

## Orientation Agenda

Friday, June 29, 2007  
Farrell Learning & Teaching Center  
Robert Emmet Conner Auditorium

12:00 noon – 2:30 p.m.

<b>12:00 noon</b>	Lunch Welcome Introductions Program Overview	<b>Victoria J. Fraser, MD</b> <i>J. William Campbell Professor of Medicine; Co-Director Infectious Diseases Division; PI, K12 Multidisciplinary Clinical Research Career Development Program</i>
<b>12:30 p.m.</b>	Scholar Financial Activities Research Travel Course Enrollment, etc.	<b>Kerry Bommarito</b> <i>K12 Grant Administrator</i>
<b>1:00 p.m.</b>	Evaluation and Tracking	<b>Jill Ringold</b> <i>K12 Evaluation Liaison</i>
<b>1:30 p.m.</b>	BREAK	
<b>1:45 p.m.</b>	Research Design Incubator	<b>J. Philip Miller</b> <i>Director, K12 RDI</i>
<b>2:00 p.m.</b>	General Program Information Seminars CCTRT Space	<b>Alison Ebers</b> <i>K12 Program Coordinator</i>
<b>2:15 p.m.</b>	Closing Remarks	<b>Victoria J. Fraser, MD</b>
<b>2:30 p.m.</b>	CCTRT Tour	<b>Alison Ebers</b>

June 29, 2007

## Welcome K12 Clinical Scholars

I would like to take this opportunity to welcome you to our Roadmap K12 Multidisciplinary Clinical Research Career Development Program at Washington University in St. Louis. We look forward to what will be accomplished through this unique and diverse group of Scholars.

We are pleased to provide you with this orientation handbook which should be a helpful resource during your association with us. It outlines the K12 guidelines, program requirements, and academic options, and provides helpful contacts and resources for course registration and navigation through the various phases of your CR Scholar experience.

The Roadmap K12 at Washington University is one of a limited number of K12 programs across the nation. We are always looking to improve our local program and contribute to the national program overall. As such, we will frequently ask for your feedback to evaluate the program and your experience during your tenure with us. We hope you will participate and help us advance and improve K12 programs locally and nationally.

We encourage you to capitalize on this unprecedented opportunity to interact with and learn from your diverse cohorts to generate and implement innovative and informative research. We are committed to providing you with professional challenge and support to help you advance your professional goals, as well as the goals of the program.



Victoria J. Fraser, M.D.  
J. William Campbell Professor of Medicine  
Co-Director Infectious Diseases Division  
Principal Investigator, K12 Clinical Scholars Program

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## Overview of the NIH Roadmap

The Multidisciplinary Clinical Research Career Development initiative of the NIH Roadmap is a key part of the Reengineering the Clinical Research Enterprise theme, which seeks to accelerate and strengthen the clinical research process. Specifically, this initiative is intended to produce new clinical research leaders who can cross the boundaries of their disciplines and draw upon the strengths of other fields. Clinical research includes epidemiologic and natural history studies, patient-oriented research, clinical trials, and outcomes research.

The NIH Roadmap for Medical Research is a series of far-reaching initiatives designed to transform the nation's medical research capabilities and speed the movement of scientific discoveries from the bench to the bedside. It provides a framework of the priorities the NIH must address in order to optimize its entire research portfolio and lays out a vision for a more efficient and productive system of medical research. The NIH Roadmap identifies the most compelling opportunities in three main areas: new pathways to discovery, research teams of the future, and re-engineering the clinical research enterprise.

*NIH MCRCDP website: <http://www.clinicalresearchscholar.org>  
NIH Roadmap website: <http://nihroadmap.nih.gov/overview.asp>*

## What is Multidisciplinary Clinical Research?

The scale and complexity of today's biomedical research problems increasingly demands that scientists move beyond the confines of their own discipline and explore new organizational models for team science. A multidisciplinary approach brings together numerous experts from diverse disciplines to collectively address a complex problem, with each expert addressing the issues from the perspective of his or her own discipline.

Clinical research is defined as patient-oriented research, that is, research conducted with human subjects or on material of human origin such as tissues, specimens and cognitive phenomena, for which an investigator or colleague directly interacts with human subjects. Clinical research embraces a spectrum of scientific disciplines (e.g. epidemiology, biostatistics, pharmacology, biology and psychology), methodologies (e.g. observational, experimental), health professions (e.g. radiology, nursing, clinical psychology), and specialties and subspecialties (e.g. internal medicine, surgery, pediatrics, obstetrics/gynecology, oncology, cardiology, nephrology and others).

