

1986-2001 Medical Director, Travelers' HealthCare Center, Univ. Hospitals of Cleveland, Cleveland, OH
1994-present Medical Director, Infection Control and Prevention, Univ. Hospitals of Cleveland, Cleveland, OH
2000-present Case Western Reserve University SOM, Million Dollar Professor, Cleveland, OH
2000-present Fellow, American College of Physicians
2001-present Fellow, Infectious Diseases Society of America

## B. Selected Peer-reviewed Publications (Selected from 89 peer-reviewed publications)

1. Lockman S, Hughes MD, McIntyre J, Zheng Y, Chipato T, Conradie F, Sawe F, Asmelash A, Hosseinipour MC, Mohapi L, Stringer E, Mngqibisa R, Siika A, Atwine D, Hakim J, Shaffer D, Kanyama C, Wools-Kaloustian K, **Salata RA**, Hogg E, Alston-Smith B, Walawander A, Purcelle-Smith E, Eshleman S, Rooney

J, Rahim S, Mellors JW, Schooley RT, Currier JS; OCTANE A5208 Study Team. Antiretroviral therapies in women after single-dose nevirapine exposure. N Engl J Med. 2010 Oct 14;363(16):1499-509. PMCID: PMC2994321

2. Morrison CS, Demers K, Kwok C, Bulime S, Rinaldi A, Munjoma M, Dunbar M, Chipato T, Byamugisha J, Van Der Pol B, Arts E, Salata RA. Plasma and cervical viral loads among Ugandan and Zimbabwean women during acute and early HIV-1 infection. AIDS. 2010;24573-82. PMCID: PMC3148071
3. Morrison CS, Chen PL, Nankya I, Rinaldi A, Van Der Pol B, Ma YR, Chipato T, Mugerwa R, Dunbar M, Arts E, Salata RA. Hormonal contraceptive use and HIV disease progression among women in Uganda and Zimbabwe. J Acquir Immune Defic Syndr. 2011 Feb 24. [Epub ahead of print]
4. Nowak RG, Gravitt PE, Morrison CS, Gange SJ, Kwok C, Oliver AE, Howard R, Van Der Pol B, Salata RA, Padian NS, Chipato T, Munjoma M, Celentano DD. Increases in Human Papillomavirus Detection During Early HIV Infection Among Women in Zimbabwe. J Infect Dis. 2011 Apr; 203(8):1182-91.
5. Nowak RG, Gravitt PE, Morrison CS, Gange SJ, Kwok C, Oliver AE, Howard R, Van der Pol B, Salata RA, Pandian NS, Chipato T, Munjoma M, Celantano DD. Increase in human papillomavirus detection during early HIV infection among women in Zimbabwe. J Infect Dis 2011 Apr 15; 203(8): 1182-91.
6. Mehlotra RK, Cheruvu VK, Blood Zikursh MJ, Benish RL, Lederman MM, Salata RA, Gripshover B, McComsey GA, Lisgaris MV, Fulton S, Subauste CS, Jurevic RJ, Guillemette C, Zimmerman PA, Rodriguez B. Chemokine (C-C motif) receptor 5-2459 genotype in patients receiving highly active antiretroviral therapy; race-specific influence on virologic success. J Infect Dis. 2011 Jul; 204(2): 291-8.
7. Lederman MM, Calabrese L, Funderburg NT, Clagett B, Medvik K, Bonilla H, Gripshover B, Salata RA, Taege A, Lisgaris M, McComsey GA, Kirchner E, Baum J, Shive C, Asaad R, KalayjianRC, Sieg SF, Rodriguez B. Immunologic failure despite suppressive antiviral therapy is associated to activation and turnover of CD4 cells. J Infect Dis. 2011 Oct 15;204(8):1217-26.
8. Webel AR, Dolansky MA, Henry AG, Salata RA. A qualitative description of women's HIV self-management techniques: Context, strategies and considerations. J Assoc Nurses AIDS Care. 2011 Nov 12.
9. Porter KA, Cole SR, Eron JJ Jr, Zheng Y, Hughes MD, Lockman S, Poole C, Skinner-Adams TS, Hosseinipour M, Shaffer D, D'Amico R, Sawe FK, Siika A, Stringer E, Currier JS, Chipato T, Salata R, McCarthy JS, Meshnick SR. HIV-1 protease inhibitors and clinical malaria: A secondary analysis of ACTG 5208. Antimicrob Agents Chemother. 2011 Nov 28. [Epub ahead of print].
10. Mavedzenge S, Morrison C, Kwok C, Van der Pol, Salata RA, Van der Stratten A, Weiss H. The association between *Mycoplasma genitalium* and HIV acquisition among African women. AIDS 26:617-624.
11. Beversluis D, Morrison C, Musoke R, Chipato T, Kwok C, Salata RA. Incidence of major clinical outcomes of Ugandan and Zimbabwean women with primary HIV-1 infection. Int J STD & AIDS. 2012;23(2)111-4.
11. Webel AR, Phillips JC, Dawson Rose C, Holzemer WL, Chen WT, Tyler-Viola L, Rivero-Mendez M, Nicholas P, Nokes K, Kemppainen J, Sefcik E, Brion J, Eller L, Iipinge S, Kriksey K, Wantland D, Chaiphibalsarisdi P, Johnson MO, Portillo C, Corless IB, Voss J, Salata RA. A cross- sectional description of social capital in an international sample of persons living with HIV/AIDS (PLWH). BMC Public Health. 2012 Mar 13;12(1):188.
12. Gangestad AK, Salata RA. Ethical Issues in Microbicide Clinical Trials for HIV Prevention. Curr HIV Res. 2012 Jan 1;; 10(1): 105-12.
13. Pantazis N, Morrison C, Amornkul PN, Lewden C, Salata RA, Minga A, Chipato T, Jaffe H, Kakhi S, Karita E, Porter K, Meyer L, Touloumi G. CASCADE Collaboration in EuroCoord and ANRS 1220 Primo-CI Study Group. Differences in HIV natural history among African and non-Africans seroconvertors in sub-Saharan Africa. PLOS One 2012; 7(3):e32369. Epub 2012 Mar 6.
14. Webel AR, Asher A, Cuca Y, Okonsky JG, Kaihura A, Rose CD, Hanson JE, Salata RA. Measuring HIV self-management in women living with HIV/AIDS: A psychometric evaluation study of the HIV Self-Management Scale. J Acquir Immune Def Syndr 2012; 60:e72-e81.
15. Kalayjian RC, Lau B, Mechekano RN, Crane HM, Rodriguez B, Salata RA, Krishnasami Z, Willig JH, Martin JN, Moore RD, Eron JJ, Kitahata MM. Risk factors for chronic kidney disease in a large cohort of

HIV-1 infected individuals initiating antiretroviral therapy in routine care. AIDS 2012 July 20. Epub ahead of print.

16. Minnis AM, Gandham S, Richardson BA, Guddera V, Chen BA, Salata RA, Kakabito C, Hoesley C, Justman J, Soto-Torres L, Patterson K, Gomez K, Hendrix CW. Adherence and acceptability in MTN-001: A randomized cross-over trial of daily oral and topical tenofovir for HIV prevention in women. AIDS Behav 2012; Oct 14. Epub ahead of print.
16. Healan AM, Gray W, Fuchs EJ, Griffis JM, Salata RA, Blumer J. Stability of colistimethate sodium in aqueous solution. Antimicrob Agents Chemoth 2012; 56(12):6432-3.Epub ahead of print.
17. Obuku E, Parikh S, Nankabirwa V, Kakande N, Mafigiri D, Mayanja-Kizza H, Kityo CM, Mugyenyi P, Salata RA. Determinants of clinician knowledge on aging and HIV/AIDS: A survey of practitioners and policy makers in Kampala District, Uganda. PLoS One. In press.
18. Webel AR, Moore SM, Hanson JE, Patel SR, Schmotzer B, Salata RA. Improving sleep hygiene behavior in adults living with HIV/AIDS: A randomized control pilot study of the SYSTEM CHANGE ™-HIV intervention. Appl Nurs Res. 2012 Dec 21. S0897-1897(12)00074-2.0.1016 [Epub ahead of print].
19. Hendrix CW, Chen BA, Guddera V, Hoesley C, Justman J, Nakabiito C, Salata R, Soto-Torres L, Patterson K, Minnis AM, Gandham S, Gomez K, Richardson BA, Bumpus NN. MTN-001: Randomized pharmacokinetic cross-over study comparing tenofovir vaginal gel and oral tablets in vaginal tissue and other compartments. PLoS One. 2013;8(1):e55013.

## C. Research Support

**Ongoing Research Support**

AI-069501 (Lederman) 12/01/06-11/30/13 1.2 CM
NIH-NIAID $2,078,158
Case Clinical Trials Unit
The major goals of this project are to develop, implement and interpret AIDS treatment trials.

BRS-ACURE-Q-06-00136 (Ghannoum) 06/01/07-05/31/13 .6 CM
Oral HIV/AIDS Research Alliance (OHARA) $220,423
To evaluate oral conditions associated with HIV/AIDS both domestically as well as internationally.

Prime Contract #HHSN 272200800026C (Salata) 06/01/08-05/31/15 4.8 CM
Phase I Clinical Trial Unit for Therapeutics $892,557
Against Infectious Diseases

5U01-AI068633 06/01/09-05/31/13 1.2 CM
NIH/Magee Women's Hospital, MTN project $38,436
To implement and advance optimal collaborative clinical trials research activities among NIH-sponsored HIV/AIDS clinical trials networks.

R18-HS020004-01A1 (Donskey, PI) 09/30/11-09/29/14 .5 CM
AHRQ $361,159 *(no salary)*
To develop evidence-based strategies to improve environmental disinfection and to test their effectiveness in reducing rates of healthcare-associated *C. difficile* infection (CDI).
Protocol A5288 06/01/12-05/31/13 .3 CM
Social & Scientific Systems
Management Using the Latest Technologies in Resource-limited Settings to Optimize Combination Therapy After Viral Failure

Dr. Salata is co-Vice Chair for ACTG protocol A5288. He will be involved on a go forward basis with efforts to get sites activated and the protocol implemented, will serve on the clinical management team, assist in choice of

antiretroviral choices for cases at the sites based upon genotyping results, be involved in study results and analysis as well as participate in preparation of all manuscripts emanating from this protocol.

**Completed Research Support**

N01-HD-0-3310-502-02 Salata (PI) 10/01/05-9/30/10
Family Health International
Hormonal Contraception and the Risk of HIV Acquisition
The major goals of this study will be to assess whether hormonal contraception use in women in Uganda, Zimbabwe and Thailand increases HIV transmission.

NO1-A125464 Salata (PI) 02/01/07-06/01/09
NIH
DMID Protocol 06-0012
The major goal is to evaluate newer and safer vaccines for smallpox infection.

AI-57160 Salata (PI) 09/04/03-02/29/09
NIH/Washington University
Smallpox Vaccine Clinical Research Center
The SVCRC at Case will support and execute translational research protocols on specific projects of special interest to the MRCE mission.
Role: PI, Case Western Reserve University

AI-51649A1 Lederman (PI) 09/15/05-06/30/08

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Sedor, John R.** | POSITION TITLE<br>MetroHealth Research Endowment Professor<br>Professor of Medicine and Physiology and Biophysics |
| eRA COMMONS USER NAME **jrsedor** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| University of Virginia, Charlottesville, VA | B.A. | 05/74 | Russian Studies |
| University of Virginia, Charlottesville, VA | M.D. | 05/78 | Medicine |
| University Hospitals/Case Western Reserve University, Cleveland, OH | Residency | 1978-1981 | Internal Medicine |
| University Hospitals/Case Western Reserve University, Cleveland, OH | Fellowship | 1981-1984 | Nephrology |
| National Kidney Foundation, New York, NY | Fellowship | 1983-1984 | Nephrology |
| Kidney Foundation of Ohio, Cleveland, Ohio | Fellowship | 1982-1983 | Research Fellowship |

**A. Positions and Honors.**

**Professional Positions:**

1984 – 1990 Assistant Professor of Medicine, Case Western Reserve University (CWRU), Cleveland, OH
1990 – 1996 Associate Professor of Medicine, CWRU, Cleveland, OH
1991 – 2003 Director, Division of Nephrology & Hypertension, MetroHealth System Campus, CWRU, Cleveland, OH
1992 – 1996 Associate Professor of Physiology and Biophysics, CWRU, Cleveland, OH
1996 – Present Professor of Medicine and Physiology and Biophysics, CWRU, Cleveland, OH
1998 – 2003 Director, O'Brien Renal Research Center, CWRU, Cleveland, OH
2003 – Present Vice President for Research, MetroHealth System Campus, CWRU, Cleveland, OH
2006 – Present Director, Case Center for the Study of Kidney Biology and Disease, CWRU, Cleveland, OH

**Honors:**

1982 – 1983 R.H. Mohrman Research Fellowship, Kidney Foundation of Ohio
1983 Trainee Research Award, Midwest Section, American Federation for Clinical Research, and Central Society for Clinical Research
1987 – 1990 The Mather Charitable Foundation Young Scholar Award
1989 – 1994 Established Investigatorship, American Heart Association
1992 Award of Tenure
2005 – Present MetroHealth Research Endowment Professorship, CWRU, Cleveland, OH
2007 Association of American Physicians
2008 The George Naff Annual Lectureship, University Hospitals Case Medical Center & Louis Stokes Veterans Health Care System
2009 American Clinical and Climatological Association
2009 Ruth Abramson Visiting Professorship, Mount Sinai School of Medicine, 2009
2009 – 2012 National Advisory Council, National Institute of Diabetes and Digestive and Kidney Diseases
2010 David Hume Award, National Kidney Foundation (highest honor given to a distinguished scientist-clinician in the field of kidney and urologic diseases)

**Select Professional Activities:**

1989 – 2008 Special Study Sections, National Institute of Diabetes and Digestive and Kidney Diseases
1990 – 1994 Cardio-renal Study Section, American Heart Association

| | |
|---|---|
| 1991 – 1994 | Young Investigator Grant Review Committee, National Kidney Foundation |
| 1992 – 1995 | Chair, Veterans Administration Nephrology Merit Review Board |
| 1993 – 1997 | Pathology A Study Section, National Institutes of Health |
| 1994 – present | Editorial Board, Kidney International |
| 1997 | Program Committee, American Society of Nephrology |
| 1999 – 2002 | Young Investigator Grant Review Committee, National Kidney Foundation |
| 2000 – 2003 | Medical Science Review Committee, Juvenile Diabetes Foundation International |
| 2002 – 2004 | General Medicine B Integrated Review Group, NIH Center for Scientific Review |
| 2002 – 2004 | Co-chair, Steering Committee, Kidney Disease Clinical Trail Consortium, NIDDK |
| 2002 – present | External Advisory Committee, Multicenter Clinical Trial Of Focal Glomerulosclerosis In Children And Young Adults, NIDDK |
| 2006 | External Advisory Committee, Animal Models of Diabetic Complications Consortium (AMDCC), NIDDK |
| 2007 | Program Committee Chair, American Society of Nephrology |
| 2007 – 2012 | Editorial Board, Journal of Clinical Investigation |
| 2007 – Present | Editorial Board, Journal of the American Society of Nephrology |
| 2012 – present | Secretary-Treasurer Designate, Council, American Society of Nephrology |

**B. Selected peer-reviewed publications (from over 100 peer reviewed publications)**

**Most relevant to the current application**

1. Werber, H., S.N. Emancipator, M.L. Tykocinski, and **J.R. Sedor**. The interleukin-1 gene is expressed by rat glomerular mesangial cells and is augmented in immune complex glomerulonephritis. *J. Immunol*. 138:3207-3212, 1987. PMID: 2883234
2. **Sedor, J.R.**, S.W. Carey, and S.N. Emancipator. Immune complexes bind to cultured rat glomerular mesangial cells to stimulate superoxide release: evidence for an Fc receptor. *J. Immunol*. 138:3751-3757, 1987. PMID: 3035013
3. Singh, R., S. Huang, T. Guth, M. Konieczkowski, and **J.R. Sedor**. The cytosolic domain of the type I spontaneously recruits signaling molecules to activate a proinflammatory gene set. *J. Clin. Invest*. 100: 419-428, 1997. PMC508206.
4. Singh, R., B. Wang, A. Shirvaikar, S. Khan, S. Kamat, J.R. Schelling, M. Konieczkowski and **J.R. Sedor**. Rho family GTPases directly associate with the IL-1 receptor (IL-1R) cytosolic domain. Coordinate organization to drive cellular activation. *J. Clin. Invest.* 103: 1561-1570, 1999. PMC408367.
5. Srichai**,** M.B., M. Konieczkowski**,** S. Barathan**,** P. S. Hayden, S. Khan**,** P. Mundel**,** S.B. Lee**,** L.A. Bruggeman**,** J.R. Schelling**,** and **J.R. Sedor.** A WT1 co-regulator controls podocyte phenotype by shuttling between adhesion structures and nucleus. *J.Biol.Chem*. 279: 14398-14408, 2004. PMID: 14736876
6. Iyengar S.K, … **J.R. Sedor**, ... and B.I. Freedman, on behalf of the Family Investigation of Nephropathy and Diabetes Research Group: Genome-Wide Scans for Diabetic Nephropathy and Albuminuria in Multi-Ethnic Populations: The FIND Study. *Diabetes* 56: 1577-1585, 2007. PMID: 17363742
7. Schelling, J.R., ..., **J.R**. **Sedor**[*]**,** …and V.O. Shah, on behalf of the Family Investigation of Nephropathy and Diabetes Research Group Whole genome scan for GFR in a large cohort with diabetic nephropathy. In press, *Diabetes* 57: 235-43, 2007. ([*]**, writing group**) PMID: 18003762
8. Arar, N.H., B.I. Freedman, S.G. Adler, S.K. Iyengar, E.Y. Chew, M.D. Davis, S.G. Satko, D.W. Bowden, R. Duggirala, R.C. Elston, X. Guo, R.L. Hanson, R.P. Igo, Jr., E. Ipp, P.L. Kimmel, W.C. Knowler, J. Molineros, R.G. Nelson, M.V. Pahl, S.R.E. Quade, R.S. Rasooly, J. Rotter, M.F. Saad, M. Scavini, J.R. Schelling, **J.R. Sedor**, V.O. Shah, P.G. Zager, and H.E. Abboud, on behalf of the Family Investigation of Nephropathy and Diabetes Research Group. Heritability of sever diabetic nephropathy: the FIND study. *Invest. Ophthalmol. Vis. Sci*. 49: 3839-45, 2008. PMC2583147
9. Kao, W.H.L., M.J. Klag, L.A. Meoni, D. Reich, Y. Berthier-Schaad, M. Li, J. Coresh, ,N. Patterson, A. Tandon, N.R. Powe, N.E. Fink, J.H. Sadler, M.R. Weir, S. Adler, J. Divers, S.K Iyengar, B.I. Freedman, P.L. Kimmel, K. Kamp, O.F. Kohn, D.J. Leehey, S. Nicholas, M. Pahl, J.R. Schelling, **J.R. Sedor**, D. Thornley-

Brown, C.A. Winkler, M.W. Smith, and R.S. Parekh, on behalf of the Family Investigation of Nephropathy and Diabetes (FIND) Research Group. A genome-wide admixture scan identifies MYH9 as a candidate locus associated with non-diabetic end stage renal disease in African Americans. *Nat. Gen.* 40: 1185-92, 2008. PMC2614692

10. Malhotra, A., R.P. Igo, F. Thameem, W.H.L. Kao, H.E. Abboud, S.G. Adler, N.H. Arar, D.W. Bowden, R. Duggirala, B.I. Freedman, K.A.B. Goddard, E. Ipp, S.K. Iyengar, P.L. Kimmel, W.C. Knowler, O. Kohn, D. Leehey, L.A. Meoni, R.G. Nelson, S.B. Nicholas[1], R.S. Parekh, R.S. Rasooly, S.S. Rich[2], Y.-D.I. Chen, M.F. Saad, M.Scavini, J.R. Schelling, **J.R. Sedor**, V.O. Shah, K.D. Taylor, D. Thornley-Brown, P.G. Zager, A. Horvath, and R.L. Hanson, on behalf of the Family Investigation of Nephropathy and Diabetes Research Group. Genome-wide linkage scan for type 2 diabetes mellitus: the Family Investigation of Nephropathy and Diabetes (FIND) Research Group. Diabetes Metab. Res. Rev. 25: 740-7, 2009. PMC2783577
11. Igo, R.P., S. K. Iyengar, S.B. Nicholas, K.A.B. Goddard, C. Langefeld, R.L. Hanson, R. Duggirala, J. Divers, H. Abboud, S.G. Adler, N.H Arar, A. Horvath, R.C. Elston, X. Guo, E. Ipp, W.H.L. Kao, P..L. Kimmel, W.C. Knowler, L.A. Meoni, J. Molineros, R.G. Nelson, M.V. Pahl, R.S. Parekh, R.S. Rasooly, J.R. Schelling, V.O. Shah, M.W. Smith, C.A. Winkler, P.G. Zager, **J.R. Sedor**[*] and B.I. Freedman on behalf of the Family Investigation of Nephropathy and Diabetes Research Group. ([*]**, writing group**). Genomewide linkage scan for diabetic renal failure and albuminuria: The FIND Study. *Am. J. Nephrol.* 33(5):381-9, 2011. PMC Journal – In Process.
12. Kim, J.H., M. Konieczkowski, A. Mukherjee, S. Schectman, S. Khan, J.R Schelling, L.A. Bruggeman, M.D. Ross, and **J.R. Sedor**. Podocyte injury induces nuclear translocation of WT1 Interacting Protein via microtubule dependent transport. *J. Biol. Chem.* 285: 9995-10004, 2010. PMID: 20086015
13. Prakash, S., N. Papeta, R. Sterken, Z. Zheng, R.L. Thomas, Z. Wu, **J.R. Sedor**, V.D. D'Agati, L.A. Bruggeman, A.G. Gharavi. A Standard Backoss and Inadvertent Selective Breeding in HIV-1 Transgenic Mice Localize a Major Nephropathy Susceptibility Gene On Mouse Chr 6 F3-G3. *J. Am. Soc. Nephrol*. 22: 1497-504, 2011. PMC3148704.
14. Madhavan S.M., J.F. O'Toole, M. Konieczkowski, S. Ganesan, L.A. Bruggeman, and **J.R.Sedor**. APOL1 localization in normal kidney and nondiabetic kidney disease. *J. Am. Soc. Nephrol*. 22: 2119-2128, 2011. PMC Journal – In Process.
15. Kim,J.H., A. Mukherjee, S. Madhavan, M. Konieczkowski and **J.R. Sedor**. WT1 interacting protein (Wtip) regulates cell phenotype by cell-cell and cell-matrix contact reorganization. *Am. J. Physiol. Renal Physiol.* 302: F103-115, 2012. PMC Journal – In Process.

