

## **Proposal Certificate Program in Clinical Research**

### **i. Approved graduate program(s) sponsoring the certificate program**

The Clinical Research Certificate program will be sponsored by the existing Clinical Research Scholars Program and administered within the Center for Clinical Investigation. The Center currently manages the Master of Science degree in Clinical Research. The certificate program will be administered by the Center's Academic Program Director, the Center's Academic Development and Training's Executive Committee, and a program coordinator. The Executive Committee will function as a steering committee for the certificate program and will be responsible for oversight of all admissions, academic, and curricular issues that may arise. The Executive Committee consists of a chairperson – the Academic Program Director – and two additional faculty members of the Clinical Research Scholars Program. The Academic Program Director is appointed by the Dean of the School of Medicine, and the additional two members of the Executive Committee are selected by the Program Director and approved by the Dean. The Executive Committee oversees the Master of Science degree program in Clinical Research as well as development of the CCI's other academic and training activities. The Executive Committee will be responsible for approving individuals into the program, handling any student or faculty concerns as arise, and periodic reviewing of the curriculum to assure maintenance of academic standards. The current Academic Program Director and chairperson of the Executive Committee is James Spilsbury, Ph.D.

Administrative aspects of the program will be conducted by the Center's Education Administrator/Manager. This position is currently filled by Natalie Milone, MA.

### **ii. Need and demand for the certificate program**

In its "Roadmap for Medical Research," the National Institutes of Health have highlighted the urgent need to speed biomedical advances and discoveries made in the laboratory to the individual patient and population as a whole. As part of the "Roadmap," the NIH launched the Clinical and Translational Science Awards (CTSA) program to energize clinical translational research and training. Currently, the CTSA program consists of a consortium of 55 medical research institutions located throughout the nation. In 2007, Case Western Reserve University (CWRU), the MetroHealth Medical Center, and the Cleveland Clinic Foundation were awarded one of the CTSA grants (NCRR CTSA Award UL1-RR02498) and formed the Clinical and Translational Science Collaborative, which has as a major goal to accelerate clinical translational research and training in the greater Cleveland area.

The Center for Clinical Investigation is located at CWRU's School of Medicine and serves as the academic home of the Clinical and Translational Science Collaborative. The Center currently directs a number of activities to enhance the clinical translational workforce and infrastructure in greater Cleveland, including a master's program (ongoing) and doctoral program (in development) in clinical research.

The proposed Certificate program will be administered by the Center for Clinical Investigation and will provide foundation training in clinical research methods for clinical-translational scientists. The proposed Certificate program targets clinicians and other health-science professionals who desire further training in clinical research skills to enhance their abilities as clinician-scientists, but who lack adequate time or resources to obtain a formal degree in clinical research. Health-science students, basic-science researchers, and other health-science professionals who desire greater knowledge and skill in clinical research may also be interested.

Experience with CWRU's existing master's program in clinical research illustrates the need for a certificate program. Enrollment in the annual introductory course for the program (CRSP 401 – Introduction to Clinical Research) consistently draws 40-80 people (Appendix 1, Table 1). Numerous residents and fellows from the University Hospitals Case Medical Center, the Cleveland Clinic Foundation, and MetroHealth Medical Center attend (Appendix 1, Table 2). After taking the course, several people have applied to the master's program, but others have cited cost or time commitment as reasons not to pursue the degree. The Certificate program will provide a more feasible alternative for residents, fellows, faculty, and other individuals who are interested in conducting clinical research or collaborating with other clinician-scientists who conduct clinical research.

Similar to CWRU, other CTSA awardees nationwide have experienced an expressed need for a certificate program, and 9 of them have developed certificate programs. For example, the certificate program at the University of Cincinnati, the closest existing certificate program in Ohio, started enrolling students in the summer of 2009. As of October 2010, 6 people completed the certificate and 20 were enrolled. Of note, the proposed CWRU Certificate program will not compete with the Cincinnati program because our program will draw from the local pool of students and trainees at the affiliated hospitals in Cleveland.

We anticipate approximately 8 individuals per year will enroll in the program during the initial 1-3 years, with increasing participation in subsequent years.

