

**Faculty Senate  
Executive Committee**  
Thursday, September 17, 2009  
2:00 – 4:00 p.m. – Adelbert Hall, Room 352

AGENDA

|        |   |                 |
|--------|---|-----------------|
| 2:00pm | Approval of Minutes from the April 16, 2009 Executive Committee meeting, <i>attachment</i>                        | C. Musil        |
|        | President's Announcements   | B. Snyder       |
| 2:05pm | Provost's Announcements   | B. Baeslack     |
|        | Chair's Announcements   | C. Musil        |
| 2:10pm | Part II of the Final Report of the <i>ad hoc</i> Committee on Grievance Process Reform<br><i>attachment</i>       | B. Leatherberry |
| 2:40pm | New Certificate Program: Clinical Translational Oncology Research Scholars Program (CTORSP)<br><i>attachments</i> | A. Levine       |
| 2:55pm | Interim approval of new post-doc to Graduate Studies and CSE faculty member to Research Committees                | L. Woyczynski   |
| 3:00pm | Review of Proposed Process/Timeline for 09-10 Senate Ranked Budget Priorities<br><i>attachment</i>                | C. Musil        |
| 3:20pm | Follow up on Spring 2009 Proposal by Faculty Senate Committee on Minority Affairs                                 | C. Musil        |
| 3:40pm | New Business  |                 |
| 3:50pm | Approval of Draft Agenda for the September 24, 2009 Faculty Senate meeting<br><i>attachment</i>                   | C. Musil        |



Faculty Senate Executive Committee  
Minutes of the September 17, 2009 meeting  
Adelbert Hall, Room 352

**Committee Members in Attendance**

|               |                |
|---------------|----------------|
| Cynthia Beall | Carol Musil    |
| Alan Levine   | Roy Ritzmann   |
| Ken Loparo    | Barbara Snyder |
| Katy Mercer   | Terry Wolpaw   |
| Diana Morris  | Liz Woyczynski |

**Committee Members Absent**

|              |                |
|--------------|----------------|
| Bud Baeslack | Glenn Starkman |
| Ken Ledford  |                |

**Others Present**

|                |                   |
|----------------|-------------------|
| Gary Chottiner | Bill Leatherberry |
| Faye Gary      | Kalle Lyytinen    |
| Julia Grant    | Lynn Singer       |
| Jim Kazura     |                   |

**Call to Order and approval of minutes**

Professor Carol Musil, chair of the faculty senate, called the meeting to order at 2:00 p.m. There being no corrections offered, the minutes of the April 16, 2009 meeting of the Faculty Senate Executive Committee were approved as submitted.

**President's announcements**

President Barbara Snyder noted the recent appointment of Rick Bischoff, Vice President for Enrollment Management, who served as director of admission at Caltech. The year's final budget report will be shared with the university community after the October Board of Trustees meeting; but it is clear that the university will finish in the black. The university had a second year of strong fundraising results. The university's new branding and marketing plan was recently presented to students and it was well received. The plan is also being shared with alumni at events on and off campus. New branding guidelines will be presented shortly. There are some slight modifications to school logos. Old letterhead stock can be depleted before new supplies are ordered. Announcements will be forthcoming in *Case Daily* shortly with details about the new initiatives for emergency childcare arrangements and funds for childcare while traveling on university business. These arrangements are available for faculty, staff and students with children.

**Provost's announcements**

Deputy Provost Lynn Singer, attending for Provost Bud Baeslack, detailed the university's planning and prevention efforts for the H1N1 virus. She announced that an RFP for funding on alliance projects has been distributed. Joanne Eustis, university librarian, will be leaving the university and a national search will

commence to appoint her replacement. A new half-time position for an LGBT coordinator has just been approved. The Committee on Undergraduate Student Advising has issued its report; the Committee on SAGES will issue an interim report shortly. The most recent COACHE (Collaboration on Academic Careers in Higher Education) Survey results have arrived and the results are being analyzed in the Office of Institutional Research; they will be distributed to the university community shortly.

### **Chair's announcements**

Prof. Carol Musil, chair of the faculty senate, encouraged faculty to attend President Snyder's state of the university address on Friday, October 2 at 12:45pm. She reviewed the faculty senate's August retreat and gave updates on the progress of the three faculty senate *ad hoc* committees.

### **Part II of the Final Report of the *ad hoc* Committee on Grievance Process Reform**

Prof. Bill Leatherberry, chair of the *ad hoc* committee on grievance process reform, summarized Part II of the committee's report which concerns proposed revisions to the grievance process outlined in Chapter 3 of the Faculty Handbook. A smaller committee of five members is proposed; this should help to address scheduling problems. A means for resolving potential conflicts of interest on the grievance committee is proposed. No more than two faculty members from the same school could serve on the grievance committee. The chair of the grievance committee would have greater authority to work with the complainant and the respondent to streamline documents and witnesses. "Academic conflicts" would be addressed through the new conciliation/mediation program; only "personnel disputes" would merit a grievance hearing. After a brief discussion, the Executive Committee endorsed Part II of final report. Prof. Leatherberry will draft the proposed changes to the Faculty Handbook for review by the By-laws Committee.

### **New Certificate Program: Clinical Translational Oncology Research Scholars Program (CTORSP)**

Prof. Alan Levine presented the updated proposal for the Clinical Translational Oncology Research Scholars Program. Since it was reviewed by the Executive Committee last spring, the dean's letter of support and a new "support statement" have been added to the proposal. Certificate classes do not require the same review and approval requirements as degree programs. There were a number of questions about the review and approval requirements, especially since the proposal stated that the certificate classes could be applied towards a master's degree at later time if a student wished. Further review is required, and approval of the certificate program was postponed.

### **Interim Approval of new post-doc to Graduate Studies and CSE faculty member to Research Committees**

The Executive Committee approved the interim 09-10 membership of Prof. Bob Kirsh as one of 10 faculty members on to the Research Committee, in order to have representative from Case School of Engineering on the committee; the membership by-laws allow for 9 faculty members. Also approved was the interim 09-10 membership of a post-doc, Christi Malbassa, to the Graduate Studies Committee; the membership by-laws don't include a post-doc. Both committees are expected to submit proposed changes to the membership by-laws for Faculty Senate approval by April 2010.

### **Review of Proposed Process/Timeline for 09-10 Senate Ranked Budget Priorities**

Prof. Musil introduced the proposed process and timeline for determining the 09-10 faculty senate budget priorities. There was some discussion of the consequences of the Faculty Senate annually reconsidering the commitment to long-term budget priorities that remain in-process and of extending the list of budget priorities beyond what can reasonably be funded. President Snyder and Prof. Julia Grant, chair of the faculty senate budget committee, informed the Executive Committee about the endeavors of the Provost's newly formed Budget System Committee which will examine the university's long-standing budget structure and formulas.

The efforts of the Budget System Review Committee provide an opportunity for the Faculty Senate to learn more about the limitations of determined revenue and expenditure cycles and to ascertain where opportunities do lie for choosing tradeoffs and funding priorities. The Executive Committee would like to see the fruition of the committee's endeavors before re-considering any high cost, long term budget priorities. This year, the Executive Committee solicits input from faculty senate standing committees and from senators for any short-term, low cost budget priorities. Any proposed initiatives should cost less than \$100,000 and should be items that can be completed in less than two years. Senators and standing committee chairs are asked to submit priorities to Liz Woyczynski, Secretary of the University Faculty, by Monday October 19, 2009. The Budget Office will cost out the proposed budget priorities for initial review by the Faculty Senate Budget Committee. Then the proposed priorities will be rank ordered by the Senate by online ballot. The process allows for the 09-10 faculty senate budget priorities to be presented to the administration in time for the Provost's Strategic Planning meeting in early November.

**Follow up on Spring 2009 Proposal by Faculty Senate Committee on Minority Affairs**

There was not time to discuss the spring 2009 proposal by the faculty senate committee on minority affairs. This will be the first item on the agenda at the October 7, 2009 Executive Committee meeting.

**Approval of the Thursday, September 24, 2009 Faculty Senate Meeting Agenda**

With slight modifications, the agenda for the September 24 faculty senate meeting was approved. The meeting was adjourned at 4:05pm.

APPROVED  
by the  
FACULTY SENATE EXECUTIVE COMMITTEE



ELIZABETH H. WOYCZYNSKI  
SECRETARY OF UNIVERSITY FACULTY



**Faculty Senate  
Executive Committee Meeting**  
Thursday, April 16, 2009  
9:30 – 11:30 a.m. – Adelbert Hall, Room 352

**Committee Members in Attendance**

Bud Baeslack  
Cynthia Beall  
Bill Deal  
Steve Garverick  
Leonard Lynn  
Katy Mercer

Shirley Moore  
Carol Musil  
Barbara Snyder  
Glenn Starkman  
Terry Wolpaw  
Liz Woyczynski

**Committee Members Absent**

David Matthiesen

**Others in Attendance**

Susan Case  
Allen Levine

**Call to Order and approval of minutes**

Professor Glenn Starkman, chair, called the meeting to order at 11:00am. There being no corrections offered, the minutes of the March 16, 2009 Executive Committee meeting were approved as submitted.

**President's Announcements**

President Barbara Snyder said that the university would like to start a fund-raising campaign directed to faculty and staff. The university would not publish the amount pledged by any one professor or staff member. The percentage of participating faculty and staff may be published. Having a high percentage of alumni, faculty or staff who contribute money to the university can benefit future university fund-raising effort; a high percentage of participants is an indicator of the support for the university's current endeavors.

**Provost's Announcements**

Provost Bud Baeslack said that the School of Engineering has agreed, for the time being, not to pursue its interest in making SAGES optional for engineering students. The Provost's Office has studied the documentation when SAGES was created. At the time, SAGES was referred to as "a common basis for undergraduate education." As such, it is "one off" from an officially established university-wide core curriculum. There is value to independence, and there is value to having a university-wide core curriculum. Case Western Reserve University is unusual in not having a core curriculum. The Faculty Senate *ad hoc* Committee on SAGES has recently been formed; the committee will consider the pedagogy of SAGES. The Faculty Senate Committee on Undergraduate Education may later consider the governance issues associated with SAGES.

### **Final Report of the Faculty Senate *ad hoc* Committee on University-Level Faculty Committees**

Prof. Carol Musil and Prof. Robin Dubin, co-chairs of the Faculty Senate *ad hoc* Committee on University-Level Committees, presented the committee's final report. The committee was charged with improving the efficiency and effectiveness of the Faculty Senate. The committee proposes that the Executive Committee should have one senator from each school, elected by the senate, who would serve *ex officio* on the schools' faculty senate executive committees. This should increase and improve university senate and school governance communications. The committee also proposes that the Nominating Committee should be made up of senators, rather than non-senators, who will be better informed when recruiting members for the faculty senate standing committees. The Executive Committee endorsed the *ad hoc* committee's final report. The *ad hoc* committee will draft the necessary changes to the Faculty Handbook and the Faculty Senate By-laws for consideration by the Faculty Senate Committee on By-laws in 09-10.

### **Proposed Changes to the Faculty Handbook**

Prof. Christine Cano, chair of the faculty senate committee on by-laws, presented a change to the Constitution of the University Faculty that would allow faculty and staff to attend the same state of the university address by the president each fall. The recent practice has been that the president gives two state of the university addresses, one to faculty and one to staff. As written in Article IV, Section A, the state of the university address is the required part of an annual fall meeting of the University Faculty. The proposed changes to the Constitution of the University Faculty allow that if there are additional agenda items after the state of the university address, the meeting of the University Faculty would continue after staff depart. The Executive Committee endorsed the changes for final consideration by the Faculty Senate at its April meeting.

### **Proposed Resolutions by the Committee on Graduate Studies**

Prof. Alan Levine, chair of the faculty senate committee on graduate studies, presented two resolutions prepared with the consent of the Committee on Graduate Studies.

One resolution proposes that a faculty member from another university or research institution could serve on a graduate student's dissertation committee. There was a question whether that faculty member could be an adjunct faculty member at another institution. And there was a question about whether non-faculty from research institutions such as Scripps or the Cleveland Clinic would be allowed to participate. The required consent of others, as detailed in the proposal, ensures the necessary quality control. Perhaps it should be stated that the outside faculty member must act in accordance with Case Western Reserve University by-laws.

The second resolution proposes that emeriti faculty could serve on the dissertation committees. There was a question whether or not emeriti faculty could chair a dissertation committee or be the primary dissertation advisor. It has happened that students have been transferred to the supervision of less expert faculty because the professor who was originally supervising the dissertation retired and couldn't continue to participate. A few emeriti faculty have already served on dissertation committees, after numerous levels of approval were confirmed; this resolution would make the pre-approval process easier. Would this resolution make it harder for deans or students to not approve emeriti professors they felt were not well connected to their fields anymore?

After some discussion, the Executive Committee encouraged the Committee on Graduate Studies to seek further review of these two proposals by the associate deans in charge of academic affairs and the executive committees at each of the schools and the college.

### **Proposed Certificate Program: Clinical Translational Oncology Research Scholars Program (CTORSP)**

Prof. Alan Levine presented the proposed new certificate program. There were a number of questions. Given the time constraints at the end of academic year, a MOTION was made to forward the proposal, without approval, to the Faculty Senate for further review. The Executive Committee requested that 1) Prof. Stan Gerson, who submitted the proposal to the Committee on Graduate Studies, be present for the discussion at the faculty senate meeting and that 2) the

standard letter of approval from the dean, which was not initially included, be attached to the proposal for consideration by the Faculty Senate.