## C. Research support

**<u>Ongoing research support</u>**

R56 DK09836 Sedor (multi-PI; admin PI) 9/30/2012 – 9/29/2013
Kidney disease mechanisms associated with human genetic variation.
The proposal will determine how *APOL1* variation regulates human kidney diseases pathogenesis using human kidney biopsy specimens and transgenic mouse and culture cell model systems.
Role: PI

T32 DK 07474 Sedor (PI) 7/1/2009 – 12/31/2014 (years 27-31)
CWRU Nephrology Training Grant
The major goals of this project are to train nephrology fellows for careers in biomedical research.
Role: PI

R01 DK079912 Kretzler (PI) 7/15/2008 – 6/30/2013
Molecular predictors of progressive renal failure in the chronic renal insufficiency cohort
The major goal is to validate a gene signature that predicts progressive kidney disease using samples from CRIC
Role: Co-PI

U54 DK083912 Kretzler (PI) 9/8/2009 – 6/30/2014
Nephrotic Syndrome Study Network
The Nephrotic Syndrome Study Network, a multidisciplinary research and education platform that brings together clinical and translational scientists and two lay research and patient education foundations, is aimed at beginning to better study and educate patients with FSGS, MN, and MCD using tools of system biology.
Role: Site PI

NHLBI 268200900049C-0-0-1. Wright (PI) 8/31/2009 – 8/30/2018
The Systolic Blood Pressure Intervention Trial (SPRINT)
SPRINT is a two-arm, multicenter, randomized clinical trial designed to test whether a treatment program aimed at reducing systolic blood pressure to a lower goal than currently recommended will reduce cardiovascular disease risk.
Role: Site PI

**Completed research support (within the last 3 years)**

R01 DK064719 Sedor (PI) 7/1/2003 – 6/30/2011
Mechanisms of Glomerulosclerosis
In vitro and in vivo experiments characterize a previously undiscovered regulator of podocyte phenotype, which is part of a growing family of cell adhesion complex molecules that may translate extracellular information into altered gene expression by shuttling between cytoplasm and nucleus.
Role: PI

R01 DK67528 Schelling (PI) 7/1/2005 – 6/30/2010
Mechanisms of tubular atrophy in renal disease
This project will establish if NHE1 $Na^+/H^+$ antiporter is a renal tubular epithelial cell survival factor in CKD.
Role: Co-Investigator

R21 DK079441 Kretzler (PI) 7/1/2007 – 6/30/2010
Molecular predictors of Progressive Renal Failure
The major goal is to validate a gene signature that predicts progressive kidney disease using samples from diabetic patients.
Role: Co-PI

Diabetes Association of Greater Cleveland Sedor (PI) 1/1/2008 – 12/31/2009
Mapping diabetic nephropathy genes
The major goal of this grant was to discover genetic susceptibility variants for diabetic nephropathy.
Role: Site PI

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Ashwini Sehgal** | POSITION TITLE<br>Professor |
| eRA COMMONS USER NAME **ASEHGAL** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| University of Rochester | BA | 1982 | Mathematics |
| Harvard Medical School | MD | 1986 | Medicine |
| Massachusetts General Hospital | -- | 1989 | Internal Medicine |
| University of California, San Francisco | -- | 1993 | Nephrology |

**A. Positions and Honors**

**Positions and Employment**

1989-1993 Robert Wood Johnson Clinical Scholar, University of California, San Francisco, California
1993-2006 Assistant/Associate Professor of Medicine, Biomedical Ethics, and Epidemiology & Biostatistics, Case Western Reserve University, Cleveland, Ohio
2004-2006 Duncan Neuhauser Associate Professor of Community Health Improvement, Case Western Reserve University
2004- Director, Center for Reducing Health Disparities, Case Western Reserve University
2006- Co-Medical Director, City of Cleveland Department of Public Health
2006- Duncan Neuhauser Professor of Community Health Improvement; Professor of Medicine, Biomedical Ethics, and Epidemiology & Biostatistics, Case Western Reserve University
2006- Associate Editor, Annals of Internal Medicine

**Other Experience and Professional Memberships**

1997-2003 Institutional Review Board, MetroHealth Medical Center, Cleveland, Ohio
2001-2009 Data and Safety Monitoring Board, Clinical Trial of Homocysteine Lowering in Renal Transplant Recipients, NIH
2003 Re-engineering the Clinical Research Enterprise Panel, NIH
2003-2004 Clinical Studies of Kidney Diseases Special Emphasis Panel, NIH
2004-2005 Protocol Review Committee, General Clinical Research Center, Case Western Reserve University
2005-2007 Vice-Chairperson, Medical Review Board, Tri-State Renal Network, Indianapolis, Indiana

**Honors**

1992-1993 Awarded National Kidney Foundation Research Fellowship
2000 National Golden Apple for Teaching Excellence Award, American Medical Student Association, Washington, DC

**B. Selected peer-reviewed publications** (selected from 94 peer-reviewed publications)

Sehgal A, LeBeau S, Youngner S. Dialysis patient attitudes toward financial incentives for kidney donation. American Journal of Kidney Diseases. 1997;29:410-418.
Sehgal A, Grey S, DeOreo P, Whitehouse P. Prevalence, recognition, and implications of mental impairment among hemodialysis patients. American Journal of Kidney Diseases. 1997;30:41-49.
Alexander G, Sehgal A. Barriers to cadaveric renal transplantation among blacks, women, and the poor. Journal of the American Medical Association. 1998;280:1148-1152.

Sehgal A, Snow R, Singer M, Amini S, DeOreo P, Silver M, Cebul R. Barriers to adequate delivery of hemodialysis. American Journal of Kidney Diseases. 1998;31:593-601.
Alexander G, Sehgal A. Dialysis patient ratings of the quality of medical care. American Journal of Kidney Diseases. 1998;32:284-289.
Gordon EJ, Sehgal AR. Patient-nephrologist discussions about kidney transplantation as a treatment option. Advances in Renal Replacement Therapy. 2000;7:177-183.
Sehgal AR, Coffin R, Cain JA. Use of transplant status codes to monitor access to kidney transplantation. Advances in Renal Replacement Therapy. 2000;7:S40-S44.
Alexander CA, Sehgal AR. Why hemodialysis patients fail to complete the transplant process. American Journal of Kidney Diseases. 2001;37:321-328.
Sehgal AR, Leon JB, Siminoff LA, Singer ME, Bunosky LM, Cebul RD. Improving the quality of hemodialysis treatment: A community-based randomized controlled trial to overcome patient-specific barriers. Journal of the American Medical Association. 2002;287:1961-1967.
Alexander GC, Sehgal AR. Variation in access to kidney transplantation across dialysis facilities: Using process of care measures for quality improvement. American Journal of Kidney Diseases. 2002;40:824-831.
Goyal M, Mehta RL, Schneiderman LJ, Sehgal AR. Economic and health consequences of selling a kidney in India. Journal of the American Medical Association. 2002;288:1589-1593.
Sehgal AR. Improving hemodialysis patient outcomes: A step-by-step approach. Seminars in Dialysis. 2002;15:35-37.
Alexander GC, Sehgal AR. Variation in access to kidney transplantation across dialysis facilities: Using process of care measures for quality improvement. American Journal of Kidney Diseases. 2002;40:824-831.
Sehgal AR. Impact of quality improvement efforts on race and gender disparities in hemodialysis patients. Journal of the American Medical Association. 2003;289:996-1000.
Sehgal AR. The net transfer of transplant organs across race, sex, age, and income. American Journal of Medicine. 2004;117:670-675.
Gordon EJ, Prohaska T, Siminoff LA, Minich PJ, Sehgal AR. Needed: tailored exercise regimens for kidney transplant recipients. American Journal of Kidney Diseases. 2005;45:769-774. PMC1242115
Gordon EJ, Prohaska T, Siminoff LA, Minich PJ, Sehgal AR. Can focusing on self-care reduce disparities in kidney transplant outcomes? American Journal of Kidney Diseases. 2005;45:935-940. PMC1249519
Mentari EK, DeOreo PB, O'Connor AS, Love TE, Ricanati ES, Sehgal AR. Changes in Medicare reimbursement and patient-nephrologist visits, quality of care, and health-related quality of life. American Journal of Kidney Diseases. 2005;46:621-627.
O'Connor AS, Wish JB, Sehgal AR. The morbidity and cost implications of hemodialysis clinical performance measures. Hemodialysis International. 2005;9:349-361.
Leon JB, Albert JM, Gilchrist G, Kushner I, Lerner E, Mach S, Majerle A, Porter D, Ricanati E, Sperry L, Sullivan C, Zimmerer J, Sehgal AR. Improving albumin levels among hemodialysis patients: a community-based randomized controlled trial. American Journal of Kidney Diseases. 2006;48:28-26.
Gordon EJ, Prohaska TR, Sehgal AR. The financial impact of immunosuppressant expenses on new kidney transplant recipients. Clinical Transplantation. 2008;22:738-48. Epub 2008 Jul 31. PMC2592494
Gordon EJ, Gallant M, Sehgal AR, Conti D, Siminoff LA. Medication-taking among adult renal transplant recipients: barriers and strategies. Transplant International. 2009;22:534-545.
Gordon EJ, Prohaska TR, Gallant MP, Sehgal AR, Strogatz D, Yucel R, Conti D, Siminoff LA. Longitudinal analysis of physical activity, fluid intake, and graft function among kidney transplant recipients. Transplant International. 2009;22:990-998.
Sullivan C, Sayre SS, Leon JB, Machekano R, Love TE, Porter D, Marbury M, Sehgal AR. Impact of food additives on hyperphosphatemia among end stage renal disease patients: a randomized controlled trial. Journal of the American Medical Association. 2009;301:629-635.
Gordon EJ, Prohaska TR, Gallant MP, Sehgal AR, Strogatz D, Conti D, Siminoff LA. Prevalence and determinants of physical activity and fluid intake in kidney transplant recipients. Clinical Transplantation. 2010;24:69-81. PMC2925539

Schold JD, Sehgal AR, Srinivas TR, Poggio ED, Navaneethan S, Kaplan B. Marked variation of the impact of ESRD duration before and after wait listing on kidney transplant outcomes. American Journal of Transplantation. 2010;10:2008-2016.

Schold JD, Buccini LD, Kattan MW, Goldfarb DA, Flechner SM, Srinivas TR, Poggio ED, Fatica R, Kayler LK, Sehgal AR. The association of community health indicators with outcomes for kidney transplant recipients in the United States. Archives of Surgery. In press.

Thornton JD, Alejandro-Rodriguez M, Leon JB, Albert JM, Baldeon E, De Jesus LM, Gallardo A, Hossain S, Perez EB, Martin JY, Lasalvia S, Wong KA, Allen MD, Robinson M, Heald C, Bowen G, Sehgal AR. Effect of an iPod intervention on consent to donate organs: a randomized controlled trial. Annals of Internal Medicine. 2012;156:483-490.

Jin J, Sandoval V, Lawless ME, Sehgal AR, McHenry CR. Disparity in the management of Graves' disease observed at an urban county hospital: a decade-long experience. American Journal of Surgery. In press.

Sullivan C, Leon JB, Sayre SS, Marbury M, Ivers M, Pencak J, Bodziak KA, Hricik DE, Morrison EJ, Albert JM, Navaneethan JM, Delos Reyes CM, Sehgal AR. Impact of navigators on completion of steps in the kidney transplant process: a randomized controlled trial. Clinical Journal of the American Society of Nephrology. In press.

## C. Research Support

**Ongoing**

P60 MD002265 Sehgal (PI) 9/11/2007 – 6/30/2017
NIH/NCMHD
Engaging Communities and Institutions to Reduce Health Disparities in Cleveland
The goals of this project are to engage Cleveland's health care providers, educational institutions, community organizations, and government agencies to understand and reduce health disparities, and to test interventions designed to reduce health disparities.
Role: PI

RR024989 Davis (PI) 9/17/2007 – 5/31/2017
NIH/NCRR
Institutional Clinical and Translational Science Award – Community Research Partnership Core
The goals of the Community Research Partnership Core are to enhance community knowledge and involvement in research and to provide researchers with training and resources in community-based research.
Role: Core Director

**Completed within past three years**

R01 DK51472 Sehgal (PI) 3/15/2002-11/30/2008
NIH/NIDDK
Overcoming Nutritional Barriers in Hemodialysis Patients
The goals of this project are to conduct a randomized controlled trial to overcome specific nutritional barriers among hemodialysis patients.
Role: PI

R01 DK61021. Wright (PI) 9/1/01-8/31/08
NIH/NIDDK
Cohort Study of Chronic Renal Insufficiency.
National prospective cohort study to determine risk factors for progression of renal insufficiency and development of cardiovascular disease.
Role: Co-Investigator

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Kathleen A. Smyth** | POSITION TITLE<br>Associate Professor<br>Co-Director, Neurological Outcomes Center |
| eRA COMMONS USER NAME **KSMYTH** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Ursuline College, Cleveland, OH | B.A. | 1967 | Sociology |
| Case Western Reserve University, Cleveland,OH | M.A. | 1973 | Sociology |
| Case Western Reserve University, Cleveland,OH | Ph.D. | 1984 | Sociology |
| Case Western Reserve University, Cleveland,OH | M.S. | 1986 | Computer Appl. in Med. |
| Ursuline College, Cleveland, OH | B.A. | 1967 | Sociology |

**A. Positions and Honors**

**Positions and Employment**

| | |
|---|---|
| 1982-1986 | Coordinator of Health Services Research, Veterans Administration Medical Center (VAMC), Cleveland, OH |
| 1982-1986 | Instructor, Department of Epidemiology and Biostatistics, Case Western Reserve University (CWRU), School of Medicine (SOM) |
| 1984-1986 | Lecturer, Department of Sociology, CWRU |
| 1986-1992 | Associate Director for Health Services Research and Development, University Alzheimer Center of University Hospitals of Cleveland/Case Western Reserve University |
| 1986-1995 | Assistant Professor, Department of Epidemiology and Biostatistics, CWRU, SOM |
| 1987-1998 | Adjunct Assistant Professor, Department of Sociology, CWRU (secondary appointment) |
| 1993-2001 | Director of Research Operations, UMAC |
| 1995-present | Associate Professor, Department of Epidemiology and Biostatistics, CWRU, SOM |
| 1997-2001 | Associate Director, University Center on Aging and Health |
| 1997-present | Associate Professor, Department of Sociology (secondary appointment) |
| 1999-2011 | Director (previously Acting Director), Health Services Research and Policy Division, Department of Epidemiology and Biostatistics, CWRU, SOM |
| 2001-2004 | Associate Director, UMAC |
| 2005-2007 | Co-Director, UMAC |
| 2006-present | Associate Member, Aging-Cancer Program, Case Comprehensive Cancer Center |
| 2007-2009 | Director of Research, UMAC |
| 2009-present | Associate Professor, Department of Neurology (secondary appointment) |
| 2009-2012 | Co-Director, Neurological Outcomes Center (NOC), University Hospitals-Case Medical Center, CWRU, SOM |
| 2012-present | Director, Training and Mentoring Program, NOC, University Hospitals-Case Medical Center, CWRU, SOM |
| 2010-present | Affiliated Faculty, Prevention Research Center for Healthy Neighborhoods |

**Other Experience and Professional Memberships**
Member. AcademyHealth

**Honors**
Keck Research Scholar, CWRU Health Systems Management Center, 1982-1986.
1995 National Information Infrastructure Award and 1997 Ameritech/National Council on the Aging Innovation in Communications Technology Award, for Alzheimer's Disease Support Center Telecomputing Project.
Community Category, National Information Infrastructure Awards, Finalist Judge, 1996; Semi-Finalist Judge, 1997.
Fellow, Gerontological Society of America.

**B. Selected Peer-reviewed Publications**

**Most relevant to the current application**
1. Smyth, KA. (2011). Do enough women and minorities take part in drug studies for neurological diseases? /About clinical trials. *Neurology 76*:4, e16 – e17.
2. McClendon, M.J., Hernandez, S., Smyth, K.A.. & Lerner, A. (2009). Memanine and Acetylcholinesterase Inhibitor Treatment in Cases of CDR 0.5 or Questionable Impairment. *Journal of Alzheimer's Disease*. 16 (3): 577-583.Smyth, KA (2011) Cost-effectiveness analyses of treatments for multiple sclerosis: Are they clinically relevant? *Neurology 77*: 4,317-318.
3. Lerner, A.J., McClendon, M.J., Sami, S., Ogrocki, P., Adams, K.B., & Smyth, K.A. (2008). Factors affecting usage patterns of memantine in Alzheimer disease. *Alzheimer Disease and Associated Disorders, 22*(2), 137-143.
4. Fritsch, T., McClendon, M.J., Smyth, K.A., Lerner A.J., Friedland, R.P., & Larsen, J.D. (2007). Cognitive functioning in healthy aging: The role of reserve and lifestyle factors early in life. *The Gerontologist, 47*(3), 307-322.
5. Smyth, K.A., Ferris, S.H., Fox, P., Heyman, A., Holmes, D., Morris, J.N., Phillips, C.D., Schulz, R., Teresi, J., & Whitehouse, P.J. (1997). Measurement choices in multi-site studies of outcomes in dementia. *Alzheimer Disease and Associated Disorders, 11*(Supplement 6), 30-44.

**Additional recent publications of importance to the field (in chronological order)**
1. Thomas Fritsch T, Smyth KA, Wallendal MS, Hyde T, Leo G, & Geldmacher D. (in press). Parkinson disease: Research update and clinical management. *Southern Medical Journal*.
2. Smyth, K.A. (2009). Current practices and perspectives on breast cancer screening, diagnosis and treatment in older women with dementia. *Journal of the American Geriatrics Society. 57:S272-S274.*
3. Babigumira, J.B., Sethi, A.K., Smyth, K.A., and Singer, M.E. (2009). Cost effectiveness of facility-based care, home-based care and mobile clinics for provision of antiretroviral therapy in Uganda. Pharmacoeconomics, 27(11) 963-973.
4. Dawson, N.V., Singer, M.E., Lenert, L., Patterson, M., Sami, S., Gonsenhouser, I., Lindstrom, H.A., Smyth, K.A., Barber, M.J., & Whitehouse, P.J. (2008). Health state valuation in mild to moderate cognitive impairment: Feasibility of computer-based, direct patient utility assessment. *Medical Decision Making*. *28*(2), 220-232.
5. Daly, B.J., Douglas, S.L., Foley, H., Lipson, A., Liou, C-F., Bowman, K., Kwilosz, D., Koroukian, S., O'Toole, E., Smyth, K., Townsend, A., VonGruenigen, V., & Rose, J. (2007). Psychosocial registry for persons with cancer: A method of facilitating quality of life and symptom research. *Psycho-Oncology, 16*, 1-7.
6. Fredman, L., Tennstedt, S., Smyth, K.A., Kasper, J.D., Miller, B., Fritsch, T., Watson, M., & Harris, E.L. (2004). Pragmatic and internal validity issues in sampling in caregiver studies: A comparison of population-based, registry-based, and ancillary studies. *Journal of Aging and Health, 16*(2), 175-203.

7. Smyth, K.A., Neundorfer, M.M., Koss, E., Geldmacher, D.S., Ogrocki, P.K., & Whitehouse, P.J. (2002). Quality of life and deficit identification in dementia. *Dementia: The International Journal of Social Research and Practice*, *1*(3), 345-358.
8. Gray, L.K., Smyth, K.A., Palmer, R.M., Zhu, X., & Callahan, J.M. (2002). Heterogeneity in Older People: Examining Physiologic Failure, Age, and Comorbidity. *Journal of the American Geriatrics Society*, *50*(12), 1955-1961.
9. Shepardson, L.B., Younger, S., Speroff, T., O'Brien, R.G., Smyth, K., & Rosenthal, G.E. (1997). Variation in the use of do-not-resuscitate orders in patients with stroke. *Arch Intern Med*, *157*, 1841-1847.
10. Patterson, M.B., Mack, J.L., Neundorfer, M.M., Martin, R.J., Smyth, K.A., & Whitehouse, P.J. (1992). Assessment of functional ability in Alzheimer disease: A review and a preliminary report on the Cleveland Scale for Activities of Daily Living. *Alzheimer Disease and Associated Disorder*, *6*(3), 145-163.

**C. Research Support**

**Ongoing Research Support**

Smyth and Sajatovic (PIs)
1RC4AG038825-01 – NIA - 2010 - 2013
Assessing Early Alzheimer and At-Risk Groups with Patient Reported Outcomes
The major goal of this study is to validate PROMIS measures of depression, physical function and applied cognition in persons at risk for Alzheimer's disease (AD0 and those with Mild Cognitive Impairment or Mild/Moderate AD.

Smyth (PI, Cleveland site)
ADC-030-HBA - NIA Alzheimer's Disease Cooperative Studies Program – 2007 - 2012 (in no cost extension)
Multi-center Trial to Evaluate Home-Based Assessment Methods for Alzheimer's Disease Prevention Research in People Over 75 Years Old.
The major goal of this study is to evaluate alternative methods of tracking cognitive and functional performance of older adults over time in their own homes.

Smyth (PI, Case Western Reserve University Site)
Fogarty International Center 8/1/09 – 7/31/14
ICOHRTA Training Grant
The purpose of the grant is to train students from Uganda in health services research and epidemiology with the goal of enhancing Uganda's capacity to provide training and conduct research in these disciplines, focusing on the treatment of HIV/AIDS and TB.

R21-NR013001 (Sajatovic**)** NINR - 6/1/12-3/31/15
Targeted Intervention for African American Males
The purpose of this study is to test whether a psycho-educational intervention using peer educators can improve the ability of African-American men with first-time stroke to adhere to recommended post stroke management recommendations.

**Completed Research Support**

Smyth (PI)
IRG-06-27302 – Alzheimer's Association - 10/1/06 – 9/30/09 (in no-cost extension until 9/30/10)
Using Personal Computers to Extend Impacts of a Caregiving Intervention
The major goal of this project is to test the potential of computer-mediated communication to maintain and enhance the impacts of time-limited in-person psycho-educational intervention for caregivers of persons with dementia.

McClendon (PI)
Alzheimer's Association - 8/1/08 – 7/31/12 (no-cost extension)
Quality of Caregiving in Alzheimer's Disease
The major goal of this project is to evaluate the impact of the quality of family caregiving on nursing home placement and the survival of persons with dementia.