### iii. Statement of educational objectives of the certificate program

The proposed Certificate program is designed to provide a firm grounding in the method and conduct of patient-oriented clinical research. After completion of the program, graduates will be better able to conduct clinical research, as well as collaborate with other clinician-scientists conducting clinical research. Based on the core competencies for the Master of Science degree in Clinical Research, we have developed a set of core competencies and educational objectives for the certificate program. Upon completion of the Certificate Program, individuals will be able to:

Domain	Core Competency	Coursework Supporting Competency
Formulation of Clinical Research Questions	Formulate important, well-defined clinical research question that are feasible to address.	CRSP 401, 402
	State succinct research questions that can be answered in specific ways, including posing and testing clinical/translational research hypotheses.	CRSP 401

<b>Domain</b>	<b>Core Competency</b>	<b>Coursework Supporting Competency</b>
	Understand relevant stakeholders in clinical research endeavors: patient groups, practitioners, policymakers	CRSP 401
<b>Literature Critique</b>	Critique and interpret results of published studies in a balanced and evidence-based fashion.	CRSP 402
	Assess major sources of bias and variations in previous studies.	CRSP 402
	Interpret previous literature/studies in a causal framework.	CRSP 402
	Place a study in the context of existing research along a translation continuum (laboratory to patient to population).	CRSP 402
<b>Study Design</b>	Describe possible study designs for addressing a research question (i.e., cohort, clinical trials, case-control, cross-sectional, genetic epidemiology studies, focus group, etc.), explaining when each study design is appropriate and the strengths and weaknesses of each.	CRSP 401, 402
	Identify a target population for a research project.	CRSP 401
	Determine expertise and resources needed to implement all components of a research project.	CRSP 401
	Design and write a protocol for clinical/translational research study	CRSP 401
<b>Analytic Methods</b>	Analyze quantitative data, working with professional methodologists, as needed.	CRSP 431
	Use the paradigms and methods in statistical science, including various sub-fields of epidemiology.	CRSP 431, 402
	Demonstrate firm understanding of the fundamental concepts of statistical reasoning, mostly traditional (frequentist), but also Bayesian.	CRSP 431
	Frame scientific questions in statistical terms; relate/translate statistical results back to the scientific questions.	CRSP 431
	Match statistical approaches with different research designs.	CRSP 431
	Distinguish research questions that require inference methods from those that require estimation methods from those that require exploratory strategies, such as data mining and statistical learning methods.	CRSP 431
	Recognize potential sources of bias/confounding and apply appropriate analytic techniques to assess and reduce such problems.	CRSP 431, 402
	Describe the differences between confounding, effect modification, and mediation.	CRSP 431, 402
	Build and compare sound statistical models that reflect alternative hypothesized biomedical mechanisms. This includes knowing how different types of outcome data (continuous, binary, multinomial, count, time-to-event) require different statistical models.	CRSP 431
	Relate the mathematical assumptions inherent in a particular statistical method to what real effect their violations have on the actual analyses.	CRSP 431
	Explain how traditional methods (based on mathematical models) can be buttressed/replaced by modern computationally intensive methods (e.g. bootstrapping).	CRSP 431
	Present statistical information, including tables and graphics.	CRSP 431
	Demonstrate proficiency in at least one statistical software system.	CRSP 431
Appreciate the issues associated with the unreliability and bias in measurements and how this can affect data analysis and interpretation.	CRSP 431, 402	
<b>Research Ethics</b>	Understand fundamental ethical, legal, and regulatory issues in clinical research. Includes various topics: Belmont Report, informed consent; IRBs, risk-benefit assessment; recruitment, compensation and coercion; commercialization; conflicts of interest; data safety monitoring.	CRSP 401, CRSP 603, CREC certification

#### **iv. Curriculum for the certificate program.**

A total of 4 courses totaling 11 credit hours are required for successful completion of the program. These courses are currently being offered as part of the Master of Science Program in Clinical Research. No new courses are needed. In addition, individuals must successfully complete the Continuing Research Education Credit (CREC) curriculum to complete the certificate program. Descriptions of the courses and CREC requirement follow:

##### **CRSP 401 (3 credit hours) - Introduction to Clinical Research**

This course is designed to familiarize students 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 mechanisms 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 (3 credit hours) - Study Design and Epidemiologic Methods**

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 hypotheses about what factors may cause a given condition. The course introduces methodologic 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 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, and effect modification.

##### **CRSP 431 (3 credit hours) - Statistical Methods I**

This course covers the application of statistical techniques in the biomedical sciences. Content includes basic probability theory, random variables, distribution functions, point and interval estimation, regression, and correlation. The course involves the use of packaged statistical programs (e.g., R).