#### **Report on University-Wide Research Needs**

Prof. Ray Muzic, chair of the faculty senate committee on research, presented a report on university-wide research needs. The Executive Committee endorsed the report, and encouraged the committee to develop a set of working points and identify with the provost the initiatives that can be started – for instance, the first 2 items would be low cost initiatives – and to forward a report on progress made to the Faculty Senate next year.

#### **Faculty Parental Leave Policy**

Prof. Susan Case, chair of the faculty senate committee on faculty compensation, presented the proposed updated Faculty Parental Leave policy, which the president submitted for the committee's review in fall 2008. Much work has gone into clarifying all the issues addressed. The new policy gives up to 16 weeks of paid parental leave that can be applied flexibly toward work in fall and/or spring semesters, depending on the date of birth or arrival of the new child(ren). Prof. Case stated that this improved policy is as good as or better than the parental leave policies at other prominent research institutions. A few edits had yet to be ironed out. The Executive Committee endorsed the policy for final review by the Faculty Senate at its April meeting.

#### **Faculty Compensation Philosophy**

Prof. Susan Case, chair of the faculty senate committee on faculty compensation, presented the committee's proposed faculty compensation philosophy. There were a number of questions and time constraints prevented full discussion. Prof. Glenn Starkman, chair, and Prof. Carol Musil, chair-elect, offered to meet with Prof. Case and to solicit the Executive Committee for further feedback by email.

#### **Chairs of 09-10 Faculty Senate Standing Committees and 09-10 Faculty Senate Meeting Dates**

All of the identified chairs for 09-10 faculty senate standing committees and the 09-10 meeting dates were approved by the Executive Committee.

#### **Approval of the Monday, April 27, 2009 Faculty Senate meeting agenda**

With slight modifications, the agenda for the April 27 faculty senate meeting was approved. The meeting was adjourned at 1:10 p.m.

**FINAL REPORT OF THE  
FACULTY SENATE *ad hoc* COMMITTEE  
ON GRIEVANCE PROCESS REFORM**

July 1, 2009

**Committee Members**

Prof. Wilbur Leatherberry, chair  
Prof. Robin Dubin  
Prof. Fady Faddoul  
Prof. Wally Gingerich  
Prof. Marion Good  
Prof. Robert Greene  
Prof. Judith Lipton  
Prof. William Merrick  
Prof. Robert Mullen  
Prof. John Orlock  
Prof. Sandra Russ  
Liz Woyczynski, secretary of the university faculty

Several *ad hoc* committee members served on a grievance hearing committee that discussed with President Snyder the creation of a mediation process that might lead to earlier, more appropriate and effective resolution of disputes than the formal grievance hearing process. President Snyder encouraged the Faculty Senate to consider such an initiative, especially if it could be implemented as a pilot program. That led to the appointment of the Faculty Senate *ad hoc* committee on Grievance Process Reform.

The *ad hoc* committee is comprised of members with considerable experience with the operation of the current grievance process; they have experience as members of hearing panels, as coordinator of the process, or as advisors to complainants or respondents. The committee carefully reviewed the provisions of the Faculty Handbook that deal with the grievance process. And the committee discussed the problems and issues that have arisen in the grievance process and considered ideas for reform.

**Committee Charges and Activities**

**Resolution to create the Committee - April 2008**

*The Faculty Senate Executive Committee hereby creates the ad hoc Committee on the Reform of the Faculty Grievance Process and charges it:*

*\* to recommend improvements to the grievance processes and, in collaboration with the Faculty Senate Bylaws Committee, to propose amendments to the Faculty Handbook to implement those reforms;*

*\* to provide a preliminary report to the Faculty Senate at its September 2008 meeting and regular reports thereafter; and*

*\* to provide its final recommendations to the Faculty Senate, including any proposed amendments to the Faculty Handbook as soon as possible, but no later than April 2009.*

October 2008 – Report to the Faculty Senate on committee activities

November 2008 – Draft proposal for Conciliation and Mediation Pilot Program shared with the Provost

February 2009 – Feedback received from Office of General Counsel

Resolution to extend the mandate of the committee – April 2009

*Whereas the Faculty Senate ad hoc grievance process reform committee is currently actively engaged in completing its charge; therefore, the Faculty Senate Executive committee extends the mandate of the committee through the end of the 2009 calendar year. The committee, at the first meeting of the Faculty Senate Executive Committee for the 2009/2010 academic year, shall submit for consideration the ad hoc committee's proposal for a pilot program offering professional mediation as an optional precursor to submission of a formal grievance; and no later than the second meeting of the Faculty Senate for the 2009/2010 academic year, shall present for discussion a preliminary proposal for reform of the grievance process.*

## **PART I**

### **HEARING PROCESSES**

#### Disciplinary Hearings

One hearing process, described in the Faculty Handbook (Chapter 3, IV. D. Hearing Procedures) relates to alleged misconduct by faculty members. That process is initiated by the Executive Committee of the Faculty Senate or—much more commonly—by a representative of the President of the University.

The proposed pilot program for conciliation and mediation, later described, is not appropriate for these types of disciplinary cases.

All allegations of research misconduct and sexual harassment are handled through other processes, as detailed in the Faculty Handbook. In addition, all claims of discrimination are handled by the Office of Inclusion Diversity and Equal Opportunity.

Some of the *ad hoc* committee's amendments to the grievance process, detailed later in this report, could affect the composition of the hearing committees in both disciplinary hearings and grievance hearings.

#### Grievance Hearings: Personnel Practice Disputes

The other process described in the Faculty Handbook provides grievance hearings for "the formal adjudication of disputes about personnel practice." (Chapter 3, V. Grievance Procedures, A. Introduction) The *ad hoc* committee takes that to mean conflicts between a faculty member and a dean, department chair, or another person in a position to take adverse action with respect

**Comment [ehw1]:** A question arose about this. The Office of General Counsel made this comment, in their review of committee's initial report, but it's not clear in the Faculty Handbook, that a faculty member who claimed discrimination couldn't file a grievance. This may need to be clarified.

to the faculty member's employment. Examples would include disputes about failure to follow required procedures with respect to retention, promotion, or tenure decisions.

As the Faculty Handbook provides, a grievance hearing cannot address the merits of decisions on retention, promotion or tenure, just the process by which the decisions were rendered. Likewise, the proposed pilot conciliation and mediation process could not address the merits of such decisions but could facilitate the resolution of disputes about the process by which those decisions would be reached.

A formal grievance hearing, as outlined in the Faculty Handbook, would be available to any faculty member with a grievance about a personnel practice. The proposed pilot conciliation and mediation process would provide an informal, optional process to resolve personnel practice disputes by an agreed settlement before a formal grievance hearing.

#### Grievance Hearings: Academic Conflicts

The *ad hoc* committee believes that the grievance process does not now and should not apply to disputes that the committee calls "academic conflicts." The term applies to conflicts between faculty colleagues about academic matters when such conflicts seriously impair the effective functioning of the academic unit. Examples include disrespectful behavior, refusal to participate or to include others in the decision process within the unit, and airing conflict to outsiders thereby causing damage to the complainant, the unit, or to the University.

The Faculty Handbook defines the grievance process as follows, "Formal grievances shall be heard in any case in which it is charged that the respondent has taken action which adversely affects the complainant and which action is a violation of the Constitution of the University Faculty, the by-laws of the Faculty Senate, and the by-laws of the constituent faculty or of the department, these policies and procedures, or of accepted norms of university academic personnel practice."

Despite these parameters, the grievance process has been used in what the *ad hoc* committee defines as "academic conflicts." The grievance process requires many hours of the Complainant, the Respondent(s), witnesses, advisors for the parties, the Secretary of the University Faculty, and the grievance committee members. The efforts of those involved should be reserved for personnel practice disputes as intended in the existing By Laws. The grievance process is not appropriate for academic conflicts because the adversarial nature of the process makes it ill-suited for the early and workable resolution of academic conflicts between colleagues.

The *ad hoc* committee proposes an amendment to the Faculty Handbook, later detailed, that better defines the differences between "academic conflicts" and "personnel practice disputes," and allows the chair of the Faculty Senate to make a judgment whether a "grievance" presented to the Secretary of the University Faculty actually falls into the category of "academic conflict," therefore making it ineligible for a grievance hearing. With the proposed pilot program in place, the Chair of the Faculty Senate would suggest that the Complainant with an "academic conflict" use the proposed pilot conciliation and mediation process to attempt to resolve the matter.

### **Informal Advice, Investigation and Conciliation**

There was consensus in the *ad hoc* committee that there is a need for a faster, less formal, and more effective process for resolving personnel practice disputes before a grievance hearing is scheduled.

The current process provided in the Faculty Handbook (Chapter 3, V. B. Informal Advice, Investigation, and Conciliation) says that the Faculty Senate Personnel Committee is “available for informal advice, investigation, and conciliation on the informal request of any faculty member. The chair and other committee members will provide information and counsel to the faculty member, investigate the facts, and where appropriate offer its services as a mediator.”

The proposed Conciliation Counselor [the Counselor] would be a member of the faculty or an administrator jointly appointed by the Provost and the Faculty Senate Executive Committee. The Counselor would provide advice about the grievance process and the conciliation and mediation process. The Counselor could gather information and offer conciliation services. If enhanced, professional mediation services are required a professional mediator from outside the University would be employed at University expense. If the proposed, pilot conciliation and mediation program is used and used successfully, more grievances would be resolved by agreement of the parties and the number of cases brought to a formal grievance hearing would be reduced. In addition, academic conflicts too could be resolved by agreement in a timely and effective way.

Many grievances arise from the promotion and tenure process. Hearing committees do not consider the merits of promotion and tenure decisions but often consider grievances about failure to follow required procedures after a decision on the merits has occurred. The pilot program would provide an informal mechanism for the resolution of procedural disputes as they occur rather than after a decision on the merits. For example, the Counselor would be in a position to advise a faculty member who is not getting the required annual reviews of performance. That problem might be addressed by conciliation or mediation and resolved by agreement before any decision on the merits of retention or promotion is made.

During the pilot program, the Counselor is intended to supplement the advising and conciliation functions of the Senate Committee on Faculty Personnel that are described in Chapter 3, V.B. with respect to personnel practice matters. The chair of the Faculty Personnel could refer parties to the Counselor. The Chair and members Committee on Faculty Personnel would be freed from the burden of the advising function. Faculty members concerned about academic conflicts also would be directed to the Counselor to get advice and to consider initiating the conciliation or mediation process.

The Committee on Faculty Personnel would still be active in its other assigned pursuits, as designated in the Faculty Senate by-laws, including the review of faculty personnel policies and procedures, including appointment, promotion, tenure and retirement, and making recommendations to the Faculty Senate for any desired changes to these policies and procedures.

The *ad hoc* committee recommends using this pilot program to provide advice, conciliation, and, in some cases, mediation, for personnel practice disputes and for academic conflicts from January 2010 through May 2011 (the equivalent of 3 semesters). That would allow time to test the program, make any necessary revisions in the approach, and prepare, with the full and careful review required by the Faculty Senate By-Laws Committee, the Senate, and the administration, the amendments to the Faculty Handbook required if such a program is to be made permanent.

### **Description of Proposed Pilot Program for Conciliation and Mediation**

#### **Conciliation**

The provost shall appoint, with the advice and consent of the Faculty Senate Executive Committee, a faculty member or an administrator to serve as Conciliation Counselor [the Counselor]. The Counselor would be available to meet with and advise any member of the University Faculty, other than the President and the Provost, with respect to disputes about personnel practice and academic conflicts. A member of the University Faculty who is a party to such a dispute or conflict could consult with the Counselor for advice and assistance in resolving the dispute or conflict. A person who is not a party but who is affected by the dispute or conflict may consult with the Counselor for advice and assistance.

The Counselor shall treat as confidential the information provided by those who seek advice and assistance. Resolution will require the cooperation of the parties involved. The Counselor would need to contact the other parties and shall do that if the person who sought advice agrees to permit the Counselor to do so. The Counselor shall gather information from the parties and shall serve as a conciliator by meeting with them individually or together as the Counselor finds appropriate.

Any member of the University Faculty who chooses to participate in the pilot conciliation and mediation program would be required to sign a waiver, acknowledging the rights provided in the Faculty Handbook, and choosing to waive or postpone, for the period of the conciliation or mediation process, (1) the advice of the Faculty Senate Committee on Faculty Personnel and (2) a formal grievance hearing, in favor of the pilot conciliation and mediation program.

#### **Mediation**

Some disputes or conflicts may, in the judgment of the Counselor or when requested by all of the parties involved, require the services of a professional mediator from outside the University. The Provost shall select and arrange for the availability of a person or firm, outside the University, with qualifications and experience in mediation so that mediation can be arranged expeditiously when needed. The costs of the mediation services, including the mediator's fee, shall be paid by the University. The Counselor will recommend to the Provost the cases that are suitable for engaging the services of a professional mediator.

There are two reasons for providing for a professional mediator from outside the University. The first is that, although the Counselor should have training, skill, and, if possible, some experience

as a mediator, some disputes will require more skill and experience and perhaps more concentrated time than the Counselor can provide. Second, in some cases, the parties may be more comfortable and more willing to be candid with a professional outside mediator than they would be with a person appointed by the Provost, even with the advice and consent of the Senate.

