

ICTS NEWS

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Special points of interest:

- BJHF and ICTS Announce Joint RFA
- PIs Needed for Industry Sponsored Research
- Becker Library Provides NIH Public Access Policy Guidelines
- Have you met Sally Anderson?

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.

HUMAN IMAGING UNIT: STATE OF THE ART FACILITIES

The ICTS Human Imaging Unit (HIU) is an integral part of the Mallinckrodt Institute of Radiology Center for Clinical Imaging Research (CCIR), an 8,800 square foot bioimaging facility with six state-of-the-art imaging scanners and staff skilled in research imaging located on the 10th floor of Barnes-Jewish Hospital.

"Although the needs are not always clear cut, the CCIR generally works with three types of scenarios", says John Kotyk, PhD, Co-Director of the HIU. These scenarios cover Investigators that:

- *Are experienced in imaging sciences* and usually have considerable experience with imaging protocols and hardware; and they may have imaging studies in progress.
- *Have some experience with imaging technology*, but may not have experience setting up or executing imaging studies. Such research may be industry-sponsored and have an existing protocol, but the protocol has never been executed locally.
- *Do not have any prior experience in imaging* and may, or

may not, recognize how imaging can play a role in their research. These investigators require help learning the technology and setting up the imaging portions of a new study.

Imaging is often a key bridge between animal studies and human application. Hence, the CCIR serves an important role in translating basic science from preclinical areas into clinical research areas. The HIU accomplishes its mission by bringing together three groups necessary for conducting clinical studies in humans using imaging:

- **CCIR Staff:** This group includes the administrative staff, lead technologies & IT support and the HIU nursing staff who may all play an important role in a specific project.
- **Clinical Research Lab (CRL):** This group, led by Jeffrey Brown, MD, Professor of Radiology, helps fill the role of coordinator for a study.
- **Electronic Radiology Lab (ERL):** This group, led by Fred Prior, PhD, Research Associate Professor of Radiology, provides

information technology infrastructure, data management software applications and image analysis.

Because of the funding support of the NIH CTSA grant, ICTS members can directly access many of the HIU services at the CCIR free of charge. An investigator can get started with the HIU by contacting anyone on CCIR staff at 314-747-2300 or by accessing the forms needed to start a research study in the CCIR

(<http://ccir.wustl.edu/services/forms.shtml>). Once all the information for the study has been collected and the research protocol has been approved, the study can begin. The form for requesting supplemental funding from the MIR department is also available on the CCIR website.

For detailed information about the Human Imaging Unit and the available equipment and services, please refer to the ICTS website (<http://icts.wustl.edu/cores/hiu.aspx>) or contact the CCIR Director Mark Mintun, MD, or the CCIR Co-Director John Kotyk, PhD, at 314-747-2300.

MESSAGE FROM THE DIRECTOR

DR. KENNETH S. POLONSKY

I am pleased to announce that the Barnes-Jewish Hospital Foundation (BJHF) and the ICTS have partnered to offer a joint Clinical and Translational Research Funding Program expected to award up to \$1.7M per year. The full RFA will be issued by mid-September and in this edition of the ICTS News we are making an early announcement in order to give

you some additional time to consider preparing an application. Since applicants must be members of the ICTS, please take a few minutes to complete the simple ICTS [member registration](#) if you have not already done so.

In addition, in the article above, we have highlighted the Human Imaging Unit (HIU) which is an extraordinary re-

source for ICTS members to access. The HIU equipment and staff support investigators (from the novice to the pro) in determining the most advantageous options for using imaging in their research. I hope you will take advantage of the free consultation services the HIU offers and inquire how imaging may benefit your research protocol.

ANNOUNCING: BJHF/ICTS CLINICAL & TRANSLATIONAL RESEARCH FUNDING PROGRAM

The Barnes-Jewish Hospital Foundation (BJHF) and the Washington University Institute of Clinical and Translational Sciences (ICTS) announce an impending joint RFA. In recent years, the BJHF has held competition 2 times annually while the ICTS is currently entering its second year of awarding pilot and feasibility grants. By combining the application processes from the programs of the two institutions, we expect to create new opportunities and eliminate potential duplicated effort for both applicants and reviewers.

