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Institute of Clinical and Translational Sciences

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ICTS NEWS

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Special points of interest:

- New Research Coordinator Mentoring Program
- ICTS Membership Required prior to Using ICTS Cores
- Study Sections Held to Review BJHF/ICTS Proposals
- Have You Met Becky Evans?

Embedded weblinks are designated by blue text and can be accessed in the online version of ICTS News on our website at icts.wustl.edu.

CLINICAL RESEARCH TRAINING CENTER PROGRAMS

BY GWEN ERICSON

Whether at the predoctoral or postdoctoral level or in the early stages of their careers, medical and allied health students and professionals at any of the partner institutions of the Washington University in St. Louis Institute for Clinical and Translational Sciences (ICTS) can participate in a comprehensive program that will prepare them to conduct clinical research.

Offered through the Clinical Research Training Center (CRTC), the program represents a leap forward in clinical research training by formally integrating dozens of diverse training programs into a single location and under one administrative umbrella.

"The CRTC has brought people together from multiple departments, disciplines and schools," says program director, Victoria Fraser, MD, the J. William Campbell Professor of Medicine and codirector of the Division of Infectious Diseases. "By enhancing collaboration and networking, it has really opened doors for people."

The CRTC offers both formal courses and mentored research experiences. Courses cover the full scope of clinical research skills, including how to design research projects, analyze data, address ethical and legal issues, write grant applications and manuscripts and compete for research funding.

Depending on which track they are in, students can earn a certificate of completion, a Master of Science in Clinical Investigation (MSCI), a Master of Science in Public Health (MSPH) or a Genetic Epidemiology Master of Science (GEMS) degree.

A dedicated program space with a classroom, break room, conference areas and office spaces for participants increases a sense of teamwork and belonging. "Getting all the trainees together has provided a nurturing, supportive environment," Fraser says. "Often being on their own in their divisions or departments, people can feel as if they are at the bottom of a steep hill going up."

Interaction among scholars at different levels and from different departments has the practical benefit of allowing them to better exchange information and experiences. "They learn from each other's successes and failures," Fraser says. "They

gain confidence, and they learn faster, mastering things in weeks or months that might have taken years on their own."

In addition to coursework, trainees meet weekly in research and career development seminars. There they can share research experiences, review each other's grant applications or discuss internal review board requirements. Specific seminars are developed in response to participants' concerns. For example, at students' requests the program has offered seminars in developing grant budgets, managing grant finances, hiring and firing, doing performance evaluations, and fostering multidisciplinary collaborations.

The CRTC offers 3 levels of programs. The Predoctoral Program gives medical and other predoctoral students the option of a summer research core or an intensive one-year research core. The Postdoctoral Program, designed for postdoctoral fellows and junior faculty members, has both a 2-year and 3-year track. The third program, the Career Development Awards, is for senior fellows and junior faculty members and includes \$25,000 per year in research funding and 75 percent salary support up to \$75,000 per year for 3 years. Currently participants in all programs number about 80, and according to Fraser demand is increasing.

Established in 2006, the CRTC is now producing its first master's graduates, many of whom started with no prior research experience. One such is a May 2008 graduate of the Postdoctoral Program, pediatrician Stephanie Fritz, M.D., who earned an MSCI degree and will continue her research on infectious diseases in children as a recipient of a Career Development Award. Fritz says that thanks to the program she gained the skills she needed to design sophisticated studies and to get her findings published in scientific journals. "The mentorship I have received has been a tremendous asset and has been instrumental in creating a research foundation upon which I hope to build," she says.

For more information about any of these programs, see the ICTS website (www.icts.wustl.edu/cores/crtc.aspx) or contact Alison Ebers at aebers@im.wustl.edu.

CLINICAL RESEARCH COORDINATOR MENTORING PROGRAM

BY MICHELLE JENKERSON

Historically, nursing schools have provided a limited amount of formal training for clinical research coordinators. Most coordinators learn their roles and responsibilities through on-the-job experience. This “learn by doing” technique often causes frustration and increased stress for the individual and results in frequent turnover in the profession. The ensuing loss of continuity for investigators, subjects and study sponsors can easily lead to losses in study recruitment and revenue.

To address this gap, Michelle Jenkerson, Research Participant Advocate, has designed and developed an extensive training and orientation program with collaboration from Sally Anderson, Director, Center for Applied Research Sciences (CARS) Clinical Research Services and Jim Moran, former Assistant Dean for Clinical Trials and Executive Director, CARS. All new study coordinators hired through CARS participate in the program.