Examples of Clinical Research include:

- 1) Patient-oriented research such as:
  - a. Mechanisms of human disease
  - b. Therapeutic interventions
  - c. Clinical trials
  - d. Development of new technologies
- 2) Epidemiologic and behavioral studies
- 3) Outcomes research and health services research

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## Vision

Our vision is to create a new, innovative clinical research training program that transcends institutional and departmental boundaries and brings diverse disciplines and individuals together into cohesive multidisciplinary teams to address the treatment and prevention of disease.

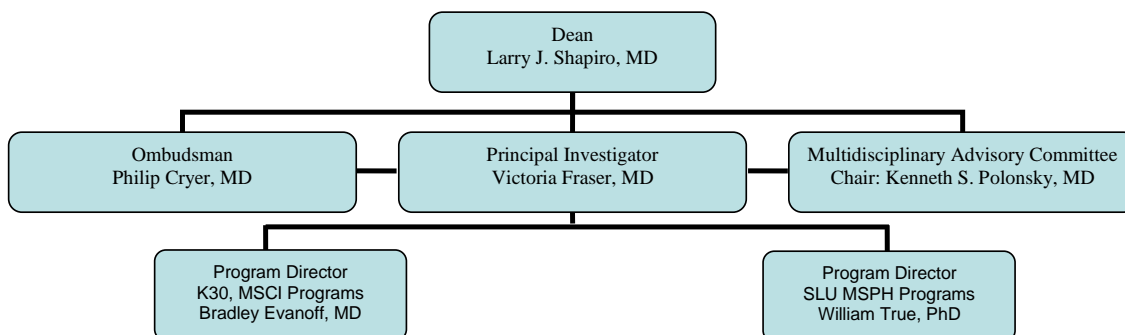
## Goals

Our goals are to provide high quality, multidisciplinary training in clinical research, offer a range of didactic degree and non-degree programs and coursework, provide supportive and interactive mentorship, and promote the career development of future clinical investigators.

## Key Partners

The Washington University K12 Program is a collaborative effort with Saint Louis University, University of Missouri at St. Louis College of Nursing, St. Louis College of Pharmacy, and Southern Illinois University at Edwardsville School of Nursing. Our partners contribute to the diverse and experienced leadership of the K12 program and enhance our extensive research capability and infrastructure. Through the K12 program, Scholars are able to enroll in courses at Washington University and Saint Louis University.

## Administrative Structure



With direction and support from Larry J. Shapiro, MD, Executive Vice Chancellor for Medical Affairs and Dean of the School of Medicine, and under the direct supervision of the Multidisciplinary Advisory Committee (MAC) chaired by Kenneth Polonsky, MD, the overall direction and day-to-day activities of the K12 are directed by the Principal Investigator, Victoria J. Fraser, MD. Philip E. Cryer, MD, Professor of Endocrinology and Metabolism in Medicine and an established clinical investigator, is Ombudsman for the program. He will help the PI address conflicts within the program, or among mentors, scholars and participating institutions.

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The Multidisciplinary Advisory Committee (MAC) is made up of 44 faculty members from various disciplines and representing all collaborative institutions (Washington University, Saint Louis University, University of Missouri at St. Louis College of Nursing, St. Louis College of Pharmacy, and Southern Illinois University Edwardsville School of Nursing). The MAC meets quarterly and is responsible for recruiting and selecting scholars, reviewing and approving didactic curricula, mentors, and the education and career development of each Scholar. The MAC will also monitor the progress of each Scholar and provide peer review of the clinical research projects submitted by each Scholar in the final stage of their training, monitor the overall effectiveness of the program, insure interaction and participation of all participating schools, and help develop an annual program progress report. A number of subcommittees or working groups have been formed to facilitate the work of the MAC (Executive Committee, Selection Committee, and Curriculum Committee).

The Executive Committee of the MAC provides additional leadership, decision-making, and direction to carry out the goals of the committee. The Selection Committee meets at least twice per year to review and select scholars and to provide feedback and recommendations to the program. The Curriculum Committee is responsible for development of the core curriculum, degree programs, and the integration of all new and existing courses that will be offered through the K12 program.

The K12 has two Co-Directors. Bradley Evanoff, MD, MPH, Chief of the Division of General Medical Sciences and Program Director for the Clinical Research Curricula, Master of Science in Clinical Investigation (MSCI). The second Co-Director is William True, PHD, MPH, Director of the PhD program at Saint Louis University School of Public Health.

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**Administrative Core**

Kerry Bommarito, Alison Ebers, Mary Favazza, Kate Kruse, and Jill Ringold comprise the administrative core of the K12 and work under the direction of the PI. Their roles and responsibilities are listed below.