The full RFA will be issued on or before September 15th with Letters of Intent due October 15th and applications due by November 17th. Peer review will occur in January, 2009 with an award start date of June 1, 2009.

Eligibility:

Applicants must be a registered member of the ICTS. Applicants from WU or its partner academic institutions must hold a faculty level appointment. Fellows in the final year of training with a commitment by their department for a faculty position effective by the time of award are also eligible. Employees of BJH or SLCH (MD, PhD, nurse, or allied healthcare professional) may apply with the permission of their department director. Community organizations are encouraged to work with the ICTS Center for Community-Based Research and apply in conjunction with an investigator from one of the ICTS partner institutions. Applicants may be the Principal Investigator on only one Letter of Intent and one proposal.

Awards will be made in two

categories:

Planning Grants: Provide up to \$25,000 direct costs for 1 year to facilitate the planning of a new clinical or translational research project.

Research Grants: Provide up to \$100,000 direct costs per year for 1-2 years to support a clinical or translational research project.

Applicants are encouraged to include use of ICTS Cores & services.

We anticipate that up to \$1,700,000 will be allocated to new projects on an annual basis to fund this program.

Specific forms and detailed instructions regarding the Letter of Intent and proposal submission will be posted on the ICTS website and the BJH/Office of Research Affairs website no later than September 15, 2008.

THE INCREASING NEED FOR PRINCIPAL INVESTIGATORS

It is well documented that the number of Principal Investigators (PIs) participating in industry sponsored clinical trials has declined steadily over the last decade. Following steady growth through the 1990s, the number of United States PIs conducting industry sponsored clinical research has declined 11% since 2001, according to a [study](#) completed in 2005 by the Tufts Center for the Study of Drug Development (Getz, KA. "Have We Pushed Our PIs Too Far?" Applied Clinical Trials Online. 2005, Sept 1). Although the decline had slowed to 5.5% annually by 2007, the numbers are still decreasing.

There are various reasons postulated as to why this is

occurring, but the reality is that the number of qualified PIs is shrinking while the number of industry sponsored clinical trials continues to increase each year.

According to the Washington University Annual Report for 2007, the increase in industry sponsored funding was 20.6% over FY06 and that has been the trend for the last three years. As we build strategic partnerships with industry sponsors, that funding will naturally increase - provided we can place the trials that are being offered to Washington University School of Medicine. One of the challenges we have already become all too familiar with is finding experienced, dedicated PIs to take on the in-

creased number of clinical trials. We have over 200 biomedical investigators at Washington University whose research capabilities are at or nearing capacity. We must motivate or implore our junior faculty and current faculty to consider venturing into a future that includes industry funded clinical trial execution. The bottom line: We need more qualified, committed Principal Investigators to get involved in clinical research!

For more information on how the Center for Applied Research Sciences (CARS) can facilitate this process, please contact Sara Kukuljan at 314-747-1073 or by e-mail at kukuljas@wusm.wustl.edu.

NIH PUBLIC ACCESS POLICY

NIH now requires that all investigators funded by the NIH submit to PubMed Central an electronic version of their final peer-reviewed manuscripts upon acceptance for publication. PubMed Central is an archive of full-text biomedical journal papers available online without a fee. This policy is intended to ensure that the public has access to the published results of NIH

funded research.

WU Becker Medical Library has created a [website](#) with guidelines and links to resources including frequently asked questions to assist investigators to meet these requirements. Most scientific journals have established policies allowing NIH-funded authors to comply with the NIH Policy. However, if au-

thors encounter journals that are unfamiliar with or unresponsive of this policy, the Becker Library staff can provide assistance. Please contact Cathy Sarli at 314-362-7865 or sarlic@wustl.edu for assistance.