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME<br>James C. Spilsbury | POSITION TITLE<br>Assistant Professor & Director, Academic Development Core, Center for Clinical Investigation<br>Case School of Medicine |
| eRA COMMONS USER NAME<br>JSPILSBURY | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Yale University, New Haven, CT | B.S. | 05/81 | Biology |
| University of North Carolina, Chapel Hill, NC | M.P.H. | 08/85 | Health Education |
| Case Western Reserve University, Cleveland, OH | Ph.D. | 05/02 | Medical Anthropology |
| NIH T32 NRSA, Post-Doctoral Fellowship<br>Case Western Reserve University, Cleveland, OH | -------- | 9/02-8/05 | Child Behavioral Health Research |
| NIH K12 Post-Doctoral Fellowship, Case Western Reserve University | -------- | 7/06-6/10 | Violence, Sleep, Clinical Research |

## A. Positions and Honors

**Positions and Employment**

1977-1981 Laboratory Technician, Dept. Molecular Biophysics & Biochemistry, Yale University, New Haven, CT.
1981-1982 Research Assistant, School of Public Health, Yale University, New Haven, CT.
1983-1985 Research Assistant, Dept. Health Education, University of North Carolina at Chapel Hill, Chapel Hill, NC.
1986-1988 Socio-Economic Study Coordinator, Schistomiasis Research Project, Yaounde, Cameroon.
1989-1992 Regional Coordinator, AIDSTECH Project, Family Health International, Durham, NC.
1993 Senior Project Officer, Family Health International, Durham, NC.
1994-1995 Consultant, Family Health International, Durham, NC.
1996-1998 Research Assistant, Neighborhood & Household Factors in the Etiology of Child Maltreatment Project, Dept. Anthropology, Case Western Reserve University, Cleveland, OH.
2002 Research Associate and Adjunct Instructor, Dept. Anthropology & Schubert Center for Child Development, Case Western Reserve University, Cleveland, OH
2002-2005 Post-Doctoral Fellow, Division of Behavioral Pediatrics & Psychology, Case Western Reserve University, Cleveland, OH.
2005-present Research Specialist, Mental Health Services, Inc. Cleveland, OH.
2006-2010 Instructor, Center for Clinical Investigation, Case Western Reserve University, Cleveland, OH.
2010-present Assistant Professor and Director, Academic Development Core, Center for Clinical Investigation, Case Western Reserve University, Cleveland, OH

**Honors:**

1981. B.S. Magna cum laude with Distinction in Biology
1985. Delta Omega, National Public Health Honor Society
1988. Certificate of Appreciation. Cameroon Ministry of Public Service
2002. Research Award Nomination for 2000 co-authored article on definitions of child maltreatment, 6th Annual Conference of the Society for Social Work and Research, San Diego, CA.

## B. Pertinent Peer-reviewed Publications

1. Korbin J, Coulton C, Lindstrom-Ufuti H, **Spilsbury J**. Neighborhood Views on the Definition and Etiology of Child Maltreatment. *Child Abuse & Neglect.* 24;2000:1509-1527.
2. **Spilsbury JC**. "If I don't know them, I'll get killed probably": how children's concerns about safety shape help-seeking behavior. *Childhood.* 2002;9:101-117.
3. **Spilsbury J**, Korbin J. Negotiating the Dance: Social Capital from the Perspective of Neighborhood Children and Adults. In P. Pufall and R. Unsworth (Eds.) *Rethinking Childhood*, Piscataway: Rutgers University Press, 2004:191-206.
4. **Spilsbury JC**, Storfer-Isser A, Drotar D, Rosen C, Kircher HL, Redline S. Sleep Patterns in an Urban Sample of U.S. School-Aged Children. *Archives of Pediatrics & Adolescent Medicine.* 2004;158:988-994.
5. **Spilsbury JC**. Children's Perceptions of the Social Supports of Neighborhood Institutions and Establishments. *Human Organization.* 2005;64:126-134.
6. **Spilsbury JC**, Storfer-Isser A, Drotar D, Rosen C, Kirchner HL, Redline S. Effects of the Home Environment on School-Aged Children's Sleep. *Sleep.* 2005;28:1419-1427.
7. **Spilsbury JC**, Storfer-Isser A, Kirchner HL, Nelson L, Rosen CL, Drotar D, Redline S. Neighborhood disadvantage as a risk factor for pediatric obstructive sleep apnea. *Journal of Pediatrics.* 2006;149:342-347.
8. **Spilsbury JC**, Belliston L, Drotar D, Drinkard A, Kretschmar J, Creeden R, Flannery DJ, Friedman S. Clinically Significant Trauma Symptoms and Behavioral Problems in a Community-based Sample of Children Exposed to Domestic Violence. *Journal of Family Violence.* 2007;22:487-499.
9. Coulton CJ, Crampton DS, Irwin M, **Spilsbury JC**, Korbin JE. How neighborhoods influence child maltreatment: A review of the literature and alternative pathways. *Child Abuse & Neglect.* 2007;31:1117-1142.
10. **Spilsbury JC**, Kahana S, Drotar D, Creeden R, Flannery D, Friedman S. Profiles of Behavioral Problems in Children Who Witness Domestic Violence. *Violence & Victims.* 2008;23:3-17.
11. **Spilsbury JC**, Fletcher KE, Creeden R, Friedman S. Psychometric Properties of the Dimensions of Stressful Events Rating Scale. *Traumatology.* 2008;14:116-130.
12. Hayes AL, **Spilsbury JC**, Patel SR. The Epworth Score in African-American Populations. *Journal of Clinical Sleep Medicine.* 2009;5:344-348. PMC2725253
13. **Spilsbury JC**, Korbin, JE, Coulton CJ. Mapping Children's Neighborhood Perceptions: Implications for Child Indicators. *Child Indicators Research.* 2009;2:111-131.
14. **Spilsbury JC**. Sleep As Mediator in the Pathway From Violence-Induced Traumatic Stress to Poorer Health and Functioning: A Review of the Literature and Proposed Conceptual Model. *Behavioral Sleep Medicine.* 2009;7:223-244.
15. **Spilsbury JC,** Korbin JE, Coulton, CJ. "Subjective" and "Objective" Views of Neighborhood Danger & Well-Being: The Importance of Multiple Perspectives and Mixed Methods. *Child Indicators Research.* 2012;5:469-482.

## C. Research Support

**Current**

R21 MD007632-01. NIH (Spilsbury, PI) 8/21/12 – 8/20/14

Study: Peer and Family Effects on African American Children's Sleep. The study will use novel technologies to investigate the role of two social factors in the duration and timing of sleep in 11-12 year old African-American children: (1) the influence of child peers, and (2) the level of family organization/structure as reflected in the presence of sleep-related rules, daily routines, and parenting practices.

William T. Grant Foundation Award #9792 (Spilsbury, PI) 10/1/09 – 9/30/12.

Study: Violence, Sleep, and Child Health. The goals of this study are to (1) understand how the physical and socio-cultural characteristics of the home settings of children exposed to violence influence sleep and other

health and behavioral outcomes in children; and (2) test whether sleep disturbance is a key mechanism (mediator) through which exposure to violence affects children's mental health. Role: Primary investigator, oversees all scientific and administrative aspects of the project, collaborates closely with project statistician in data analysis and interpretation, supervises research assistants, assures collaboration of study partners (community agencies),

1U79SM058252 SAMHSA (Creeden, PI) Mental Health Services for Homeless Persons, 09/30/07-09/29/12 Study: Transforming care for traumatized youth in child welfare. The purpose of the project is to (1) improve capacity of Cuyahoga County's child welfare workers to provide trauma-informed care and case management to children with posttraumatic stress; and (2) develop an in-house counseling program to provide trauma-focused cognitive behavioral therapy to children in the child welfare system with posttraumatic stress. Role: Design and implement project evaluation activities, analyze data, and prepare evaluation reports.

**Past**

5KL2RR024990-02 NIH (Pamela Davis, PI) Case Western Reserve/Cleveland Clinic CTSA, 09/17/07–5/31/12. Community –Academic Partnership Grant. Study: Translating a Secondary-Trauma Intervention into Community Practice. The purpose of the study is to translate a promising, new intervention for secondary trauma into an effective intervention for use among the diverse staff of a community mental-health agency. The study's specific aims are to: (1) Identify the extent of secondary trauma throughout the agency; (2) Develop an effective modification of the current intervention to reduce secondary trauma among other targeted types of workers.

5KL2RR024990-02 NIH (Pamela Davis, PI) Case Western Reserve/Cleveland Clinic CTSA, 09/17/07–5/31/10. Study: Violence, Sleep, and Behavioral /Health Outcomes in Children. The goals of the Investigation are to develop and test appropriate, sensitive methods for measuring sleep in children traumatized by violence, characterize sleep patterns of a community-based sample of children exposed to violence, and assess associations of sleep characteristics with behavioral and health outcomes. Role: Primary Investigator of KL2 study, responsible for all phases of study.

| BIOGRAPHICAL SKETCH | | | |
|---|---|---|---|
| NAME **Stange, Kurt C.** | POSITION TITLE<br>Professor | | |
| eRA COMMONS USER NAME **KSTANGE** | | | |
| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
| Dartmouth College, Hanover, NH | A.B. | 1979 | Biology |
| Albany Medical College, Albany, NY | M.D. | 1983 | Medicine |
| University of North Carolina, School of Public Health, Chapel Hill, NC | Ph.D. | 1989 | Epidemiology |

**A. Positions and Honors**

**Positions and Employment**

1983-1986 Resident Physician and Chief Resident, Duke-Watts Family Medicine Program, Durham, NC
1986-1988 Fellow in the Preventive Medicine Residency, University of North Carolina, Chapel Hill, NC
1988-1999 Assistant to Associate Professor, Case Western Reserve University (CWRU), Cleveland
1995-1999 Associate Professor of Family Medicine, Epidemiology & Biostatistics, and Sociology, CWRU
1995-2007 Associate Director for Prevention & Population Research, Case Comprehensive Cancer Center
1999- Professor of Family Medicine, Epidemiology & Biostatistics, Oncology and Sociology, CWRU
1999- Director, Center for Research in Family Practice and Primary Care, CWRU and four other sites
2002- Gertrude Donnelly Hess, MD Professor of Oncology Research, Case, Cleveland, OH
2002- Editor, *Annals of Family Medicine*
2007- American Cancer Society Clinical Research Professor

**Other Experience and Professional Memberships**

Past President, North American Primary Care Research Group; Member, National Committee on Clinical Preventive Service Priorities; grant reviewer for the NCI, AHRQ, NIA, PCORI, American Cancer Society

**Honors**

1988 Certificate of Merit from the Secretary of Health & Human Services "For a Proposal for an Innovative Approach to Health Promotion and Disease Prevention"
1991- Fellow, American College of Preventive Medicine
1994-1998 Robert Wood Johnson Generalist Physician Faculty Scholar
1999, 2002, 2011 Award: Best Family Medicine Research Paper, Society of Teachers of Family Medicine
1999- Institute of Medicine of the National Academy of Sciences
2007-2017 American Cancer Society Clinical Research Professorship
2012 Family Medicine Education Consortium's Champion of Family Medicine Award
2012 Curtis G. Hames Research Award, Society of Teachers of Family Medicine

**B. Selected Peer-reviewed Publications**

1. **Stange, K. C.,** & Zyzanski, S. J.. Integrating qualitative and quantitative research methods. Family Medicine, 1989:21(6), 448–451.
2. Crabtree BF, Miller WL, **Stange KC**. Understanding practice from the ground up. *J Fam Pract*, 2001; 50:881-887.
3. Blankfield RP, Goodwin M, Jaén CR, **Stange KC**. Addressing the unique challenges of inner-city practice: A direct observation study of inner city, rural, and suburban family practices. *J Urban Health*, 2002; 79:173-185.

4. Hudson SV, Harris-Haywood S, **Stange KC**, Orzano AJ, Crabtree BF. Recruiting minority primary care practices into practice-based research. *Med Care*, 2006; 44(7): 696-700.
5. Heath, I., Rubinstein, A., **Stange, K.**, & van Driel, M.. Quality in primary health care: a multidimensional approach to complexity. British Medical Journal, 2009: 338, b1242.
6. Lanham HJ, McDaniel RR Jr, Crabtree BF, Miller WF, **Stange KC**, Tallia AF, Nutting PA. How improving practice relationships among clinicians and nonclinicians can improve quality in primary care. *Jt Comm J Qual Patient Saf* 2009; 35: 457-466.
7. Green LW, Glasgow RE, Atkins D, **Stange K**. Making evidence from research more relevant, useful, and actionable in policy, program planning, and practice: Slips "twixt cup and lip." *Am J Prev Med*, 2009; 37 (6S1): S187-S191.
8. Crabtree, B., Nutting, P., Miller, W., McDaniel, R., **Stange, K.**, & Jaén, C. Primary care practice transformation is hard work: insights from a 15 year developmental program of research. Medical Care, 2010:49, S28-35.
9. Fagnan LJ, Davis M, Deyo RA, Werner JJ, **Stange KC**. Linking practice-based research networks and Clinical and Translational Science Awards: new opportunities for community engagement by academic health centers. *Acad Med* 2010; 85(3): 476-83.
10. **Stange KC**, Nutting PA, Miller WL, Jaén CR, Crabtree BF, Flocke SA, Gill JM. Defining and measuring the Patient-Centered Medical Home. *J Gen Intern Med.* 2010; 25(6): 601-612.
11. Nutting PA, Crabtree BF, Miller WL, Stewart EE, **Stange KC,** Jaén CR. Journey to the Patient-Centered Medical Home: a qualitative analysis of the experiences of practices in the National Demonstration Project. *Ann Fam Med.* 2010; 8 (Suppl 1): S45-S56.
12. Epstein RM, Fiscella K, Lesser C, **Stange KC**. Why the nation needs a policy push on patient-centered health care. *Health Aff (Millwood).* 2010; 29(8): 1489-1495.
13. Nutting PA, Crabtree BF, Miller WL, **Stange KC**, Stewart E, Jaen C. Transforming physician practices to patient-centered medical homes: Lessons from the national demonstration project. *Health Aff* (Millwood) 2011; 30: 439-445.
14. Hartung DM, Guise J-M, Fagnan LJ, Davis MM, **Stange KC**. Role of practice-based research networks in comparative effectiveness research. *J Compar Effect Res* 2012; 1(1): 45-55. (doi: 10.2217/cer.11.7)
15. Glasgow RE, Green LW, Taylor MV, **Stange KC**. An evidence integration triangle for aligning science with policy and practice. *Am J Prev Med* 2012, 42(6): 646-654.

**C. Research Support**

**<u>Ongoing Research Support</u>**

1 R01 CA098966 E. Kahana (PI) 12/01/11 to 12/31/15
Health Care Partners in Cancer Prevention & Care of Aged
This project examines the efficacy of an educational intervention to improve cancer prevention and screening among elderly persons based on enhanced doctor-patient communication.
Role: Co-Investigator

(Stange, PI) 06/01/11-5/31/13
National Cancer Institute-DCCPS
Intergovernmental Personnel Act Mobility Program
Research and Development to understand the role of boundary spanning in advancing health.

CRP-07-236-06 (Stange, PI) 07/01/12-06/30/17
American Cancer Society
Promoting Health Across Boundaries
This Clinical Research Professorship fosters understanding of ways in which integrating primary care with health care systems and communities can reduce the cancer burden. It also is helping to launch a new initiative on Promoting Health Across Boundaries.

UL1TR 000439 (Davis, PI) 6/1/12-05/31/17
NIH/NCRR
Case Western Reserve University/Cleveland Clinic CTSA
The CWRU/Cleveland Clinic Clinical & Translational Science Collaborative coordinates the existing resources relevant to translational and clinical research and training at CWRU, 3 of its hospital affiliates, with practice-based research network (PBRN) and community partners.
Role: Steering Committee Member and Practice-Based Network Research & Development Mentor

P30 HS021648-01 (Werner, PI) 09/01/12-8/31/17
AHRQ
Collaborative Ohio Inquiry Networks (COIN) Research Center
Goal: The mission of the Collaborative Ohio Inquiry Network (COIN) is to develop the capacity of PBRNs, to do practice-based research by stimulating and fostering research collaborations, and to disseminate research findings by effectively sharing knowledge and translating research into practice.
Role: PBRN Director, Research and Development Mentor

R01 NR010271 (Kahana, PI) 09/01/12-08/31/17
NINR
Elders Marshaling Responsive Care & Enhancing Quality of Life in the Final Years (Continuation)
Goal: Planned education intervention, "Be Prepared" program, an advocacy skills training program to educate older adults to become knowledgeable about community resources and engage in conversations with family members and health care providers about their preferences for care, should serious illness arise. They will also develop toolkits for health events, in order to be better prepared to obtain responsive care.
Role: Co-Investigator

P30 CA043703 (Gerson, PI) 09/30/91-03/31/13
NIH/NCI
Comprehensive Cancer Center Support Grant
Goals: 1) improve the prevention, diagnosis, and therapy of cancer through research; 2) stimulate and support innovative, coordinated, interdisciplinary research on cancer diagnosis, treatment, and control; 3) develop clinical applications of research discoveries and to make these applications available as quickly as possible; and 4) develop cancer prevention and control activities to reduce cancer morbidity and mortality.
Role: Member, CRC Practice-Based Research Management Core

(Stange, PI) 07/01/12-06/30/14
Patient-Centered Outcomes Research Institute (PCORI)
Group Model Building to Engage Patient & Clinician Wisdom to Design Primary Care
Goal: To use a participatory group model building approach to develop an agent-based model of the paradox of primary care.

D55 HP20649 (Werner, PI) 09/01/10-06/30/2015
HRSA
"Strengthening the Behavioral Health Training Skills of Family Medicine Faculty"
The goal of this project is to train faculty physician preceptors to provide high levels of integrated, culturally competent care to patients with complex behavioral and physical co-morbid conditions. Further, they will be trained to impart these important skills to residents and when precepting.
Role: Integration Specialist
(Stange, PI) 07/01/12-06/30/13
American Board of Family Medicine Foundation
" Developing Facilitation and Practice Manuals for Group Part IV MOC Projects "

Goals: 1) create a learning collaborative--members of the Northeast Ohio Academy of Family Physicians (NEOAFP) partnered with CWRU help family physicians to improve quality of healthcare and to meet Part 4 MOC requirements; 2) evaluate the effect of collaborative learning on participants' satisfaction with practice, quality of care, improvement initiatives, practice network learning & mutual support, success in meeting board requirements; 3) develop shared learning & facilitation manuals for Part IV MOC work.

(Stange, PI) 06/01/13-05/31/16
Patient-Centered Outcomes Research Institute (PCORI)
Patient-Identified Personal Strengths (PIPS) vs. Deficit-Focused Models of Care
Goal: This research will generate a useful new patient assessment tool, simulation models, and CER knowledge that can be used to make health care more effective in producing patient-centered outcomes.

**Completed Research Support**

(Stange, PI) 07/01/10-06/30/12
American Board of Family Medicine Foundation
"Northeast Ohio Learning Collaborative to Support American Board of Family Medicine Diplomates in Meeting Performance in Practice Requirements"
This project is establishing a learning collaborative of members of the Northeast Ohio Academy of Family Physicians (NEOAFP) in partnership with CWRU to help family physicians to improve the quality of healthcare and to meet Part 4 MOC requirements, and evaluating the effect of collaborative learning on participants' satisfaction with practice, improvement initiatives, quality and quantity of practice network learning and mutual support, success in meeting board certification requirements, and quality of care.

Case Western Reserve University (Stange, PI) 07/01/11-06/30/12
Promoting Health Across Boundaries - Forward Thinking Interdisciplinary Alliance Investment Grant
The goal of Promoting Health Across Boundaries is to develop and share new knowledge about the connections that foster health.

P30 NR010676-03 (Moore, PI) 09/29/07-06/30/12
National Institute for Nursing Research
Center of Excellence to Build the Science of Self-Management: A Systems Approach
The SMART Center will prepare a critical mass of researchers to extend and disseminate this knowledge, contribute to the development of emerging bio-behavioral research methods, focus on critical issues related to health disparities, and incorporate economic considerations as part of their research.
Role: Co-Investigador

MEDTAPP (Cuttler, PI) 11/01/09-6/30/12
Cuyahoga County Board of Commissioners
Center of Excellence in Child Healthcare: A University-Practice-Public Partnership
Consortium of university-based researchers and community level providers coalescing into a single umbrella entity devoted to excellence in improving child health through translation of research-based evidence into effective practice.
Role: Co-Investigator

R25 CA111898-05 (Stange, PI) 09/28/05-08/31/11
Practice-Based Research Network-Cancer Control Training
Integrated post-doctoral program; prepares fellows for careers as academic cancer control researchers with skills and relationships to generate important new knowledge, and to translate research into practice.
Role: PI

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Strohl, Kingman Perkins** | POSITION TITLE<br>Professor of Medicine |
| eRA COMMONS USER NAME **KSTROHL** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Yale University, New Haven, CT | BA | 1970 | Anthropology |
| Northwestern University, Chicago, IL | MD | 1974 | Medicine |
| University of Kentucky Medical Center, Lexington KY | | 1974-1977 | Internal Medicine |
| Peter Bent Brigham Hospital and Harvard Medical School, Boston MA | | 1977-1980 | Pulmonary Research Fellow in Medicine |

**A. Positions and Honors**

**Positions and Employment**

1980-1985 Assistant Professor of Medicine, Case Western Reserve University, Cleveland, Ohio.
1985-1990 Associate Professor of Medicine, Case Western Reserve University.
1989-1993 Chief, Division of Pulmonary and Critical Care Medicine, University Hospitals
1990- Professor of Medicine, Case Western Reserve University
1994- Director, CWRU Center for Sleep Disorders Research
1995- Professor of Anatomy and Oncology, Case Western Reserve University
2009-present Acting Chief, Division of Pulmonary, Critical Care, and Sleep Medicine, University Hospitals, Cleveland, Ohio.

**Other Experience and Professional Memberships**

American Thoracic Society
Sleep Research Society
American Academy of Sleep Medicine

**Honors**

American Society for Clinical Investigation
NIH Committee: member, Committee on Assessments for Sleep Education NCSDR: 2002
NIH Committee Chair: Special Emphasis Panel, 2004 and 2006
Distinguished Service Award American Thoracic Society 2008

**B. Selected Peer-reviewed Publications** (Selected from 178 peer-reviewed publications)

**Relevant to the application (Peer Reviewed)**

Moore MW, Chai S, Gillombardo CB, Carlo A, Donovan LM, Netzer N, Strohl KP. Two Weeks of Buspirone Protects against Posthypoxic Ventilatory Pauses in the C57BL/6J Mouse Strain. Respiratory Physiology and Neurobiology 2012 Jul 31;183(1):35-40. Epub 2012 May 15

Gillombardo CB, Yamauchi M, Adams MD, Dostal J, Chai S, Moore MW, Donovan LM, Han F, Strohl KP. Identification of Novel Mouse Genes Conferring Post-Hypoxic Pauses. J Appl Physiol 2012 Jul;113(1):167-74. Epub 2012 Apr 26.PubMed PMID: 22539170.

Friedman L, Dick TE, Jacono FJ, Loparo KA, Yeganeh A, Fishman M, Wilson CG, Strohl KP. Cardio-Ventilatory Coupling in Young Healthy Resting Subjects. J Appl Physiol. 2012 Jan 19. [Epub ahead of print] PMID: 22267392

Miller CM, Rindflesch TC, Fiszman M, Hristovski D, Shin D, Rosemblat G, Zhang H, Strohl KP. A closed literature-based discovery technique suggests a mechanistic link between hypogonadism and diminished sleep quality in aging men. Sleep. 2012 Feb 1;35(2):279-85. PMID:22294819

Han F, Lin L, Li J, Aran A, Dong SX, An P, Zhao L, Li QY, Yan H, Wang JS, Gao HY, Li M, Gao ZC, Strohl KP, Mignot E. TCRA, P2RY11, and CPT1B/CHKB associations in Chinese narcolepsy. Sleep Med. 2011 Dec 14. [Epub ahead of print] PMID: 22177342.