#### Confidentiality

The Counselor—or the Mediator, if mediation is pursued—shall work with the parties to assist in resolving the dispute or conflict only if all parties agree to participate and only if all parties agree to keep the process confidential. At the inception of the process, the parties, the counselor—or the mediator, if involved—shall agree not to discuss what is said by anyone in the process with outsiders and shall agree that the communications within either process are confidential unless otherwise prohibited by law. Each person is protected under Ohio Revised Code § 2710.01 et seq. from being required to testify about the process in a subsequent legal proceeding, including a grievance hearing, with limited exceptions such as threats of harm or crimes. The parties shall agree not to call opposing parties or the Counselor or the Mediator as witnesses with respect to the process or to demand production of the notes of the process from the Counselor or the Mediator in any subsequent grievance hearing or legal proceeding. Neither the Counselor nor the Mediator may report to others about the substance of the process. The Counselor or Mediator may report only whether the process took place and whether the dispute or conflict was resolved.

#### Resolution

Both conciliation and mediation are facilitated settlement processes. Resolution of the dispute or conflict will occur only by the voluntary agreement of all parties. Neither the Counselor nor the Mediator shall have any power or authority to decide any issues in the dispute or conflict, but the Counselor or the Mediator may, when appropriate, recommend solutions for the parties to consider.

Neither the Counselor nor the Mediator, if one is involved, has any power to make a decision with respect to a dispute or conflict. Their roles are to facilitate resolution of the matter by the agreement of the parties. Even a hearing committee does not have the power to decide the issues before it (Chapter 3, IV or V). Decisions are to be made by the President after receiving the committee's report and recommendations (Chapter 3, IV.D.6. and Chapter 3, V.C.8.).

Any resolution of the dispute or conflict shall be reduced to writing and the writing shall be signed by all parties and by the Counselor or the Mediator. The agreement may be presented in evidence in a subsequent grievance hearing or legal proceeding only for the purpose of showing that a party failed to live up to its terms.

#### Assessment and Reports

The Counselor shall report at the end of the academic year to the Provost and to the Faculty Senate with respect to the functioning of the pilot program. The report should provide

information about the number of matters in each category, personnel practice and academic conflict, which were brought to the Counselor's attention and the number that went to conciliation, to mediation, and to formal grievance hearing. The Counselor shall not report any information about a particular matter unless specifically authorized in writing by all parties to the matter.

We sought advice from the Provost's Office and the University Attorney's Office. This proposal responds to and incorporates their feedback.

## **PART II**

### **Proposed Amendments to the Grievance Process**

The *ad hoc* committee proposes the following changes for grievance hearings. Would the Faculty Senate and the administration be open to considering these changes for disciplinary hearings as well? If not, the *ad hoc* committee would like to pursue the following changes just for grievance hearings. The Faculty Handbook would have to make clear that the differences in panel selection and the pre-hearing activities for the chair of the hearing committee would just be for grievance hearings.

#### **The Complaint**

The Complainant would be required to submit a written complaint containing a short, clear statement of the grievance with respect to the specific rules allegedly violated by the Respondent(s). The Complainant would also be required to include in the written complaint a clear statement of the remedy sought.

#### **Channeling Academic Conflicts**

There is need for an amendment that would clarify what we believe is the intended purpose for grievance hearings. The amendment would define the difference between "personnel practice disputes" and "academic conflicts," as they are defined above. The amendment would empower the Chair of the Faculty Senate, whom the Faculty Handbook designates the person in charge of overseeing the grievance process, to assess a "grievance" complaint to determine whether it is a grievance or an "academic conflict." An academic conflict would be ineligible for the grievance process and the complainant would be directed to the Counselor for advice about the conciliation and mediation process.

#### **Changes to the Grievance Panel**

Scheduling a grievance hearing is an arduous process often requiring several months. The *ad hoc* committee recommends reducing the number of faculty members on a grievance panel as one step to ease scheduling and reduce delays. The following recommendations would reduce the grievance hearing committees from seven members to five.

The *ad hoc* committee recommends an amendment to establish a panel of 25 faculty members who would be available to serve on grievance committees during each academic year. We suggest that the list include at least three faculty members from each school or college. Up to eight panelists should be designated as eligible to chair a grievance panel. Those so designated should have had multiple experiences with the grievance process as members of hearing committees or as advisors to complainants or respondents or should have other relevant training or experience.

The Secretary of the University Faculty would 1) solicit faculty interested in serving on grievance committees through the annual faculty interest survey and 2) assemble a list of faculty who have served as advisors or members of recent grievance committees. The Nominating Committee would nominate interested faculty to serve as members of the grievance committees and experienced faculty for chairs of the grievance committees. The Nominating Committee would submit a potential grievance panel (indicating which faculty are to be eligible to chair grievance committees) to the Faculty Senate for approval in April, for use the following academic year.

When a grievance is filed, the Secretary of the University Faculty would contact all panelists to determine availability. The Chair of the Faculty Senate would select three of the available panelists to serve. One of three would be selected from those eligible to chair committees and would be designated as chair of the committee. The chair should not come from the school or college of either the Complainant or Respondent.

The requirements that one committee member comes from the Faculty Senate Personnel Committee and that two members come from the Faculty Senate would be repealed.

The Complainant and the Respondent would each pick one faculty member from the panel to serve on the grievance committee. No more than two of the five panelists could be from the same school as the Complainant or Respondent.

#### Conflict of Interest

When the Secretary of the University Faculty has confirmed appointment and the availability of all five panelists, the Secretary would share the information about the Complainant, the Respondent(s), and the nature of the issues in the complaint with the committee members. Committee members would be asked to excuse themselves if they were too well-acquainted with Complainant, Respondent(s) or the issues at hand or for other reasons could not serve impartially. Any committee member who is excused would be replaced by following the same procedure by which that member was selected.

The Complainant and Respondent would then be informed about the membership of the grievance committee. They would be have one week to raise issues about potential conflicts of interest with respect to any of the committee members. The Chair of the grievance committee would decide whether there is a conflict of interest that requires removal of a committee member. If a party asserted that the Chair of the committee had a conflict of interest, the Chair

of the Faculty Senate would consider and rule on whether the Chair of the grievance committee should be removed and replaced.

The following grounds would justify removal and replacement of a grievance committee member, including the Chair:

- (1) The member is a witness or is otherwise directly involved in the dispute.
- (2) The member has a history of conflict with the Complainant or Respondent.
- (3) The member is reasonably believed by the Complainant or Respondent to be unable to approach the issues in a fair and neutral way.

The following grounds would justify removal and replacement of a committee member selected by the Complainant or Respondent:

- (1) The member is a witness or is otherwise directly involved in the dispute.
- (2) The member is or has been directly involved in other conflicts between the Complainant and the Respondent.

#### New Responsibilities for the Chair of the Grievance Panel

The *ad hoc* committee believes that the Chair of the grievance committee, chosen from a small group of panel members most experienced with the grievance process, can help the parties focus the presentation of the issues in dispute and limit the amount of written evidence and the number of witnesses. That will make the hearing more efficient and the presentations of the parties clearer and more effective.

The Chair of grievance committee would rule on procedural matters such as relevancy of written evidence, the relevancy and number of witnesses, redundancy or repetition with respect to both written evidence and witnesses, and, as mentioned earlier, conflict of interest objections to service of hearing panelists. The rulings, both before and during the hearing, would be subject to being overturned by majority vote (three of five members) of the committee.

The Chair of the grievance committee would review the written evidence the parties propose to provide to the grievance committee before that evidence is copied and provided to the members of the committee. The Chair would discuss with the parties the need for the written evidence submitted and work with them to eliminate material that is irrelevant, repetitive, or otherwise unnecessary. If the Chair rules that material should not be considered by the grievance committee, the party submitting it would have the right to appeal the decision to the committee. In that case, the material would be provided to each committee member so that the members could decide whether to vote to overrule the Chair with respect to admitting that evidence for consideration by the committee.

The parties would be required to submit their proposed witness lists not less than ten days before the hearing. The Chair would meet with the parties in person or by telephone to discuss their proposed witness lists and the possibility that they could agree to stipulate some facts. The Chair would work with them to eliminate witnesses that are irrelevant or repetitive or otherwise

unnecessary. If the Chair rules that a witness should testify before the grievance committee, the party submitting the witness would have the right to appeal the decision to the committee. In that case, the party would provide a brief written summary of the witness's expected testimony to each committee member so that the member could decide whether to vote to overrule the Chair with respect to permitting the testimony.

These changes would address the problems with hearings in the past. Many hearings were far too long and unfocused. They involved presentation of numerous documents and witnesses that were irrelevant or redundant with respect to the issues involved. With the active assistance of the Chair of the committee, parties will be able to agree to stipulate facts not in dispute and that will save the time of the parties, committee members, and witnesses whose testimony is not necessary.

#### Limit the Time of the Presentation made by the Complainant and Respondents

The *ad hoc* committee recommends that in the usual grievance hearing the Complainant and the Respondent should each have ninety minutes, including the testimony of witnesses, to present the case. Time spent on questions by members of the grievance committee would be additional and there would be no limit on that. The Complainant and the Respondent would also be provided ten minutes each to summarize their cases at the conclusion of the hearing.

The *ad hoc* committee would like to add this suggested time limit to the Faculty Handbook, but allow the Chair of the grievance committee to make changes when exceptional circumstances warrant an extension of time, so long as the time allowed to both the Complainant and Respondent are equal.

The Chair of the grievance committee would have the power to grant the parties additional time if requested. If additional time is granted to one party, the same amount of additional time shall be granted to the opposing party.

#### President or Provost as the Final Arbiter

The administration asked the *ad hoc* committee to consider an amendment that would allow the Provost rather than the President to be the final decision maker on grievances. However, the *ad hoc* committee recommends that the President continue to serve in this role. The primary reason is that many grievances are filed against the deans, and the deans serve at the pleasure of the President. Although the Provost may be the decision-maker at larger universities, the *ad hoc* committee felt that at a smaller, private university like Case Western Reserve the President should continue to serve as the decision maker since the number of grievance hearings is small and, we believe, will be reduced by the introduction of conciliation and mediation.

The *ad hoc* committee believes that it is important to preserve the option of dialogue between members of hearing committees and the President now provided in Chapter 3, V.C. 8. (last sentence) which reads:

*At the end of the academic year, members of the Grievance Committee Panels may request a meeting to discuss the grievance process in general terms without reference to the specific cases that have been heard.*

## **NEXT STEPS**

The *ad hoc* committee, through its Chair, will work with the administration and the Faculty Senate to get the Conciliation and Mediation Pilot Program implemented and operating by January 2010.

The *ad hoc* committee will prepare drafts of amendments to implement the changes we have described in "Proposed Amendments to the Grievance Process." We will submit the drafts of those proposed amendments to the Faculty Personnel Committee, the By Laws Committee, and the administration for their review. We hope that process can be completed during the 2009-10 academic year so that the Faculty Senate will have amendments to consider and vote on before the end of the year.



# CASE COMPREHENSIVE CANCER CENTER

A Comprehensive Cancer Center Designated by the National Cancer Institute



**Stanton L. Gerson, MD**  
Director

March 12, 2009

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Alan Levine, MD  
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Professor of Oncology, Case Comprehensive Cancer Center  
Director of Surgical Research  
Case Western Reserve University BRB 426  
10900 Euclid Avenue  
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Dr. Levine & Members of the CWRU Faculty Senate Graduate Education Review Committee:

Thank you for your review of the attached proposal for a new Certificate program Clinical Translational Oncology Research Scholars Program (CTORSP) in the School of Medicine and administered through the Case Comprehensive Cancer Center.

Moving forward with this Certificate program will allow us be compliant with an NIH requirement for career-development training grants. All institutions that are awarded a Paul Calabresi Career Development Award for Clinical Oncology (K12) are expected to receive formal recognition from the parent institution with a special certification in clinical research.

We look forward to the opportunity to discuss this Certificate proposal at your meeting on March 19<sup>th</sup>.

Sincerely,

Stanton L. Gerson, MD  
Director, Clinical Translational Oncology Research Scholars Program (CTORSP)  
Director, Case Comprehensive Cancer Center  
Director, Ireland Cancer Center



## Clinical Translational Oncology Research Scholars Program (CTORSP)

The Clinical Translational Oncology Scholar's Program (CTORSP) is a 16-20 hour two-year program that culminates in a Certificate in Clinical Translational Oncology Research. This program has been developed to provide structured training for clinical oncology junior faculty who are interested in pursuing academic research careers as physician scientists. This training will address the need for clinician investigators to translate fundamental cancer research discoveries to medical care of cancer patients. Training will draw on the basic science and clinical investigators who are CWRU School of Medicine faculty and Case Comprehensive Cancer Center members.

The CTORSP will be directed by Stanton L. Gerson, MD, Professor of Medicine and Director of the Case Comprehensive Cancer Center (Case CCC) and Ireland Cancer Center, University Hospitals Case Medical Center (UHCMC) and Alvin H. Schmaier, MD, Professor of Medicine and Chief, Division of Hematology and Oncology, CWRU and UHCMC. CTORSP will be administered through the Case CCC in the School of Medicine. Margy Weinberg, MSW, Training Program Manager at the Case CCC, will serve as the administrator of the program.

Eligible CTORSP candidates are physicians (MD, DO or MD/PhD) with a clinical training background in one of the oncology disciplines, including medical, surgical, dermatological, pediatric, or radiation oncology. Eligibility and recruitment are detailed below. Up to five candidates will be accepted into the program every other year. The program will graduate up to five candidates every other year. This Certificate program combines individualized training plans with courses offered through the University. Each Scholar is guided by a mentoring committee in addition to a basic science and clinical mentor as described in the program details. The Scholars' individual training plan will consist of a formal didactic curriculum consisting of course work and longitudinal training addressing important topics in clinical research. In addition, each Scholar will design an hypothesis-driven, laboratory-based research that they will translate into a patient-oriented, clinical cancer trial. Their research will culminate in application for independent funding as a physician scientist.