##### **CRSP 603 (2 credit hours) – Research Ethics and Regulation: Emerging Issues and Ongoing Challenges**

This course introduces students to the ethical, policy, and legal issues raised by research involving human subjects. Topics include (among others): regulation and monitoring of research, research in the developing world; research with special populations; stem cell and genetic research; commercialization and conflicts of interest; informed consent; study recruitment; risk-benefit assessment; the use of deception and placebos.

The required courses will be offered every year. CRSP 401 is offered Monday through Friday, 3 hours daily for over a 3-week period in July to accommodate clinician schedules. CRSP 402 and

431 are offered in the Fall semester. CRSP 603 has most recently been offered in the Fall semester, but may move to the Spring semester. Because CRSP 401 is the recommended preparation for CRSP 402, the anticipated order of courses would be: CRSP 401 (summer), with the other CRSP courses taken in subsequent Fall semester(s). However, there is no requirement that the coursework be taken in a specified order or period of time.

### **Certificate Curriculum for Medical Students**

Counterpart courses for CRSP 401, 402, and 431 are currently available to medical students attending either the University Program or the Cleveland Clinic Lerner College of Medicine (CCLCM):

#### **CMED 401 (3 credit hours) - Introduction to Clinical Research**

This course is designed to provide an overview of skills necessary to plan and conduct clinical research. The goals of the 15-week course are to learn the basic skills necessary to develop and describe a clinical research project and apply these skills by working with a research mentor to develop a project proposal, which can be submitted for funding. Special emphasis is placed on study design and statistical considerations, ethical and legal considerations of clinical research, and specific methodologies such as cost-benefit studies, analyses of large data sets, outcomes research, qualitative methods in clinical research, and development of the necessary components of a written research proposal. Students and faculty devote the last session of the course to conducting a mock-NIH review of their proposals.

#### **CMED 403 (3 credit hours) - Introduction to Clinical Epidemiology**

This course introduces basic concepts of epidemiology, with specific focus on application of these concepts in the clinical research arena. Topics include: measures of disease frequency and the strength of their relationships with possible causative factors; primary observational research designs; clinical trials; interpretation of diagnostic and screening tests, and designs for assessing whether disease screening benefits patients; threats to research validity, including selection and measurement biases and confounding; and ethical and regulatory issues in the conduct of human research.

#### **CMED 402 (3 credit hours) - Statistical Science for Medical Research**

This course introduces core concepts and methods of statistical inference for interpreting and precisely communicating information from health science data, with emphasis on clinical research. A comprehensive perspective on statistical modeling unifies several important methods in order to encourage recognition of the breadth and power of modern biostatistics and its role in the health sciences.

CMED 401 is offered in the Spring semester, and CMED 402 and 403 are taught in the Summer.

There is currently no counterpart course for CRSP 603 at the CCLCM; students in the CCLCM will be required to take CRSP 603.

### **Continuing Research Education Credit (CREC) Certification**

CREC is CWRU's program to provide documented training in the protection of human participants in research that is conducted at University Hospitals Case Medical Center, the

MetroHealth System, and CWRU. Researchers from the Louis Stokes Cleveland Department of Veterans Affairs Medical Center and the Cleveland Clinic may also participate. CREC subscribes to the training program that was developed and is currently offered online by the Collaborative Institutional Training Initiative (CITI), an organization founded in 2000 to develop web-based training in human subjects research protections. As of May 2010, the CITI Program has been utilized by over 1130 participating institutions and facilities from around the world. Individuals who complete the CITI Basic Course in The Protection of Human Research Subjects are certified for 3 years to conduct human subjects research, with continuing certification possible through completion of other Office of Research Administration and CITI educational activities. The Basic Course consists of 18 modules and covers the following topics: History and ethical principles; Basic Institutional Review Board (IRB) regulations and review Process; Informed consent; Social and behavioral research for biomedical researchers, Records-based research; Genetic research in human populations; Research with protected populations – vulnerable subjects; Group harms: FDA-regulated research, HIPAA and Human Subjects Research; Workers as research subjects; Conflicts of interest in research involving human subjects. The basic course takes approximately 3 hours to complete.

To obtain the Certificate in Clinical Research, individuals must be CREC-certified. CREC certification is administered through CWRU's Office of Research Administration and equivalent offices at the Cleveland Clinic, University Hospitals, and MetroHealth Center. Individuals who receive CREC certification are provided a certificate to this effect, and their current CREC-certification status is monitored by the institutions' offices of research administration.

