

Clinical Research Training Center (CRTC)
KL2 Career Development Awards and Postdoctoral Program

Scholar Handbook 2009-2010

Orientation Agenda

Thursday, June 18, 2009

Clinical Research Training Center Conference Room 1

8:00 – 10:30 am

| | | |
|-----------------|------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8:00 am | Breakfast Welcome Introductions Program Overview | Victoria J. Fraser, MD <i>J. William Campbell Professor of Medicine; Co-Director Infectious Diseases Division; Director Clinical Research Training Center; KL2 Career Development Awards Program Director</i> Jane M. Garbutt, MBChB, FRCP <i>Associate Professor of Medicine and of Pediatrics; Co-Director, Postdoctoral Program Director</i> |
| 9:00 am | Research Design & Biostatistics Group | Missy Krauss <i>Senior Statistical Data Analyst ICTS Research Design & Biostatistics Group</i> |
| 9:15 am | BREAK | |
| 9:30 am | Scholar Financial Activities: Research, Travel, Course Enrollment, etc. | Jennifer Wever <i>CRTC Sr. Financial Analyst</i> |
| 10:00 am | CRTC Scholar Seminars: Schedule, CME disclosure, Seminar Evaluations, Attendance | Julie Headrick <i>CRTC Seminars</i> |
| 10:15 am | General Program Information, Evaluation and Tracking, Curriculum, CRTC Space, etc. | Alison Ebers <i>CRTC Program Coordinator KL2 Career Development Awards and Postdoctoral Program</i> |
| 10:30 am | Closing Remarks | Vicky Fraser and Jane Garbutt |

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Welcome Clinical Research Training Center Scholars

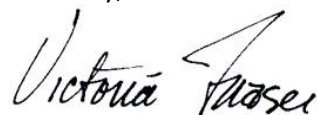
We would like to take this opportunity to welcome you as a Scholar in the Clinical Research Training Center (CRTC). We look forward to what will be accomplished through this unique and diverse group of Scholars.

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

The CRTC is part of the Institute of Clinical and Translational Sciences (ICTS) at Washington University in St. Louis. The ICTS is one of a limited number of Clinical and Translational Science Awards (CTSA) programs across the nation. We are always trying 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 inquire about your experience during your tenure with us. We hope that you will participate and help us advance and improve programs locally and nationally.

We encourage you to capitalize on this unprecedented opportunity to interact with and learn from your colleagues and faculty 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.

Sincerely,



Victoria J. Fraser, MD
J. William Campbell Professor of Medicine
Co-Director Infectious Diseases Division
Director Clinical Research Training Center
KL2 Career Development Awards Program Director



Bradley A. Evanoff, MD, MPH
Richard A. and Elizabeth Henby Sutter Associate Professor
of Occupational, Industrial, and Environmental Medicine
Chief Division of General Medical Sciences
Postdoctoral Program Director

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Overview of the ICTS

The Washington University Institute of Clinical and Translational Sciences (ICTS) is one of 39 medical research institutions working together as a national consortium to improve the way biomedical research is conducted across the country. The consortium, funded through the Clinical and Translational Science Awards (CTSA), shares a common vision to reduce the time it takes for laboratory discoveries to become treatments for patients, and to engage communities in clinical research efforts. It is also fulfilling the critical need to train the next generation of clinical researchers. The CTSA initiative is led by the National Center for Research Resources (NCRR) at the National Institutes of Health (NIH).

Clinical Research Training Center

The KL2 Career Development Awards and Postdoctoral Program are housed within the Clinical Research Training Center (CRTC). The CRTC is also the physical home of the TL1 Predoctoral Program and the Doris Duke Clinical Research Fellowship Program. The CRTC is centrally located on the second floor of the Wohl Clinic Building on the Washington University School of Medicine campus.

As a CRTC Scholar, you have access to this space and its amenities. Additional information regarding the CRTC is located at “CRTC General Information” in the appendices of this handbook.

CRTC Vision

Our vision is to provide an innovative clinical and translational research training program that transcends institutional and departmental/divisional boundaries and brings diverse disciplines and individuals together into cohesive multidisciplinary teams to address the treatment and prevention of disease.

CRTC Goals

Our goals are to provide high quality, multidisciplinary training in clinical and translational 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.

What is Multidisciplinary Clinical and Translational Research?

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).