### Leadership, Faculty, and Resources

The CTORSP Certificate program will utilize the resources of nine outstanding interdisciplinary scientific programs within the Case CCC. These research programs bring together basic research scientists and clinical investigators from the three institutions of the Case CCC: CWRU, University Hospitals Case Medical Center (UHCMC), and Cleveland Clinic and include members from the other University-affiliated hospitals; MetroHealth Medical Center and the Louis Stokes Cleveland Veteran Affairs Medical Center. All of these institutions provide mentors who have strong cancer research programs and experience in clinical and research oncology training.

The program's Steering Committee will be composed of senior researchers selected by Drs. Gerson and Schmaier. The two primary mentors will work with the Scholar to select a mentoring committee. Together these clinicians and researchers will assist with developing the individualized training plan for each Scholar. Through formal meetings and presentations, the mentors and the program's Steering Committee will evaluate the Scholars' progress toward their research and training goals. Mentors and Steering Committee members are accomplished basic and physician scientists, with experience and success in achieving extramural support for their research.

### PROGRAM DETAILS

**1. Program Overview:** The CTORSP Scholars select one of three areas of concentration: 1) Mechanism Based Therapeutic Development and Clinical Trials, 2) Stem Cell Biology and Hematologic Malignancy Clinical Trials, and 3) Prevention, Aging and Cancer Genetics and Clinical Trials. The Certificate program creates multiple opportunities for the Scholars to work with PhDs and MDs in order to establish transdisciplinary teams to develop an original cancer-related research project effectively carrying a laboratory observation through a clinical trial to improve an aspect of patient care. Scholars will be taught to make novel observations about the nature and progression of disease and to frame

questions that will stimulate their laboratory investigations that will become the basis for clinical investigations.

Each Scholar will be co-mentored by both a basic scientist and a clinical investigator. A mentoring committee comprised of faculty in the Scholar's focus of oncology research provides additional guidance and support. Mentors will be selected from one of nine scientific programs of the Case CCC. During the period of mentored laboratory training, the Scholars will develop original hypothesis-based experiments related to disease mechanisms at a molecular or cellular level. As the Scholars build on their laboratory conclusions to create and implement clinical trials, they will be mentored by clinical investigators. Clinical trials will be aimed at developing new methods for diagnosis and testing promising ideas for novel therapeutic interventions.

## **2. General Recruitment Strategies**

The Steering Committee oversees, implements and monitors recruitment of Scholars. This responsibility includes assurance that the different clinical oncology disciplines are well represented. The specific recruitment strategies to assure a talented and diverse applicant pool are presented below in detail.

### **Scholar Candidate Eligibility**

a. All candidates will be physicians holding the MD, DO or MD/PhD degrees and have completed specialty clinical training and are board-eligible in a cancer-related specialty. The Scholars will have a clinical training background in one of the following oncology disciplines: medical, surgical, dermatological, pediatric or radiation oncology.

b. All clinician candidates must be eligible to obtain NIH funding.

c. Clinician candidates who have equivalent training or clear experience in clinical trial design and leadership in clinical oncology trials would not normally be candidates for this Certificate program.

### **Scholar Candidate Pool**

The primary source of candidates to this Certificate program will be junior faculty with primary or secondary CWRU appointments in the various fields of oncology. Candidates coming from existing clinical training programs corresponding to multiple oncology disciplines will also serve as an important applicant pool. These individuals will have training in oncology disciplines including surgery, gynecology, dermatology, medical, pediatrics and radiation oncology. For all candidates the Steering Committee will only accept candidates for review for whom their Department makes a minimum of a 2-year commitment so they can complete their Certificate program's requirements. The oncology disciplines with strong track records in recruiting and supporting research-oriented trainees are summarized as follows:

Medical Oncology Trainees: The fellowship program in Medical Oncology is under the direction of Dr. Alvin H. Schmaier, Chief of the Division of Hematology Oncology. The fellowship is approved for 5 years under ACGME. The fellowship program recruits 4-5 new trainees per year from a pool of 260 applicants of whom 30 are interviewed and 20 are ranked and placed in the fellowship ranking lottery between institutions. Applicants are selected on the basis of their promise as academic investigators.

Radiation Oncology Trainees: This Residency Program is approved under ACGME for 5 years. Over the last 4 years Radiation Oncology faculty has grown to include 12 physicians, 7 PhD medical physicists, and 6 PHD radiation biologists. NCI and other peer reviewed funding is approximately \$3.5M.

Pediatric Oncology Trainees: The fellowship program in Pediatric Hematology/Oncology at Case and Rainbow Babies and Children's Hospital is under the direction of Dr. John Letterio, who served as Chief from the Carcinogenesis Branch of the NCI. Dr. Letterio has developed an academic division, recruited two physician scientists for laboratory-based research, and has established a 3-year fellowship for which the latter 2 years are research based.

## **3. Clinical Translational Oncology Research Certificate Program Details:**

The Certificate program consists of three separate, yet integrated, sections: A) a formal didactic curriculum consisting of core course work and ongoing longitudinal training, B) an intensive mentored research project, and C) submission of an application for independent funding. Each of these components is described in detail below. Upon the successful completion of all program requirements, Scholars will receive a Certificate in Clinical Translational Oncology Research.

### 3A. FORMAL DIDACTIC CURRICULUM

#### 3A1. COURSEWORK

##### 3A1a. Required Courses

**Translational Cancer Research** (CNCR 501:1-4) (Fall & Spring for two years) Requirement: Attendance and participation at a minimum of 10 classes per year and presentation of research a total of 4 times over two years.

**Translational Cancer Research** (CNCR 501-1) (1 Fall) Course Directors: Stanton L. Gerson, MD & Alvin Schmaier, MD

**Goal:** This section of the course teaches clinicians the language and concepts of translational research and provides opportunities for problem-solving and practical application to the student's individual research project. Topics: development of hypothesis and specific aims for original laboratory research question, developing and nurturing interdisciplinary collaborations, available resources through the Case CCC Core Facilities, understanding the regulatory environment governing research and learning the process of obtaining relevant approvals. Each student will write a sample hypothesis and specific aims which will be critiqued by the other members of the class. Pre-req: Consent of Instructor. 6:00 – 7:45pm Wearn 137. Pass/No Pass.

**Translational Cancer Research** (CNCR 501-2) (1 Sp) Course Director: Stanton L. Gerson, MD & Alvin Schmaier, MD

**Goal:** This course teaches clinicians how to develop and manage a Phase I innovative cancer clinical trial. Topics: defining and designing the trial: 1) the purpose and parameters of the protocol, 2) incorporating laboratory research/ correlative science, 3) managing regulatory, legal, and ethical issues, 4) the purpose and process for the Letter of Intent (LOI), 5) choice of single or multi-site trials, 6) sample size calculations and how to accrue appropriate patient population, and 7) an introduction to the special statistical methods in the research design. Funding and budget issues: 1) attaining CTEP approval for therapeutic agents, 2) working with pharmaceutical companies, and 3) seeking NIH or foundation funding. Clinical trial management: 1) overseeing quality collection and management of data, 2) monitoring for evidence of adverse or beneficial treatment effects, 3) data analysis procedures, and 4) common mistakes. Additional topics: how to hire and supervise staff, and becoming involved with Eastern Cooperative Oncology Group (ECOG) or other Cooperative Groups. Each clinician will present his/her research twice during the semester. Pre-requisite: Consent of Instructor. 6:00 – 7:45pm Wearn 137. Pass/No Pass.

**Translational Cancer Research** (CNCR 501-3) (1 Fall) Course Director: Stanton Gerson, MD & Alvin Schmaier, MD

**Goal:** This course teaches clinicians how to analyze and evaluate all aspects of the Phase I clinical trial including clinical results and findings. Topics: An introduction to the special statistical methods in the analysis of clinical trials based on the student's individual clinical trial design. Topics can include: intent-to-treat analysis, analysis of compliance data, equivalency testing, multiple comparisons, and sequential testing. Each Scholar will make a presentation explaining the progress they have made in writing their protocol through their attendance at the summer Clinical Protocol writing workshop. Pre-requisite: Consent of Instructor. 6:00 – 7:45pm Wearn 137. Pass/No Pass.

**Translational Cancer Research** (CNCR 501-4) (1 Sp) Course Director: Stanton L. Gerson, MD & Alvin Schmaier, MD

**Goal:** Professional development. 1) This section of the course will focus on oral presentations with attention on the content and style of the presentation materials (PowerPoint), and oral presentation style. Each clinician will present his/her research twice during the semester. Written evaluation included. 2) This section of the course builds basic knowledge and develops core skills in scientific writing for peer reviewed journals, the anatomy of the scientific grant proposal, and how to serve as reviewer in the peer review process. 3) This section focuses on grantsmanship; sources of grant funding and strategies in applying and responding to reviews. 4) This section of the course teaches how to recognize and understand effective leadership traits

with interdisciplinary research teams in academic and clinic settings. Group discussion of article *Social Intelligence and the Biology of Leadership* by Goleman and Boyatzis; Topic 2: grantsmanship and the peer review process. Pre-requisite: Consent of Instructor. 6:00–7:45pm Wearn 137. Pass/No Pass.

In addition, Scholars will be required to take a special ethics course designed for clinical investigators. (If the Scholar shows proof of prior attendance at this or an equivalent course, this requirement is waived.)

**Research Integrity and Ethics** (IBMS 500) (0 Sum) Jessica Berg, PhD/Eric Juengst, PhD

**Goal:** To introduce 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 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. IBMS 500 meets for 3 days in May.

### 3A1b. Elective Courses

**(6 credit hours)** Requirement: A minimum of one course must address clinical trial design. Courses must be taken for credit and completed during the two year program. Should the Scholar receive a fail or no pass, the Scholar is required to successfully repeat the course or receive a pass or a passing grade in an alternative course.

### INTRODUCTORY COURSES

#### Theme: Clinical Trial Design

**Introduction Clinical Research Summer Series** (CRSP 401) (3 Summer) Douglas Einstadter, MD & E. Regis McFadden, MD

**Goal:** This course is designed to familiarize one 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, & draw and disseminate the conclusion(s). Regular Grading System.

**Biostatistics for Clinical Research** (CRSP 403) (3 Fall) Thomas Love, PhD

**Goal:** Learn the statistical process: how to conduct studies, what the results mean, and what can be inferred about the whole from pieces of information. Understanding and describing relationships between phenomena and measuring how well these relationships fit data. A project involves problem specification, data collection, management, analysis, and presentation. Will use statistical software extensively; exposed to multiple packages. Topics: descriptive statistics, exploratory data analysis, the fundamentals of probability, sampling, inferential statistics, power & sample size, experimental design, correlation, regression, & association. Prereq: CRSP 401. Regular Grading System.

**Study Design and Epidemiology Methods** (CRSP 402) (3 Fall) Douglas Einstadter, MD

**Goal:** Learn methods used in the conduct of epidemiologic and health services research; considers how epidemiologic studies may be designed to maximize etiologic inferences. Topics: measures of disease frequency, measures of effect, cross-sectional studies, case-control studies, cohort studies, randomized controlled trials, confounding, bias, and effect modification. Prereq: CRSP 401 or permission of instructor. Regular Grading System.

**Health Disparities** (CRSP 510) (3 Fall) Drs. Joseph J. Sudano and Ashwini Sehgal, and Michele E. Petrick

**Goal:** Provide theoretical and application tools for students from many disciplinary backgrounds to conduct research and develop interventions to reduce health disparities. The course is 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 are used for investigating and discussing the empirical evidence on disparities among other subgroups (e.g., the poor, women, uninsured, disabled, and non-English speaking populations) are also included and discussed. Students are expected to develop a research proposal (observational, clinical, and/or intervention) rooted in their disciplinary background that incorporates 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. Offered as CRSP 510, EPBI 510, MPHP 510, NURS 510, and SASS 510. Mon. 5:30– 8:00 pm, Location: NOA 31A. Regular Grading System.

**Introduction to Behavioral Medicine (EPBI 411) (3 Fall) Kristina Noel Knight, MPH**

**Goal:** Using a biopsychosocial perspective, students will learn the measurement and modeling of behavioral, social, psychological, and environmental factors related to disease prevention, disease management, and health promotion. EPBI 411 or MPHP 411. Tue/Thurs 1:15–2:30 pm, Loc: WHITE 324. Regular Grading System.

**Theme: Communication and Leadership**

**Communication in Clinical Research (Part 1) (CRSP 412) (1 Fall) Drs. Ralph O'Brien and John J. Lewandowski**

**Goal:** Parts 1 and 2 of this course build basic knowledge and develop core skills in scientific communication, grantsmanship, and the peer review process. Written and oral communication in clinical science, applying for grants, submitting abstracts and manuscripts, giving presentations, and the peer review process is covered. Recommended preparation: CRSP 401 or equivalent and consent of instructor. Mon 8:30–10:30am, Location: Cleveland Clinic JJ3-107 A & B. Pass/NoPass or Pass/Fail grading only.

**Communication in Clinical Research (Part 2) (CRSP 413) (1 Sp) Ralph O'Brien, PhD**

**Goal:** Parts 1 and 2 of this course build basic knowledge and develop core skills in scientific communication, grantsmanship, and the peer review process. Written and oral communication in clinical science, applying for grants, submitting abstracts and manuscripts, giving presentations, and the peer review process is covered. Prereq: CRSP 401 or equivalent and consent of instructor. Mon. 3:00 – 5:00 pm, Location: Cleveland Clinic, JJ3-107 A & B. Course offered for Pass/NoPass or Pass/Fail grading only.