#### **v. Justification for the number of credit hours for the certificate program.**

The Clinical Research Certificate program is a 11 credit hour program. Students who successfully complete the required coursework will receive a Certificate in Clinical Research issued by the Center for Clinical Investigation. Based on consideration of the critical competency-knowledge areas described above, the required 11-credit hour coursework for the Certificate program was identified: Introduction to Clinical Research; Study Design and Epidemiologic Methods; Statistical Methods 1, and Research Ethics and Regulation. Required CREC certification takes approximately 3 hours to complete. Credit hour requirements and the breadth of curricula of several existing certificate programs in clinical research were also considered (Appendix 2). The examined programs range from 6 to 24 required credit hours and cover similar information.

#### **vi. Entrance, performance, and exit standards for the certificate program.**

**Entrance Standards:** Entrance to the Certificate program will be administered by the Center for Clinical Investigation. Individuals who want to participate in the program will complete an application form that includes a brief personal statement describing the reason(s) for seeking clinical research training and a recent CV or resume.

We expect that most applicants to the certificate program will have already obtained or are enrolled in a program to obtain an advanced clinical (e.g., MD, MSN, DMD) or academic (MS, PhD) degree. However, we also anticipate that research assistants, study recruiters, or other

members of research teams working at CTSC institutions, who already have a baccalaureate degree or higher, will be interested in the certificate program. Thus, to include all these individuals, we will require that applicants must have already attained a baccalaureate degree to be admitted to the certificate program. Per CWRU School of Graduate Studies requirements, individuals who are not already graduate-degree-seeking students at CWRU must submit to the School of Graduate Studies a completed non-degree application form. Individuals who are not faculty, staff, or employees of CWRU must also submit a transcript or copy of their diploma, documenting completion of a baccalaureate degree. Per School of Graduate Studies requirements, non-degree-seeking individuals will not need to provide their Test of English as a Foreign Language (TOEFL).

Individuals will be accepted into the program based on the Executive Committee's review of the personal statement and any supporting documentation required by the School of Graduate Studies. Majority vote of acceptance by the Committee members will be necessary for admittance. Once accepted into the Certificate program, participants will register for the courses through the Student Information System.

The program will have rolling admissions, and students will be able to start taking courses in the summer, fall, or spring semester. The coursework for the Certificate will be listed on the official CWRU transcript. However, the Certificate in Clinical Research will be issued by the Center for Clinical Investigation, not the University. Although course credits will appear on the official CWRU transcript and be transferable to fulfill requirements for advanced degrees, the certificate itself will not appear on the official CWRU transcript.

**Length of Program:** Once accepted into the program, individuals will have 3 calendar years to complete the requirements.

**Performance Standards:** A grade of B or higher in each graded course will be required for successful completion of the Certificate program. Enrollees will be responsible for keeping track of the courses they take. To oversee students' progress in the program, enrollees will be required to submit a one-page Program Progress Checklist to the Education Manager at the end of each semester indicating the course(s) completed that semester. The Education Manager will notify the Executive Committee if any students are not making an adequate progress towards the Certificate. The Committee will make recommendations for remediation or any further action to assist students in successfully completing the program.

**Exit Standards:** Students who complete all required coursework will submit a checklist to the Center for Clinical Investigation notifying the Center for Clinical Investigation's Education Administrator/Manager that all coursework is completed. Students will also submit a copy of their CREC certification. This administrator will verify with the registrar's office that all requirements have been met. After this verification, the Academic Program Director will approve the awarding of the certificate in writing, and the Administrator/Manager will issue a certificate to the enrollee, documenting completion of the program.

#### **vii. Faculty expertise contributing to the certificate program.**

Faculty responsible for the Certificate program will be drawn from the CWRU School of Medicine's Department of Epidemiology and Biostatistics, the Department of Medicine, the Center for Clinical Investigation, the MetroHealth Medical Center, and the Cleveland Clinic Lerner College of Medicine. Faculty members currently responsible for the required coursework are:

### **CRSP 401 – Introduction to Clinical Research**

#### **Lecturer & Coordinator**

Doug Einstadter, MD, MPH

Professor, Department of Medicine, CWRU School of Medicine; Member, Center for Health Care Research and Policy; Staff Physician, Department of Medicine, MetroHealth Medical Center. Research interests include: use of large databases in health services research; application of geographic information systems to health services research; use of informatics to improve quality of care.