McDowell AL, Strohl KP, Feng P. Sleep-related epilepsy in a Long-Evans hooded rat model of depression. Sleep Breath. 2011 Dec 29. [Epub ahead of print] PMID:22205358

Chai S, Gillombardo CB, Donovan L, Strohl KP. Morphological differences of the carotid body among C57/BL6 (B6), A/J, and CSS B6A1 mouse strains. Respir Physiol Neurobiol. 2011 Apr 28. PMID:21555000 [Epub ahead of print]

Yamauchi Y, Tamaki S. Yoshikawa M, Ohnishi Y, Nakano H, Jacono F, Loparo KA, Strohl KP, Kimura H. Differences in Breathing Patterning during Wakefulness in Patients with Mixed-Apnea Dominant vs. Obstructive-Dominant Sleep Apnea. Chest 2011 Mar 10. [Epub ahead of print] PMID: 21393396

Decker M, Rye D, Strohl K. cFOS activation in the SCN resulting from REM sleep. Front Neurol. 22;1:122, 2010. PMID: 21173892

Koo B, Strohl K, Gillombardo C, Strohl KP,. Cheyne-Stokes Respiration in a Mouse Model of Stroke. Respir Physiol Neuro Respir Physiol Neurobiol. 2010 Jul 31;172(3):129-35. Epub 2010 May 21

Han F, Mignot E, Wei YC, Dong SX, Li J, Lin L, An P, Wang LH, Wang JS, He MZ, Gao HY, Li M, Strohl KP. Ventilatory chemoresponsiveness, narcolepsy-cataplexy, and HLA-DQB1*0602 status. Eur Respir J. 2010 Jan 28. [Epub ahead of print]PMID: 20110394

Feng P, Hu Y, Li D, Vurbic D, Fan F, Wang S, Strohl KP. The Effect of clomipramine on wake/sleep and orexinergic expression in rats. J Psychopharmacol. 2009 Jul;23(5):559-66.

Yamauchi M, Hasan O, Dostal J, Jacono FJ, Loparo KA, Strohl KP. Post-Sigh Breathing Behavior and Spontaneous Pauses in the C57BL/6J (B6) Mouse. Respir Physiol Neuro 162 (2):117-25, 2008.

Yamauchi M, Dostal J, Kimura H, Strohl KP. Buspirone and its Effects on Ventilatory Behavior in the A/J and C57BL/6J Mouse Strains. J Appl Physiol 105 (2):518-26, 2008.

Koo BB, Patel SR, Strohl K, Hoffstein V. REM-Related Sleep Disordered Breathing: Influence of Age and Gender Chest. 134(6):1156-61, 2008. Epub 2008 Sep 23.

Yamauchi M, Dostal J, Strohl KP. Effect of acetazolamide on post-hypoxic periodic breathing in the mouse. J Appl Physiol 103(4):1263-8, 2007.

Strohl KP, Gallaugher L, Lynn A, Friedman L, Hill A, Singer JC, Lander ES, Nadeau J. Sleep-related epilepsy in the A/J Mouse. Sleep 30(2):169-76, 2007.

Subramanian S, Dostal J, Erokwu B, Han F, Dick TE, Strohl KP. Domperidone Effects on Ventilatory Behavior: Sprague Dawley vs. Brown Norway Rats. Respiratory Physiology and Neurobiology 15;155(1):22-8, 2007. Epub 2006 Apr 252006 Apr 25; [Epub ahead of print]

Price ER, Paladino FV, Strohl KP, Santidrián P, Klann K, Spotila JR. Ontogeny of respiration in hatchling sea turtles. Comparative Biochemistry and Physiology 146: 422-528, 2007.

Friedman L, Haines A, Klann K, Gallaugher L, Salibra L, Han F, Strohl KP. Sleep and Ventilatory Behavior among A/J and C57BL/6J Mouse Strains. J Appl Physiol 97(5):1787-95, 2004.

Gonsenhauser I, Han F**,** Wilson CG, Strohl KP, Dick TE. Strain Differences in Murine Ventilatory Behavior Persists after Anesthesia. J Appl Physiol 97(3):888-894, 2004

Price ER, Han F, Dick TE, Strohl KP. 7-nitroindazole and post-hypoxic ventilatory behavior in the A/J and C57BL/6J mouse strains. J Appl Physiol 95: 1097-1104, 2003

Han F, Subramanian S, Price E, Nadeau J, Strohl KP. Periodic Breathing in the Mouse. J Appl Physiol : 92 1133-1140, 2002.

Subramanian S, Erokwu B, Han F, Strohl KP. Differential Effects of L-NAME on the Sprague Dawley and Brown Norway Rat. J Appl Physiol 93(3):984-9, 2002.

Strohl KP, Thomas AJ. Ventilatory behavior and metabolism in two strains of obese rats. Respiratory Physiol 124: 85-93, 2001.

Thomas AJ, Erokwu BO, Yamamoto BK, Ernsberger P, Bishara O, Strohl KP. Alterations in respiratory behavior, brain biochemistry and receptor density induced by pharmacologic suppression of sleep in the neonatal period. Developmental Brain Research 120: 181-189, 2000.
Abu-Shaweesh JM, Thomas AJ, Haxhiu MA, Dreshaj IA, Strohl KP, Martin RJ. Maturation of the hypercapnic ventilatory response in rats. J Appl Physiol 87: 484-490, 1999.
Strohl KP, Thomas AJ, Schlenker EH, Koletsky RJ, St. Jean P, Schork NJ. Ventilation and metabolism among rat strains. J Appl Physiol 82(1):317-323, 1997.
Smith ML, Niedermaier ONW, Hardy SM, Decker MJ, Strohl KP. Role of hypoxemia in sleep apnea-induced sympathoexcitation. J Autonomic Nervous System 56:184-190, 1996.
Thomas AJ, Friedman L, MacKenzie CN, Strohl KP. Modification of conditioned apneas in rats: Evidence for cortical involvement. J Appl Physiol 78:1215-1218, 1995.
Khoo MN, Kronauer J, Strohl KP, Slutsky AS. Factors inducing periodic breathing in humans: a general model. J Appl Physiol 53:644-659, 1982.

**Relevant to the current application (Reviews and Chapters)**

(Book Chapter) Strohl KP. Neonatal Models and Ventilatory Behavior. Ed. Carley and Radulovacki. Animal Models for Respiratory Control. Marcel Dekker New York 2003 pp. 239-264.
(Review Article) Strohl KP. Periodic Breathing and Genetics. Respiratory Physiology & Neurobiology 135: 179-185, 2003.
(Book Chapter) Strohl KP. Inheritance and Ventilatory Behavior in Animal Models. Eds. D.S. Ward, A. Dahlen, L.J. Teppema. Pharmacology and Pathophysiology of the Control of Breathing. Marcel Dekker New York 2005 pp. 261-292.
(Chapter) Baekey DM, Feng P, Decker MJ, Strohl K. Breathing and sleep: measurement methods, genetic influences, and developmental impacts. ILAR J 50(3):248-61, 2009
(Review) Donovan L, Welford SM, Haaga J, LaManna J, Strohl KP. Hypoxia-implications for pharmaceutical developments. Sleep Breath. 2010 Jul 14. [Epub ahead of print]

**Additional recent publications (in chronological order)**

Feng P, Hu Y, Li D, Vurbic D, Fan F, Wang S, Strohl KP. The Effect of clomipramine on wake/sleep and orexinergic expression in rats. Journal of Psychopharmacology 22(7):784-91, 2008.
Feng P, Vurbic D, Wu Z and Strohl KP. Wake Regulation in Rats Exposed to Maternal Deprivation. Brain Res. 1154C:163-172, 2007. Epub 2007 Mar 31.
Feng P, Vurbic D, Wu Z and Strohl KP. Wake Regulation in Rats Exposed to Maternal Deprivation. Brain Res. 1154C:163-172, 2007. Epub 2007 Mar 31.
Brown E, Beall CM, Strohl KP, Mills PS. Exhaled nitric oxide decreased upon acute exposure to high-altitude hypoxia Am J Human Biol Am J Human Biol 18:196-202, 2006
Netzer NC, Hoegel JJ, Loube D, Netzer CM, Hay B, Alvarez-Sala R, Strohl KP. Prevalence of symptoms and risk of sleep apnea in primary care. Chest 124:1406-1412, 2003.
Beall C, Decker M, Brittenham G, Kushner I, Gebremedhin A, Strohl KP. An Ethiopian pattern of human adaptation to high-altitude hypoxia. Proc Natl Acad Sci U S A. 99(26):17215-8, 2002.
Beall CM, Laskowski D, Strohl KP, Soria R, Villena M, Vargas E, Alarcon AM, Gonzales C, Erzurum SC. Pulmonary nitric oxide in mountain dwellers. Nature 414:411-412, 2001.
Netzer NC, Stoohs RA, Netzer CM, Clark K, Strohl KP. Using the Berlin Questionnaire to identify patients at risk for sleep apnea syndrome. Ann Int Med 131: 485-491, 1999.
Netzer N, Werner P, Jochums I, Lehmann M, Strohl KP. Blood flow in the middle cerebral artery with sleep disordered breathing: Correlation with obstructive hypopnea. Stroke 29(1):87-93, 1998.
Redline S, Tishler PV, Hans MG, Tosteson TD, Spry K, Strohl KP. Sleep-disordered breathing in african-americans and caucasions: Racial differences in age of onset and underlying risk factors. Am J Respir Crit Care Med 155:186-192, 1997.
Beall CM, Strohl KP, Blangero J, Williams-Blangero S, Brittenham GM, Goldstein MC. Quantitative genetic analysis of arterial oxygen saturation in Tibetan highlanders. Hum Biol 69(5):597-604, 1997.

Cahan C, Decker MJ, Arnold JL, Goldwasser E, Strohl KP. Erythropoietin levels with treatment of obstructive sleep apnea. J Appl Physiol 79(4):1278-1285, 1995.
Hoffstein V, Herridge M, Mateika S, Redline S, Strohl KP. Hematocrit levels in sleep apnea. Chest 106(3):787-791, 1994.
Strohl KP, Novak RD, Singer W, Cahan C, Boehm KD, Denko CW, Hoffstein VS. Insulin levels, blood pressure, and sleep apnea. Sleep 17(7):614-618, 1994.
Haxhiu MA, Erokwu B, van Lunteren E, Cherniack NS, Strohl KP. Central and spinal effects of sodium cyanide on respiratory activity. J Appl Physiol 74(2):574-579, 1993.
Decker MJ, Haaga J, Arnold JL, Atzberger D, Strohl KP. Functional electrical stimulation and respiration during sleep. J Appl Physiol 75(3):1053-1061, 1993.
Strohl KP, Feldman NT, Saunders NA, Hallett M. Obstructive sleep apnea syndrome in family members. N Engl J Med 299:969-973, 1978.

## C. Research Support

**Ongoing Research Support**

*Buspirone as a Potential Treatment for Recurrent Central Apneas* (K. Strohl P.I.)
VAMC 7/01/08 - 9/30/12
VAMC – Merit Award
The major goals of this project are to determine if buspirone vs. acetazolamide vs. placebo alter the appearance of recurrent apneas in the mouse as well as in patients with Cheyne-Stokes Respiration.

*Sleep Medicine Neurobiology and Epidemiology* (K. Strohl P.I.)
NIH-HL/NS 07913 T series 07/01/11-6/30/15
This is an institutional training grant application for sleep disorders. There are two graduate and three post-doctoral positions.

Inspire (STAR) Clinical Trial (K.Strohl, Site Investigator) 2009-competetion of recruitment for 6-site study
This is a Phase II-III trail of the use of electrical stimulation of the hypoglossal nerve for the treatment of obstructive sleep apnea.

*Rhythmogenesis: A Genomic Approach*
VA Research Service 10/01/11 - 9/30/15
VAMC – Merit Award
The major goals of this project are to determine the genetic architecture for chemosensitivity and the appearance of recurrent apneas in the C57BL/JB mouse.

*Effect of OxR2 agnoist and antagonist on sleep apnea.*
NIH 09/01/11 - 8/31/12
1R41HL107037 STTR sub-contract to Strohl, KP
The major goals of this Phase I project are to determine if orexin agonists and antagonists alter the expression of recurrent apneas in the C57BL/JB mouse.

**Completed Research Support**

*Breathing Stability: Linear and Non-Linear Features* (K.Strohl P.I.)
(R33) HL 087340 - 01 9/01/08-5/31/11
The major goals are to utilize novel computational methodology to identify underlying features relating to the patterns of tidal volume and respiratory frequency over time in healthy subjects and in patients with a variety of cardiopulmonary diseases.

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Daniel James Tisch** | POSITION TITLE<br>Assistant Professor |
| eRA COMMONS USER NAME **DTISCH** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| Alma College, Alma, MI | Transferred | 1992-1994 | Biology |
| University of Glasgow, Glasgow Scotland, UK | B.Sc., Hons. | 1994-1996 | Medical Parasitology |
| University of Michigan, Ann Arbor, MI | M.P.H. | 1998-2000 | International Health |
| Case Western Reserve University, Cleveland OH | Ph.D. | 2000-2004 | Epidemiology |

**A. Positions and Honors**

| | |
|---|---|
| 1995 | Research Intern, Blair Research Laboratories, Harare, Zimbabwe |
| 1995-1996 | Undergraduate Research Assistant, Biochemical Parasitology, University of Glasgow |
| 1999 | Research Intern, Malaria Research Project, Queen Elizabeth Hospital, Blantyre, Malawi |
| 1988-2000 | Graduate Research Assistant, Department of Epidemiology, University of Michigan |
| 2000-2002 | Graduate Assistant, Division of Geographic Medicine, Case Western Reserve University |
| 2002-2004 | Research Assistant, Center for Global Health and Diseases, Case Western Reserve University |
| 2004-2005 | Senior Instructor, Department of Epidemiology and Biostatistics, Case Western Reserve University |
| 2005-present | Assistant Professor, Department of Epidemiology and Biostatistics and Center for Global Health & Diseases, Case Western Reserve University |

**B. Selected peer-reviewed publications** (in chronological order).

1. Tisch DJ, Hazlett FE, Kastens W, Alpers MP, Bockarie MJ, **Kazura JW**. Ecologic and biologic determinants of filarial antigenemia in bancroftian filariasis in Papua New Guinea. J Infect Dis. 2001 Oct 1;184(7):898-904. Epub 2001 Aug 22.
2. Bockarie MJ, **Tisch DJ**, Kastens W, Alexander ND, Dimber Z, Bockarie F, Ibam E, Alpers MP, Kazura JW. Mass treatment to eliminate filariasis in Papua New Guinea. N Engl J Med. 2002 Dec 5;347(23):1841-8.
3. Hise AG, Hazlett FE, Bockarie MJ, Zimmerman PA, **Tisch DJ**, Kazura JW. Polymorphisms of innate immunity genes and susceptibility to lymphatic filariasis. Genes Immun. 2003 Oct;4(7):524-7.
4. King CH, Dickman K, **Tisch DJ**. Reassessment of the cost of chronic helminthic infection: a meta-analysis of disability-related outcomes in endemic schistosomiasis. Lancet. 2005 Apr 30-May 6;365(9470):1561-9.
5. **Tisch DJ**, Michael E, Kazura JW. Mass chemotherapy options to control lymphatic filariasis: a systematic review. Lancet Infect Dis. 2005 Aug;5(8):514-23. Review.
6. Malhotra I, Mungai PL, Wamachi AN, **Tisch D**, Kioko JM, Ouma JH, Muchiri E, Kazura JW, King CL. Prenatal T cell immunity to Wuchereria bancrofti and its effect on filarial immunity and infection susceptibility during childhood. J Infect Dis. 2006 Apr 1;193(7):1005-13. Epub 2006 Feb 22.
7. Moormann AM, John CC, Sumba PO, **Tisch D**, Embury P, Kazura JW. Stability of interferon-gamma and interleukin-10 responses to Plasmodium falciparum liver stage antigen-1 and thrombospondin-related adhesive protein in residents of a malaria holoendemic area. Am J Trop Med Hyg. 2006 Apr;74(4):585-90.
8. Canaday DH, Chakravarti S, Srivastava T, **Tisch DJ**, Cheruvu VK, Smialek J, Harding CV, Ramachandra L. Class II MHC antigen presentation defect in neonatal monocytes is not correlated with decreased MHC-II expression. Cell Immunol. 2006 Oct;243(2):96-106. PMID: 17324388; PMCID: PMC1904503.

9. Bockarie MJ, Tavul L, Ibam I, Kastens W, Hazlett F, **Tisch DJ**, Alpers MP, Kazura JW. Efficacy of single-dose diethylcarbamazine compared with diethylcarbamazine combined with albendazole against Wuchereria bancrofti infection in Papua New Guinea. Am J Trop Med Hyg. 2007 Jan;76(1):62-6.
10. Moormann AM, Chelimo K, Sumba PO, **Tisch DJ**, Rochford R, Kazura JW. Exposure to holoendemic malaria results in suppression of Epstein-Barr virus-specific T cell immunosurveillance in Kenyan children. J Infect Dis. 2007 Mar 15;195(6):799-808. Epub 2007 Feb 6.
11. Ostrout ND, McHugh MM, **Tisch DJ,** Moormann AM, Brusic V, Kazura JW. Long-term T cell memory to human leucocyte antigen-A2 supertype epitopes in humans vaccinated against smallpox. Clin Exp Immunol. 2007 Aug;149(2):265-73. Epub 2007 May 4. PMID: 17488297; PMCID: PMC1941954.
12. Tobian AA, Sokoll LJ, **Tisch DJ**, Ness PM, Shan H. N-terminal pro-brain natriuretic peptide is a useful diagnostic marker for transfusion-associated circulatory overload. Transfusion. 2008 Feb 21. [Epub ahead of print]
13. **Tisch DJ**, Bockarie MJ, Dimber Z, Kiniboro B, Tarongka N, Hazlett FE, Kastens W, Alpers MP, Kazura JW. Mass drug administration trial to eliminate lymphatic filariasis in Papua New Guinea: changes in microfilaremia, filarial antigen, and Bm14 antibody after cessation. Am J Trop Med Hyg. 2008 Feb;78(2):289-93.
14. Asiimwe S, Whalen CC, **Tisch DJ**, Tumwesigye E, Sethi AK. Prevalence and predictors of high-risk human papillomavirus infection in a population-based sample of women in rural Uganda. Int J STD AIDS. 2008 Sep;19(9):605-10. PMCID: PMC2847363
15. Dent AE, Bergmann-Leitner ES, Wilson DW, **Tisch DJ**, Kimmel R, Vulule J, Sumba PO, Beeson JG, Angov E, Moormann AM, Kazura JW. Antibody-mediated growth inhibition of Plasmodium falciparum: relationship to age and protection from parasitemia in Kenyan children and adults. PLoS ONE. 2008;3(10):e3557. PMCID: PMC2570335.
16. Bajunirwe F, **Tisch DJ,** King CH, Arts EJ, Debanne SM, Sethi AK. Quality of life and social support among patients receiving antiretroviral therapy in Western Uganda. AIDS Care. 2009 Mar;21(3):271-9. doi: 10.1080/09540120802241863
17. Bajunirwe F, Arts EJ, **Tisch DJ,** King CH, Debanne SM, Sethi AK. Adherence and Treatment Response Among HIV-1-Infected Adults Receiving Antiretroviral Therapy in a Rural Government Hospital in Southwestern Uganda. J Int Assoc Physicians AIDS Care (Chic Ill). 2009. doi: 10.1177/1545109709332470. Epub 2009 Mar 3.
18. Tobian AA, Shirey RS, Montgomery RA, **Tisch DJ**, Ness PM, King KE. Therapeutic plasma exchange reduces ABO titers to permit ABO-incompatible renal transplantation. Transfusion. 2009. doi: 10.1111/j.1537-2995.2008.02085.x. Epub 2009 Feb 6.
19. Malhotra I, Dent A, Mungai P, Wamachi A, Ouma JH, Narum DL, Muchiri E, **Tisch DJ**, King CL. Can prenatal malaria exposure produce an immune tolerant phenotype? A prospective birth cohort study in Kenya. PLoS Med. 2009 Jul;6(7):e1000116. PMCID: PMC2707618.
20. Dent AE, Chelimo K, Sumba PO, Spring MD, Crabb BS, Moormann AM**, Tisch DJ,** Kazura JW. Temporal stability of naturally acquired immunity to Merozoite Surface Protein-1 in Kenyan adults. Malar J. 2009 Jul 16;8(1):162. PMCID: PMC2719655.
21. Moormann AM, Sumba PO, **Tisch DJ,** Embury P, King CH, Kazura JW, John CC. Stability of interferon-gamma and interleukin-10 responses to Plasmodium falciparum liver stage antigen 1 and thrombospondin-related adhesive protein immunodominant epitopes in a highland population from Western Kenya. Am J Trop Med Hyg. 2009 Sep;81(3):489-95.
22. Heaphy EL, Loue S, Sajatovic M, **Tisch DJ.** Impact of psychiatric and social characteristics on HIV sexual risk behavior in Puerto Rican women with severe mental illness. Soc Psychiatry Psychiatr Epidemiol. 2009 Oct 24. PMCID: PMC3483882
23. Canaday DH, Amponsah NA, Jones L, **Tisch DJ**, Hornick TR, Ramachandra L. Influenza-Induced Production of Interferon-Alpha is Defective in Geriatric Individuals. J Clin Immunol. J Clin Immunol. 2010 May;30(3):373-83. PMCID: PMC2875067