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Examples of Clinical Research:

1. Patient-oriented research, including:
 - 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

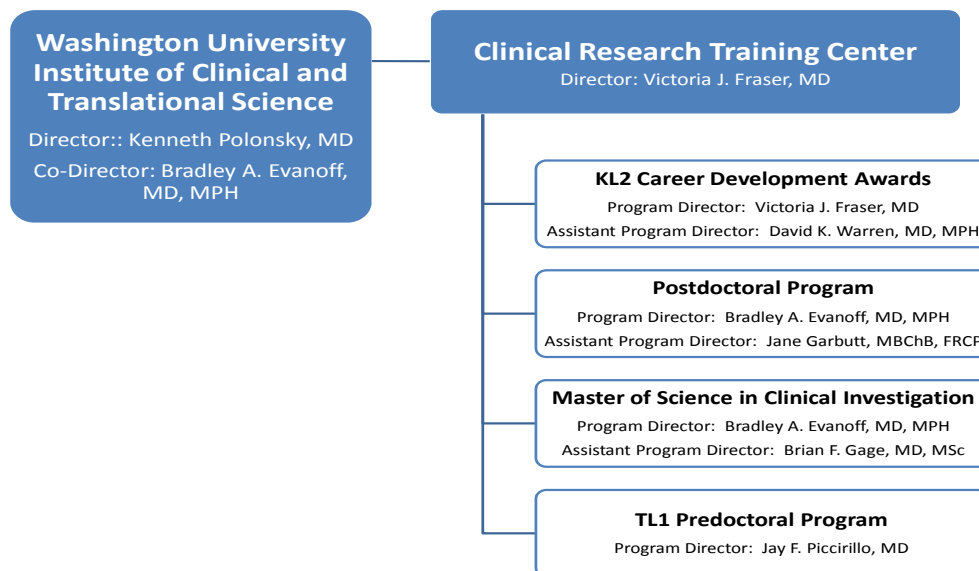
"T1 translational research" may include laboratory-based research aimed at clarifying mechanisms of disease; developing measures or markers of disease presence, severity, or improvement; and developing drugs, devices, or interventions to treat disease or to improve health.

"T2 translational research" generally identifies community, patient, physician, and organizational factors that serve as barriers and facilitators to translation; develops novel intervention and implementation strategies to increase translation, such as quality improvement programs or policies; and evaluates the impact of strategies to increase translation of relevant healthy behaviors and processes of care.

Key Partners

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

CRTC Administrative Structure



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CRTC Administrative Core

Alison Ebers, Jennifer Wever, Mary Favazza, Julie Headrick, Dan Detlefsen, Joe Wilson, and a Curriculum Coordinator to be named comprise the administrative core of the CRTC and work under the direction of the CRTC Director and Program Directors. Their roles and responsibilities are listed below.

| CRTC Staff | General Roles and Responsibilities |
|------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Alison Ebers <i>Program Coordinator</i> <i>KL2 Career Development Awards and Postdoctoral Program</i> 314-454-8255 aebers@dom.wustl.edu | Overall KL2 Career Development Awards and Postdoctoral Program coordination; Scholar recruitment and selection; Scholar orientation; KL2 Scholar national meeting; mentors; Annual CRTC Career Development Retreat; CRTC program evaluation; CRTC monthly career development seminars; CRTC Progress reports; CRTC physical space; CRTC Multidisciplinary Advisory Committee; ICTS Council of NIH-funded Training Programs at Washington University |
| Jennifer Wever <i>CRTC Sr. Financial Analyst</i> 314-362-1022 jwever@dom.wustl.edu | Oversight of CRTC Program and Scholar financial activities; Approval of Program and Scholar purchases; Assistance with Scholar budget preparation |
| Mary Favazza <i>CRTC Secretary</i> 314-454-8224 mfavazza@dom.wustl.edu | Overall administrative secretarial responsibilities for the CRTC and Council of NIH-funded Training Programs at Washington University |
| Julie Headrick <i>CRTC Data Assistant</i> 314-454-8957 jheadric@dom.wustl.edu | CRTC Scholar Seminar; general administrative assistance to KL2 and Postdoctoral Programs |
| Dan Detlefsen <i>Program Coordinator</i> <i>TL1 Predoctoral Program</i> 314-454-8540 ddetlefs@dom.wustl.edu | Overall TL1 Predoctoral Program coordination; TL1 recruitment and selection; TL1 orientation; Annual trainee research symposium |
| Joe Wilson <i>CRTC Special Project Assistant</i> 314-454-8960 jawilson@dom.wustl.edu | CRTC conference room bookings; CRTC audiovisual setup; General assistance to TL1 Predoctoral Program |
| To Be Named <i>CRTC Curriculum Coordinator</i> | Overall coordination of CRTC Master of Science in Clinical Investigation; CRTC Curriculum Committee; CRTC Scholar course registrations |