WHAT HAPPENED LAST MONTH?

HIGHLIGHTS FROM AUGUST

- August 8 (3–4:30 PM) ICTS Governing Council Meeting. The 2nd meeting of the ICTS Governing Council was attended by representatives from St. Louis College of Pharmacy, Southern Illinois University Edwardsville, Saint Louis University, University of Missouri-St. Louis, Barnes-Jewish Hospital, Center for Emerging

Technologies, City of St. Louis Department of Human Services and Washington University. James DuBois, PhD, DSc, Mader Endowed Professor of Health Care Ethics at Saint Louis University and Director of the ICTS Center for Clinical Research Ethics presented an overview of the Center's services and activi-

ties. The Council meets 3 times annually and explores opportunities to leverage best practices and develop systems and programs to facilitate interactions of trainees and investigators across institutions. For more information see the ICTS [website](#) or contact the administrative core at icts@im.wustl.edu.

EVENTS & ANNOUNCEMENTS

Major ICTS Events

- September 5: (8 AM–5 PM) *Center for Community-Based Research* hosts the Community Research Southeast Regional Workshop at the Eric P. Newman Education Center. Contact Amy Hepler at 314-286-2252 or hepler@wustl.edu for more information.

- September 22: (3:30–4:30) *Center for Clinical Research Ethics* Lecture, "Decision-making Capacity" by James DuBois, PhD, DSc, Department Chair, Center Director and Mader Endowed Profes-

sor of Health Care Ethics, Saint Louis University, in the Center for Advanced Medicine, Farrell Conference Room #1. Dr. DuBois is the Director of the ICTS Center for Clinical Research Ethics.

- September 30: (5 PM CST) *ICTS KL2 Career Development Awards* deadline for applications. These awards are aimed at fellows, post-doctoral scholars, and junior faculty committed to multidisciplinary clinical and translational research. Information on how to apply may be found at

<http://crscholars.im.wustl.edu/home-apply.php> or contact Alison Ebers at aegers@im.wustl.edu or 314-454-8255.

- October 31: Applications for the Goldfarb Patient Safety and Quality Fellowship Program due. Appointments begin July 1, 2009. See the [Patient Safety](#) website at <http://patientsafety.im.wustl.edu/content/index.php> for more information or contact Kerry Bommarito at 314-454-8221.

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.

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Translational Sciences

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

IN THE NEWS:

- "We were amazed at how quickly the rates of drugs used have climbed." Dr. Donna R. Halloran, an ICTS KL2 scholar and assistant professor at St. Louis University is quoted in a New York Times article. Dr. Halloran participated in a study about the increased number of American children taking adult medications. The [article](#) was published in the Business Section of the July 26, 2008 New York Times.

- Dr. Jill Firszt, Associate Professor of Otolaryngology, Director of the Cochlear Implant Program and Electrophysiological Laboratory and recipient of a 2008 ICTS Pilot Funding Award has received her first R01 from NIH. The R01 project is designed to study the effects of asymmetric hearing in three patient populations, all of whom have one deaf ear; however, they differ in their "better" hearing ear, which has either normal hearing, moderate hearing loss, or hears with a cochlear implant. The study includes behavioral measures that simulate real-life listening (e.g. listening in noise and localization) and imaging studies to investigate the consequence for individuals whose hearing at each ear differs significantly. Dr. Firszt is collaborating with Rosalie M. Uchanski, PhD, Research Assistant Professor of Otolaryngology and Harold Burton, PhD, Professor of Anatomy and Neurobiology, of Radiology and of Cell Biology and Physiology. See the August 14th [Medical News Release](#) from the WU School of Medicine (<http://mednews.wustl.edu/news/page/normal/12146.html>).

HAVE YOU MET? SALLY ANDERSON

Sally Anderson, RN, BSN, CCRC clearly has tremendous passion for educating Clinical Research Coordinators. She is the Director of Clinical Research Services in the Center for Applied Research Sciences (CARS) and the Program Coordinator for the University College Clinical Research Management Programs.