**ADVANCED**

**Theme: Clinical Trial Design**

**Statistics of Controlled Trials (EPBI 458) (3 Fall) Jeffrey Albert, PhD**

**Goal:** Learn the special statistical methods and philosophical issues in the design and analysis of clinical trials. The emphasis is on practical important issues that are typically not covered in standard biostatistics courses. Topics include: randomization techniques, intent-to-treat analysis, analysis of compliance data, equivalency testing, surrogate endpoints, multiple comparisons, sequential testing, and Bayesian methods. Offered as EPBI 458 and MPHP 458. Tue/Thurs 1:15 – 2:30 pm, Location NOA 300. Regular Grading System.

**Clinical Trials and Intervention Studies (EPBI 450) (3) Mark Schluchter, PhD**

**Goal:** Learn 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. Prereq: EPBI 431 or consent of instructor. XLIST: MPHP 450, Mon/Wed 1:30 – 2:45, Location: MEDS WG73. Regular Grading System.

**Observational Studies (CRSP 500) (3 Sp) Thomas Love, PhD**

An observation 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. **Goal:** Learn 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 are minimized, and the presentations 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 and regression adjustments. Prereq: EPBI 432, EPBI 441, CRSP 406 or consent of instructor. Tue/Thurs 9:00–11:30am, Location: MetroHealth. Regular Grading System.

### **Theme: Bioinformatics**

**Introduction to SAS Programming (CRSP 406) (2 Fall)** Rhoderick Machekano, PhD and Steven Lewis, MS

**Goal:** Students learn how to use SAS version 8.2 in the context of clinical research. Topics include an overview of the SAS "data step" and procedures commonly used to explore, visualize, and summarize clinical data. Students learn the basics of the SAS programming language, how to troubleshoot SAS code, as well as how to interpret selected SAS output. Clinical research datasets are used in class examples, computer laboratory sessions, and homework. Each session includes a lecture immediately followed by a computer lab to reinforce the concepts introduced. Students work in small groups or individually. Recommended preparation: CRSP 403 or consent of instructor. Tues/Thurs 8:30–11:00am, Location: MetroHealth, Rammelkamp, Rm R219, Course offered for Pass/NoPass or Pass/Fail grading only.

**Logistic Regression/ Survival Analysis (CRSP 407) (3 Sp)** Denise Babineau, PhD

**Goal:** Learn how to use the two most common 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 use statistical software extensively and are 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. Prereq: CRSP 403, CRSP 406 or consent of instructor. Mon 1:00–2:30; Wed 3:30–5:00pm. Regular Grading System.

**The Biology and Mathematics of Biochemistry Microarray Studies (BIOC 460) (3 Sp)** Patrick Leahy, PhD

**Goal:** This is a hands-on computer-based course, which upon completion will enable participants to conduct meaningful analyses of expression microarray and proteomics data. The course is multi-faceted and cross-disciplinary in nature. Upon completion, participants will have a thorough understanding of the principles underlying available micro-array technologies, including: sample preparation, sample processing on microarrays, familiarity with the use of Affymetrix Expression Console software, generation of microarray data sets, an ability to move data effortlessly from EC MS Excel and from there into MS Access in order to trim, query and globally manipulate and pre package data. Importation of data into other third party software such as, GeneSpring (Agilent), DecisionSite (Spotfire) and PathwayStudio (Ariadne, Genomics) will enable participants to cluster and mine the data in search of higher-order patterns and pathway annotation and assignment. A new module on proteomics and introduction to systems Biology has been added this year. Permission from course co-ordinator required. Payment of Lab fee (\$600). Regular Grading System.

## **Theme: Communication and Leadership**

### **Working in Interdisciplinary Research Teams (CRSP 501) (1 Fall) Shirley Mason Moore, PhD, RN, FAAN**

**Goal:** Understand why and how different professional disciplines, each representing a body of scientific knowledge, must work together to develop and disseminate knowledge. Learners 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 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 are discussed. Prereq: K12 Appointment or permission of instructor. Fri 9:00am–3:00pm, S 8:00am–3:00pm, Location: NOA 228, Course offered: Pass/No Pass or Pass/Fail grading only.

### **Leadership Assessment and Development (CRSP 502) (2 Sp) Tony Lingham, PhD**

**Goal:** Learn a method for assessing their knowledge, abilities, and values relevant to management; and for developing and implementing plans for acquiring new management related knowledge and abilities. The major goals of this course include generating data through a variety of assessment methods designed to reveal your interests, abilities, values, and knowledge related to leadership effectiveness; learning how to interpret this assessment data and use it to design/plan developmental activities; small group sharing of insights from the various assessments. Prereq: K12 appointment. Tue 1:00–4:00 pm. Regular Grading System.

### **Innovation and Entrepreneurship (CRSP 503) (2 Sp) Scott Shane, PhD**

**Goal:** 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 lectures and case discussion facilitated by the instructor. Some sessions include members of the business community as guest lecturers. As an example, students discuss the financing of new companies with local venture capitalists. Student products include the evaluation of the commercial potential of a university technology in which they apply their new knowledge about commercialization of scientific discoveries. ECON 406, HSMC 406. Prereq: Consent of instructor. Wed 1:00 – 2:45 pm, Location: PBLB 121. Regular Grading System.

## **3A2. LONGITUDINAL TRAINING**

Formal coursework supplemented by longitudinal training provided through seminars, meetings, conferences and retreats, as well as institutional conferences, which will allow the Scholar to have interaction with their peers, colleagues, and mentors.

### **3A2a. Protocol Review & Monitoring Committee (PRMC), Chair, David Adelstein, MD**

**Purpose:** Observe and participate in PRMC deliberations. This committee provides the scientific review required for all cancer related human subject research prior to IRB review. 2nd/4th Tues/Wearn 137, 4:30-6:00PM.

**3A2b. Clinical Trial Protocol Development:** Each Scholar will make a presentation during the Translational Cancer Research (Fall CNCR 501-3) detailing the progress and skills they have acquired through participation in one of the following Clinical Protocol Writing workshops.

American Society of Clinical Oncology and American Association for Cancer Research - Methods in Clinical Cancer Research <http://www.vailworkshop.org/>.

A 7-day intensive workshop in the essentials of effective clinical trial designs of therapeutic interventions in the treatment of cancer for junior faculty clinical researchers. AACR and ASCO have designed this intensive Workshop to increase the reliability and effectiveness of clinical trials by:

Introducing clinical fellows and junior faculty with an oncology subspecialty to the principles of good clinical trial design. **Goal:** This Workshop will give them the tools they need to conduct clinical trials that will yield clear results that investigators can use to proceed to the next level of research. **Goal:** Exposing early career clinical scientists to the full spectrum of challenges in clinical research – from surgery, radiotherapy, conventional and investigational antineoplastic agents and multidisciplinary treatment regimens to gene therapy, biologic therapy, and multimodality and combination treatments. Workshop faculty seek to inspire participants to devote all or a portion of their future careers to some aspect of clinical research. **Goal:** Developing a cadre of well-trained, experienced clinical researchers whose expertise will foster better clinical trial design. **Goal:** Learn such expertise to thereby hasten the introduction of improved regimens for cancer therapy and prevention into everyday medical practice and patient care.

**The American Society of Hematology: Clinical Research Training Institute Curriculum**  
[http://www.hematology.org/education/training/crti\\_brochure\\_2008.pdf](http://www.hematology.org/education/training/crti_brochure_2008.pdf)

3-part program: summer workshop, a week-long immersion course in the basics of clinical research. Participants work from their own proposed clinical research protocols and refine and revise their plans with input from the expert faculty. Two subsequent sessions, one at the ASH annual meeting and one in the spring, provide an opportunity for further interaction and mentoring opportunities.

**Participants will:**

- Discuss the principles of clinical research design and execution
- Examine the methodology for interpreting results of clinical research studies
- Detail the ethical and regulatory issues of clinical research, emphasizing human research protection
- Discuss the fundamentals of competitive grant writing, abstract presentation, & manuscript preparation
- Further develop & improve the quality of their own research proposals through input from faculty & peers
- Learn strategies for pursuing and developing a successful career in hematologic research
- Meet leaders in clinical hematologic research who can enhance networking opportunities for career development

**3A2c. Clinical Trials Disease Teams** pre-review all therapeutic trials for scientific merit, prioritization, and intent to accrue patients.

**Goal:** Through observation and participation in these meetings Scholars will gain an appreciation of the methods by which the clinical research agenda is developed within the disease teams.

| Clinical Trials Disease Teams | Leaders                                     |
|-------------------------------|---|
| Brain Tumors                  | Andrew Sloan, MD, Gene Barnett, MD          |
| Head and Neck Cancer          | Panos Savvides, MD, David Adelstein, MD     |
| Thoracic/Esophagus Cancers    | Afshin Dowlati, MD, Tarek Mekhai, MD        |
| Breast Cancer                 | Joseph Baar, MD, G.Thomas Budd, MD          |
| Gastrointestinal Cancer       | Smitha Krishnamurthi, MD, Robert Pelley, MD |
| Genitourinary Cancer          | Matthew Cooney, MD, Robert Dreicer, MD      |
| Gynecologic Cancer            | Steven Waggoner, MD, Peter Rose, MD         |
| Malignant Melanoma            | Kevin Cooper, MD, Ernest Borden, MD         |
| Soft Tissue Sarcoma           | Patrick Getty, MD, G. Thomas Budd, MD       |

|  |  |
|--|--|
| Lymphoma, Hematologic Malignancies/<br>Stem Cell Transplant, Myeloma, Leukemia | Hillard Lazarus, MD, John Sweetenham, MD |
| Pediatric Malignancies   | John Letterio, MD, Gregory Plautz, MD    |
| Phase I Program  | Afshin Dowlati, MD                       |

### 3A2d. Designated Tumor Board Conference

**Goals:** The Tumor Board Conferences bring together multidisciplinary team to evaluate the diagnosis, classify the stages, discuss management modalities and selection of treatment modalities of various cancers.

| Conference        | Directors                                     | Day                                     | Time        |
|-------------------|---|---|-------------|
| Thoracic          | Afshin Dowlati, MD                            | Monday                                  | 7:00-8:30AM |
| Sarcoma           | Patrick Getty, MD                             | 2 <sup>nd</sup> /4 <sup>th</sup> Monday | 5:00-6:00PM |
| GU                | Matt Cooney, MD                               | Tuesday                                 | 7:00-8:00AM |
| Neuro/Gamma Knife | Robert Maciunas, MD                           | Wednesday                               | 1:30-2:30PM |
| GI                | Thomas Stellato, MD                           | Wednesday                               | 4:30-5:30PM |
| Lymphoma/Leukemia | Brenda Cooper, MD                             | Thursday                                | 8:00-9:00AM |
| Breast            | Paula Silverman, MD                           | Thursday                                | 4:00-6:00PM |
| Head/Neck         | Panos Savvides, MD/PhD,<br>Pierre Lavertu, MD | Friday                                  | 7:00-8:00AM |

All conferences are held in the Radiation Oncology Conf Room, Lerner Tower (B-151)

### 3A2e. Institutional Conferences:

**Goals:** Provide an opportunity for multidisciplinary cancer focused clinicians & researchers to be introduced to research discoveries and treatment modalities from peers, national and international experts in their fields

| Conference                             | Day/Location                                 | Time         |
|--|--|--------------|
| Ireland Cancer Center Grand Rounds     | Wednesday/Lerner B-151                       | 8:00-9:00AM  |
| Cancer Center Blood Club Seminar       | Friday/BRB 105                               | 12:00-1:00PM |
| Hematology/Oncology Fellows Conference | Friday/Wearn 137                             | 8:00-9:00AM  |
| Pathology Grand Rounds                 | 2 <sup>nd</sup> Wed Sept.-June/Pathology Amp | 8:00-9:00AM  |
| Research and Progress                  | Monday/WRB 2-136                             | 12:00-1:00PM |
| Hematology Conference                  | Wednesday/WRB 2-136                          | 1:00-2:00PM  |

### 3A2f. Case Comprehensive Cancer Center Annual Retreat (Held for 2 days each July)

**Goals:** 1) To interact and network with Case Cancer Center members, 2) to learn first hand about individual member's current and future cancer research with the possibility of creating collaborations, and 3) develop a finer understanding of the resources available through the Case Cancer Center.

## 3B. INTENSIVE MENTORED RESEARCH PROJECT (10 credit hours)

In addition to the core courses and longitudinal training described above, each Scholar will participate in an intensive mentored research project centered on a specific hypothesis-based research problem that will result in a clinical trial and a first authored publication in a peer-reviewed journal. This program will include twice-yearly mentoring committee meetings and a review of a minimum of one manuscript for a journal.

### 3B1. Primary Co-Mentors and Mentoring Committee

Each Scholar will be guided in choosing two primary co-mentors along with a mentoring committee consisting of specialists in the Scholar's field of oncology research. One mentor represents a clinical oncology discipline (medical, surgical, dermatological, pediatric, or radiation oncology); and a

second mentor represents a basic or prevention/ population science discipline (cancer genetics, cancer biology, clinical pharmacology, epidemiology, and health care outcomes). This pairing of clinical and basic investigators as primary co-mentors fosters a complementary interdisciplinary clinical and basic training experience that involves the hands-on exposure to translational research projects involving the clinician and basic scientist. Early in the first year, Scholars, in consultation with their mentors, will develop an individualized plan which will identify their current level of learning in key areas for review as well as identify areas for future development. Together, they will identify key learning objectives, the means for meeting them and a timeline for completion of the certificate requirements. At this point, Scholars also identify various sources of learning appropriate to identified short and long-term career goals (including research scope, clinical trial plans, manuscript preparation and timeline for the Certificate program requirements), and learning needs essential to achieving their goals. Scholars will meet, on an ongoing basis, with their primary co-mentors and a minimum of twice a year with their mentoring committee, which includes Dr. Alvin H. Schmaier. Dr. Schmaier will have oversight of the mentoring committees for each Scholar.