#### **Lecturers**

David Aron, MD, MS

Professor, Department of Medicine, CWRU School of Medicine; Associate Chief of Staff for Education, Louis Stokes Cleveland VA Medical Center; Director, VA National Quality Scholar Fellowship Program in Ohio; Director, Center for Quality Improvement Research, VA Medical Center.

Shari Bolen, MD, MPH

Assistant Professor, Department of Medicine, CWRU School of Medicine; Physician, Division of Internal Medicine, MetroHealth Medical Center. Dr. Bolen conducts health services research in diabetes and obesity, with an emphasis on ways to improve care. Research interests include: comparative effectiveness, systematic reviews/meta-analyses.

Randall Cebul, MD

Professor, Department of Medicine, CWRU School of Medicine; Director, Center for Health Care Research and Policy, MetroHealth Medical Center; Director, Better Health Greater Cleveland. Research interests involve: epidemiologic methods; information technology and the decision sciences to examine and improve health care delivery, emphasizing preventive services and the care and outcomes for persons with chronic illnesses.

Philip Cola, MA

Vice-President, Research and Technology, IRB Administrative Office Head, University Hospitals Case Medical Center. Areas of expertise include: ethical conduct of research, research regulations.

David Kaelber, MD, PhD, MPH

Assistant Professor, Departments of Medicine and Pediatrics, CWRU School of Medicine; Chief Medical Informatics Officer, Division of Internal Medicine and Pediatrics, MetroHealth Medical Center. Research interests include: medical informatics, medical education, chronic diseases (hypertension and obesity) in children and adolescents.

Steven A. Lewis, MS, MBA

Research Biostatistician, MetroHealth Medical Center. Research interests consist of: categorical data analysis, generalized linear models, multivariate methods, sample size determination, and data visualization.

Thomas Love, PhD

Associate Professor, Department of Medicine, CWRU School of Medicine; Director, Biostatistics and Evaluation Unit, Center for Health Care Research and Policy, MetroHealth Medical Center. Research interests include: biostatistics, observational studies and propensity methods, risk adjustment, health information technology, education.

Joe Sudano, PhD

Assistant Professor, Department of Medicine, CWRU School of Medicine; Senior Researcher, Center For Health Care Research and Policy, MetroHealth Medical Center; Associate Director of Education, Center for Reducing Health Disparities, MetroHealth Medical Center. Research interests include: health care disparities; social determinants of health; measurement equivalence, validity, and item-response theory in cross-cultural health status measurement; health outcomes research.

Tracy J. Wilson-Holden

Director, Research Integrity and Education, Office of Research Compliance, CWRU. Area of expertise: ethical conduct of research, especially management of research data.

Mark Votruba, PhD

Associate Professor, Department of Economics, Weatherhead School of Management; Director, Health Economics Research Unit, Center For Health Care Research and Policy, MetroHealth Medical Center. Research Interests include health economics (allocation of medical resources, incentives for care, insurance markets) and public economics (social program participation, social interactions effects).

### **CRSP 402 – Study Design and Epidemiologic Methods**

Doug Einstadter, MD, MPH

Professor, Department of Medicine, CWRU School of Medicine; Member, Center for Health Care Research and Policy; Staff Physician, Department of Medicine, MetroHealth Medical Center. Research interests include: use of large databases in health services research; application of geographic information systems to health services research; use of informatics to improve quality of care.

### **CRSP 431 – Statistical Methods I**

Ralph O'Brien, PhD

Professor, Department of Epidemiology & Biostatistics, CWRU School of Medicine. Areas of expertise include: statistical science, especially sample-size analysis and robust tests for assessing variability differences.

### **CRSP 603 – Research Ethics and Regulation**

Nicole Deming, JD, MA

Assistant Professor, Department of Bioethics, CWRU School of Medicine; Center for Biomedical Ethics at MetroHealth Medical Center. Research interests include: informed consent process, patient/physician communication, professionalism, research regulations, and living organ transplants.

### **Faculty Expertise for Counterpart Medical School Courses**

#### **CMED 401 – Introduction to Clinical Research**

##### **Course Director**

Matthew Karafa, PhD

Assistant Professor, CCLCM; Quantitative Health Sciences Project Staff, Cleveland Clinic Foundation.