24. Gambhir M, Bockarie M, **Tisch D,** Kazura J, Remais J, Spear R, Michael E. Geographic and ecologic heterogeneity in elimination thresholds for the major vector-borne helminthic disease, lymphatic filariasis. BMC Biol. 2010 Mar 17;8:22. PMCID: PMC2848205.
25. Mugwanya KK, Baeten JM, Nakku-Joloba E, Katabira E, Celum C, **Tisch D**, Whalen C. Knowledge and Attitudes About Male Circumcision for HIV-1 Prevention among Heterosexual HIV-1 Serodiscordant Partnerships in Kampala, Uganda. AIDS Behav. 2010 Apr 13. doi: 10.1007/s10461-010-9696-x
26. Mehlotra RK, Gray LR, Blood-Zikursh MJ, Kloos Z, Henry-Halldin CN, **Tisch DJ,** Thomsen E, Reimer L, Kastens W, Baea M, Baea K, Baisor M, Tarongka N, Kazura JW, Zimmerman PA. Molecular-based assay for simultaneous detection of four Plasmodium spp. and Wuchereria bancrofti infections. Am J Trop Med Hyg. 2010 Jun;82(6):1030-3. PMCID: PMC2877407
27. Spring MD, Chelimo K, **Tisch DJ**, Sumba PO, Rochford R, Long CA, Kazura JW, Moormann AM. Allele-specificity of IFN-{gamma} Responses to the Carboxyl Terminal Region of Plasmodium Falciparum Merozoite Surface Protein 1 by Kenyan Adults with Naturally Acquired Immunity to Malaria. Infect Immun. 2010 Aug 9. PMCID: PMC2950343
28. Blaine KP, Tuohy MJ, Wilson D, Procop GW, **Tisch DJ**, Shrestha NK, Hall GS. Progression to bacteremia in critical care patients colonized with methicillin-resistant Staphylococcus aureus expressing Panton-Valentine leukocidin. Diagn Microbiol Infect Dis. 2010 Sep;68(1):28-33. doi: 10.1016/j.diagmicrobio.2010.04.013.
29. Tobian AA, Savage WJ, **Tisch DJ**, Thoman S, King KE, Ness PM. Prevention of allergic transfusion reactions to platelets and red blood cells through plasma reduction. Transfusion. 2011 Aug;51(8):1676-83. Epub 2011 Jan 7.doi: 10.1111/j.1537-2995.2010.03008.x.
30. **Tisch DJ**, Alexander ND, Kiniboro B, Dagoro H, Siba PM, Bockarie MJ, Alpers MP, Kazura JW. Reduction in Acute Filariasis Morbidity during a Mass Drug Administration Trial to Eliminate Lymphatic Filariasis in Papua New Guinea. PLoS Negl Trop Dis. 2011 Jul;5(7):e1241. PMCID: PMC3134431.
31. Hileman CO, Wohl DA, **Tisch DJ**, Debanne SM, McComsey GA. Initiation of an Abacavir-Containing Regimen in HIV-Infected Adults Is Associated with a Smaller Decrease in Inflammation and Endothelial Activation Markers Compared to Non-Abacavir-Containing Regimens. AIDS Res Hum Retroviruses. 2012 Apr 26. PMCID: PMC3505065
32. Mupere E, Malone L, Zalwango S, Chiunda A, Okwera A, Parraga I, Stein CM, **Tisch DJ**, Mugerwa R, Boom WH, Mayanja H, Whalen CC. Lean Tissue Mass Wasting is Associated With Increased Risk of Mortality Among Women With Pulmonary Tuberculosis in Urban Uganda. Ann Epidemiol. 2012 Jul;22(7):466-73. Epub 2012 May 9. PMCID: PMC3377556
33. Mupere E, Parraga IM, **Tisch DJ**, Mayanja HK, Whalen CC. Low nutrient intake among adult women and patients with severe tuberculosis disease in Uganda: a cross-sectional study. BMC Public Health. 2012 Dec 5;12:1050. PMCID: 23217171
34. Dent AE, Moormann AM, Yohn CT, Kimmel RJ, Sumba PO, Vulule J, Long CA, Narum DL, Crabb BS, Kazura JW, **Tisch DJ**. Broadly reactive antibodies specific for Plasmodium falciparum MSP-1(19) are associated with the protection of naturally exposed children against infection. Malar J. 2012 Aug 21;11:287. PMCID: PMC3502150

## C. Research Support

**Ongoing Research Support**

NIAID 1 U19 AI089686-03 7/01/10-6/30/17

Project Leader Core B: Data Management and Statistical Core: International Centers for Excellence for Malaria Research: "Research to control and eliminate malaria in SE Asia and SW Pacific"

The overall objective of this ICEMR is to advance knowledge of how national and regional programs to control and eliminate malaria in Papua New Guinea (PNG) and Solomon Islands affect the epidemiology, transmission and pathogenesis/immunity of *Plasmodium falciparum* and *P. vivax* infection and morbidity in 2 distinct endemic settings which represent a wide spectrum of malaria endemicity (holoendemic in mainland PNG, meso/hypoendemic in Western Province, Solomon Islands). A related goal is to build local capacity and

infrastructure to monitor, evaluate and guide ongoing and future malaria interventions used by national health authorities in the region.

NIAID 2 R01 AI064687-07A1 7/1/11-6/30/16
Co-I: "Fetal Immunity of malaria" (CL King, PI)
This grant aims to determine the phenotype and frequency of malaria-specific T cells acquired *in utero* from newborns in a malaria endemic population and to define the mechanisms of the fetal exposure to malaria and how this exposure regulates the phenotype of malaria specific T cells acquired *in utero*.

NIAID 1 R01 AI097262-01 8/7/12-7/31/16
PI: "Lymphatic Filariasis transmission and elimination in PNG" (D Tisch, PI).
This project will determine how to accurately measure lymphatic filariasis elimination program goals using available diagnostic/monitoring tools. Two study sites will be followed longitudinally to quantify and compare human and mosquito vector breakpoints in lymphatic filariasis transmission for application to ongoing disease elimination efforts.

**Completed Support**

FIC 1R24TW008801-02 8/31/10-8/31/12
Co-PI. Recovery Act Limited Competition: Framework Programs for Global Health Signature Innovations Initiative. "GhREAT: Global health Research Expanding Advanced Training". An innovative interdisciplinary post-doctoral training program for scholars from three disciplines: epidemiology, nursing, and anthropology. The program reflects the respective disciplines' distinct and integrated approaches to eliminating lymphatic filariasis (LF) and adding behavioral science components from the science of patient self-management in order to better understand how RCT study participants respond holistically to treatment for filariasis in low-income countries/regions

CWRU-Provost's Investment Fund 1/1/10-12/31/12
PI: "The Alliance for Global Health"
Alliance members from the participating Schools and the College. Based on our collective earlier experience with students who have been supported by the existing NIH Fogarty-supported Framework for Global Health.

FIC 1R01TW007872-05 9/15/06-7/31/12
Co-Investigator: "Changing dynamics of anopheline transmission of malaria" (P Zimmerman, PI)
This study proposes to provide insight into the fine- and medium-scale factors that contribute to village-by-village risk differences for mosquito-borne parasite transmission. It will also include refinement of strategies for monitoring and implementing control of mosquito-borne transmission of malaria and filaria in Papua New Guinea.

NIAID 1U19AI065717-05 8/15/05-4/30/11
PI: Core B "Data Management and Biostatistics Core". International Collaboration in Infectious Disease Research (ICIDR). "Mass drug treatment and vector control of filariasis" (J Kazura, Program Director)
The long-term goals of this multi-project ICIDR application are to advance knowledge of human, parasite and mosquito variables and related implementation and policy issues that will inform and enhance success of controlling disease morbidity and permanently stopping transmission of the filarial parasite *Wuchereria bancrofti* in Papua New Guinea, and by extension, other areas where lymphatic filariasis is endemic.

FIC 3R25TW007735-03SI 9/1/09-8/31/11
PI: ARRA Supplement to Framework Programs in Global Health: "Integrated Programs & Curricula for Global Health Education"

NCI 1 R01 CA134051-02 6/5/08-4/30/13
Role: Co-Investigator. “T cell Immunity and Endemic Burkitts Lymphoma”
The long-term goal of this proposal is to understand the etiology of endemic Burkitt’s lymphoma (eBL), the most prevalent pediatric cancer in equatorial Africa.

FIC 1 D43 TW007377-05 7/26/05-3/31/11
Co-Investigator “CASE-PNG Infectious Disease Research Training Program: Global Infectious Disease Research Training Program” (P Zimmerman, Program Director)
This application represents a new effort to develop a collaborative training program in infectious disease research between Case Western Reserve University and the Papua New Guinea Institute of Medical Research.

FIC/NIH 1R25 TW07735-03 9/15/06-8/31/10
PI: Framework Programs in Global Health: “Integrated Programs & Curricula for Global Health Education”. The overall goal of this program is to interest and retain undergraduate, graduate and professional students in international health related careers by expanding the perception of potential relevant fields, facilitating interdisciplinary study and providing opportunities for applied experiences.

NIH 5 U01 AI45473-05 9/1/99-6/30/07
Co-Investigator: “Urinary Schistosomiasis Determinants of Infection and Disease.”
This single project center examines underlying host immune mechanisms and genetic differences responsible for variable disease penetration in populations infected with the parasite *Schistosoma haematobium.* The international center for infectious disease research (ICIDR) is a collaborative project with investigators in Kenya based at the Ministry of Health and Kenya Medical Research Institute.

NIH/NIAID 5 U19 AI33061-10 9/30/99-6/30/06
Project Director: "Heterogeneity of Infection and Disease in Lymphatic Filariasis"
Co-Investigator "Project 1: Heterogeneity of Infection and Disease in Lymphatic Filariasis". In Project 1, to understand the role of host immunity in the pathogenesis of the major disease manifestations of bancroftian filariasis, why they are distributed heterogeneously in at-risk populations, and how control programs will affect this morbidity. The long-term goals of this ICIDR are to advance our understanding of the role of transmission dynamics, host immunity, and parasite genetic structure in the pathogenesis of bancroftian filariasis.

**BIOGRAPHICAL SKETCH**

| NAME **Wang, Bingcheng** | POSITION TITLE<br>Professor |
|---|---|
| eRA COMMONS USER NAME<br>**BINGCHENG_WANG** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Nanjing University, China | BS | 1982 | Chemistry |
| University of Wisconsin-Madison | PhD | 1991 | Toxicology/Oncology |
| The Burnham Institute (with Dr. Erkki Ruoslahti) | Postdoc | 1996 | Cell Adhesion & signaling |

**A. POSITIONS AND HONORS.**

**Positions**

| | |
|---|---|
| 1985-1991 | Research and Teaching Assistant, University of Wisconsin-Madison. |
| 1991-1994 | Postdoctoral Fellow, The Burnham Institute (La Jolla Cancer Research Foundation) |
| 1994-1996 | Research Associate, The Burnham Institute (La Jolla Cancer Research Foundation) |
| 1997-2002 | Assistant Professor, Department of Medicine and Pharmacology, Case Western Reserve University School of Medicine |
| 2003-2009 | Associate Professor with Tenure, Department of Medicine and Pharmacology, Case Western Reserve University School of Medicine |
| 2005-Present | Adjunct Associate Professor, Department of Chemistry, Cleveland State University |
| 2009-Present | Professor, Departments of Medicine, Pharmacology and Oncology, Case Western Reserve University School of Medicine |
| 2005-Present | Adjunct Professor, Graduate Training Program, Cleveland State University |
| 2009-Present | Adjunct Professor and Trainer, Molecular Medicine Graduate Program, The Lerner Research Institute, Cleveland Clinic Foundation |
| 2011-Present | Co-leader, Genitourinary Malignancies Program, Case Comprehensive Cancer Center, Case Western Reserve University |
| 2012 –Present | John A. and Josephine B. Wootton Professor in Cancer Research, Case Western Reserve University School of Medicine |

**Honors**

Prayer From Maria Foundation Award, 2010
FAMRI Investigator Award: 2008
Joan's Legacy Investigator Award, 2007
CaP CURE Awards, 2000
Prostate Cancer Foundation Award, 2003
California Tobacco-Related Disease Research Award 4IT0147 (1993-1995)
Human Oncology Training Fellowship (1987-1991)

**Federal Government Public Advisory Committee Services**

1. NIH-NCI: Cancer Molecular Pathobiology [CAMP] *Chartered Member*: 2013 to 2019
2. NIH Special Review Panel: Grants on "Research Answers to NCI's Provocative Questions", 2012
3. NIH-NCI: Cancer Molecular Pathobiology [CAMP] *ad hoc*: 2011-present
4. NIH-NCI: Tumor Progression and Metastasis (TPM) study section *ad hoc*: 2010-11
5. NIH Director's Opportunity for Research in Five Thematic Areas (RC4), June 2010
6. NIH-NHLBI. P01 Program Project Review Committee, Oct., 2009
7. NIH-NCI: Discovery, Development, and Diagnosis P01 Special Emphasis Panel, June 2009

8. NIH-NCI: Challenge Grant reviewer, 2009
9. NIH-NCI: Drug Discovery and Mol. Pharmacology (DMP) study section ad hoc: 2006, 2007, 2008.
10. NIH-NCI: Tumor Progression and Metastasis study section ad hoc, 2008-2010
11. US Department of Army, Prostate Cancer Research Program, Path-2 Review Panel, 2003
12. NIH-NHLBI Special Emphasis Panel, 2002

**Patents**

1. U.S. Patent Number 5,215,904. "*in situ* gene transfer to breast epithelial cells, which was one of the first three biotech patents issued in the U.S." Inventors: Michael N. Gould and Bing-Cheng Wang.
2. US Patent Number 8,222,253 B2. "Targeting EphA kinase by dobutamine and other small compounds", Issued July 17, 2012. Inventors: Myshkin, Eugene; Miao, Hui; Wang, Bing-Cheng
3. US Patent Number 12/519,294. "Peptide and Small Molecule Agonists of Epha and Their Uses in Disease". Inventors: Myshkin, Eugene; Wang, Bing-Cheng
4. US Patent Number 12/795,142. "EphA Kinase Cancer Diagnostic". Inventors: Miao, Hui; Wang, Bing-Cheng

**B. SELECTED PEER-REVIEWED PUBLICATIONS**

**Most relevant to the current application**

1. Miao, H., Burnett, E., Kinch, M. S., Simon, E., and Wang, B**.** (2000). EphA2 kinase activation suppresses integrin function and causes focal adhesion kinase dephosphorylation. **Nature Cell Biology** 2:62-69. PMID: 11331884.
2. Miao, H., Wei, B.-R., Peehl, D. M., Li, Q., Burnett, E., Alexandrou, T., Sedor, J. R., Schelling, J. R., and Wang, B. (2001). EphA kinase activation inhibits Ras/MAPK pathway. **Nature Cell Biology** 3:527-530. PMID: 10655584
3. Guo, H., Miao, H., Gerber, L., Singh, J., Denning, M. F., Gilliam, A. C., and Wang, B. (2006) Disruption of EphA2 kinase led to increased susceptibility to skin carcinogenesis. **Cancer Research** 66:7050-7058. PMID: 16849550
4. Himanen J, Goldgur Y, Myshkin E, Miao H, Nguyen M, Rajashankar KR, Wang, B.*, and Nikolov, D.* (2009). Ligand Recognition by A-Class Eph Receptors: Crystal Structures of the EphA2 Ligand-Binding Domain and the EphA2/ephrin-A1 Complex. **EMBO Report** 10:722-728, PMID: 19525919. *Co-corresponding authors.
5. Miao H, Li D-Q, Mukherjee A, Guo, H., Petty, A. Cutter J, Basilion J, Sedor J, Wu, J., Danielpour, D., Sloan, A. E., Cohen, M., and Wang, B.. (2009). EphA2 Mediates Ligand-Dependent Inhibition and Ligand-Independent Promotion of Cell Migration and Invasion via a Reciprocal Regulatory Loop with Akt, **Cancer Cell**, 16:9-20, PMID: 19573808.
   *This article was featured in **Nature** (461:149, 2009) under Research Highlights.
6. Wang, B.. (2011). Cancer cells exploit Eph kinases for invasion and metastasis: Tales of unwitting partners. **Science Signaling**. 4:pe28. PMID: 21632467
7. Myshkin, E. and Wang, B. (2003). Chemometrical classification of ephrin ligands and Eph kinases using GRID/CPCA approach. **Journal of Chemical Information and Computer Sciences** 43:1004-1010. PMID: 12767159
8. Deroanne, C., Valérie Vouret-Craviari, V., Wang, B. and Pouysségur J. (2003). EphrinA1 inactivates integrin-mediated vascular smooth muscle cell spreading via the Rac/PAK pathway. **Journal of Cell Sciences** 116:1367-1376. PMID: 12615978
9. Miao, H., Nickel, C., Cantley, L. G., Bernaddo, L., Bruggeman, L. and Wang, B. (2003) EphA kinase activation regulates epithelial branching morphogenesis. **Journal of Cell Biology** 162:1281-1292. PMID: 14517207
10. Miao, H., Guan, J.-L., Shen, T. L., Strebhardt, K., Paquale, E. B., and Wang, B. (2005) Inhibition of integrin-mediated cell adhesion and spreading, but not migration requires the catalytic activity of EphB3 kinase. (Published online Nov. 2004). **Journal of Biological Chemistry** 280:923-932. PMID: 15536074

*Recommended by the Faculty of 1000 as a "Must Read Paper",*
http://www.f1000biology.com/article/id/1023728/evaluation

11. Jun, G., Guo, G., Klein, E.E.K., Klein, R., Wang, J.J., Mitchell, P., Miao, H., Lee, K., Joshi, T., Buck, M., Chugha, P., Bardenstein, D., Klein, A., Bailey-Wilson, J.E., Gong, X., Spector, T.D., Andrew, T., Hammond, C.H., Iyengar, S.K., and Wang, B. (2009). Converging evidence from mice and humans show that EphA2 is associated with age-related cataract. **PLoS Genetics.** 5:e1000584. PubMed PMID:19649315; PubMed Central PMCID: PMC2712078.
12. Khan, S., Lakhe-Reddy, S., McCarty, J. H., Sorenson, C. M., Sheibani, A., Reichardt L. F., Kim, J., Wang, B., Sedor, J. R., and Schelling , J. R. (2010). Mesangial Cell Integrin □v□8 Provides Glomerular Endothelial Cell Cytoprotection by Sequestering TGF-□ and Regulating PECAM-1. **American Journal of Pathology** 178 :609-20. PubMed PMID:21281793.
13. Lu X, Guo H, Molter J, Miao H, Gerber L, Hu Y, Barnes EL, Vogel H, Lee Z, Luo G, Wang B. (2011) Alpha-fetoprotein-thymidine kinase-luciferase knockin mice: A novel model for dual modality longitudinal imaging of tumorigenesis in liver. **J Hepatol.** [Epub ahead of print 2010 Dec 7] PubMed PMID: 21354236.
15. H. J. Lee, H.J., Hota, P.K., Chugha, P., Guo, H., Miao, H., Zhang, L., Kim, S.J., Stetzig, L., Wang B.*, and Buck. M*. (2012). Refined NMR structure of a heterodimeric SAM:SAM complex. Characterization and manipulation of the EhpA2 interface leads to new cellular functions of SHIP2. **Structure**. 20:41-55 PMID:22244754.
    * Co-corresponding authors.
16. Petty, A.*, Myshkin, E.*, Qin, H.*, Guo, H., Miao H., Tochtrop, G.P., Hsieh, J.-T., Page, P., Acharya, C., MacKerell, A., Ficker, E., Song, J., and Wang, B. (2012) A Small Molecule Agonist of EphA2 Receptor Tyrosine Kinase Inhibits Tumor Cell Migration In Vitro and Prostate Cancer Metastasis In Vivo. **PLoS One** 7(8): e42120. doi:10.1371/journal.pone.0042120. *Equal contributors.

## C. RESEARCH SUPPORT

**ONGOING**

5R01CA155676 (Wang) 9/1/2011 – 6/30//2016
NIH/NCI
"EphA2 kinase in prostate cancer"
The major goals of this project are to investigate the role of EphA2 in promoting prostate cancer invasion and metastasis.
Role: Principle Investigator

5R01CA152371 (Wang and Miao) 6/7/10 to 4/30/15
NIH/NCI
"Akt-EphA2 Crosstalk in Glioma Invasion"
The goal of this project is to investigate the molecular basis underlying the diffuse infiltrative invasion of human high grade glioma, with a focus on role of Akt-EphA2 signaling axis.
Role: co- Principle Investigator

1R01DK077876-01 (Wang) 6/1/2008 - 5/31/2013
NIH/NIDDK (NCE)
"Eph kinase signaling in renal epithelial cells"
The goal of this project is to test the hypothesis that EphA kinases and their ephrin-A ligands are previously unrecognized regulators of renal epithelial morphogenesis in vitro and in vivo.
Role: Principle Investigator

NIH-NIDDK R01DK095832 (Bruggeman) 9/20/12 to 8/31/16
"Cell Junction Proteins in Podocyte Injury Repair"

The goal of this project is to characterize the role of how cell junction proteins contribute to kidney diseases.
Role: Co-investigator

NIH-NCI 5P30CA043703-22 (Gerson) 7/1/11 to 3/31/2018
Case Comprehensive Cancer Center Support Grant.
Role: Program Leader

072216_CIA (Wang) 7/1/2008 – 6/30/2013
FAMRI Foundation (NCE)
"EphA2 kinase as a target for treatment and early detection of lung cancer"
The goal of this project is to investigate whether EphA2 overexpressed on human lung cancer cells can be targeted for early detection and treatment of lung cancer.
Role: Principle Investigator

Research Award (Wang) 5/1/2010 – 4/30/2013
Prayers from Maria Foundation
"Eph/ephrin system in childhood glioma"
The goal of this project is to evaluate how Eph/ephrin system may contribute to malignant progression of childhood glioma
Role: Principle Investigator

**COMPLETED RESEARCH**

R01 CA92259 (Wang) 6/1/02 to 5/31/09
NIH-NCI
Title: EphA2 agonists as novel inhibitors of tumor progression
The goal of this project is to test whether native and peptide-based EphA2 agonists can be used in prostate cancer therapy.

**BIOGRAPHICAL SKETCH**

| NAME **Zhenghe Wang** | POSITION TITLE<br>Associate Professor |
|---|---|
| eRA COMMONS USER NAME **ZHENGHEWANG** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Sichuan University | B.S. | 1989 | Biology |
| Shanghai Institute of Immunology | M.S. | 1992 | Immunology |
| University of Virginia | Ph.D. | 2001 | Microbiology |
| Johns Hopkins University School of Medicine | Postdoctoral Fellow | 2001-2005 | Cancer Genetics |

**A. Positions and Employment**

1995-2001 Graduate student, Department of Microbiology, University of Virginia, Charlottesville, Virginia. Mentor: Dr. Michael Christman.
2001-2005 Postdoctoral Fellow, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University, Baltimore, Maryland. Mentor: Dr. Bert Vogelstein.
2005-2012 Assistant Professor of Genetics, Case Western Reserve University, Department of Genetics and Case Comprehensive Cancer Center, Cleveland, Ohio.
2006- Adjunct Staff Member of the Genomic Medicine Institute, Cleveland Clinic Foundation, Cleveland, Ohio.
2012- Associate Professor of Genetics, Case Western Reserve University, Department of Genetics and Case Comprehensive Cancer Center, Cleveland, Ohio.

**Other Experience and Professional Memberships**

2006-2008 Member, NCI cancer epidemiology and cancer prevention study section
2007 Grant review Committee, American Cancer Society Ohio division.
2009 Member, NCI GO grant study section.
2010 Member, American Association for Cancer Research
2011 NIH Special Emphasis Panel/Scientific Review Group 2011/05 ZRG1 PSE-B (04) M meeting

**Honors**

2001 Michael Peach Award Honorable Mention, University of Virginia
2005 Basic Research Award, The Sydney Kimmel Cancer Center at Johns Hopkins
2006 V Scholar
2008 Outstanding Junior Faculty Award, Department of Genetics, Case Western Reserve University

**B. Peer-reviewed Publications (Selected from 42 publications, in chronological order)**

1. **Wang Z,** Castano IB, De Las Penas A, Adams C and Christman MF. (2000) Pol kappa: A DNA polymerase required for sister chromatid cohesion. *Science* 289:774-9.
2. **Wang Z,** Shen D, Parsons W, Bardelli A, Sager J, Szabo S, Ptak J, Silliman N, Peters BA, van der Heijden MS, Parmigiani G, Yan H, Wang TL, Riggins G, Powell S, M,James, Willson KV, Markowitz S, Kinzler KW, Vogelstein B, and Velculescu VE. (2004) Mutational analysis of the tyrosine phosphatome in colorectal cancers. *Science* 304: 1164-1166. (Featured by Faculty 1000. http://f1000biology.com/article/id/1019248**)**
3. Samuels Y**, Wang Z,** Bardelli A, Silliman N, Ptak J, Szabo S, Yan H, Gazdar A, Powell SM, Riggins GJ, Willson JK, Markowitz S, Kinzler KW, Vogelstein B, Velculescu VE. (2004) High frequency of mutations of

the PIK3CA gene in human cancers. *Science* 304:554. (Featured by Faculty 1000. http://f1000biology.com/article/id/1004498).