<b>K12 Staff</b>	<b>General Roles &amp; Responsibilities</b>
<b>Kerry Bommarito</b> <i>Grant Administrator</i> 314-454-8221 kbommari@im.wustl.edu	Oversight of all Program and Scholar financial activities; Approval of Program and Scholar purchases; Assistance with Scholar budget preparation
<b>Alison Ebers</b> <i>Program Coordinator</i> 314-454-8255 aegers@im.wustl.edu	Overall Program coordination; Multidisciplinary Advisory Committee (and subcommittees); Program Mentors; Scholar recruitment and selection; Scholar Orientation; National meeting; Annual Retreat; Weekly seminars; Progress reports; Physical program space (access, network computing issues, etc.)
<b>Mary Favazza</b> <i>Program Secretary</i> 314-454-8224 mfavazza@im.wustl.edu	Overall administrative secretarial responsibilities for the program
<b>Kate Kruse</b> <i>Office Assistant</i> 314-454-8224 kkruse@im.wustl.edu	Weekly conferences, special conferences, and CCTRT conference room bookings
<b>Jill Ringold</b> <i>Evaluation Coordinator</i> 314-454-8629 jringold@im.wustl.edu	Program, Scholar and Mentor evaluation and tracking; Scholar recruitment and selection; Program website

Other key personnel include J. Phil Miller, Director of the Research Design Incubator (RDI), Missy Krauss, Research Coordinator, and Cherie Hill, Data Manager. They provide hands-on help to the scholars regarding research design, statistical analysis, forms design, data management and biostatistical and epidemiological issues.

<b>RDI Staff</b>	<b>Roles &amp; Responsibilities</b>
<b>Phil Miller</b> <i>RDI Director</i> 314-362-3617 phil@wubios.wustl.edu	Research design Statistical analysis
<b>Missy Krauss</b> <i>Research Coordinator</i> 314-454-8570 mkrauss@wustl.edu	Data management Statistical analysis Research coordination
<b>Cherie Hill</b> <i>Data Manager</i> 314-454-8240 chill@im.wustl.edu	Data management

## Expectations of K12 Scholars

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**Continuation in the K12 program is determined yearly based upon satisfactory research progress, professional effort, academic grades and attendance, as well as participation at the seminars, annual retreat, and national meeting.**  
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### **Professional Effort**

Unless other terms have been negotiated, Scholars are expected to devote 75% of their full time effort to the training and clinical research activities of the K12 program. The remaining effort may be devoted to other clinical or academic pursuits consistent with the award. NIH policy requires that the remainder of your salary NOT paid by the K12 must come from non-federal sources.

### **Participation and Attendance**

Scholars are expected to attend and should give high priority to the weekly Clinical Research Faculty Seminar. These seminars, scheduled Tuesdays at 1:00 p.m., will address a wide variety of topics, in keeping with our multidisciplinary goals. Scholars are also required to attend the weekly CCTRT Scholar Seminar and make at least 2 work-in-progress presentations per year at that seminar. The CCTRT Scholar Seminar is jointly conducted with K12 and K30 Scholars and is scheduled on Tuesdays from 2:10 – 3:40 p.m.

### **Career Development Plan**

Scholars must establish a Career Development Plan in consultation with their mentors. This Plan must be submitted by August 1, 2007 to Alison Ebers. The Plan should include career goals for the next 2-5 years, career objectives for each goal, research activities/projects that will assist the Scholar in meeting the objectives, and an overview of the courses, workshops and other education/training activities that the Scholar plans to pursue. For each objective, the Scholar should indicate what individual products (degrees, publications, presentations, grants, etc.) are expected. A timeline should be constructed to display the individual objectives, educational activities, research activities and products.

### **Research Design Incubator / Research Plan**

The purpose of the Research Design Incubator (RDI) is to provide you with guidance on data management and statistical analysis, if needed. For example, you may need assistance with planning your study design, developing data collection forms and databases, data cleaning, and data analysis. The RDI requires that you:

- 1) complete a Needs Assessment to determine your data management / statistical support needs (due July 2)
- 2) provide your updated research plan (due July 2)

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- 3) schedule an appointment with the RDI and your mentors in July or August to discuss your research plans and specific needs (to schedule an appointment contact Robin Woltman at 314-362-1318 or robinw@wubios.wustl.edu).

**Research Budget**

Scholars are expected to follow the financial policies described in Appendix D. Failure to follow these policies may result in denial of reimbursement or purchase requests.

**Program Evaluation**

Scholars are expected to complete required program evaluations twice per year. These evaluations are administered via the web and are mandatory for all scholars.