Sally's first exposure to clinical research was in Cardiology in 1986 at Saint Louis University while working in cardiac rehab, and then on to the Cardiac Arrhythmia Suppression Trial (CAST) where she was the lead coordinator. She began working at Washington University in 1997 as a Clinical Research Nurse Coordinator in the Center for Clinical Studies (CCS) becoming a Team Leader in 1999 before moving on to Marketing Coordinator. After 5 years as the Director of the Volunteer for Health program, Sally began supervising the CARS Clinical Research Coordinators in

2006. She says the 9 Clinical Research Nurse Coordinators, the Research Patient Coordinator and the Data Control Coordinator she supervises are "wonderful, dedicated staff, all encouraged to become certified through the Association of Clinical Research Professionals (ACRP)".

Convinced of the need for standardized education for clinical research management, she has instigated both formal and informal educational opportunities. Sally organizes a monthly Brown Bag Seminar designed to promote networking and sharing best practices among Clinical Research Coordinators. She was also instrumental in establishing a new more formal training program in the form of both Certificate and Bachelor of Science programs in Clinical Research Management (CRM) through WU's University College with the first classes being offered this fall. She expects a graduate level program to be available



by fall 2009.

When not in the CARS, Sally enjoys spending time with her family (four children), a 150 pound Rottweiler/Lab mix and a 15 pound Jack Russell Terrier. Anyone that can keep pace with that combination surely has a lot to teach us all.

For more information about the University College program see the attached brochure or contact Sally at sallyanderson@wustl.edu or 314-747-2293. The October ICTS News will include a feature about the CARS Clinical Trials Unit with more information about the work Sally and her team can support or see the ICTS [website](#).

For more information click:

ucollege.wustl.edu

Contact:

University College at
Washington University
(314) 935-6700

ucollege@artsci.wustl.edu

or our program coordinator

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Clinical Research Management Programs



Washington
University in St. Louis
UNIVERSITY COLLEGE
IN ARTS & SCIENCES



The Bachelor of Science in Clinical Research Management is designed for students in the early stages of a career in clinical research, as well as more experienced individuals such as investigators, coordinators, or sponsor representatives, who want to expand their knowledge and skills in the field. The program lays a foundation in principles and applications from the basic sciences, and then covers in greater depth the processes necessary in the management of studies that develop drugs, devices, and treatment protocols for patient care.

This customized program focuses on the scientific methods of clinical research, good clinical practice, research ethics, and the regulatory guidelines that protect human subjects—all integral components of clinical research management in academic, private and pharmaceutical industry settings.

Designed for research professionals in

- ◆Academic Medical Centers
- ◆Pharmaceuticals
- ◆Biotechnology
- ◆Medical Device industries
- ◆Other Research and Development facilities



Clinical Research Management Programs

- Bachelor of Science
- Certificate

Core Courses

(36 units)

- Introduction to Anatomy and Physiology I with Lab
- Introduction to Anatomy and Physiology II with Lab
- Principles of Biology I with lab
- Principles of Biology II with lab
- Introduction to Chemistry
- Introduction to Microbiology with Lab
- Human Growth and Development
- Biomedical Ethics
- Psychology of Health
- Leadership for Organizational Success

Career-Related and Certificate Courses

(21 units)

- Fundamentals of Clinical Research Management I
- Fundamentals of Clinical Research Management II
- Pharmacology
- Research Ethics and Regulatory Affairs
- Business of Clinical Research
- Introduction to Statistics for the Health Sciences
- Practicum/Capstone

All core and career-related courses required for the B. S. in Clinical Research Management.

All career-related courses required for the Certificate in Clinical Research Management

Related Programs in University College at Washington University

- B.S. Health Science and Administration
- B.S. Psychology
- M.A. Biology
- M.S. Health Care Services
- Certificate in Applied Behavior Analysis
- Certificate in Somatic Studies
- Post-Baccalaureate Premedical Study