Michelle serves as a mentor to the new coordinators during their six-month orientation period. During this structured period, coordinators attain research knowledge and perform responsibilities to demonstrate competencies. Michelle also assists in the enrollment of the first 3 participants in each coordinator’s first trial.

Newly-hired coordinators meet with Michelle

on a weekly basis to discuss the foundation for ethics and regulations of research. They work together to establish short and long term goals. These meetings are used to accomplish such agenda items as maneuvering through the HRPO web site, attending a HRPO New Protocol Committee Meeting, reviewing regulations and IRB submissions, providing informed consent, developing trial specific documents, such as source documents, and any other study related responsibilities.

At the completion of this training program, coordinators must pass a written test.

This mentored training promotes confidence since the coordinator is guided through the research project until they are comfortable in the process. They gain expertise and learn to use tools that allow them to perform their tasks more efficiently, competently and productively.

By mentoring new coordinators and addressing many of the frustrations inherent in the “learn by doing” approach, Michelle expects the program to increase retention of top quality coordinators who follow consistent procedures, thus benefitting both CARS and the University.

For information on the mentorship program, or to discuss developing a program for your area, contact Michelle Jenkerson at 362-5626.

Career Development

Seminar Series

Includes:

*Advancing Methodology
for Implementation*

Research

by Enola Proctor,

PhD

*System Dynamics of
Implementing a New*

Diabetic Retinopathy

Screening Program

by Peter S.

Hovmand, PhD

February 10

1:00—3:15 p.m.

See attached flyer

ICTS MEMBERSHIP REQUIRED BEFORE USING ICTS CORES AND SERVICES

ICTS Cores will soon begin requiring investigators to register for ICTS membership prior to providing the requested service.

Why is membership required?

One condition of the National Institutes of Health CTSA grant that supports the ICTS is that investigators benefitting from the services provided by a CTSA sponsored Core must be reported in the annual NIH progress report. Information must be included about both the investigator and the grant used to fund the service from the Core. Member registration and the log of services completed by the Core provide the information needed to fulfill those reporting requirements.

Who should be a member of the ICTS?

Investigators who conduct or participate in clinical and/or translational research from an ICTS [Partner Institution](http://icts.wustl.edu/about/partnerinstitutions.aspx) (<http://icts.wustl.edu/about/partnerinstitutions.aspx>) should be ICTS members. This includes faculty, hospital clinical staff, practicing physicians, students (medical, graduate, nursing, pharmacy, occupational and physical therapy, predoctoral and postdoctoral students, etc), residents and fellows.

Obligations of Membership

- Provide requested information when using and ICTS Core
- Log publications and awards resulting from use of ICTS Cores and respond to ICTS tracking and evaluation requests
- Acknowledge NIH Funding for all publications and projects that use any ICTS Core

How do you register?

Register at:

<http://icts.wustl.edu/membertools/registration.aspx>

Before starting registration, have the following available:

- Your Biosketch: you will be asked to submit it during the registration process
- A short description of your “Area of Clinical or Research Interest” which will be available to and searchable by others on the ICTS website. <http://icts.wustl.edu/membertools/directory/>

Since the next annual progress report is due April 1, 2009, please take the 5 minutes to register now.

BJHF/ICTS FUNDING PROGRAM COMPLETES STUDY SECTIONS

The Barnes-Jewish Hospital Foundation (BJHF) and the ICTS have partnered to offer a joint Clinical and Translation Research Funding Program that will award up to \$1.4M for new projects this year. The program includes a rigorous review process, modeled on an NIH study section, designed to expose new investigators to the peer review process and provide specific feedback to strengthen proposals and improve the odds of gaining outside funding.

Over 100 research or planning proposals were submitted in November, 2008. Thanks to the more than 80 people that volunteered to serve as reviewers, each application was assigned to a primary, secondary and tertiary reviewer with an area of expertise applicable to the proposal. Written reviews and scores on a scale from 1.0 to 5.0 were submitted by primary and secondary reviewers. Tertiary reviewers were asked to submit a score, but many also included written comments.

On January 21, 22 and 23, Robert W. Thompson, MD, FACS and Bradley A. Evanoff, MD, MPH chaired an NIH-style study section each after-

noon. Based on the scores submitted by the 3 reviewers, approximately one-half of the proposals each day were triaged. Over 50 proposals were discussed and scored by the panel of reviewers participating in the meeting.

Given the results of this scientific review, the ICTS and BJHF Executive Committees will determine how the funding will be distributed to the top contenders. Once funding decisions are finalized, each applicant will receive a summary statement combining anonymized feedback from the 3 reviewers.

