CASE WESTERN RESERVE UNIVERSITY EST. 1826

**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, *attachment* | 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 *ad hoc* Committee on Grievance Process Reform<br>*attachment* | B. Leatherberry |
| 2:40pm | New Certificate Program: Clinical Translational Oncology Research Scholars Program (CTORSP)<br>*attachments* | 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>*attachment* | 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>*attachment* | C. Musil |

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

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

Bud Baeslack
Ken Ledford
Glenn Starkman

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

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 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

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.

---

Prof. Carol Musil, chair of the faculty senate, encouraged faculty to attend President

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

CASE WESTERN RESERVE UNIVERSITY EST. 1826

Thursday, April 16, 2009
9:30 – 11:30 a.m. – Adelbert Hall, Room

Susan Case
Allen Levine

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 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 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.

Lev el

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

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*

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 aff5(efl)8.8(-.2( 3H9f6(with )6.ctiis to p)dispu( fo)-7.3(r)7(ic conf5.2( )]TTJ19.j0

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

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*

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

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:

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.

*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

**Case Comprehensive Cancer Center**
11100 Euclid Avenue
Wearn 151, WRN 5065
Cleveland, OH 44106-5065
216 844 8562 Phone
216 844 4975 Fax
Stanton.Gerson@case.edu Email

March 12, 2009

Alan Levine, MD
Professor of Medicine, Surgery, Pathology, and Pharmacology
Professor of Oncology, Case Comprehensive Cancer Center
Director of Surgical Research
Case Western Reserve University BRB 426
10900 Euclid Avenue
Cleveland, OH 44106-4952

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 19th.

Sincerely,

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

[redacted]

**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.

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

## 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

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.

cultural, legal, and ethical theories related to disparities in general, with a central focus on health

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 to cpackagta efrray. Imn of a effo MS Aoe inre irdtici

**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

| | |
|---|---|
| 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 |

**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 | 2nd/4th 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, 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 | 2nd Wed Sept.-June/Pathology Amp | 8:00-9:00AM |
| Research and Progress Hematology Conference | Monday/WRB 2-136 | 12:00-1:00PM |

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.

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 2nd 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 |
|---|---|---|---|---|---|
| **A** | **Formal didactic curriculum** | | | | |

| | | | | | |
|---|---|---|---|---|---|
| **C** | | | | | journal |

| | |
|---|---|
| | 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 |
| | |
| **Competency 4:** Recognize and understand effective leadership traits | |
| 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 |
| | |
| **Competency 5:** Demonstrate ability to disseminate, in both oral and written form, the key scientific foundations and the clinical findings | |
| 5.1 | |

| | | |
|---|---|---|
| | | 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

| | | |
|---|---|---|
| | (Hematology/Oncology) | |
| **Steering Committee** | **Title** | **Affiliations** |
| 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 |
| **Mentors** | **Title** | **Affiliations** |
| 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 | |

| | | |
|---|---|---|
| | Surgery | |
| Nancy L. Oleinick, PhD | Professor of Radiation Oncology | CWRU and UHCMC |
| Paula Silverman, MD | Associate Professor of Medicine (Hematology/Oncology) , | CWRU and UHCMC |
| Andrew E. Sloan, MD, FACS | Associate Professor of Neurological Surgery | CWRU and UHCMC |
| Kurt C. Stange, MD, PhD | Professor of Family Medicine; Director, Center for Research in Family Practice & Primary Care | CWRU |
| Steven E. Waggoner, MD | Associate Professor of Reproductive Biology, 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 |


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

School of Medicine

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.

**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 genera 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-
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

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 – At September Executive Committee meeting, confirms budget

Liz - Email standing committee chairs to submit confirms