The goal of the mentoring committee is to provide a mentoring that focuses on developing the skills necessary for translating basic cancer research findings into clinical experiments, procedures, and trials directly involving cancer patients in a clinical environment. This includes an understanding and working knowledge of the scientific method, particularly hypothesis development, experimental design, and statistical methods. Further, the clinical mentoring relationship will provide the Scholar with clinical research skills that will deal directly with aspects of cancer detection, diagnosis, prognosis, or treatment, experience and instruction in how to interact and communicate with basic research scientists in the design and implementation of collaborative translational research involving patients. In this context, basic scientists are involved in the training program in clinical seminars, protocol planning sessions, and interdisciplinary program working groups.

Oversight for this portion will be achieved through presentations of research progress. This will occur via poster or PowerPoint presentations to peers as well the twice-yearly mentoring committee meeting that includes feedback/recommendations on their research/clinical trials/publications/grant submission progress and annual progress report given as PowerPoint presentation at the Steering Committee meeting. Drs. Stanton Gerson and Alvin Schmaier will also monitor the Scholar's progress at the monthly Translational Cancer Research course including during their PowerPoint presentations of their progress at this course. In addition, Margy Weinberg will oversee the Scholar's registration to national oncology meetings; organize the CNCR 501 Translational Cancer Research course, the Steering Committee Annual Evaluation; and schedule the Scholar's PowerPoint presentations.

### **3B2. Faculty Mentors and Thematic Research Focus Areas**

All scientific programs of the Case CCC will contribute mentors and provide a scientific focus area of investigation for the Scholar. This allows for the co-ordination of multidisciplinary and transdisciplinary investigation into the training and research focus of the Scholars in a manner that cuts across the Scientific Programs of the Case CCC. All clinical research mentors are involved in investigator-initiated clinical trials, have outside funding for clinical research, and participate in Case CCC multidisciplinary research initiatives. They will provide Scholars with training in clinical trial hypothesis testing through study design, including involvement by the biostatisticians, patient eligibility and ethical conduct during early phase clinical trials, patient accrual and assessment in the conduct of the interventional trial and careful review of the endpoints of the trial. Basic research mentors have successful and accomplished laboratory or prevention and interventional programs that will provide the framework for the Scholar to develop hypotheses that form the basis for interventional clinical trials.

| <b>Case CCC Scientific Programs and Clinical Trials Disease Teams</b> |  |
|---|--|
| <b>Program</b>  | <b>Leaders</b>   |
| <b>Cancer Genetics</b>  | Sanford D. Markowitz, MD, PhD*<br>Professor of Medicine (Hematology/Oncology)<br>Robert C. Elston, PhD*<br>Professor of Epidemiology & Biostatistics |

|   |  |
|---|--|
| <b>Cell Death Regulation</b>  | Clark W. Distelhorst, MD*<br>Professor of Medicine (Hematology/Oncology) & Pharmacology<br>Nancy L. Oleinick, PhD*<br>Professor of Radiation Oncology<br>Alexandru Almasan, PhD<br>Associate Professor of Cancer Biology, Radiation Oncology |
| <b>Molecular Basis of Cancer</b>  | George R. Stark, PhD<br>Professor of Molecular Genetics<br>Susann M. Brady-Kalnay, PhD<br>Associate Professor of Molecular Biology & Microbiology  |
| <b>GU Malignancies</b>  | Eric A. Klein, MD*<br>Professor of Urology<br>Warren D.W. Heston, PhD<br>Professor of Cancer Biology, Urology  |
| <b>Stem Cells &amp; Hematologic Malignancies</b>                            | Kevin D. Bunting, PhD*<br>Associate Professor of Medicine (Hematology/Oncology)<br>Hillard M. Lazarus, MD*<br>Professor of Medicine (Hematology/Oncology)  |
| <b>Developmental Therapeutics</b>   | Afshin Dowlati, MD*<br>Associate Professor of Medicine (Hematology/Oncology)   |
| <b>Cancer Prevention, Control, &amp; Population Research</b>                | Gregory S. Cooper, MD*<br>Professor of Medicine (Gastroenterology)<br>Susan A. Flocke, PhD*<br>Associate Professor of Family Medicine  |
| <b>Aging-Cancer Research</b>  | Nathan A. Berger, MD*<br>Director, Center for Science, Health and Society<br>Hanna-Payne Professor of Experimental Medicine<br>Julia Hannum Rose, PhD<br>Professor of Medicine (Geriatrics)  |
| <b>Cancer Imaging (Developing Program)</b>                                  | James Basilion, PhD<br>Associate Professor of Radiology, Biomedical Engineering<br>Jeffrey L. Duerk, PhD<br>Professor of Radiology, Biomedical Engineering   |
| <b>Clinical Disease Teams</b>   | <b>Leaders</b>   |
| Brain Tumors  | Andrew Sloan, MD*, Gene Barnett, MD  |
| Head and Neck Cancer  | Panos Savvides, MD, David Adelstein, MD  |
| Thoracic/Esophagus Cancers  | Afshin Dowlati, MD*, Tarek Mekhai, MD  |
| Breast Cancer   | Joseph Baar, MD, G.Thomas Budd, MD   |
| Gastrointestinal Cancer   | Smitha Krishnamurthi, MD, Robert Pelley, MD  |
| Genitourinary Cancer  | Matthew Cooney, MD, Robert Dreicer, MD   |
| Gynecologic Cancer  | Steven Waggoner, MD*, Peter Rose, MD   |
| Malignant Melanoma  | Kevin Cooper, MD*, Ernest Borden, MD   |
| Soft Tissue Sarcoma   | Patrick Getty, MD, G. Thomas Budd, MD  |
| Lymphoma, Hematologic Malignancies/ Stem Cell Transplant, Myeloma, Leukemia | Hillard Lazarus, MD*, John Sweetenham, MD  |
| Pediatric Malignancies  | John Letterio, MD*, Gregory Plautz, MD   |
| Phase I Program   | Afshin Dowlati, MD*  |

\*Serves as a mentor or on the Certificate Steering Committee

### 3C. Applications for Independent Funding

In the 1st year of the program, Scholars will be encouraged to apply for additional research support funding to support their clinical trials. Resources include ACS, Leukemia and Lymphoma Foundation and pharmaceutical companies. During the 2<sup>nd</sup> year in the program, Scholars will be required to submit applications for funding to such sources as: NIH K22 Career Transition Award, NIH K23 Mentored Patient Oriented Research Career Development Award or Independent awards such as R01 or R03. Oversight for this component will be accomplished, in part, through the mentors who will be involved in the review of their Scholar's grant submissions. Further, Drs. Gerson and Schmaier will discuss grant submissions during the Translational Research Course. Applications for funding are listed in the annual progress report that is reviewed by the Steering Committee.

### 3D. Overview and Timeline Of Certificate Requirements

|          | Requirements                               | Details  | Credit Hours                           | Timeline   | Product   |
|----------|--|--|--|--|---|
| <b>A</b> | <b>Formal didactic curriculum</b>          | <ol style="list-style-type: none"> <li>1. CNCR 501(1-4)- Translational Cancer Research</li> <li>2. IBMS 500 Research Integrity &amp; Ethics</li> <li>3. Two courses; 6 hrs from list of courses in section A.</li> <li>4. Protocol Review Monitoring Committee</li> <li>5. ASCO/AACR or ASH Protocol Writing Course</li> <li>6. Clinical Disease Teams</li> <li>7. Designated Tumor Board: Thoracic, Sarcoma, GU, Neuro/Gamma Knife, GI, Lymphoma/Leukemia, Breast, or Head/Neck</li> <li>8. Institutional Conferences: Ireland Cancer Center Grand Rounds, Cancer Center Blood Club Seminar, Hematology Conference, Hematology/Oncology Fellows Conference, Pathology Grand Rounds, Research and Progress</li> <li>9. Case Comprehensive Cancer Center Retreat</li> </ol> | <p>4 hrs</p> <p>0 hrs</p> <p>6 hrs</p> | <ol style="list-style-type: none"> <li>1. 1<sup>st</sup> Wed eve. both yrs</li> <li>2. 3 days in May/ 2<sup>nd</sup> yr</li> <li>3. Anytime during 2yrs</li> <li>4. Longitudinal</li> <li>5. Summer 2<sup>nd</sup> yr</li> <li>6. Longitudinal</li> <li>7. Longitudinal</li> <li>8. Longitudinal</li> <li>9. July/2 days annually</li> </ol> | <ol style="list-style-type: none"> <li>1. Passing grade on presentation to CNCR 501 directors/students &amp; to Steering Committee, credit for 4 courses</li> <li>2. Transcript</li> <li>3. 6 hours credit, course required projects</li> <li>4. Presentation of IRB proposal</li> <li>5. Presentation of protocol at CNCR 501</li> <li>6. Presentation of LOI</li> <li>7. Active participation</li> <li>8. Presentation when requested</li> <li>9. Presentation or poster when requested.</li> </ol> |
| <b>B</b> | <b>Intensive mentored research project</b> | <ol style="list-style-type: none"> <li>1. Laboratory cancer related research</li> <li>2. Developmental Therapeutics Program Meetings</li> <li>3. Developmental Therapeutic Clinical Trial</li> <li>4. Mentoring committee meetings</li> </ol>  | 10 hrs                                 | <ol style="list-style-type: none"> <li>1. Primarily 1<sup>st</sup> yr</li> <li>2. Longitudinal</li> <li>3. 1<sup>st</sup> &amp; 2<sup>nd</sup> yr</li> <li>4. Twice a yr</li> <li>5. Publication in either yr</li> <li>6. Review of manuscript anytime during 2 years</li> </ol>   | <ol style="list-style-type: none"> <li>1. Develop original hypothesis &amp; specific aims</li> <li>3. From concept to successfully opening a clinical trial</li> <li>4. Passing grade in research presentation in CNCR 501&amp; Steering Committee meeting</li> <li>4. Summary of meeting &amp; annual progress report</li> <li>5. 1<sup>st</sup> author publication in peer reviewed journal</li> <li>6. Review of at least 1 manuscript for national</li> </ol>                                     |

|          |  |   |   |   |   |
|----------|--|---|---|---|---|
|          |  |   |   |   | journal   |
| <b>C</b> | <b>Application for independent funding</b> | 1. Fellowships: ie ACS, LLF<br>2. Pharmaceutical companies<br>3. R or K grant-mentored or independent career awards | 0 | 1. & 2. During 1 <sup>st</sup> yr<br><br>3. During 2 <sup>nd</sup> yr | 1-3. Written application for funding submitted to SC for review |

*\* If the Scholar shows proof of prior attendance at either of these or an equivalent course, this requirement is waived.)*

**CLINICAL TRANSLATIONAL ONCOLOGY RESEARCH CERTIFICATE PROGRAM  
CORE COMPETENCIES**

|  |  |
|--|--|
| <b>Competency 1: Develop a rational scientific hypothesis based on clinical knowledge and research findings with the potential for improving the medical care of cancer patients</b> |  |
| 1.1  | Develop an understanding of cross disciplinary concepts and language in order to develop original cancer research hypothesizes   |
| 1.2  | Demonstrate ability to communicate, verbally and in writing, with basic and behavioral research scientists (PhD) in order to effect the translation of basic/behavioral information into patient-oriented research                                 |
| 1.3  | Demonstrate the ability to formulate specific aims to validate the research hypothesis   |
| 1.4  | Identify Case Comprehensive Cancer Center Core Facility resources available to support and enhance the implementation of the scientific research (Biostatistics, Gene Expression & Genotyping, Imaging Research, Tissue Procurement and Histology) |
| 1.5  | Attain required research subject approval(s) to conduct laboratory based research, if appropriate  |
| 1.6  | Demonstrate the ability to translate laboratory-based scientific knowledge into a developmental therapeutic cancer clinical trial  |
| 1.7  | Demonstrate an understanding of, and the ability to manage, ethical issues that may arise during the course of the study   |
| <b>Competency 2: Develop, conduct, manage and evaluate the results of an innovative cancer clinical trial</b>  |  |
| 2.1  | Translate basic research findings into an innovative clinical trial designed to improve the medical care of cancer patients  |
| 2.2  | Identify Case Comprehensive Cancer Center Core Facility resources available to support and enhance the implementation of the cancer clinical trial (Clinical Trials, Biostatistics, Translational Research, Cancer Pharmacology)                   |
| 2.3  | Demonstrate an understanding of the principles involved in producing an accepted Letter of Intent (LOI)  |
| 2.4  | Attain Cancer Therapy Evaluation Program (CTEP) approval (when appropriate) for utilization of the selected therapeutic agent  |
| 2.5  | Attain required Institutional Review Board (IRB) approval to perform the clinical trial  |
| 2.6  | Accrue the appropriate patient population necessary to perform the desired clinical trial  |
| 2.7  | Oversee data collection and management of clinical results and findings  |
| 2.8  | Analyze clinical results and finding   |
| 2.9  | Critically evaluate all aspects pertaining to the clinical trial   |
| 2.10   | Demonstrate an understanding of, and the ability to manage, ethical issues that may arise during the course of the clinical trial  |
| <b>Competency 3: Develop and nurture transdisciplinary collaborations</b>  |  |
| 3.1  | Work with a mentoring team to identify and initiate potential professional collaborations  |
| 3.2  | Identify potential collaborations opportunities with other Scholars in the certificate program   |
| 3.3  | Establish an effective relationship with various scientific (PhD), clinical (oncology disciplines), and program leadership within the certificate program  |
| 3.4  | Identify a potential network of collaborations locally (Cleveland), regionally (Ohio and Tri-State),   |