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Other key personnel include J. Philip Miller, Director of ICTS Research Design & Biostatistics Group (RDBG) and Missy Krauss, RDBG Senior Statistical Data Analyst. They provide hands-on help to Scholars regarding research design, statistical analysis, forms design, data management, and biostatistical and epidemiological issues.

| ICTS RDBG Staff | General Roles and Responsibilities |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|
| Phil Miller <i>Director, ICTS Research Design & Biostatistics Group</i> 314-362-3617 phil@wubios.wustl.edu | Research design Statistical analysis |
| Missy Krauss <i>Senior Statistical Data Analyst</i> <i>ICTS Research Design & Biostatistics Group</i> 314-362-3663 missy@wubios.wustl.edu | Data management Statistical analysis Research coordination |

Expectations of CRTC Scholars

Continuation in the KL2 Career Development Awards and Postdoctoral Program is determined yearly based upon satisfactory research progress, professional effort, academic grades and attendance, as well as participation at the weekly seminars, annual retreat, and (for KL2) national meeting.

Professional Effort

KL2 Career Development Awards

Unless other terms have been negotiated prior to matriculation into the program, KL2 Scholars are expected to devote 75% of their full-time effort to the training and clinical research activities of the KL2 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 KL2 must come from non-federal sources.

Postdoctoral Program

Unless other terms have been negotiated prior to matriculation into the program, Postdoctoral Scholars are expected to devote 60% of their full-time effort to the training and clinical research activities of the Postdoctoral Program. The remaining effort may be devoted to other clinical or academic pursuits consistent with the award.

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Tuesday Scholar Seminar Participation and Attendance

CRTC Scholar Seminars are scheduled for Tuesdays at 1:00 pm, and will begin on August 11, 2009. In addition, scholars are required to attend a monthly special career development seminar. These special seminars are scheduled for the second Tuesday of the month and will replace the weekly scholar seminar on those Tuesdays. **All** Scholars are required to attend the weekly CRTC Scholar Seminar and monthly CRTC Career Development seminar. First and second year Scholars are further required to make 2 work-in-progress presentations per year (once per semester). A schedule for the 2009-2010 year is located at "CRTC General Information" in the appendices of this handbook.

Scholars are expected to attend the complete duration of each seminar session (1:00 – 3:15) and should give high priority to attendance. An attendance rate of less than 75% per semester (14 of the 19 scheduled weekly sessions) will require viewing of taped seminars and submission of evaluations related to the viewed session(s) to bring a Scholar to an acceptable attendance rate.

Career Development Plans

KL2 and Postdoctoral Scholars must establish a Career Development Plan in consultation with their mentors and advisory committee. The plan must be submitted by **September 15, 2009**, to the Alison Ebers. The Plan should include career development 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 educational/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. Specific guidance and direction regarding the preparation of this Plan will be presented to Scholars at the initial CRTC Scholar Seminar on August 11, 2009 (see also information included at "Career Development Plan" in the appendices of this handbook).

ICTS Research Design & Biostatistics Group (RDBG)/Research Plan

All Scholars are required to schedule an appointment with the RDBG and your mentors to discuss your research plan and specific needs at the start of each program year. To schedule an appointment, contact Robin Woltman at 314-362-1318 or robinw@wubios.wustl.edu. Two weeks prior your appointment, you must send your research plan to Missy Krauss at missy@wubios.wustl.edu. The purpose of the ICTS Research Design & Biostatistics Group (RDBG) 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.

Additional information regarding the RDBG is located at "RDBG" in the appendices of this handbook.

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IRB Approvals

Scholars are required to provide to the Program current IRB approvals for their research project(s). These approvals are to be current and a copy of the approval(s) must be submitted to Mary Favazza in a timely manner.