4. Zhang X, Guo A, Yu J, Possemato A, Chen Y, Zheng W, Polakiewicz RD, Kinzler KW, Vogelstein B, Velculescu VE and **Wang Z**. (2007) Identification of STAT3 as a substrate of Receptor Protein Tyrosine Phosphatase T. *Proc Natl Acad Sci U S A* 104:4060-4064. (Featured by Faculty 1000. http://f1000biology.com/article/id/1065986/evaluation). PMC1802729.
5. Zhang X, Guo C, Chen Y, Shulha H, Schnetz M, LaFramboise T, Bartels S, Markowitz S, Weng Z, Scacheri P and **Wang Z.** (2008) Epitope tagging of endogenous proteins for genome-wide ChIP-chip studies. *Nature Methods* 5:163-5. (Featured by Faculty 1000 http://f1000biology.com/article/id/1104948/evaluation). PMC2435063.
6. Guo C, Zhang X, Fink S, Platzer P, Myeroff L, Wilson K, Willson J, **Wang Z*,** Markowitz S*.Ugene, a newly identified protein that is commonly overexpressed in cancer and binds uracil DNA glycosylase. *Cancer Research*, 2008, 68(15):6118-26. *****Equal contribution. PMC2614906.
7. **Wang Z**. Epitope tagging of endogenous proteins for genome wide Chromatin immunoprecipitation analysis. Methods in Molecular Biology (Chromatin Immunoprecipitation Assays). The Humana Press. 2009; 567:87-98. PMC2921570
8. Schnetz M, Bartels F, Shastri K, Balasubramanian D, Balaji R, Zhang X , Song L, Zhenghe **Wang Z**, LaFramboise T, Crawford G, and Scacheri P. (2009) Genomic distribution of CHD7 on chromatin tracks H3K4 methylation patterns. *Genome Research***,** 19:590-601. PMC2665778.
9. Du Z, Song J, Wang Y, Zhao Y, Guda, Yang S, Kao H, Xu Y, Willis J, Markowitz S, Sedwick D, Ewing R and **Wang Z**. (2010) DNMT1 stability is regulated by proteins coordinating de-ubiquitination and acetylation-driven ubiquitination. *Science Signaling* 3:ra80. (*Featured on the cover; a commentary on this paper was published in Science Signaling 4:pe3, 2011*). PMC3116231.
10. Zhao Y, Zhang X, Guda K, Lawrence E, Sun Q, Watanabe T, Iwakura Y, Asano M, Wei L, Yang Z, Zheng W, Dawson D, Willis J, Markowitz S, Satake M, and **Wang Z** (2010) Identification and functional characterization of paxillin as a target of protein tyrosine phosphatase receptor T. *Proc Natl Acad Sci USA* 107:2592–2597. (Featured by Faculty 1000. http://f1000biology.com/article/id/1954957/evaluation). PMC2823898.
11. Yang J, Huang J, Dasgupta M, Sears N, Miyagi M, Wang B, Chance M, Chen X, Du Y, An L, Wang Q, Lu T, Zhang X, **Wang Z** and Stark G. (2010) Reversible methylation of promoter-bound STAT3 by histone-modifying enzymes. *Proc Natl Acad Sci USA* 107:21499-21504. PMC3003019.
12. Zhang P, Zhao Y, Zhu X, Sedwick D, Zhang X, **Wang Z**. (2011) Cross-talk between phospho-STAT3 and PLCγ1 plays a critical role in colorectal tumorigenesis. *Molecular Cancer Research* 9:1418-28. PMC3196678.
13. Zhang P. Guo, A, Possemato A, Wang C, Beard L, Carlin C, Markowitz S, Polakiewicz R and **Wang Z**. Identification and functional characterization of p130Cas as a substrate of protein tyrosine phosphatase non-receptor 14. *Oncogene* June 18, 2012 (Epub ahead of print). NIHMS374721.
14. Lee H, Zhang P, Herman A, Yang C, Xin H, **Wang Z**, Hoon D, Riggs A, Forman S, Jove R, Yu H. (2012) Lysine acetylation of STAT3 is crucial for CpG methylation and gene repression in cancer. *Proc Natl Acad Sci U S A***.** 109:7765–7769.
15. Hao Y, Wang C, Bo C, Hirsch B, Song J, Markowitz S, Ewing R, Sedwick D, Liu L, Zheng W and **Wang Z**. (2013) Gain of direct interaction with IRS1 by the helical domain mutations of p110α is crucial for their oncogenic functions. *Cancer Cell* [in press]

## C. Ongoing Research Support

R01CA127590 (Wang, PI) 09/2007-07/2018
NIH/NCI
Mechanisms of suppression of colon cancer by receptor tyrosine phosphatase PTPRT

R21 CA160060-01A1 (Wang and Ewing PIs) 09/2012-08/2014
NIH/NCI
Developing novel technology for mapping dynamic oncoprotein interaction networks

V scholar grant (Wang, PI) 10/2006-
Dissecting tumor suppressor signaling of receptor tyrosine phosphatase T in colorectal cancer

1P50CA150964-01A1 (Markowitz, PI) 07/01/11-06/30/16
NIH/NCI
Case GI SPORE
Role: Basic science leader of Project 3
Title of Project 3: Identifying mutational drivers of late stage colon cancer

1R21CA149349-01A1 (Willis, PI) 09/2011-08/2013
Role: Co-Investigator
Identification of Significant Race Associated Colon Cancer Driver Gene Mutations

**Completed Research Support**

R01 HG004722 (Wang and Scacheri, PIs) 09/2008-06/2012
NIH/NHGRI
Development of a universal tagging method for genome-wide ChIP analyses

Conquer Cancer Now grant (Wang, PI) 06/2006-05/2008
Dissecting the cell signaling pathway regulated by PTPN13 in colorectal cancer

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Winkelman, Chris** | POSITION TITLE<br>Associate Professor |
| eRA COMMONS USER NAME **CWINKELMAN** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| Marquette University, Milwaukee, WI | BSN | 1977 | Nursing |
| Duke University, Durham, NC | MSN | 1983 | Nursing |
| Case Western Reserve University (CWRU), Cleveland, OH | PhD | 1999 | Nursing |

**A. Positions and Honors**

**PROFESSIONAL EXPERIENCE:**

1978-1980 Staff Nurse, Coronary Care Unit, St. Luke's Hospital, Milwaukee, WI
1979-1980 Charge Nurse, Surgical Intensive Care Unit (ICU), St. Mary's Hospital, Milwaukee, WI
1980-1982 Staff Nurse and Preceptor, Medical-Surgical ICU, Providence Medical Center, Seattle, WA
1982-1984 Staff Nurse, Surgical ICU, Veteran's Administration Medical Center, Durham, NC
1984 Visiting Instructor, University of North Carolina, Chapel Hill, NC
1984-1987 Clinical Nurse Education Specialist, Critical Care, UNC Hospitals, Chapel Hill, NC
1986-1992 Adjunct Faculty, School of Nursing, University of North Carolina, Chapel Hill, NC
1987-1992 Clinical Nurse Supervisor II, Neurosurgery ICU, UNC Hospitals. Chapel Hill, NC
1992-1998 Lecturer, Frances Payne Bolton School of Nursing, CWRU, Cleveland, OH.
1992-present Clinical Nurse, Trauma/Critical Care Float Pool, MetroHealth Medical Center, Cleveland, OH
1999-2010 Assistant Professor, Frances Payne Bolton School of Nursing, CWRU, Cleveland, OH
2010-present Associate Professor, Frances Payne Bolton School of Nursing, CWRU, Cleveland OH

**Other Experience and Professional Memberships**

1979-present American Association of Critical-Care Nurses
Member, Triangle chapter workshop (1984, 1986, 1988) and newsletter editor (1989, 1990)
Member and chair, national Education Special Interest Group (1985-1987)
Research Grant Review Committee (2000-2002, 2005-2006) (Ambassador, 2010-present)
1981-present: Certified as a critical care nurse (CCRN) through the American Association of Critical-Care Nurses
1983-present Sigma Theta Tau, Beta Epsilon Chapter, Member
2001 Fellow, National Institute of Nursing Research Summer Genetics Institute
2004-present Society for Critical Care Medicine (SCCM)
2005 Member, National Research Committee
1986-1992 Carolina/Virginia Chapter SCCM, Board Member (1987-1989)
2009 Founding member, Ohio Chapter SCCM
2012 National Program Committee
2002-present Reviewer, *Applied Nursing Research*
2004-present Council for the Advancement of Nursing Science. 2007 abstract reviewer
2004-present Certified as an Acute Care Nurse Practitioner (ACNP) through the American Nurse Credentialing Center.
2005-present ad hoc Reviewer, *American Journal of Critical Care*
2005-present American Academy of Nurse Practitioners, Member
2006-present Sentinel reader, McMaster Online Rating of Evidence Based Nursing Project (MORE-EBN)
2007-present Reviewer, *Critical Care Medicine*

2009-2011 Contributing editor, *Critical Care Nurse*
2010-present Editorial Board, *International Scholarly Research Network*

**Honors**

1993 Lambert Award for Scholarly Writing, Frances Payne Bolton School of Nursing, CWRU
1996-1997 AACN Educational Advancement Scholarship
Summer 2001 Fellow, Summer Genetics Institute, NIH, National Institute of Nursing Research
2001-2002 Glennan Fellow, CWRU
2002 Mary Kay Lehman Teaching Award, Frances Payne Bolton School of Nursing. CWRU
2005 Fellow, University Center for Innovation and Excellence in Teaching, CWRU
2011 Fellow, Society for Critical Care Medicine (FCCM) (Induction Houston February 2012)

**B. Selected peer-reviewed publications (in chronological order).**

1. **Winkelman, C**. & Maloney, B. (2005). Resource utilization and outcomes in obese, critically ill patients. *Clinical Nursing Research, 14*(4), 303-323.
2. **Winkelman, C**., Higgins, P.A., & Chen, Y-J. K. (2005). Measuring activity in the chronically critically ill. *Dimensions of Critical Care Nursing, 24*(6), 281-290.
3. Higgins, P.A., **Winkelman, C.**, Lipson, A.R., Guo, S-E., & Rodgers, J. (2007). Light measurement in the hospital: A comparison of two methods. *Research in Nursing and Health, 30*, 120-128.
4. **Winkelman, C**., Higgins, PA, Chen Y-J. K. & Levin, A. (2007) Cytokines in chronically critically ill patients after activity and rest. *Biologic Research for Nursing, 8(4)*, 261-71.
5. **Winkelman, C** & Best, K. (2009). Formula for success: Deliver enteral nutrition using best practices. (CE article) *American Nurse Today, 4*(3), 18-23.
6. **Winkelman, C**. (2009). Bedrest in health and critical illness: A body systems approach. *AACN Advanced Critical Care, 20*(3), 254-66.
7. **Winkelman, C.,** Maloney, B., Kloos, J. (2009). Impact of obesity on critical care resource utilization and outcomes. *Critical Care Nursing Clinics of North America, 21*(3), 403-22.
8. **Winkelman, C**. (2010) Investigating activity in hospitalized patients with chronic obstructive pulmonary disease: A pilot study. Heart & Lung, 39(4), 319-30. DOI: 10.1016/j.hrtlng.2009.09.004
9. Winkelman, C. & Peereboom, K. (2010). Staff-perceived barriers and facilitators to ICU patient mobility. *Critical Care Nurse, 30*(2); S13-6
10. Wiencek, C. & **Winkelman, C**. (2010).+ Chronic critical illness: Prevalence, profile, and pathophysiology. AACN Advanced Critical Care, 21(1): 44-61; quiz 63. DOI 10.1097/NCI.0b013e3181c6a162
11. **Winkelman, C.** & Chiang, L-C. (2010) Manual turns in patients receiving mechanical ventilation. Critical Care Nurse, 30(4), 36-44. DOI:10.4037/ccn2010106
12. Morris, P.E., Griffin, L., Goad, A., Thompson, C., Howard, A.E., Harry, B., Taylor, K., Berry, M., Hite, R.D., **Winkelman, C.,** Hopkins, R.O., Ross, A., Dixon, L., Leach, S., Small, R., Haponik, E. (2011).*+ Receiving Early Mobility During An ICU Admission Is A Predictor Of Improved Outcomes In Acute Respiratory Failure *American Journal of Medical Science, 341*(5), 373-7. DOI: 10.1097/MAJ.0b013e31820ab4f6
13. **Winkelman, C.**, Johnson, K.D., Hejal, R., Gordon, N., Rowbottom, J., Daly, J., Peereboom, K., Levine, A. (2012) Examining the Positive Effects of Exercise in Intubated Adults in ICU: A Prospective Repeated Measures Clinical Study. * + *Intensive & Critical Care Nursing* DOI: 10.1016/j.iccn.2012.02.007
14. Morrow, DA, Fang, JC, Fintel, DJ, Granger CB, Katz, JN, Kushner, FG, Kuvin, JT, Lopez-Sendon J, McAreavey D, Nallamothu, B, Page RL, Parrillo, JE, Peterson, PN, **Winkelman, C**; on behalf of the American Heart Association Council on Cardiopulmonary, Critical Care, Perioperative and Resuscitation, Council on Clinical Cardiology, Council on Cardiovascular Nursing, and Council on Quality of Care and Outcomes Research Circulation. (epub August 13, 2012; print September, 2012) Evolution of Critical Care Cardiology: Transformation of the Cardiovascular Intensive Care Unit and the Emerging Need for New Medical Staffing and Training Models. A Scientific Statement from the American Heart Association. *Circulation 126* ( ): 00-00. DOI: 10.1161/CIR.0b013e31826890b0

15. Farid K.J., **Winkelman C,** Rizkala A, & Jones K. (2012) * + Using Temperature of Pressure-related Intact Discolored Areas of Skin to Detect Deep Tissue Injury: An Observational, Retrospective, Correlational Study. *Ostomy Wound Management 58(*8), 20-31.

## C. Research Support

**Active**

1R01NR011186 (Morris, PI) 06/1/09-5/31/13
NIH/NINR
*Standardized Rehabilitation for ICU Patients with Acute Respiratory Failure*
This application will test the impact of an activity intervention for patients in the intensive care unit with acute respiratory failure requiring mechanical ventilation on hospital stay, functional measures, quality of life, biomarkers of inflammation, and cost outcomes.
Role: Co-Investigator

**Completed Research Support**

1R21NR010781 (Winkelman, PI) 05/01/09 – 04/30/12
NIH/NINR
*Dose of Early Therapeutic Mobility: Does Type or Frequency of Activity Matter?*
This innovative study will examine the impact of ETM activity on inflammatory biomarkers in adults receiving mechanical ventilation. It investigates for the first time the effect of passive range of motion and orthostatic conditioning on recovery in patients in the intensive care unit.

Winkelman, PI 10/01/09-3/31/10
Clinical & Translational Science Collaborative
*Myogenic Markers of Activity Response in ICU Adults*
The purpose of this pilot study is to investigate muscle-derived cytokines in a sample of critically ill adults who experienced prolonged mechanical ventilation.

P50 HG 003390 (Juengst, PI) 09/1/04 – 07/31/09, renewed through 7/2014
Human Genome Institute
*Center for Genetic Research Ethics and Law (Center for Excellence Grant)*
Specific Aims: To coordinate and support interdisciplinary research projects examining the ethical and legal issues arising in six kinds of human genetic research: genetic family studies, community-based genetic epidemiology, human genetic variation research, genome-wide scanning research, commercially-based research and research aimed at genetic enhancements.
Role: Faculty Associate

Winkelman (PI) 10/17/07 – 3/31/09
Hill-Rom
*Early Therapeutic Mobility: Patient Responses, Facilitators and Barriers*
The purpose of this study is to compare the effects of specific activities with and without an ETM protocol among patients who experience three or more days of mechanical ventilation. A second purpose is to examine staff/delivery system and patient factors that influence the initiation and progression of activity with and without an ETM protocol.

1 D09 HP03351(Clochesy, Project Director) 2004 – 2007
HRSA/BHPr
*Taking Critical Care from the Bedside to the Roadside*

The purpose of this training grant is to prepare acute care nurse practitioners to function in unstructured environments with an emphasis on air medical services.
Role: Co-Investigator

1 D64 HP03097 (Clochesy, Project Director) 2004 – 2007
HRSA/BHPr
*RN Residency Program in Critical Care*
The purpose of this training grant is to develop bedside critical care nurses over a six-month period using classroom, experiential learning and simulation technologies.
Role: Co-Investigator

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME<br>Jackson T. Wright, Jr., MD, PhD, FACP | POSITION TITLE<br>Professor of Medicine |
| eRA COMMONS USER NAME **JTWRIGHT** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| OHIO WESLEYAN UNIVERSITY | BA | 1967 | Zoology |
| UNIVERSITY OF PITTSBURGH, PITTSBURGH, PA | MD | 1976 | Medicine |
| UNIVERSITY OF PITTSBURGH, PITTSBURGH, PA | PHD | 1977 | Pharmacology |
| UNIVERSITY OF MICHIGAN, ANN ARBOR, MI | RESIDENT | 1977-80 | Internal Medicine |

## A. POSITIONS AND HONORS

1980-86 Assistant Professor of Pharmacology and Medicine
1986-90 Associate Professor of Medicine and Pharmacology (Tenured)
Medical College of VA, VA Commonwealth University
1990-96 Associate Professor of Medicine (Tenured), Case Western Reserve University
1990- Director, Clinical Hypertension Program, University Hospitals of Cleveland and Chief, Case Western Reserve University, Hypertension Section, Louis Stokes VAMC
1996- Professor of Medicine, Case Western Reserve University, University Hospitals Case Medical Center
2002- 2007 Program Director, General Clinical Research Center, Case Western Reserve University
2007-Present Director, William T Dahms Clinical Research Unit and Co-Chair Clinical Research Unit Directors Committee of the Clinical and Translations Science Collaborative

**HONORS**

1971-1973 Woodrow Wilson, Martin L. King Fellow
1972-1977 University of Pittsburgh Equalization of Higher Education Fund Award
1987 Fellow, American College of Physicians
1992-Present Vice Chair, NIDDK African-American Study of Kidney Disease in Hypertension and Cohort Steering Committee (AASK) Chair, Design Subcommittee, African-American Study of Kidney Disease in Hypertension (AASK)
1993-Present Vice Chair, NHLBI Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial (ALLHAT)
1996-2002 Chair, Executive Committee, ALLHAT
2002-Present Chair, ALLHAT Editorial Subcommittee
2007-Present Co-Chair, Chronic Renal Insufficiency Cohort Study Publications SubCommittee

## B. SELECTED PEER-REVIEWED PUBLICATIONS


1. Einhorn, PT, Davis BR, Wright JT Jr., Rahman M, Whelton PK, Pressel S. ALLHAT: Still providing correct answers after seven years. Curr Opin Cardiol 2010. July 25; (4): 355-365.
2. Alves TP, Wang X, Wright JT Jr, Appel LJ, Greene T, Norris K, Lewis J, for the AASK Collaborative Research Group. Rate of ESRD Exceeds Mortality among African Americans with Hypertensive Nephrosclerosis. J Am Soc Nephrol 2010; 21: 1361-69.
3. Appel LJ., Wright JT Jr, Greene T, Agodoa LY, Astor B, Bakris G, Cleveland W, Charleston J, Contreras G, Faulkner M, Gabbai F, Gassman J, Hebert L, Jamerson J, Kopple J, Kusek J, Lash J, Lea J, Lewis J, Lipkowitz M, Massry S, Miller E, Norris K, Phillips RA, Pogue V, Randall OS, Rostand S, Smogorzewski M,

Toto R, Wang X, for the AASK Collaborative Research Group. Intensive Blood Pressure Control in Hypertensive Chronic Kidney Disease. N Engl J Med 2010:363:918-29.