Evaluation Instrument	Time Period Administered
Scholar Annual Activity Form	Entrance to Program, Annually
Scholar Clinical Research Appraisal Inventory	Entrance to program, Annually
Scholar Course Evaluation <i>(if taking coursework)</i>	End of each semester they are taking courses
Scholar Mentor Evaluation	Every 6 months, Mid-Year and End-of-Year
Scholar Mid-Year Progress Report	6 months after start of program
Scholar Research Evaluation	Entrance to Program, Annually
Scholar Satisfaction Evaluation	Every 6 months, Mid-Year and End-of-Year

**Scholar Progress**

Scholars are to keep the K12 program informed of their individual progress. Scholars are required to forward to Alison Ebers all published manuscripts, abstracts, submitted grant applications, awards, etc. in a timely manner. Additionally, scholars are required to provide at least annually a detailed progress report to be submitted to the NIH. An outline detailing the content of the components of the report will be provided to the scholar. Scholars are to note that they are to secure from their mentors a brief mentor report to be included with their progress report. Mentor reports will also be submitted to the NIH.

**NIH Roadmap K12 Annual Meeting**

Each year a national meeting of the K12 programs is hosted. This two-day meeting presents an exceptional opportunity to meet and interact with key clinical research leaders from the NIH, to hear and read about multidisciplinary clinical research at other K12 awarded institutions, to network with Clinical Research Scholars and leaders from across the nation, and to form collaborative partnerships in multidisciplinary clinical research.

Each scholar's expenses will be paid to attend the annual meeting of the Roadmap K12 annual meeting. Scholars are expected to attend this meeting annually while in the program and to present their research at this meeting.

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**Mentors and Mentees**

Developing a successful clinical and translational research career requires strong relationships with mentors and a research team. Each Scholar must have a program-approved primary and secondary mentor. The primary mentor will be the Scholar's main source of research supervision and career development. It is expected that Scholars will meet weekly with their mentors and that mentors will be available for consultation and support concerning the Scholar's current projects and future progress. Mentors are expected to attend and present occasionally at K12 seminars, attend the annual K12 retreat, and provide formal feedback to the Scholar as least annually.

Both you and your mentors will have the opportunity to evaluate the relationship. Please give us regular feedback about your experience. If for any reason you feel it might be best to change mentors, it is important for us to discuss the matter as soon as possible to determine a suitable and acceptable solution for everyone. Please contact Alison Ebers to discuss the process for requesting a change in mentor.

**Didactic Instruction**

K12 Scholars have the opportunity to earn a Master of Science Degree in Clinical Investigation (MSCI) or a Genetic Epidemiology Master of Science (GEMS) both from Washington University or a Masters of Science Degree in Public Health (MSPH) from Saint Louis University. K12 Scholars have the opportunity to enroll in coursework at both institutions.

**Masters of Science in Clinical Investigation**

Specific information regarding course offerings for the MSCI may be found at:  
<http://k30.im.wustl.edu/program/program.html>.

MSCI contact: Julie Follman, [jfollman@im.wustl.edu](mailto:jfollman@im.wustl.edu), 314-454-8540

**Masters of Science in Public Health**

Specific information regarding course offerings for the MSPH may be found at:  
<http://publichealth.slu.edu/Schedules.htm>.

MSPH contacts: Bernie Backer, [backerb@slu.edu](mailto:backerb@slu.edu), 314-977-8144 (Admissions) and Nancy Murphy, [nmurphy1@slu.edu](mailto:nmurphy1@slu.edu), 314-977-8141 (course registration)

**Genetic Epidemiology Master of Science**

Specific information regarding course offerings for the GEMS may be found at:  
<http://www.biostat.wustl.edu/gems/>.

GEMS contact: June Mueller, [pa@wubios.wustl.edu](mailto:pa@wubios.wustl.edu), 314-362-1052

**To sign up for electives or courses not associated with the programs noted above:**

Your specialized course of study or elective selections must be approved by your mentor(s) and by the program PI, Vicky Fraser, MD. To sign up for courses not included in the MSCI, GEMS, or MSPH, you must register through the school/program that is offering the course. Please contact Alison Ebers prior to enrollment in courses not included in the listed programs.

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**Center for Clinical and Translational Research Training**

The K12 program is housed within the Center for Clinical and Translational Research Training (CCTRT). The CCTRT is physically located on the second floor of the Wohl Clinic building on the campus of Washington University School of Medicine.

As a K12 scholar, you have access to this space. A dedicated workroom which includes networked desktop computers, network connections for laptop computers, a printer, and two telephones is available for your use. The CCTRT space also includes conference rooms you may reserve to conduct meetings. Each conference room is equipped with a network connection and telephone. Additional amenities for K12 scholars include a library, locker room with an assigned locker for each scholar, and kitchen with microwave, toaster oven, dishwasher, refrigerator, and coffee service. Office equipment available to K12 scholars includes a photocopier, fax, color laser printer, and poster printer.