##### **Lecturers**

Carolyn Apperson-Hansen, Mstat

Director, Research Concierge, Clinical and Translational Science Collaborative, CWRU. Ms. Apperson-Hansen provides support in all phases of clinical and translational sciences in the regulatory and technology areas as well as assists inexperienced investigators to understand research study needs and navigate multi-disciplinary research processes. She has extensive experience in statistical analyses and database management.

Alex Fu, PhD

Assistant Professor, CCLCM; Associate Staff, Quantitative Health Sciences, Cleveland Clinic Foundation. Dr. Fu's research interests include: pharmacoconomics, utility assessment, health policy evaluation, propensity score method, and econometrics, particularly in the areas of diabetes and mental illness.

Gretchen Hallerberg, Medical Library Director, Cleveland Clinic Foundation

Michael Kattan, MBA, PhD

Professor, Department of Medicine, CCLCM; Chairman, Department of Quantitative Health Sciences, Cleveland Clinic Foundation.

Amy Moore, Scientific Publications, Cleveland Clinic Foundation

Nancy Obuchowski, PhD

Professor, CCLCM; Vice Chair, Quantitative Health Sciences, Cleveland Clinic Foundation. Research interests include: design and analysis of studies of screening and diagnostic tests; extension of Receiver Operating Characteristic (ROC) analysis to nominal, ordinal, or continuous outcomes; testing the equivalence of diagnostic tests.

Ralph O'Brien, PhD

Professor, Department of Epidemiology & Biostatistics, CWRU School of Medicine. Areas of expertise include: statistical science, especially sample-size analysis and robust tests for assessing variability differences.

Carmen Paradis, MD

Clinical Assistant Professor, CCLCM; Center for Ethics, Humanities and Spiritual Care, Cleveland Clinic Foundation; Member, Institutional Review Board, Cleveland Clinic Foundation; Research Subject Advocate, Clinical and Translational Science Collaborative Research Unit, CWRU. Research interests include: research ethics, informed consent, and ethics education.

Shannon Morrison, MS

Statistical Programmer, Quantitative Health Sciences, Cleveland Clinic Foundation.

### **CMED 402 – Statistical Science for Medical Research**

Amy Nowacki, PhD

Assistant Professor, CCLCM; Assistant Staff, Department of Quantitative Health Sciences, Cleveland Clinic Foundation. Research interests include: clinical trial design and randomization schemes, prediction, validation, and statistical education.

### **CMED 403 – Introduction to Clinical Epidemiology**

#### **Course Directors**

Peter Imrey, PhD

Professor, Department of Medicine, CCLCM; Staff, Department of Quantitative Health Sciences, Cleveland Clinic Foundation. Research interests include: analysis of multivariate categorical data; linear models; sample survey methods; quantitative epidemiology.

Daniel Sessler, MD

Professor, Department of Anesthesiology, CCLCM; Chair, Department of Outcomes Research, Cleveland Clinic Foundation. Dr. Sessler coordinates more than a hundred studies, including large, multi-center outcome trials.

#### **viii. New resources, courses, etc., if any, necessary to support certificate program.**

Managerial and administrative tasks necessary for the proposed Certificate program will be added to the Center for Clinical Investigation's Executive Committee and Education Administrator/Manager's responsibilities, respectively. The extra effort to implement the program is minimal. The CRSP Master's degree program generates adequate financial resources to conduct the courses, and the current CRSP courses will be able to handle additional students that are projected. No other input is required to support the program.

## Appendix 1

**Table 1: Annual Enrollment in CRSP 401 “Introduction to Clinical Research”**

Year	Number
2002	44
2003	26
2004	47
2005	40
2006	55
2007	62
2008	45
2009	49
2010	78
<b>Total:</b>	446

**Table 2: Annual Enrollment in CRSP 401 by Academic Level\***

		ACADEMIC LEVEL			
Year	Total	Faculty	Fellows	Medical Residents	Other
2006	55	8	31	15	1
2007	62	5	33	23	1
2008	45	5	22	15	3
2009	49	3	32	12	2
2010	78	4	62	11	1
<b>Total</b>	289	25	180	76	8