4. Appel LJ, Wright JT, Greene T. Intensive Blood-Pressure Control in Hypertensive Chronic Kidney Disease. N Engl J Med 2010, 363:2564-2566.
5. Gabriel Contreras C, Hu B, Astor BC, Greene T, Erlinger T, Kusek JW, Lipkowitz M, Lewis JA, Randall OS, Hebert L, Wright JT Jr, Kendrick CA, Gassman J, Bakris G, Kopple JD, and Appel LJ, for the African-American Study of Kidney Disease and Hypertension Study Group. Malnutrition–inflammation, cholesterol and cardiovascular disease in African Americans with hypertensive chronic kidney disease. JASN 2010; 21: 2131-42
6. Wright JT Jr, Lacourcière Y, Samuel R, Zappe D, Purkayastha D, Black HR. 24-Hour Ambulatory Blood Pressure Response to Combination Valsartan/Hydrochlorothiazide and Amlodipine/Hydrochlorothiazide in Stage 2 Hypertension by Ethnicity: The EVALUATE Study. J Clin Hypertens 2010; 12: 833-40.
7. Wright JT Jr., Agodoa LY, Appel L, Cushman WC, Taylor AL, Obegdegbe GG, Osei K, Reed J. Invited Editorial: New Recommendations for Treating Hypertension in Black Patients: Evidence and/or Consensus? Hyp 2010; 363:918-29
8. Townsend RR, Chirinos JA, Parsa A, Weir MA, Sozio SM, Lash JP, Chen J, Steigerwalt SP, Go AS, Hsu CY, Rafey M, Wright JT Jr., Duckworth MJ, Gadegbeku CA, Joffe MP. Central Pulse Pressure in Chronic Kidney Disease: A Chronic Renal Insufficiency Cohort Ancillary Study. Hypertension 2010; 56:518-524
9. Davis EM, Appel LJ, Wang X, Greene T, Astor BC, Rahman M, Toto R, Lipkowitz MS, Pogue VA, and Wright JT Jr for the AASK Disease and Hypertension Research Collaborative Group. Limitations of analyses based on achieved blood pressure: Lessons from the AASK and Hypertension Trial. Hyp 2011; 57:1061-1068.
10. Long-Term Follow-up of Participants with heart Failure in the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT). MSID# Ciculation AHA/2010012575. Circ 2011; 124: 1811-1818.
11. Renal Outcomes in Hypertensive Black Patients at High Cardiovascular Risk. MR Weir, GL Bakris, MA Weber, B Dahlof, RB Devereux, SE Kjeldsen, B Pitt, JT Wright, RY Kelly, TA Hua, RA Hester, E Velazquez and KA Jamerson. Kid Int advance online publication 21 December 2011.
12. Haywood, S, Ong T, Simpson LM, Stanford C, Weiss RJ, Alderman, J, Basile N, Black HR, Grimm, RH Jr., Hamilton BP, JulianFord L, Oparil S, Probstfield JL, Whelton PK, Wright, JT Jr., Michael H, Cushman WC, Barry R Davis BR, Pressel SL, Cutler JA, Einhorn PT, Charles E. Mortality and Morbidity during and after the Antihypertensive and Lipid-Lowering Treatment. Kidney International 2011; published online December 3, 2011.
13. Cushman WC, Davis BR, Pressel SL, Cutler JA, Einhorn PT, Ford CE, Oparil S, Probstfield JL, Whelton PK, Wright JT Jr., Alderman MH, Basile JN, Black HR, Grimm RH Jr., Hamilton BP, Haywood LJ, Ong ST, Simpson LM, Stanford C, Weiss RJ for the ALLHAT Collaborative Research Group. Mortality and Morbidity During and After the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial. J Clin Hyp 2012; Vol. 14, No. 1, 20-31.
14. Barzilay JI, Davis BR, Pressel SL, Cutler JA, Einhorn PT, Black HR< Cushman WC, Ford CE, Margolis KL, Moloo J, Oparil S, Piller LB, Simmons DL, Sweeney ME, Whelton PK , Wong, ND, Wright JT Jr. Long-Term Effects of Incident Diabetes Mellitus on Cardiovascular Outcomes in People Treated for Hypertension the ALLHAT Diabetes Extension Study. Cir Cardio Qual Outcomes 2012;5:153-162.
15. Liang L, Astor BC, Lewis J, Hu B., Appel LJ, Lipkowitz MS, Toto RD, Wang X, Wright JT Jr, Greene TH. Longitudinal Progression Trajectory of GFR Among Patients with CKD. Am J Kidney Dis. 2012;59(4):504-512.
16. Rahman M, Ford CE, Cutler JA, Davis BR, Piller LB, Whelton PK, Wright Jr, JT, Barzilay JI, Brown CD, Colon, Sr., PJ, Fine LJ, Grimm, Jr., RH, Gupta AK, Bainbridge C, Haywood LJ, Henriquez MA, Hamaythi E, Oparil S, Preston R, for the ALLHAT Collaborative Research Group. Long-Term Renal and Cardiovascular Outcomes in Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) Participants by Baseline Estimated GFR. Clin J Am Soc Nephrol 7; 989-1002, 2012.
17. Hu B, Gadegbeku, C, Lipkowitz, M, Rostand S, Lewis J, Wright JT, Appel L, Greene T, Gassman J, Astor B.

Kidney function can improve in patients with hypertensive chronic kidney disease. J Am Soc of Neph. 2012 Apr, 23:706-13.

18. Gabbai FB, Rahman M, Hu B, Appel LJ, Charleston J, Contreras G, Faulkner ML, Hiremath L, Jamerson KA, Lea JP, Lipkowitz MS, Pogue VA, Rostand SG, Smogorzewski MJ, Wright JT, Greene T, Gassman J, Wang X, Phillips RA; for the African American Study of Kidney Disease and Hypertension (AASK) Study Group. Relationship between Ambulatory BP and Clinical Outcomes in Patients with Hypertensive CKD.Clin J Am Soc Nephrol. 2012

## C. RESEARCH SUPPORT

### ACTIVE GRANT SUPPORT

NHLBI (Wright)
HHSN 260200900049C $23,140,105 9/1/2009-9/31/2018
5.54 calendar months
*Systolic Blood Pressure Intervention Trial (SPRINT) Clinical Center Network.* To determine whether treating systolic blood pressure (SBP) to a lower goal (<120 mmHg) than currently recommended (<140 mmHg) will reduce cardiovascular disease (CVD) events, renal progression, and cognitive decline in non-diabetic hypertensive patients.

NCRR UL1RR024989 (Davis)
Co-Chair Clinical Research Unit $65,500,000 9/1620/07-9/30/2012
4.2 calendar months
**Case Western Reserve University CTSA**

UO1 DK61021-09 (Wright) NIH/NIDDK - Co-I $1,484,616 9/28/2008-8/31/2013
0.6 calendar months
*Chronic Renal Insufficiency Cohort Study.* The major focus of this study is to recruit and follow a cohort (separate from the AASK Cohort) with renal insufficiency to determine the factors associated with progression of renal disease and cardiovascular adverse outcomes.

1U01HL103622 (Cuttler) $12,527,754 8/17/2010-4/30/2017
0.36 calendar months
NHLBI - Co-I
*Targeting Obesity and Blood Pressure in Urban Youth.* This proposal focuses on interventions to treat obesity and reduce BP in overweight/obese urban youth. Although childhood obesity is multi-factorial in origin with contributors at the child-family, schoolcommunity, and policy environments, few studies have targeted multiple environments and examined innovative behavioral interventions that may be beneficial to disadvantaged youth. This proposal addresses these deficits, focusing on lifestyle change through both child-family and school-community environments. It asks two main questions: (1) What is the differential impact on BMI and BP of three distinct psycho-educational interventions targeting the child-family environment? (2) Will an enriched school-community environment (echoing the interventions' messages and providing a venue for their implementation) influence the interventions' impact?

### APPLICATIONS PENDING REVIEW

*Trial of Antihypertensive Medications on Risk of Dysglycemia: Co-I.* The objectives of theTAMAD Study is to investigate the potential mechanisms of thiazide-induced dysglycemia, and to test whether intervention on hypokalemia or blockade of the renin-angiotensin-aldosterone system will prevent thiazide-induced dysglycemia.

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Zauszniewski, Jaclene A.** | POSITION TITLE<br>Kate Hanna Harvey Professor in Community Health Nursing |
| eRA COMMONS USER NAME **JZAUSZNIEWSKI** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| St. Alexis Hospital School of Nursing, Cleveland, OH | Diploma | 1975 | Nursing |
| Cleveland State University, Cleveland, OH | BA | 1981 | Psych/Interp Comm |
| John Carroll University, Cleveland, OH | MA | 1983 | Couns/Hum Serv |
| Case Western Reserve University (CWRU), Cleveland, OH | MSN | 1989 | Psych/Mental Health |
| CWRU, Cleveland, OH | PhD | 1992 | Nursing |

**A. Positions and Honors.**

**Positions and Employment**

1975-1984 Staff Nurse - Obstetrics, Head Nurse - Newborn Nursery, Nurse Recruiter, Patient Care Coordinator - Obstetrics/Gynecology, St. Alexis Hospital, Cleveland, OH
1984-1987 Staff Nurse - Psychiatry, Clinical Preceptor- Psychiatry, MetroHealth Hospital, Cleveland, OH
1987-1992 Staff Nurse - Psychiatry, Clinical Nurse - Psychiatry University Hospitals, Cleveland, OH
1988-1992 Instructor - Baccalaureate Nursing, Cleveland State University, Cleveland, OH
1992-2004 Assistant Professor, Associate Professor, CWRU, Cleveland, OH
1999-present Director, PhD in Nursing Program, CWRU, Cleveland, OH
2003-2012 Associate Dean for Doctoral Education, School of Nursing, CWRU, Cleveland, OH
2004-present Kate Hanna Harvey Professor of Community Health Nursing, CWRU, Cleveland, OH

**Honors**

1988 Sigma Theta Tau, Nursing Honor Society
1993 Virginia Trotter Betts Scholar, American Nurses Assoc./American Nurses Foundation
1994 New Investigator-Psychiatric Nursing, Society for Education & Research in Psychiatric Nursing
1998 Research Award, International Society of Psychiatric Consultation Liaison Nurses
1998 Research Award, Midwest Nursing Research Society
2000 Best Presentation of Research, American Psychiatric Nurses Association
2000 Excellence in Research, American Psychiatric Nurses Association
2002 Research Award, Psychiatric Mental Health Research, Midwest Nursing Research Society
2002 Best Presentation of Research, American Psychiatric Nurses Association
2003 Best Presentation of Research Data, International Society of Psychiatric Nurses
2004 Endowed Chair: Kate Hanna Harvey Professor of Community Health Nursing
2004 Fellow, American Academy of Nursing
2006 Great Women of the 21st Century, American Biographical Institute
2007 Hartford Geriatric Leadership Award, Midwest Nursing Research Society
2008 Senior Nurse Scientist, Midwest Nursing Research Society
2008 Best Contribution to Psychiatric Nursing, International Society of Psychiatric Nurses
2009 Melva Jo Hendrix Award for Mentorship, International Society of Psychiatric Nurses
2010 Hildegard Peplau Award, American Nurses Association
2011 Mentorship Award, Midwest Nursing Research Society
2011 Paper Citation Award, Association for Applied Psychophysiology and Biofeedback
2012 Research Award, International Society of Psychiatric Nurses
2013 Paper Citation Award, Association for Applied Psychophysiology and Biofeedback

**B. Selected peer-reviewed publications (most recent / relevant - from over 100 peer-reviewed publications)**

1. Zauszniewski, J.A. (1997). Teaching resourcefulness skills to older adults. *J Gerontol Nurs, 23*, 16-20.
2. Zauszniewski, J.A. (1997). Evaluation of a measure of resourcefulness in older adults. *J Nurs Meas, 5,* 71-86.
3. Zauszniewski, J.A., Picot, S.J.F., Debanne, S., Wykle, M., & Roberts, B.L. (2002). Psychometric characteristics of the Depressive Cognition Scale in African American women. *J Nurs Meas, 10*(2), 83-95.
4. Zauszniewski, J.A., Eggenschwiler, K., Preechawong, S., Roberts, B. L., & Morris, D. L. (2006). Effects of teaching resourcefulness skills in elders. *Aging Ment Health, 10,* 1-9.
5. Zauszniewski, J.A., Lai, C.Y., & Tithiphumturong, S. (2006). Development and testing of the Resourcefulness Scale for older adults. *J Nurs Meas, 14*(1), 55-66.
6. Zauszniewski, J.A., Bekhet, A.K., Lai, C.Y., McDonald, P.E., and Musil, C.M. (2007). Effects of teaching resourcefulness and acceptance on affect, behavior, and cognition of chronically ill elders. *Issues Ment Health Nurs*, 28(6), 575-592.
7. Musil, C.M., Warner, C.B., Zauszniewski, J.A., Wykle, M.L., Standing, T.S. (2009). Grandmother caregiving, family stress, and strain, and depressive symptoms. *Western Journal of Nursing Research, 31*(3), 389-408. PMCID: PMC2883890.
8. Zauszniewski, J.A., & Suresky, M.J. (2010). Psychometric testing of the Depressive Cognition Scale in women family members of seriously mentally ill adults. *Issues Mental Health Nurs, 31*(7), 483-490.
9. Zauszniewski, J.A., & Bekhet, A.K. (2011). Measuring use of resourcefulness skills: Psychometric testing of a new scale. *ISRN Nursing Online.*
10. Musil, C., Gordon, N., Warner, C., Zauszniewski, J., Standing, T., & Wykle, M. (2011). Grandmothers and caregiving to grandchildren: Continuity, change, and outcomes over 24 months. *Gerontologist,* 51(1), 86-100. PMCID: PMC3018867
11. Zauszniewski, J.A. (2012). Intervention development: Assessing critical parameters from the intervention recipient's perspective. *Applied Nurs Res, 25*(1), 31-39.
12. Zauszniewski, J.A., & Bekhet, A.K. (2012). Developing a screening measure for early detection of depressive symptoms: The Depressive Cognition Scale. *West J Nurs Res, 34*(2), 228-242. Zauszniewski, J.A. (2012). Resourcefulness. In J.J. Fitzpatrick & M. Wallace (Eds.), *Encyclopedia of Nursing Research* (pp. 448-449). New York: Springer Publishing.
13. Zauszniewski, J.A., Au, T.Y., & Musil, C.M. (2012). Resourcefulness training for grandmothers raising grandchildren: Is there a need? *Issues Mental Health Nurs, 33*(10), 680-686. PMCID: PMC Journal - In Process.
14. Zauszniewski, J.A., Au, T.Y., & Musil, C.M. (2013, in press). Biofeedback in grandmothers raising grandchildren: Effects on stress, emotions, and cognitions. *Biofeedback.*
15. Zauszniewski, J.A., Musil, C.M., & Au, T.Y. (2013, in press). Resourcefulness training for grandmothers raising grandchildren: Acceptability and feasibility of two methods. *Issues Mental Health Nurs.* PMCID: PMC Journal - In Process

**C. Research Support**

**Ongoing Research Support**

P30 NR010676-05 Moore (PI) 09/30/07-06/30/13
NIH/NINR
Center of Excellence to Build the Science of Self-Management: A Systems Approach
The SMART Center will prepare a critical mass of researchers to extend and disseminate knowledge related to self-management.
Role: Faculty

**Completed Research Support**

R21 NR010368-02 Zauszniewski (PI) 09/01/09-07/31/12
NIH/NINR
Teaching Resourcefulness to Women Caregivers of Elders with Dementia
To pilot test and refine an adapted intervention that teaches resourcefulness skills to women caregivers of elders with dementia. Such interventions will be useful in promoting optimal, healthy functioning among caregivers caring for elders with dementia so that they can continue to provide adequate care for their care recipients without sacrificing their own health and avoid placement of the elder in a long-term care facility.

KL2 RR024990-04 Kilanowski (PI) 09/17/07-05/31/12
NIH
Case/Cleveland Clinic Multidisciplinary Clinical Research Training Program
Subproject of Institutional Clinical and Translational Science Award (CTSA) (Davis, PI)
To support early career development of clinical researchers from a variety of disciplines.
The goal of this training grant is to train scholars who will conduct cutting-edge clinical research and to lead teams of investigators who recognize the mutuality of different research paradigms.
Role: Mentor

T32 NR009761-05 Moore (PI) 05/18/06-04/30/12
NIH/NINR
Multiple Morbidities in Vulnerable Populations: Nurse Scientist Training
The proposed predoctoral and postdoctoral training program provides research training for nurses pursuing research careers focused on vulnerable populations with multiple morbidities.
Role: Core Training Faculty

R21 NR010581 Zauszniewski (PI) 09/13/07-05/31/10
NIH/NINR
Promoting Resourcefulness in Grandmothers Raising Grandchildren
The goal of this R21 exploratory research grant is to pilot test and refine an adapted intervention that teaches personal and social resourcefulness skills to grandmothers raising grandchildren.

R15 NR009490 Gonzalez (PI) 08/01/06 – 07/01/10
NIH/NINR
Enhancing Resourceful Skills in Family Caregivers
This study determined effects of resourceful skill intervention on family caregivers' resourcefulness.
Role: Consultant

R01 NR005067 Musil (PI) 09/05/06-12/31/10
NIH/NINR
Grandmothers, Caregiving, Families, and Transitions
The specific aims of this continuation study are to: 1) extend the evaluation of grandmother's caregiving experience across time, including caregiving transitions; 2) evaluate grandchildren's perceptions of family functioning, support and depressive symptoms and compare these data with data from grandmothers; 3) examine effects of caregiving transitions on grandchildren, and 4) identify perceived needs for interventions.
Role: Co-Investigator

| BIOGRAPHICAL SKETCH | |
|---|---|
| NAME **Zhang, Amy Y.** | POSITION TITLE<br>Associate Professor of Nursing |
| eRA COMMONS USER NAME **AMYZHANG** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | YEAR(s) | FIELD OF STUDY |
|---|---|---|---|
| Peking University, Beijing, China | BA | 1982 | Journalism |
| Pennsylvania State University, University Park, PA | MS | 1992 | Clinical Psychology |
| Pennsylvania State University, University Park, PA | PhD | 1995 | Cross-Cultural Studies in Behavioral and Social Sciences |
| University of California, Berkeley, CA | Postdoctoral fellow | 1998 | Health Services Research |

**A. Positions and Honors**

**Positions and Employment**

1987-1989 Clinical Trainee, Psychiatric Outpatient Department, the Worker's Hospital of the Capital Steel Corporation, Beijing, China (the first Psychotherapy Clinic opened in China)
1989-1992 Clinical Trainee, Psychological Clinic, Department of Psychology, The Pennsylvania State University, University Park, PA
1995-1998 AHCPR, NIMH Postdoctoral Fellow, School of Public Health, University of California, Berkeley
1999-2000 Senior Research Associate, Department of Medicine, Case Western Reserve University (CWRU), Cleveland, OH
2001-2003 Assistant Professor of Medicine, Division of General Internal Medicine and Health Care Research, Department of Medicine, CWRU, Cleveland, OH
2003-2009 Assistant Professor, Frances Payne Bolton School of Nursing, CWRU, Cleveland, OH
2009- Associate Professor, Frances Payne Bolton School of Nursing, CWRU, Cleveland, OH
2011- Associate Professor, Department of Urology, School of Medicine, CWRU, Cleveland, OH (secondary appointment)

**Other Experience and Professional Memberships**

2005- Member, Institutional Review Board of the University Hospitals, Cleveland, OH
2007- Member, the Scientific Program Committee of the American Psychosocial Oncology Society
2009 NIH the Challenge Grant Integrated Review Group (ZRG1 RPHB-E)
6/2010-6/2011 Ad Hoc member. NIH National Institute of Nursing Research Initial Review Group (NRRC).
7/2011- Standing member. NIH National Institute of Nursing Research Initial Review Group (NRRC).
2011 NIH Healthcare Delivery and Methodologies (HDM) Integrated Review Panel

**Honors**

1986 Golden Key Prize for Books, awarded for the translation of *The Psychology of Emotion*. Sponsored by six leading Chinese book review magazines
1987 Second Place Award of Excellent Books in Social Science, awarded for the translation of Sigmund Freud's *The Interpretation of Dreams*. Sponsored by fifteen cities and provinces in Northern China
1987 National Best Seller Prize, awarded for the translation of *The Psychology of Emotion*. Sponsored by ten of the largest presses in Beijing, China
1995-1998 Recipient of the National Research Service Award (NRSA) for postdoctoral fellowship, the School of Public Health, University of California at Berkeley

2007-08 The Glennan Fellowship Awards, University Center for Innovation in Teaching and Education (UCITE), Case Western Reserve University, May 29, 2007

**B. Selected peer-reviewed publications (in chronological order)**

1. Zhang AY, Snowden LR, Sue S. (1998). Differences Between Asian and White Americans' Help Seeking and Utilization Patterns in the Los Angeles Area. *Journal of Community Psychology, 26*(4), 317-326.
2. Zhang AY, Snowden LR. (1999). Ethnic Characteristics of Mental Disorders in Five U.S. Communities. *Cultural Diversity and Ethnic Minority Psychology, 5*(2), 134-146.
3. Zhang AY, Scheffler R, Snowden L. (2000). The Effects of Program Realignment on Severely Mentally Ill Persons in California's Community-Based Mental Health System. *Psychiatric Services, 51*(9),1103-1106.
4. Zhang AY, Siminoff LA. (2003). Silence and Cancer: Why Do Families and Patients Fail To Communicate? *Health Communication, 15*(4), 415-29.
5. Zhang AY, Siminoff LA. (2003). The Role of the Family in Treatment Decision Making By Cancer Patients. *Oncology Nursing Forum, 30*(6), 1022-28.
6. Siminoff LA, Rose JH, Zhang AY, Zyzanski SJ. (2005). Measuring discord in treatment decision-making; progress toward development of a cancer communication and decision-making assessment tool. *Psycho-Oncology* 15, 528-540..
7. Zhang, A. Y., Strauss, G. J., & Siminoff, L. A. (2006). Intervention of Urinary Incontinence and Quality of Life Outcome in Prostate Cancer Patients. *Journal of Psychosocial Oncology,* 24 (2), 17-30.
8. Zhang, A. Y., Strauss, G. J., & Siminoff, L. A. (2007). Effects of Combined Pelvic Muscle Exercises and Support Group on Urinary Incontinence and Quality of Life of Prostate Cancer Patients. *Oncology Nursing Forum*, 34 (1), 47-53.
9. Zhang, A. Y., Galanek, J., Strauss, G. J., & Siminoff, L. A. (2008). What It Would Take For Men to Attend and Benefit From Support Groups After Prostatectomy for Prostate Cancer: A Problem-Solving Approach. *Journal of Psychosocial Oncology*, 16 (3).
10. Siminoff, L. A., Rose, J. H., Zhang, A. Y., & Zyzanski, S. J. (2008). The Cancer Communication Assessment Tool for Patients and families (CCAT-PF): A New measure. *Psycho-Oncology*, 17(12), 1216-24.
11. Zhang, A. Y., Zyzanski, S. J, & Siminoff, L. A. (2010). Differential patient-caregiver opinions of treatment and care for advanced lung cancer patients. *Social Science & Medicine,* 70 (2010), 1155–1158.
12. Zhang, AY, Zyzanski, SJ, & Siminoff, LA. (2011). Ethnic Differences in the Caregiver's Attitudes and Preferences for the Treatment and Care of Advanced Lung Cancer Patients. *Psycho-Oncolog,* 21, 1250-1253 (also published at http://onlinelibrary.wiley.com/doi/10.1002/pon.2031/pdf, Aug. 12 2011).
13. Zhang, AY, Gary, F. (2011). Discord of Measurements in Assessing Depression among African Americans with Cancer Diagnoses. *International Journal of Culture and Mental Health* (in print, published at http://www.tandfonline.com/doi/abs/10.1080/17542863.2011.623042 [DOI: 10.1080/17542863.2011.623042], Dec 13, 2011)
14. Zhang, AY. (2011). Discord of biological and psychological measures in a group of depressed African American and White cancer patients. *The Open Nursing Journal,* 5, 60-64 (http://www.benthamscience.com/open/tonursj/openaccess2.htm [DOI: 10.2174/1874434601105010060], Sept. 30, 2011).
15. Zhang, AY., Gary, F., & Zhu, H. (2012). What precipitated depression in African American cancer patients? Triggers and stressors. *Palliative & Supportive Care,* 10 (4), 279-286 (also published at http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=8518895 [DOI: 10.1017/S1478951511000861], Mar 22, 2012)

## C. Research Support

**Ongoing Research Support**

R01 CA127493-04 Zhang (PI) 01/01/09-11/30/12
NIH/NCI
Improving Urinary Continence and Quality of Life in Prostate Cancer Patients
This study tests a "STAY DRY" intervention program that combines biofeedback-based pelvic floor muscle exercises (PFME) with a telephone or support group intervention to improve persistent urinary continence, mood and quality of life.