This program is designed to not only provide funding for new and experienced investigators but also to support new investigators in developing their skills at writing proposals. The ICTS Administrative Core includes staff that has over 30 years of experience in grant management. That expertise combined with the feedback experienced researchers provide through written evaluations will hopefully assist investigators as they navigate the application process to pursue outside funding for their research.

Investigators using
ICTS Cores & Services
to support their research
should acknowledge the
CTSA Grant

[UL1 RR024992](#)

Scholars and Trainees
should acknowledge the
appropriate CTSA
Linked Grant

[KL2 RR024994](#) or
[TL1 RR024995](#)

The funding
acknowledgement
[statement](#) is posted on
the ICTS website.

WHAT HAPPENED LAST MONTH?

HIGHLIGHTS FROM JANUARY

- January 21, 22, 23: Study sections were held for 3 to 4 hours each afternoon to review 118 proposals to the BJHF/ICTS Clinical & Translational Research Funding Program. See story on page 2 for further details.

- January 23: *Center for Clinical Research Ethics (CCRE)*: James DuBois, PhD, DSc, CCRE Director, Mader Endowed Professor of Health Care Ethics, Department of Health Care Ethics, St. Louis University presented a lecture entitled "Understanding Vulnerability in Research and Appropriate Addi-

tional Safeguards." Approximately 50 people attended the lecture. Dr. DuBois defined vulnerability in research, illustrated types of populations that have enumerated special protections, described some problems with additional safeguards for specific populations and suggested ways to improve addressing vulnerability in research.

- January 29: 14 members of the ICTS Governing Council met for an update on ICTS activities and to discuss collaboration opportunities.

EVENTS & ANNOUNCEMENTS

The Institute for Public Health has initiated a Faculty Seminar Series the first and third Wednesday of each month from 4-5 pm. See the attached brochure for a complete listing. The next seminar is:

- February 18: Ross Brownson, PhD of the George Warren School of Social Work and the School of Medicine, Surgery. Goldfarb Hall, Room 132 on the Danforth Campus.

-February 10 (1:00–3:15 pm): *Clinical Research Training Center: Career Development Seminar Series* features two speakers from the George Warren Brown School of Social Work:

- Enola Proctor, PhD, Frank J. Bruno Professor of Social Work Research, Associate Dean for Research, "Advancing Methodology for Implementation Research (Translation 2).

- Peter S. Hovmand, PhD, Assistant Professor of Social Work, Assistant Professor of Women, Gender, and Sexuality Studies. "System Dynamics of Implementing a New Diabetic Retinopathy Screening Program".

-February 16 (7:30 am–3:30 pm): The 2nd annual ICTS External Advisory Board meeting will be held in the Center for Advanced Medicine, Farrell Conference Room.

Institute of Clinical &
Translational Sciences

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WU School of Medicine to Host National NIH Women's Health Conference

On March 4 – 6, 2009, Washington University School of Medicine is hosting a national meeting on behalf of the National Institutes of Health [Office of Research in Women's Health](#) (ORWH). The "Seeking New Dimensions and Strategies for Women's Health Research for the National Institutes of Health" conference supports the strategic planning process to develop research priorities for the next 5 to 10 years. Several NIH Program officers and leaders will be attending and will take the ideas and themes of the meeting back to their home Institutes and Centers.

The meeting will consist of 3 parts:

- A public hearing during which interested individuals or groups are invited to provide testimony on issues related to women's health research to a panel of scientists, clinicians and NIH representatives.
- Panel discussions and presentations
- Concurrent work group sessions

Kenneth Polonsky, MD, Chairman, Department of Medicine, Director of the ICTS and Victoria Fraser, MD, Co-director, Infectious Disease Division and Program Director of the ICTS Clinical Research Training Center will participate in a panel "Perspectives from Washington University".

Details about the conference and options for providing testimony are available on the conference website at <http://research.wustl.edu/womenshealth/Pages/default.aspx>.



HAVE YOU MET? BECKY EVANS

Chances are you have met Becky Evans. You most likely first interacted with her during her 20 year career in the School of Medicine's Office of Gifts, Grants and Contracts (GG&C) where she began as a Grant Assistant immediately upon graduating from college with a business degree in 1981. She was part of the team that developed the original Grants Budgeting System, now the Proposal Development System (PDS), moving pencil copy rough budgets to the electronic era. Becky served as the Director of GG&C for 8 years and after managing thousands of proposal submissions and awards she moved to the University Compliance Office and performed some of the first research compliance audits as this activity was initiated. With her entire career in Central Administration she wanted to broaden her experience and see what it was like in "the real world" of the departments as she had been told. She accepted the position of Division Administrator in the Division of Nuclear Medicine for the Mallinckrodt Institute of Radiology in 2004, a position that would, unexpectedly, help prepare her for her future role with the ICTS. "From Barry A. Siegel, M.D. and the other faculty in Nuclear Medicine I was directly exposed to clinical and translational research. It was a very stimulating environment." That history and rich, diverse experience serves her well in her role as Business Director of the ICTS.