\*Enrollment breakdowns by academic level unavailable for years previous to 2006

## Appendix 2

### Example Certificate Programs

Institution	Required Coursework Topics	Credit Hr Requirements
Columbia (pre-doc)	<ul style="list-style-type: none"> <li>• Principles of Epidemiology</li> <li>• Biomedical Informatics</li> <li>• Research Ethics</li> <li>• Clinical Trials</li> <li>• Biostatistics</li> <li>• Practicum</li> </ul>	6 semester hrs
University of Pennsylvania	<ul style="list-style-type: none"> <li>• Research methods/study design</li> <li>• Biostatistics</li> <li>• Database management</li> <li>• Ethical Scientific-Research conduct</li> </ul>	9 semester hrs
University of Tennessee	<ul style="list-style-type: none"> <li>• Fundamentals of Clinical Investigation</li> <li>• Biostatistics</li> <li>• Principles of Epidemiology</li> <li>• Ethical and Legal Issues in Clinical Research</li> </ul>	12 semester hrs
UC Berkeley	<ul style="list-style-type: none"> <li>• Introduction to Clinical Research: Clinical Trial Phases and Design</li> <li>• Clinical Trial Planning: Protocol Development, Data Management, and Clinical Site Activities</li> <li>• Clinical Trial Implementation: Site Initiation, Subject Recruitment, Monitoring, and Safety Reporting</li> <li>• Clinical Trial: Data Analysis, Regulatory Audits, Vendor Selection, and Project Management</li> </ul>	12 semester hrs
University of Pittsburgh	<ul style="list-style-type: none"> <li>• Clinical research methods</li> <li>• Biostatistics</li> <li>• Computer Methods</li> <li>• Measurement</li> <li>• Ethics and Regulation of Research</li> </ul>	15 credit hrs
University of Oregon (bench focus)	<ul style="list-style-type: none"> <li>• Clinical Research design</li> <li>• Biostatistics</li> <li>• Proposal development</li> <li>• Evidence Based medicine</li> <li>• Molecular Biology</li> </ul>	24 semester hrs

Pamela B. Davis, M.D., Ph.D.  
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To: Pamela B. Davis, M.D., Ph.D.  
Dean, School of Medicine

From: Jill Barnholtz-Sloan, Ph.D.  
Chair, Faculty Council 2011-2012



Date: January 24, 2012

Re: Proposal for the Certificate Program in Clinical Research

At its meeting on January 23, 2012, Faculty Council reviewed a proposed new Certificate Program in Clinical Research.

The proposed Certificate program will be administered by the Center for Clinical Investigation and will provide foundation training in clinical research methods for clinical-translational scientists. The proposed Certificate program targets clinicians and other health-science professionals who desire further training in clinical research skills to enhance their abilities as clinician-scientists, but who lack adequate time or resources to obtain a formal degree in clinical research. Health-science students, basic-science researchers, and other health-science professionals who desire greater knowledge and skill in clinical research may also be interested.

The proposed Certificate program is designed to provide a firm grounding in the method and conduct of patient-oriented clinical research. After completion of the program, graduates will be better able to conduct clinical research, as well as collaborate with other clinician-scientists conducting clinical research.

Accordingly, the Faculty Council concluded the Certificate Program in Clinical Research would be beneficial for the initial estimated 8 students that would be interested in enrolling per year (with increasing participation anticipated in subsequent years). By a vote of 33 in favor; 0 against, 0 abstain, the proposal was recommended for approval.

Please review the proposal and add any additional comments; then forward to the University Faculty Senate for its review and recommendation.

Thank you.



SCHOOL OF MEDICINE

CASE WESTERN RESERVE  
UNIVERSITY

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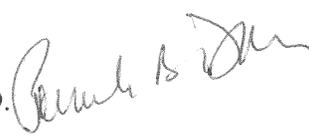
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Memorandum

To: Gary Chottiner, Ph.D.  
Chair, Faculty Senate

From: Pamela B. Davis, M.D., Ph.D.  
Dean, School of Medicine



Date: January 25, 2012

Re: Proposal for the Certificate Program in Clinical Research

Enclosed please find a proposal for a new Certificate Program in Clinical Research. The program has been recommended for approval by the Faculty Council of the School of Medicine, acting under our Bylaws for the Faculty of Medicine, and has my enthusiastic endorsement.

I understand that the process for further review includes oversight by the Faculty Senate's Graduate Studies Committee and the Faculty Senate as a whole. Please let me know if I can provide any additional information.

Thank you for your consideration.

C: (all w/o enclosures): Jill Barnholtz-Sloan, Ph.D.  
James Spilsbury, Ph.D.



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