P30 NR010676-05 Moore (PI) 09/29/07-06/30/13
NIH/NINR
Center of Excellence to Build the Science of Self-Management: A Systems Approach
The SMART Center will prepare researchers to extend and disseminate knowledge related to self-management, contribute to the development of biobehavioral research methods, and focus on critical issues related to health disparities. Role: Method Expert

**Completed Research Support (in past two years)**

R21 NR010368-02 Zauszniewski (PI) 09/01/09-07/31/12
NIH/NINR
Teaching Resourcefulness to Women Caregivers of Elders with Dementia
The major goal of this R21 exploratory research grant is to pilot test and refine an adapted intervention that teaches resourcefulness skills to women caregivers of elders with dementia.
Role: Co-Investigator

T32 NR009761-05 Moore (PI) 05/18/06-04/30/12
NIH
Multiple Morbidities in Vulnerable Populations: Nurse Scientist Training
The proposed predoctoral and postdoctoral training program provides research training for nurses pursuing research careers focused on vulnerable populations with multiple morbidities.
Role: Collaborating Faculty

R01 CA127493 REVISED Zhang (PI) 09/01/09-08/31/10
Admin Supplement: Economic Impact of Interventions Targeting Cancer Survivors and/or Their Families
The goal of this sub-analysis is to elucidate the cost and benefits for society and the health care provider and to aid the decision-making process for whether to incorporate the proposed intervention with standard care.

R03 CA115191 Zhang (PI) 07/17/06-06/30/09
Assessing Depression in African American Cancer Patients
The goal of this study is to investigate depressive experiences of African American cancer patients and identify their depressive symptoms in order to develop a culturally sensitive screening tool for depression.

Research Infrastructure Grant Zhang (PI) 01/01/08-12/31/09
CWRU/UHCMC Cancer Center
Using Biomarkers to Assess Depression in African American Cancer Patients
The study assesses correlation of biomarkers and self-reported depression of African American cancer patients in comparison with depressed Caucasian cancer patients.

| BIOGRAPHICAL SKETCH | | | |
|---|---|---|---|
| NAME<br>Zhang, Guo-Qiang (GQ) | POSITION TITLE<br>Professor, Electrical Engineering and Computer Science<br>Division Chief, Medical Informatics<br>Associate Director, Case Comprehensive Cancer Center<br>Co-director for Biomedical Informatics, Case Western CTSA | | |
| eRA COMMONS USER NAME<br>zhanggq | | | |
| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
| Nanking Aeronautical Inst. Tech. | B.S. | 7/1982 | Applied Mathematics |
| Peking University | M.S. | 7/1984 | Informatics Sciences |
| Cambridge University | Ph.D. | 1/1990 | Computer Science |

## A. Positions and Honors

**Positions and Employment**

| | |
|---|---|
| 1989-1996 | Assistant Professor, Dept. of Computer Sci., University of Georgia, Athens (on leave 91-93) |
| 1991-1993 | Research Assistant Professor, Artificial Intelligence Lab., University of Michigan, Ann Arbor |
| 1996-2000 | Associate Professor, Dept. of Computer Science, University of Georgia, Athens |
| 1998-1999 | Visiting Associate Professor, Dept. of EECS, Case Western Reserve University (CWRU) |
| 2000-2008 | Associate Professor, Department of Electrical Engineering and Computer Science, CWRU |
| 2008- | Professor, Department of Electrical Engineering and Computer Science, CWRU |
| 2008- | Professor (Secondary Appointment), Center for Proteomics and Bioinformatics, CWRU |
| 2010- | Professor (Secondary Appointment), Center for Clinical Investigation, CWRU |
| 2010- | Chief, Division of Medical Informatics, CWRU |
| 2010- | Associate Director for Cancer Informatics, Case Comprehensive Cancer Center |
| 2010- | Co-director, Biomedical Informatics Core, CTSA, CWRU |

**Other Experience and Professional Memberships**

| | |
|---|---|
| 1999-2006 | Program Committee Co-Chair, Int. Symposium on Domain Theory |
| 2000-2001 | Selection Panel. Computer Science Division, Chinese National Science Foundation |
| 2000-2006 | Editor-in-Chief, Semantic Structures in Computer, Springer-Verlag book series |
| 2003-2004 | Member, Program Committee, Int. Conf. Math. Foundations of Programming Semantics |
| 2004-2008 | Selection Panel, Computer Science Division, Science Foundation Ireland |
| 2005-2006 | Member, Program Committee, Int. Conf. on Formal Concept Analysis |
| 2005-2011 | Member, Program Committee, Int. Conf. on Conceptual Structures |
| 2006- | Editor-in-Chief, Studies in Informatics, Chapman & Hall/CRC book series |
| 2006- | Member, Program Committee, Int. Workshop on Applications of Semantic Technologies |
| 2007- | Member, Steering Committee, Ohio Bioinformatics Consortium |
| 2008- | Member, Financial Committee, American Medical Informatics Association |
| 2008- | Editorial Board Member, International Journal of Computational Bioscience |
| 2008- | Editorial Board Member, Springer Journal: Frontiers of Computer Science in China |
| 2009 | Keynote Speaker, 5th International Symposium on Domain Theory |
| 2009 | Program Chair, 4th Ohio Collaborative Conference on Bioinformatics |
| 2009 | Member, NIH-NIDCR Special Emphasis Panel *ZDE1 JH 24* |
| 2010 | Member, NIH Study Sections *ZRG1 IMST-B 14*, *ZRG1 BCMB-T 90*, *ZRG1 IMST-K 14* |
| 2010- | Leader, Informatics Alliance Working Group for University Strategic Initiatives, CWRU |
| 2010- | Editorial Board Member, Semantic Web Journal, IOS Press |
| 2010 | Member of Program Committee, International Semantic Web Conference |
| 2011 | Member of Scientific Program Committee, AMIA Joint Summits on Translational Science |

**Honors**

| | |
|---|---|
| 2000-2001 | Glennan Fellowship Award, Case Center for Instruction and Teaching Excellence |
| 2006-2007 | Best Poster Award, the ImTK Consortium for Multi-center Information Management |
| 2005-2009 | NIH Career Development Awardee, NIH |
| 2010-2011 | Change Leader, NSF Institutions Developing Excellence in Academic Leadership Award |
| 2010 | Best Paper Award Finalist, International Semantic Web Conference, 2010 |
| 2010 | Distinguished Paper Award, AMIA 2010 Annual Symposium |

**B. Selected Peer-reviewed Publications (Selected from over 80 peer-reviewed publications)**

1. Dai, J., Mueller, R., Szymanski, J., **Zhang, GQ** (2009). Towards WYDIWYS for MIMI using Concept Analysis, the 24th Annual ACM Symposium on Applied Computing, pp. 91-97, ACM Press.
2. **Zhang, GQ**, Siegler, T., Saxman, P., Sandberg, N., Mueller, R., Johnson, N., Hunscher, D., Arabandi, S (2010). VISAGE: A Query Interface for Clinical Research, Proceedings of the 2010 AMIA Clinical Research Informatics Summit, San Francisco, March 12-13, pp. 76-80, 2010. PMCID: PMC3041531
3. Ogbuji, C., Arabandi, S., Zhang, S., **Zhang, GQ** (2010). Segmenting and Merging Domain-specific Ontology Modules for Clinical Informatics, 6th International Conference on Formal Ontology in Information Systems, Toronto, Canada, May 11-14, pp. 414-427, 2010, IOS Press.
4. Chen, G, Choi, J.H., Song, B., Szymanski, J., **Zhang, GQ**, Tung, A., Kang, J., Kim, S., Yang, J (2006). ARCS: aggregated related column scoring scheme for aligned sequences. Bioinformatics, Vol. 22, pp. 2326-32. PMID: 16870930
5. **Zhang, GQ** and Bodenreider, O (2010). Large-scale, exhaustive lattice-based structural auditing of SNOMED CT. AMIA Annual Symposium Proc 2010, pp. 922-926, (**Distinguished Paper Award**). PMCID: PMC3041382 (acceptance rate 19%).
6. **Zhang, GQ** and Bodenreider, O (2010). Using SPARQL to test for lattices: application to quality assurance in biomedical ontologies. Proceedings of the 9th International Semantic Web Conference (ISWC 2010) Lecture Notes in Computer Science Vol. 6497, 2010 (**Best Paper Award Finalist)**.
7. Sahoo, S, Ogbuji, C,' Luo, L, Dong, X, Cui, L, Redline, S, **Zhang, GQ** (2011). *MiDas*: Automatic Extraction of a Common Domain of Discourse in Sleep Medicine for Multi-center Data Integration AMIA Annu Symp Proc. 2011; 2011: 1196–1205. PMCID: PMC3243207 (acceptance rate 19%).
8. Tran, V, Johnson, N, Redline, S, **Zhang, GQ** (2011). OnWARD: Ontology-driven Web-based framework for multi-center studies. Journal of Biomedical Informatics, Dec 2011, 1:S48-53. PMCID: PMC3251701
9. Huang F, Narayan S, Wilson D, Johnson D, **Zhang, GQ** (2011). A fast iterated conditional modes algorithm for water-fat decomposition. IEEE Trans Med Imaging, 30:1480-92.
10. **Zhang GQ**, Luo L, Ogbuji C, Joslyn C, Mejino J, Sahoo S (2012). An analysis of multi-type relational interactions in FMA using graph motifs. AMIA Ann. Symposium Proc 2012 (acceptance rate 18%).
11. Sahoo S, Zhao M, Luo L, Bozorgi A, Gupta D, Lhatoo S, **Zhang GQ** (2012). OPIC: Ontology-driven patient information capturing system for epilepsy. AMIA Ann. Symposium Proc 2012 (acceptance rate 18%).
12. **Zhang GQ**, Sahoo S, Lhatoo S (2012). From classification to epilepsy ontology and informatics. Epilepsia, 53;28-32, 2012.
13. Cui L, Bozorgi A, Lhatoo S, Zhang GQ, Sahoo S. EpiDEA: Extracting structured epilepsy and seizure information from patient discharge summaries for cohort identification. AMIA Ann. Symposium Proc 2012 (acceptance rate 18%).

C. Research Support

**Ongoing Research Support**

P20 NS076965-01 (Lhatoo, PI) 9/2011 – 8/2014
NIH-NINDS

Prevention and Risk Identification of SUDEP Mortality – the PRISM Project
This is a planning grant in response to RFA NS-11-006 to develop infrastructure for the development of efforts related to the creation of a Sudden Death in Epilepsy (SUDEP) "Centers Without Walls (CWOW)."
Role: Co-director for Bioinformatics and Co-Investigator

1R01HS019738 (Kushida, PI) 10/1/2010 - 10/1/2013
Agency for Healthcare Research and Quality (AHRQ), PROSPECT Studies
"Comparative Outcomes Management with Electronic Data Technology (COMET) Study"
Goal: To develop an electronic network that will enable the transfer of information from various hospitals and medical centers, patients and research subjects, different types and severity of medical problems, various equipment and test types, and across several patient visits; to allow physicians and scientists to access comprehensive information about their patients and research subjects, and the sharing of this information across several academic institutions may ultimately lead to improvement in medical outcomes; to conduct a study evaluating two common treatments for obstructive sleep apnea (OSA) and provide comparative data for determining the effectiveness of these treatments and enhancing clinical decision making in determining the optimal treatment strategies for patients with OSA.
Role: CWRU-PI

UT15439 (Welch, PI) 08/2008 - 07/2013
Ohio Board of Regents
"Ohio Bioinformatics Consortium"
Goal: CWRU is a partner with 23 institutions to attract and graduate an estimated 345 STEM students over a 5-year period. The program, "Ohio Consortium for Bioinformatics," is a true statewide collaboration, which will recruit Ohio students to the highly innovative field of bioinformatics and help make Ohio a leader in the bioinformatics industry.
Role: site-PI & Steering Committee Member

5P30 CA043703-16 (Gerson, PI) 08/01/07 - 07/31/13
National Cancer Institute
"Comprehensive Cancer Center Support Grant"
Goal: 1) to improve the prevention, diagnosis, and therapy of cancer through research; 2) to stimulate and support innovative, coordinated, interdisciplinary research on cancer diagnosis, treatment, and control; 3) to develop clinical applications of research discoveries and to make these applications available as quickly as possible; and 4) to develop cancer prevention and control activities to contribute to the reduction of cancer morbidity and mortality in Northeast Ohio and the surrounding region and nation.
Role: Associate Director for Cancer Informatics

UL1TR000439 (Davis, PI) 6/2012 - 05/2017
National Institutes of Health, NCATS
"Clinical and Translational Science Collaborative"
Goal: CWRU is one of the 60 medical research institutions receiving NIH Clinical and Translational Science Award to build a multi-institutional infrastructure with a vision to reduce the time it takes for laboratory discoveries to become treatments for patients, engage communities in clinical research efforts and train the next generation of clinical researchers.
Role: Co-director for Biomedical Informatics Core

**Recently Completed Research Support**
UL1-RR024989 (Davis, PI) 6/2007 - 05/2012
National Institutes of Health, NCRR
"Clinical and Translational Science Collaborative"

Goal: CWRU is one of the 60 medical research institutions receiving NIH Clinical and Translational Science Award to build a multi-institutional infrastructure with a vision to reduce the time it takes for laboratory discoveries to become treatments for patients, engage communities in clinical research efforts and train the next generation of clinical researchers.
Role: Co-director for Biomedical Informatics Core

UL1-RR024989-05S (Davis, PI; Zhang, PD) 8/2011 - 5/2012
National Institutes of Health, NCRR
"Dissemination of Physio-MIMI to the National CTSA Consortium"
Goal: This NCRR administrative supplement falls into the category of "Support of On-going Activities – Resources." The primary objective of this project is to accelerate the dissemination of the data integration framework developed under the Multi-Modality, Multi-Resource Environment for Physiological and Clinical Research (Physio-MIMI) project to the CTSA national consortium.
Role: PD

NCRR-94681DBS78 (Zhang & Redline, Multiple PI) 12/2008 - 12/2010
National Institutes of Health
"Physio-MIMI: Multi-Modality, Multi-Resource Environment for Physiological and Clinical Research"
Goal: To develop novel, flexible informatics methodologies, tools and infrastructure to facilitate the collection, management, and analysis of clinical, physiological, and genomic data and address how variations in physiology (for example, patterns of heart rate or sleep stages) vary in individuals with different genotypes, disease risk factors and health outcomes.
Role: PI

K25EB004467 (Zhang, PI)
National Institutes of Health, 1/8/05 – 31/7/09
"Phenotyping of Mice using Bioimaging"
Goal: One of the important components consists of projects in genetic phenotyping of small animals using in vivo bioimaging. The research will first tackle the technically easier problem of measuring and analyzing regional fat distribution in mice so as to identify potential subgroups with specific health problems; e.g., increased levels of visceral fat have been associated with insulin resistance, cardiovascular disease, and other metabolic syndromes. Building on this experience, the project will proceed to the identification of skeletal phenotypes using 3D micro-CT imaging.
Role: PI

**BIOGRAPHICAL SKETCH**

| NAME **Xiaofeng Zhu** | POSITION TITLE<br>Professor |
|---|---|
| eRA COMMONS USER NAME **ZHUXIAOFENG** | |

EDUCATION/TRAINING

| INSTITUTION AND LOCATION | DEGREE | MM/YY | FIELD OF STUDY |
|---|---|---|---|
| Peking University, Beijing, China | BS | 1986 | Mathematics |
| Peking University, Beijing, China | MS | 1989 | Mathematics |
| University of Cincinnati, Cincinnati, Ohio | MS | 1994 | Statistics |
| Case Western Reserve University, Cleveland, OH | PhD | 1999 | Epid. & Biostatistics |

**A. Positions and Honors**

Senior Lecturer, Beijing University of Aeronautics and Astronautics, Beijing, China. 1989 - 1992
Teaching Assistant, Department of Mathematics, University of Cincinnati, Cincinnati, Ohio. 1992 - 1994
Research Assistant, Department of Epidemiology and Biostatistics, School of Medicine, Case Western University, Cleveland, Ohio 1995 -1999
Research Assistant Professor, Department of Preventive Medicine and Epidemiology, Loyola University Chicago, Maywood, Illinois 1999-2001
Assistant Professor, Department of Preventive Medicine and Epidemiology, Loyola University Chicago, Maywood, Illinois 2001-2006 June
Associate Professor, Department of Preventive Medicine and Epidemiology, Loyola University Chicago, Maywood, Illinois 2006
Associate Professor, Department of Epidemiology and Biostatistics, Case Western Reserve University, Cleveland, Ohio, 2006-2011 June
Professor, Department of Epidemiology and Biostatistics, Case Western Reserve University, Cleveland, Ohio, 2011 June - present
Member of NIH Cardiovascular and Sleep Epidemiology Study Section, July 2009-

**Professional Membership**
The American Society of Human Genetics
The International Genetic Epidemiology Society
Fellow, the Royal Statistical Society

**B. Selected Peer-reviewed Publications (Selected from over 120 peer-reviewed publications)**


1. Zhu X, Boureki N, Southm L, Adeyemo A, Cooper RS, McKenzie CA, Luke A, Chen G, Elston R, Ward R. Linkage and association analysis of angiotensin I converting enzyme (ACE) gene polymorphisms with ACE activity and blood pressure. *Am J Hum Genet*. 2001 68:1139-1148.
2. Zhu X, Zhang S, Zhao H, Cooper RS. Association mapping using a mixture model for complex traits. *Genetic Epidemiology*. 2002 23: 181-196.
3. Zhu X, McKenzie Colin, Forrester T, Nickerson DA,Ulrich Broeckel, Heribert Schunkert, Angela Doering, Howard Jacob, Cooper RS, Rieder MJ. Localization of a small genomic region associated with elevated ACE. Am J Hum Genet. 2000; 67:1144-1153.
4 Zhu X. Chang C, Yan D, Weder A, Cooper R, Luke A, Kan D., Chakravarti A. Associations between hypertension and genetic variants in the genes of the rennin-angiotensin system. *Hypertension*. 2003 41: 1027-1034.

5. Zhu X, Yan D, Cooper RS, Luke A, Weder A, Chakravarti A. Linkage disequilibrium and haplotype diversity in the genes of the rennin-angiotensin system. *Genome Research*. 2003 13: 173-181
6. Zhu, X, Fejerman L, Luke A, Adeyemo A, Cooper RS. Haplotypes Produced from Rare Variants in the Promoter and Coding Regions of Angiotensinogen Contribute to Variation in Angiotensinogen levels. *Hum Mol Genet*. 2005 ; 14:639-43.
7. Zhu X, Luke A, Cooper RS, Quertermous T, Hanis C, Mosley TH, Gu C, Risch N, Rao DC, Weder A. Admixture mapping for hypertension loci with genome scan markers. Nature Genetics 2005; 37, 177-181.
8. Zhu X, Feng T, Li Y, Lu Q, Elston RC Detecting rare variants for complex traits using family and unrelated data. Genet Epidemiol. 2010;34(2):171-87
9. Feng T, Zhu X.Genome-wide searching of rare genetic variants in WTCCC data. Hum Genet. 2010;128(3):269-80.
10. Fox ER, Young JH,Li Y, et al. Zhu X,Levy D. Association of Genetic Variation with Systolic and Diastolic Blood Pressure among African Americans: the Candidate Gene Association Resource (CARe) Study. Hum Mol Genet, 2011, 20(11):2273-2284.
11. Zhu X, Young JH, et al. Combined admixture mapping and association analysis identifies a novel blood pressure genetic locus on 5p13: contributions from the CARe consortium. Hum Mol Genet. 2011;20:2285-95.
12. Zhu X, Cooper RS. Admixture Mapping Provides Evidence of Association of the VNN1 Gene with Hypertension. Plos One. 2007. 2 (11):e1244.
13. Qin H, Morris N, Kang SJ, Li M, Tayo B, Lyon H, Hirschhorn J, Cooper RS, Zhu X. Interrogating local population structure for fine mapping in genome-wide association studies. Bioinformatics. 2010 ;26:2961-8
14. Feng T, Elston RC, Zhu X. Detecting rare and common variants for complex traits: sibpair and odds ratio weighted sum statistics (SPWSS, ORWSS). Genet Epidemiol. 2011, 35:807-23 PMID: 21594893
15. The International Consortium for Blood Pressure Genome-Wide Association Studies. Genetic variants in novel pathways influence blood pressure and cardiovascular disease risk. Nature 2011. PMID: 21909115

## C. Research Support

**Ongoing**

1 R01 HG003054 Zhu (PI) 12/01/05-4/30/13
NIH/NHGRI
Statistical methods for analyzing high-throughput genotype data
The primary aims of this research are to: 1) Develop statistical methods to detect rare genetic variants using whole genome scan or sequence data. We will develop a variety of designs to cluster rare risk haplotypes and then perform association analysis with these risk haplotypes as a group in candidate gene association studies. 2) Develop statistical association methods that control for population stratification using whole genome data. 3) Develop statistical methods to jointly model admixture mapping and association in order to search for potential causal variants contributing to the admixture mapping signals. 4) Develop corresponding software that will be made available in the S.A.G.E.

1 R01HL086718 Zhu (PI) 08/15/07-06/31/12
NIH/NHLBI
Fine mapping of hypertension genes detected by admixture mapping in the FBPP
we propose to perform an admixture mapping study in African Americans using ancestry-informative SNP markers (AIMs), followed by gene-based case-control association studies in the well-characterized cohorts recruited by the Family Blood Pressure Program (FBPP). We will also conduct further replication studies in two independent African-American cohorts, and estimate population-specific risks for the identified variants in European-Americans, Mexican Americans, Nigerians and Jamaicans.

5 RO1 HL53353 Cooper (PI) 4/1/05-12/31/14
Role: Co-Investigator
NIH

Genetics of Hypertension in Blacks
This competitive renewal application requests support to continue a study of the genetics of hypertension in populations of West African origin. We propose to combine high-throughput genotyping with a sophisticated epidemiologic design to examine potential gene-environment interactions for known candidate genes.

RO1 HG005854 Li (PI) 09/09/10-6/30/13
Role: Co-investigator
NIH
Statistical Methods for Gene Mapping Studies in Admixed Populations
In this project, we will 1) Develop a unified statistical framework for genetic association analysis of unrelated individuals and family data sampled from admixed populations; 2) Develop statistical methods to identify SNPs that can explain an admixture mapping signal; 3) Develop statistical methods for association analysis of CNVs in admixed populations; Develop statistical methods for analysis of secondary phenotypes in a case-control GWAS in admixed populations; 5) Develop, distribute and support freely available software packages for methods proposed in this application.

**Completed**
5 R01 HL074166 Zhu (PI) 4/01/04-3/31/10
Role: Principal Investigator
NIH
Defining an Obesity QTL on Chromosome 3q
To examine the linkage peak centered on position 188 Chromosome 3q (7cM 1-LOD support interval), with the following step-wise strategy: (a) Genotype 80 SNPs in this region on 300 families (1,000 individuals) to confirm/narrow this peak. (b) Conduct linkage, linkage disequilibrium and admixture mapping to potentially further narrow the region. (c) Conduct resequencing and haplotype-based association studies for all candidate genes under the peak.

1 R03 HL65702 Zhu (PI) 4/01/01-3/31/03
Role: Principal Investigator
NIH/NHLBI
A Genome Scan for Obesity in a Multi-Ethnic Sample
Investigators will work closely with the FBPP Coordinating Center to find evidence for the consistency between results obtained from analyses of the genome scan performed and have the literature results summarized with those from the meta-analysis.