In July 2006 she accepted the ICTS Business Director position with Kenneth S. Polonsky, MD, Chairman of the WU Department of Medicine

and Director of the ICTS. Her first responsibility was coordinating the resubmission of the CTSA grant for a January 2007 deadline. The award was then received in September 2007. As Business Director, Becky wears a variety of hats. Whether coordinating all the details of hosting guests from across the country for an ICTS External Advisory Board meeting or identifying the best WU contact to answer a nagging question, Becky is adept. With an incredible memory, meticulous organizational skills and superb eye for detail, she has helped develop the infrastructure, processes and relationships that support the Institute.

Bradley A. Evanoff, MD, MPH, Co-Principal Investigator of the ICTS, gives this praise, "Becky's leadership and organizational skills have been critical to the success of the ICTS. She has managed the complex logistical and budgetary details of the ICTS with verve and aplomb."

Living in Swansea, Illinois, with her husband and two sons, Becky usually spends the 40 minute Metro Link commute on ICTS work. When she does take time for herself, she enjoys her two Jack Russell Terriers, reading, gardening, movies and power walking.

For questions related to the ICTS or to reconnect with Becky, contact her at revans@dom.wustl.edu or 314-362-9386.

Comments about ICTS News, suggested articles or questions should be directed to ICTS@dom.wustl.edu or by contacting Jae Allen at 314-362-9331.

Institute for Public Health: Faculty Seminar Series

First and Third Wednesdays, 4-5 pm

<i>Date</i>	<i>Location</i>	<i>Presenting</i>
2/4/09	Steinberg Auditorium Medical School	Ramesh Raghavan, MD, PhD George Warren Brown School of Social Work
2/18/09	Goldfarb Hall, Room 132 Danforth Campus	Ross Brownson, PhD George Warren Brown School of Social Work/ School of Medicine, Surgery
3/4/09	Steinberg Auditorium Medical School	Peter Benson, PhD Arts & Sciences, Anthropology
3/18/09	Goldfarb Hall, Room 132 Danforth Campus	Jane Garbutt, MB, ChB, FRCB School of Medicine, Pediatrics
4/1/09	Steinberg Auditorium Medical School	Enola Proctor, PhD George Warren Brown School of Social Work
4/15/09	Goldfarb Hall, Room 132 Danforth Campus	Rick Grucza, PhD, MPE School of Medicine, Psychiatry
5/6/09	Steinberg Auditorium Medical School	Tim McBride, PhD George Warren Brown School of Social Work
5/20/09	TBD Danforth Campus	James Galvin, MD, MPH School of Medicine, Neurology, Psychiatry, Neurobiology
6/3/09	Steinberg Auditorium Medical School	Paul Shattuck, PhD, MSW, MS George Warren Brown School of Social Work
6/17/09	TBD Danforth Campus	Mark Manary, MD School of Medicine, Pediatrics
7/1/09		CANCELLED
7/15/09		CANCELLED
8/5/09		CANCELLED
8/19/09		CANCELLED
9/2/09	Steinberg Auditorium Medical School	Debra Haire-Joshu, PhD, MSED George Warren Brown School of Social Work School of Medicine, Surgery
9/16/09	TBD Danforth Campus	Jeff Peipert, MD, PhD School of Medicine, Obstetrics & Gynecology
10/7/09	Steinberg Auditorium Medical School	William Tate, PhD Arts & Sciences, Education, Urban Studies, Applied Statistics
10/21/09	TBD Danforth Campus	Brad Racette, MD School of Medicine, Neurology
11/4/09	Steinberg Auditorium Medical School	Heather Corcoran, MA Sam Fox School of Design & Visual Arts
11/18/09	TBD Danforth Campus	Arpana Agrawal, PhD School of Medicine, Psychiatry
12/2/09	Steinberg Auditorium Medical School	Matthew Gabel, PhD Arts & Sciences, Political Science
12/16/09	TBD Danforth Campus	Richard Griffey, MD, MPH School of Medicine, Emergency Medicine