|  |  |
|--|--|
|  | nationally, and internationally (when appropriate) to enhance future cancer based research   |
| 3.5  | Identify and utilize (when appropriate) resources available through the Eastern Cooperative Oncology Group (ECOG)                              |
| 3.6  | Demonstrate effective relationships with CTEP, IRB and other regulatory agencies to aid in the advancement of the proposed clinical trial      |
| 3.7  | Develop and nurture productive collaborations  |
| <b>Competency 4: Recognize and understand effective leadership traits</b>  |  |
| 4.1  | Actively participate in appropriate clinical and scientific based workshops, seminars, retreats, and other learning opportunities              |
| 4.2  | Establish an effective relationship mentors, mentoring committee members, and colleagues.  |
| 4.3  | Demonstrate the ability to effectively provide constructive feedback and receive criticism   |
| 4.4  | Recognize effective and ineffective leadership traits  |
| <b>Competency 5: Demonstrate ability to disseminate, in both oral and written form, the key scientific foundations and the clinical findings</b> |  |
| 5.1  | Acceptance to present their original cancer research findings at a nation oncology conference  |
| 5.2  | Acceptance of a first authored research manuscript to a peer reviewed journal  |
| 5.3  | Submission of a grant proposal with clear specific aims  |
| 5.4  | Review and edit a manuscript for a national journal  |
| 5.5  | Demonstrate the ability to translate data from the laboratory setting to the clinical setting and back to the laboratory (bench-bedside-bench) |

#### **4. INTERACTION BETWEEN THE CERTIFICATE PROGRAM AND OTHER PROGRAMS:**

##### **4A. CTSC**

The Certificate program will take advantage of resources available through the School of Medicine's Clinical Translational Science Center, through their programs for research and career development of junior faculty. Both the Certificate and the CTSC programs take advantage of the courses offered through the CRSP.

##### **4B. CRSP (The Masters in Clinical Research Program):**

The Masters in Clinical Research Program (CRSP) will review courses and research proposals in order to decide on an individual basis which of the credits, presented here, can be transferred to CRSP Master Program.

#### **5. PROGRAM OVERSIGHT, ADDITIONAL RESOURCES, AND EVALUATION**

##### **5A. Program Oversight**

Dr. Gerson, Director of the Case CCC, will serve as the Program Director of the Certificate Program. Dr. Gerson will be responsible for the oversight of the CTORSP training program, including appointment of mentors, decisions regarding the curriculum, and implementation of Steering Committee recommendations. He will oversee and promote high quality mentoring of clinical investigators and will support their multidisciplinary training by taking advantage of all of the resources of the Case CCC. Dr. Gerson's career interests reflect the goals of the Certificate Program and his status as Program Director ensures the seamless linkage to the Cancer Center and the commitment by the Cancer Center to the goals of the Certificate Program.

Dr. Schmaier, Chief of the Division of Hematology Oncology, serves as the Co-Director. Dr. Schmaier is an outstanding laboratory-based investigator, an excellent clinician and has an extensive track record mentoring students, fellows and junior faculty. As Certificate Program Co-Director, Dr. Schmaier will have oversight of the mentoring committees for each Scholar and will co-chair the Steering Committee.

##### **5B. Additional Resources**

###### **5B1. Shared Resources**

As part of the Case CCC, Scholars will have access to the expertise and services of the Case CCC Shared Resources to aid in their training and to advance their research goals. The resources are described, briefly, below.

### Shared Resources of the Case Comprehensive Cancer Center

| Shared Resource                           | Leadership                | Description   |
|---|---------------------------|---|
| <b>Athymic Animal &amp; Xenograft</b>     | Lili Liu, PhD             | Preparation of mouse xenografts for drug screening and immunodeficient animals for human stem cell engraftment.             |
| <b>Behavioral Measurement</b>             | Susan Flocke, PhD         | Measure development and resource for analysis of human responses.   |
| <b>Biostatistics</b>                      | Mark Schluchter, PhD      | Support for clinical trials and preclinical data analysis.  |
| <b>Cancer Pharmacology</b>                | Yan Xu, MD                | Detection methods development and pharmacokinetic measurements during clinical trials.                                      |
| <b>Clinical Trials</b>                    | Smitha Krishnamurthi, MD  | Management of all investigator-initiated clinical trials.   |
| <b>Confocal Microscopy</b>                | James Jacobberger, PhD    | High quality microscopic analysis.  |
| <b>Cytometry</b>                          | James Jacobberger, PhD    | Flow analysis of cell phenotype, apoptosis, cell cycle, and drug effect of TK inhibitors.                                   |
| <b>Gene Expression &amp; Genotyping</b>   | Martina Veigl, PhD        | Affymetrix chips for gene expression, SNIPS, genome scanning to clinical samples.   |
| <b>Hematopoietic Stem Cells</b>           | Luis Solchaga, PhD        | Analysis of stem cells, distribution of hematologic malignancies cell samples.  |
| <b>High Throughput Sequencing</b>         | Mark Adams, PhD           | High throughput sequencing<br>Examination of genetic alterations associated with clinical and experimental cancers          |
| <b>Hybridoma</b>                          | Clemencia Colmenares, PhD | Preparation of antibodies.  |
| <b>Imaging Research</b>                   | Christopher Flask, PhD    | Animal and human imaging with MR, PET, luciferase, SPECT, imaging and radionuclide preparation.                             |
| <b>Practice Based Research Network</b>    | James Werner, PhD         | 130 practice network in Northern Ohio for analysis of practice trends and interventions in cancer screening and prevention. |
| <b>Proteomics</b>                         | Mark Chance, PhD          | Mass spectrometry and peptide identification.   |
| <b>Radiation Resources</b>                | Nancy Oleinick, PhD       | Research equipment for radiation of animals and cell lines.   |
| <b>Tissue Procurement &amp; Histology</b> | Gregory MacLennan, MD     | Collection and distribution of human tumors discarded at surgery.   |
| <b>Tissue Biorepository</b>               | Joseph Willis, MD         | Preparation of tissue specific biorepository with clinical outcome annotation.  |
| <b>Transgenic &amp; Targeting</b>         | Ronald A. Conlon, PhD     | Creation of transgenic and knockout mice.   |
| <b>Translational Research</b>             | John J. Pink, PhD         | Coordinating center for collection, processing, storage and distribution of   |

|  |                                     |
|--|-------------------------------------|
|  | human samples from clinical trials. |
|--|-------------------------------------|

## **5B2. Special Training Environment**

There are a number of specific training sessions for this program. All involve active working groups and scientific collaborating teams that meet regularly to review results, develop new concepts, review clinical trials based on laboratory efforts and manage patients on early phase clinical trials. The specific scheduled meetings are:

Drug Development Working Group Committee monthly meeting (Monday 4-6 pm). All laboratory and clinical investigators involved in development of novel anti cancer drugs either in preclinical or early phase clinical trials including laboratory correlates evaluated during early clinical development of new drugs attend this meeting.

Included are pharmacokinetics of clinical drugs with methods development and validation for new agents; pharmacodynamic measurements of targets, enzyme, protein, DNA damage, cell cycle analysis, and apoptosis, depending on the agent, using biochemical cytometry, IHC, and imaging technologies; and preclinical evaluation of new markers to be used in clinical trials.

Angiogenesis Working Group (monthly, Wednesday, noon): This team evaluates new molecules that have anti-angiogenic properties in cancer, develops research and clinical questions involving basic biologists in the Vascular Biology of Cancer initiative, the imaging research group and the clinical trials group.

Phase I Patient Protocol Review (Friday, 9-11 am). This weekly meeting reviews all active patients on Phase I clinical trials at Case CCC. New trials, adverse events, dose escalation, regulatory, safety and privacy issues are addressed. Scholars develop clinical protocols with mentors and seek input from the Translational Core Facility (John Pink, PhD, Director) and from laboratory investigators. Statisticians from the Cancer Center Biostatistics Core are actively involved in study design and post-activation study review and analysis.

Developmental Therapeutics Program Meetings (Wednesday 5-60 pm) This weekly meeting will aid Scholars in the understanding the development and prioritization of clinical trials, and promote the discovery and evaluation of new mechanism-based therapeutics for the cancer patient. Program investigators lead innovative Phase I and Phase II clinical trials with novel agents, incorporating pharmacokinetic and pharmacodynamic studies to monitor drug effects, and to develop relevant biomarkers by integrating correlative laboratory endpoints and capitalizing on cancer imaging technologies.

## **5C. Program Evaluation**

### **5C1. Evaluation of Mentoring: Mentors and Scholars**

Mentoring is regarded as a powerful catalyst and essential for professional development, and is considered critical for establishing a strong career in clinical research and academic medicine. Evaluations will assess the extent to which Scholars and their mentors identify and meet expectations within the mentor-scholar relationship; the extent to which short- and long-term career goals are set; and whether scholars participate in close, collaborative relationships with their mentors. Special attention will be given to the extent to which women and minorities are supported in the mentoring relationship; to the assessment of issues in such areas as gender and power; negotiation and conflict management; performance pressures, isolation, and role-limiting expectations. Both surveys and individual interviews will be used to assess the quality of the mentoring relationships.

### **5C2. Steering Committee and Evaluation**

The Steering Committee will have a very active role evaluating the Certificate program, providing feedback on mentor and Scholar interactions and will serve as the central review during the evaluation of scholars, mentors, and the Certificate program. The Steering Committee will review each Scholar's progress on a yearly basis. At this annual meeting Scholars will provide a PowerPoint presentation outlining their research progress and advancement in the Certificate program according to the goals and established timeline. The Steering Committee will review the Scholar's evaluation of their

mentors and Certificate program and the mentor's evaluation of the Scholar's progress and the Certificate program. The mentoring committee issues an evaluation on a yearly basis or more frequently, if the mentoring committee report raises concerns. This process is longitudinal and continuous over the course of the training period. The goal is to assure that Scholars are developing the skills and confidence to design and manage clinical trials; to fine tune the didactic training to meet current and future needs; and successfully apply for independent funding.

### 5C3. Evaluation Process and Results

The continued evolution of the Certificate program keeps it current with mentor and Scholar expectations and needs. A core value of the CTORSP is that regular assessment of all elements of the program is essential to its continued evolution. The input of Steering Committee members and research mentors is sought as well as the evaluations of the Scholars themselves, so that programs may be tailored to the Scholars needs and interests.

### 5C4. Tracking

For tracking purposes, a variety of data regarding applicants and selected Scholars will be collected and reviewed yearly with the Steering Committee. These outcomes, tracked and recorded in a database, will include: 1) all scholars who applied for admission or positions within the department(s) participating in the Program; 2) scholars who were offered admission to or a position within the participating department(s); 3) scholars actually enrolled in the participating departments; 4) applicant characteristics (i.e., degree, gender, ethnicity, prior institution, topic of research); 5) information on the recruitment and retention of underrepresented minorities will be collected.

In addition, in order to monitor and evaluate the Certificate Program and Scholars' performance in the longer term, Scholars' perceptions of program quality and impact, as well as specific outcomes consistent with the goals of this program, will be measured annually from matriculation and up to 7 years following graduation. Specific longer term outcomes to be monitored annually will include publications; presentations at national and international scientific meetings; grant proposals submitted and funded, with special attention to multidisciplinary grants and program project and center-type grants; mentorship and pertinent outcomes of mentoring others; research-related leadership posts and awards at local through international levels; and any evidence of commercial translation of research (e.g., business spin-offs, patents, etc.). Routine data will be collected using an internet-accessible survey, using a modified version of the Case School of Medicine Annual Faculty Activity Summary Form. The Case CCC Training Program Manager, Ms. Margy Weinberg, MSW, will assemble these and report them to the Steering Committee. In addition, each previous Scholar will be contacted by telephone to discuss and describe their career accomplishments and reflect on elements of the Certificate program that were particularly useful to them in their current positions.

## 6. TUITION

The Clinical Translational Oncology Research Scholar's Program (CTORSP) does not provide support for the Scholar's tuition.

Scholars are encouraged to apply for institutional training programs that provide tuition support.

Many employers provide a tuition benefit. Please contact your administrator or the Human Resources Department (Benefits Office) for limits/details.