Research Funds

Scholars are expected to follow the financial policies included at “Financial Management” in the appendices of this handbook. 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. Information regarding evaluation instruments and administration is noted below and at “Evaluation” in the appendices of this handbook:

| Evaluation Instrument | Time Period Administered |
|---------------------------------------------------------|----------------------------------------|
| Scholar Clinical Research Appraisal Inventory | Entrance to Program, Annually |
| Scholar Course Evaluation (if taking coursework) | End of each semester in which enrolled |
| Scholar Evaluation of Mentors | Mid-year, End-of-year |
| Scholar Mid-Year Progress Report | Mid-year |
| Scholar Satisfaction Evaluation | Mid-year, End-of-year |

Scholar Progress

Scholars are to keep the 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. KL2 Scholars may also be required to annually present their research to mentors and advisory committee members of the CRTC. Additionally, all Scholars are required to provide at least annually a detailed progress report. Scholars are to note that they are to secure from their mentors a brief mentor report to be included with their progress report. An outline detailing the content of the components of the report will be provided to the Scholar. An example is included at “CRTC General Information” in the appendices of this handbook.

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National NIH and Upper Midwest Consortium Scholar Meetings

Each year a meeting of all national KL2 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 CTSA-awarded institutions, to network with scholars and leaders from across the nation, and to form collaborative partnerships in multidisciplinary clinical research. Each KL2 Scholar's expenses will be paid to attend the annual meeting. KL2 Scholars are expected to attend this meeting annually while in the program and to present their research at this meeting. Postdoctoral Scholars are invited to attend this meeting. Limited funds may be, but are not guaranteed to be, available to facilitate travel for Postdoctoral Scholars.

In addition to this national meeting, an annual meeting of the Upper Midwest Consortium is conducted. Scholars and program leadership from CTSA institutions are invited to attend the consortium's annual meeting. It is the objective of this meeting to provide a forum to build a network for mutual support and collaboration through networking of scholars and promote the building of research collaborations between institutions.

Mentors and Mentees

Developing a successful clinical and translational research career requires strong relationships with mentors and a research team. Each Scholar must have program-approved primary and secondary mentors. 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 (Postdoctoral Program Scholars will meet weekly with their primary mentor and monthly with their secondary mentor) and that mentors will be available for consultation and support concerning the Scholar's current projects and future progress. Mentors are expected to provide formal feedback to the Scholar at least annually.

Both the Scholar and 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 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.

Additional information is located at "Mentors/Mentees" in the appendices to this handbook.

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Didactic Instruction

KL2 Career Development Awards

KL2 Scholars are required to complete Ethical and Legal Issues in Clinical Research (offered through the MSCI program) or a similar course during their time in the program. Additionally, KL2 Scholars have the opportunity to earn a Master of Science in Clinical Investigation (MSCI), a Master of Public Health (MPH) or a Genetic Epidemiology Master of Science (GEMS) from Washington University, or a Master of Science in Public Health (MSPH) from Saint Louis University.

Specific information regarding these programs may be found at <http://crtcpostdoc.wustl.edu/> (MSCI), <http://gwbweb.wustl.edu/Admissions/MPH/Pages/MPHLanding.aspx> (MPH), <http://www.biostat.wustl.edu/gems/> (GEMS), and <http://publichealth.slu.edu/> (MSPH). Additional information may also be found at “Didactic Information” in the appendices of this handbook.

KL2 Scholars wishing to enroll in a specialized course of study or elective selections must be approved by your mentors and by the Program Director, Vicky Fraser. To enroll in courses not included in the MSCI, MPH, GEMS, or MSPH, you must register through the school/program that is offering the course. Further, you must contact Alison Ebers, prior to enrollment in courses not included in the listed programs.

Postdoctoral Program

The Postdoctoral Program requires that scholars complete the following core curriculum in clinical investigation:

- Designing Outcomes and Clinical Research
- Introduction to Statistics for the Health Sciences
- Ethical and Legal Issues in Clinical Research
- Epidemiology for Clinical Research
- Intermediate Statistics for the Health Sciences

Postdoctoral Scholars must also take at least one of the following two courses:

- Grantsmanship
- Scientific Writing and Publishing

Postdoctoral Scholars may receive advanced standing for coursework that they have previously taken. Scholars may also substitute similar coursework with permission of the Postdoctoral Program Director, Brad Evanoff (for example, taking a different statistics or epidemiology course that better suits their needs).

Postdoctoral Scholars may enroll in the MSCI program. Additional requirements beyond the core curriculum include two elective courses. A list of possible electives is available on the MSCI website at <http://crtcpostdoc.wustl.edu/program.php>. Other electives that better meet the needs of individual scholars are encouraged but must be approved by the Program Director. A Research and Thesis progress report form must be submitted twice per year, and a Final Thesis Approval form must be submitted the semester in which they will graduate from the program.