Should the Scholar receive a fail or no pass, the Scholar will be required to repeat the course or take an alternative course within the two years of the Certificate program.

| <b>Clinical Translational Oncology Research Scholars Program (CTORSP)</b> |  |                     |
|---|--|---------------------|
| <b>Leadership</b>   |  |                     |
| <b>Directors</b>  | <b>Title</b>   | <b>Affiliations</b> |
| Stanton L. Gerson, MD   | Professor of Medicine (Hematology/Oncology);<br>Director, CWRU and UHCMC, Director,<br>Comprehensive Cancer Center; Director,<br>Director, Ireland Cancer Center | CWRU and UHCMC      |
| Alvin H. Schmaier, MD   | Professor and Division Chief of Medicine   | CWRU and UHCMC      |

|                                       | (Hematology/Oncology)  |   |
|---------------------------------------|--|---|
| <b>Steering Committee</b>             | <b>Title</b>   | <b>Affiliations</b>                             |
| Randall D. Cebul, MD                  | Professor of Medicine, Director of the Center for Health Care Research and Policy                                    | CWRU and MetroHealth                            |
| Kevin Cooper, MD                      | Professor and Chair of Dermatology   | CWRU and UHCMC                                  |
| Clark W. Distelhorst, MD              | Professor of Medicine (Hematology/Oncology) and Pharmacology   | CWRU and UHCMC                                  |
| Julian A. Kim, MD                     | Professor of Surgical Oncology   | CWRU and UHCMC                                  |
| John Letterio, MD                     | Professor and Division Chief of Pediatrics (Hematology/Oncology)   | CWRU and UHCMC                                  |
| Sanford D. Markowitz, MD, PhD         | Professor of Medicine (Hematology/Oncology)  | CWRU and UHCMC                                  |
| Kurt C. Stange, MD, PhD               | Professor of Family Medicine; Director, Center for Research in Family Practice & Primary Care                        | CWRU  |
| Jackson T. Wright, Jr., MD, PhD, FCAP | Professor of Medicine  | CWRU, UHCMC and VAMC                            |
| <b>Mentors</b>                        | <b>Title</b>   | <b>Affiliations</b>                             |
| Nathan A. Berger, MD                  | Professor of Medicine (Hematology/Oncology), Experimental Medicine, Director, Center for Science, Health and Society | CWRU and UHCMC                                  |
| Kevin D. Bunting, PhD                 | Associate Professor of Medicine (Hematology/Oncology),   | CWRU and UHCMC                                  |
| Kenneth R. Cooke, MD                  | Professor of Pediatrics,   | Rainbow Babies and Children's Hospital and CWRU |
| Gregory S. Cooper, MD                 | Professor of Medicine (Gastroenterology)   | CWRU and UHCMC                                  |
| Kevin Cooper, MD                      | Professor and Chair of Dermatology   | CWRU and UHCMC                                  |
| Afshin Dowlati, MD                    | Associate Professor of Medicine (Hematology/Oncology)  | CWRU and UHCMC                                  |
| Robert C. Elston, PhD                 | Professor and Interim Chair of Epidemiology & Biostatistics  | CWRU  |
| Susan A. Flocke, PhD                  | Associate Professor of Family Medicine   | CWRU and UHCMC                                  |
| Sanjay Gupta, PhD                     | Associate Professor of Urology   | CWRU  |
| Charles L. Hoppel, MD                 | Professor of Clinical Pharmacology   | CWRU and VAMC                                   |
| David Kaplan, MD, PhD                 | Professor of Pathology   | CWRU  |
| Jeffery A. Kern, MD                   | Professor and Chief of Pulmonary and Critical Care Division  | CWRU and UHCMC                                  |
| Eric A. Klein, MD                     | Professor of Urology, CWRU; Chair of Urology, Cleveland Clinic   | CWRU and Cleveland Clinic                       |
| Eric D. Kodish, MD                    | Professor and Chair of Bioethics, Cleveland Clinic; Professor of Pediatrics and Bioethics, CWRU                      | CWRU and Cleveland Clinic                       |
| Mary J. Laughlin, MD                  | Associate Professor of Medicine (Hematology/Oncology)  | CWRU and UHCMC                                  |
| Hillard M. Lazarus, MD                | Professor of Medicine (Hematology/Oncology)  | CWRU and UHCMC                                  |
| John Letterio, MD                     | Professor and Division Chief, Pediatrics (Hematology/Oncology)   | CWRU and UHCMC                                  |
| Sanford D. Markowitz, MD, PhD         | Professor of Medicine (Hematology/Oncology)  | CWRU and UHCMC                                  |
| Keith R. McCrae, MD                   | Professor of Medicine (Hematology/Oncology)  | CWRU and UHCMC                                  |
| Robert H. Miller, PhD                 | Professor of Neurosciences and Neurological  | CWRU  |

|                              |  |                |
|------------------------------|--|----------------|
|                              | Surgery  |                |
| Nancy L. Oleinick, PhD       | Professor of Radiation Oncology  | CWRU and UHCMC |
| Paula Silverman, MD          | Associate Professor of Medicine<br>(Hematology/Oncology) ,                                       | CWRU and UHCMC |
| Andrew E. Sloan, MD,<br>FACS | Associate Professor of Neurological Surgery  | CWRU and UHCMC |
| Kurt C. Stange, MD, PhD      | Professor of Family Medicine; Director, Center<br>for Research in Family Practice & Primary Care | CWRU           |
| Steven E. Waggoner, MD       | Associate Professor of Reproductive Biology,<br>Division Chief of Gynecological Oncology         | CWRU and UHCMC |
| Georgia L. Wiesner, MD       | Associate Professor of Genetics  | CWRU and UHCMC |
| Yu-Chung Yang, PhD           | Professor of Biochemistry  | CWRU           |



CASE WESTERN RESERVE  
UNIVERSITY  
SCHOOL OF MEDICINE

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

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June 18, 2009

Alan D. Levine, Ph.D.  
Chair, Graduate Studies Committee  
Case Western Reserve University  
School of Medicine

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To the Faculty Senate,

I endorse the development of the Clinical Oncology Research Training Program Certificate program led by Drs. Gerson and Schmaier that was recently reviewed by members of Faculty Senate. In the intervening period since review, it became clear to me that we do not have a satisfactory process at the School of Medicine, nor at the University, to review new or continuing certificate programs, and I apologize for any contributions from the SOM to the confusion. I have now reviewed the proposal, and support it. In particular, I would like to address several concerns that were apparently raised about the proposed certificate program.

*1. Why is it a certificate, rather than a MS program?* This certificate program has a clear focus on Cancer Biology training for junior clinical oncology faculty who are supported by an extramural training program for the express purpose of enhanced clinical oncology training. There is little career currency for these folks who already hold an MD in completing the components of an academic master's degree, but much to be gained in developing their specific knowledge and interests in cancer clinical trials. I should add that such certificates are becoming the rule in clinical research, to demonstrate a basic level of competency in these areas of study. In particular, the certificate will demonstrate that the scholars have fulfilled the basic course requirements of the program and developed their abilities to cogently write a translational clinical trial. The proposed certificate outlines 19 curricular hours in a thoughtful plan of study that allows other professional work to continue, while most MS programs require perhaps twice as many hours of coursework. Thus, it is a focused program with a focused purpose in training young faculty to prepare cancer therapeutics clinical trials.

*2. Does it duplicate the CRSP program?* The Clinical Scholars Research Program, currently led by Dr. Randy Cebul, in the process of transition to the Center for Clinical Investigation as an academic home, is an approved MS degree intended for individuals who have completed their clinical training and wish to develop a professional career based upon clinical investigation, rather broadly. The CRSP is a Master's "Plan A"

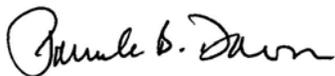
June 18, 2009  
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substantial academic and research program that requires 36 credit hours including a formal thesis. Scholars may receive up to 18 hours of credit for thesis research. Scholars select one of four areas of concentration or specialty tracks with additional required coursework: Clinical Trials; Health Services/Outcomes Research; or Multidisciplinary/Translational Research. Some specific course electives are likely to be attractive to trainees in each program, but it is clear that the CRSP is a more substantive undertaking for which a MS is conferred, and had a broader scope. The CTSC (Clinical and Translational Science Collaborative) has considered adding a certificate program, and is actively working on a PhD curriculum, but at the present time only the MS is approved. Our faculty are active on national committees that are setting the standards for competencies at each of these levels, and the proposed certificate program is in line with national expectations.

*3. Why wasn't there a letter from the Dean?* Although both the SOM and Faculty Senate have clear review mechanisms for doctoral and master's programs (through Graduate Education and Faculty Affairs, and that require Dean's support), certificate programs currently fall between the cracks, both for initial review of new certificates and for periodic quality review once underway. It was not clear to any of us that a Dean's letter was required. To my knowledge, the SOM administers only one other certificate program (in Global Health). We will take steps to clarify that the initial review process for certificates is similar to that of a Master's program at the SOM. I anticipate that this will reduce confusion in the future.

I apologize for the delay in providing this information to you.

Sincerely,



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

cc: Charles E. Rozek, Ph.D.  
Dean, School of Graduate Studies  
Case Western Reserve University

## **Certificate in Clinical Translational Oncology Research Support Statement**

The certificate program has its basis in the NCI funded K12 Clinical Oncology Research Program (CORP). The goal of the NCI in establishing this program is to train the next generation of oncology physician scientists who “1) primarily perform clinical oncology therapeutic research that develops and tests scientific hypotheses based on fundamental and clinical research findings, 2) design and test hypothesis-based, clinical therapeutic protocols and adjunct biological analyses and for clinician candidates to administer all phases (i.e., pilot/Phase I, Phase II, and Phase III) of cancer therapeutic clinical trials, and 3) conduct cancer therapeutic research in team research settings in which basic research and clinical scientists collaborate and interact to expedite the translation of basic science research discoveries into patient-oriented therapeutic cancer research.” (NIH program announcement 06-449). Further, the certificate program provides an excellent roadmap for training a broader range of junior faculty and senior fellows in cancer therapeutic clinical research, and thus will be open to additional trainees beyond those enrolled in the NCI K12.

The certificate program codifies the expectations of the CORP curriculum, which requires K12 awardees to specify the didactic, clinical research and basic science research core components that trainees must complete to “graduate” from the program. Thus the certificate program that is proposed is targeted to oncology specialties and is heavily weighted toward specific elements that are deemed essential to a career in cancer research. Among these elements are:

Teaching the language and concepts of translational research and guiding them in the development of a hypothesis and specific aims of an original laboratory research question;

Instructing in critical aspects of managing a Phase I cancer clinical trial, with particular emphasis on incorporating laboratory research and correlative science and managing the regulatory, legal and ethical issues involved in the clinical trial for cancer patients; overseeing quality collection and management of data, monitoring for evidence of adverse or beneficial treatment effects, data analysis procedures;

Teaching analysis and evaluation of all aspects of Phase I trials including such topics as intent to treat analysis, analysis of compliance data, equivalency testing, multiple comparisons, and sequential testing.

Mentoring fellows in their professional development so that they may collaborate effectively with interdisciplinary colleagues.

These elements are part of the required curriculum which is supplemented by elective courses that are taken through CRSP. The focus and challenge of the clinical translational oncology research program is to provide a strong curriculum for training junior faculty in oncologic specialties and to do this in a way that incorporates as much practical application as possible, minimizing classroom hours and emphasizing individual mentorship to prepare them to develop strong and worthwhile hypotheses and develop proposals for research for improving the medical care of cancer patients that may be successfully supported by extramural funding agencies.

PI: Stanton L. Gerson, MD  
Case Comprehensive Cancer Center

Margy Weinberg 216-844-5375  
Administration

Last year, the Senate held the first two priorities from 07-08 (child care center and faculty salaries) as primary commitments for 08-09, and the Senate ranked these 5 investments as the next most important:

- 1) undergraduate financial aid
- 2) technology enhanced classrooms
- 3) expansion of health care coverage for students
- 4) core funding of high performance computing facility
- 5) experiential learning fund for students.

## **Proposed Timeline 09-10**

### **Thursday, September 17**

Executive Committee – At September Executive Committee meeting, confirms budget priority process.

### **Friday, September 18**

Liz - Email standing committee chairs to submit their committee's budget priorities by October 19.  
*(They have a month to submit budget priorities.)*

### **Thursday, September 24**

Alan – At September Senate meeting, summarize Executive Committee's proposed budget priority process, solicit senators to submit their own priorities.

### **Friday, September 25**

Liz – Email reminder to senators to submit their budget priorities.

### **Monday, October 19**

Standing Committee Chairs/Senators – Submit budget priorities to Liz.

### **Tuesday, October 20**

Liz – Submit final list of senate budget priorities to Julia Grant and Ginny Leitch to determine cost estimates by October 30.

*(They have 10 days to submit cost estimates. To help speed things up, Liz will email any "carry-over" priorities from 08-09 to Julia and Ginny ASAP, and as 09-10 priorities are submitted – before 10/20 – Liz will forward them immediately to Julia and Ginny.)*

### **Friday, October, October 30**

Faculty Senate Budget Committee – Submit cost estimates to Liz.

### **Monday – Wednesday, November 1- 3**

Faculty Senate - Complete online survey to rank faculty senate budget priorities.  
*(They have 3 days to complete the ranking online.)*

### **Thursday, November 5**

Executive Committee – At November Executive Committee meeting, review senate rankings.

### **Friday, November 6**

Liz – Submit senate budget priority rankings to the Provost.

**Wednesday and Thursday, November 11 and 12**

Provost's Strategic Planning Meeting

## **Proposed Process 09-10:**

Present two categories of budget priorities for rankings.

- 1) Long-term, high-cost investments for re-ranking to determine top TWO:
  - a. **On campus child care center**
  - b. **Faculty salaries**
  - c. Undergraduate Merit Scholarships (#1 from last year)
  - d. Technology Enhanced Classrooms (#2 from last year)
  - e. Expansion of Health-care coverage for students (#3 from last year)
  - f. Core Funding for High Performance Computing Facility (#4 from last year)
  
- 2) Short-term (2-year), low-cost (<\$100K total) investments for re-ranking, and submit new ones:
  - a. Experiential Learning Funding (Travel Awards) for Students (#5 from last year, it's also <\$100k/year)
  - b, c, d, e, etc. Solicit new budget priorities