

ICTS NEWS

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Special points of interest:

- Center for Clinical Research Ethics
- 24 Predoctoral Students Give Presentations
- Correspondence and Advertisements for Participant Recruitment
- Have you met Dr. Mae Gordon?

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.

CENTER FOR APPLIED RESEARCH SCIENCES (CARS) REPLACES GCRC

The Clinical and Translational Science Award (CTSA) program is part of a national effort to help institutions translate basic science discoveries into medical therapy and community practice. One goal of the CTSA is to enhance the conduct of clinical research by fostering collaboration across departmental and institutional boundaries and eliminate duplication of effort and process. Accordingly, the CTSA subsumes the General Clinical Research Center (GCRC) and the Center for Applied Research Sciences (CARS) has been established within the Institute of Clinical and Translational Sciences (ICTS).

Through CARS, the ICTS improves access to specialized clinical research units that contain state-of-the-art resources where studies can be performed safely, ethically and efficiently across a spectrum of study populations, research designs and physical sites.

CARS Units

1) The Clinical Trials Unit (CTU), formerly the Center for Clinical Studies, is an outpatient research unit that offers dedicated research space, equipment, and nursing support for a wide range of clinical studies, particularly multicenter clinical trials (11th floor Center for Advanced Medicine, Suite B).

2) The Intensive Research Unit (IRU), formerly the Adult GCRC, operates as an inpatient and out-patient clinical research unit for studies that require more "intense" nursing services than the studies performed in the CTU or that require an inpatient stay. The IRU is structured to be able to provide services 24 hours/day, 7 days/week when needed (4th & 5th floor Barnard Hospital).

3) The Pediatric Research Unit (PRU), formerly the Pediatric GCRC, provides space and nursing and bionutritional support for clinical research projects conducted with

projects conducted with children (11th floor St. Louis Children's Hospital).

Clinical Research Units Coordinated with CARS

4) The new Human Imaging Unit (HIU) resides in the Center for Clinical Research Imaging and provides the latest in advanced imaging technology, equipment and expertise to support basic and translational inpatient and outpatient clinical research. (10th floor West Pavilion BJH)

5) The new Brain, Behavior and Performance Unit (BBPU) has specialized infrastructure and expertise in the performance of clinical research studies of the nervous system. (Lower Level McMillan Hospital)

For detailed information about Unit Directors and staff and the available services, refer to the ICTS [website](http://icts.wustl.edu/cores/phenotyping.aspx) (<http://icts.wustl.edu/cores/phenotyping.aspx>) or contact Jim Moran, JD, CPA at 362-6903.

MESSAGE FROM THE DIRECTOR

DR. KENNETH S. POLONSKY

The ICTS supports investigators at each stage of their research project, from development of an idea through application in the community. The Cores featured in this edition of ICTS news exemplify support in protocol development (Center for Clinical Research Ethics) and study implementation (the Units under the umbrella of the CARS). We are pleased to

have James Dubois, PhD, from Saint Louis University directing the ICTS Ethics program as part of our collaborative effort with other institutions in the region. You will also learn in this edition what became of the 46 year old General Clinical Research Center (GCRC). It has been transformed into a new Center for Applied Research Sciences (CARS) which provides

specialized expertise to carry out a broad range of clinical research studies. Subsidized in whole or part by a combination of NIH and institutional funds, services from all of the ICTS Cores are available to registered ICTS members. Explore our [website](http://icts.wustl.edu) or contact our Administrative Core (icts@im.wustl.edu) to see how the ICTS can support your research efforts.

PROGRAM HIGHLIGHT: CENTER FOR CLINICAL RESEARCH ETHICS

The Center for Clinical Research Ethics (CCRE) is an example of how the ICTS capitalizes on the strength of regional partners. James DuBois, PhD, DSc of Saint Louis University (SLU) is Director of the CCRE and Rebecca Dresser, JD of Washington University is co-Director. Ana Iltis, PhD of SLU is Consultation Service Director and Course Director for Ethical and Regulatory Issues in Clinical Research. This team of experts supports the three main areas of focus for the CCRE.

Education: In Spring, 2008, Dr. Iltis coordinated a course for WU Masters of Clinical Investigation students taught by various experts, including her, that covered legal and ethical issues in clinical research. In addition, the 2008-2009 Ethics Series, began on July 21st with a presentation by Dr. Iltis entitled "Payments for Research Participants". This series of five lectures by Dresser, DuBois and Iltis will offer continuing education credits for health professionals. These lectures are open

to anyone interested in clinical research. (Register at <http://hrpo.wustl.edu>). Working with the Human Research Protection Office and other WU faculty and staff, the CCRE staff is exploring additional educational options. To request educational services, contact Dr. DuBois at duboisjm@slu.edu.

Research Ethics Consultations: Like biostatistics, the key to success in addressing ethical considerations in research is to consult with CCRE early in the study design. For example, if an investigator overlooks the need to include a translator in the protocol to address a diverse population, the budget may be short. As Dr. Iltis suggests, "NIH conducts an ethics review. Researchers should simply include this step in their study design process". Although CCRE doesn't replace or duplicate the regulatory oversight provided by the IRB, it does assist in study design in such a way as to smooth the process for the IRB review. To request an ethics consultation, contact Dr. Ana Iltis at

iltisas@slu.edu. A service request form is also available on the ICTS website at <http://icts.wustl.edu/cores/core.aspx>.

Research on Research Ethics: In addition to their own research, Drs. DuBois and Iltis also collaborate with investigators conducting clinical research that are interested in research on research ethics. Investigators that want to explore using their clinical research as a foundation for the research on research ethics should contact the CCRE. CCRE faculty are currently involved in several funded projects, gathering data on how IRBs address matters of decisional capacity and what existing data suggest investigators may need to do to enhance capacity to consent. To request a consultation on a research ethics project, contact Dr. DuBois at duboisjm@slu.edu.

As Dr. Iltis notes, "We are not the ethics police. We help you determine the best study plan to avoid problems in the future."

"Over 120 people attended the Ethics Series lecture on Payments for Research Participation. This was the first in a series of five presentations."

Ana S. Iltis, PhD

Assistant Professor
Consultation Service Director
Course Director for Ethical and
Regulatory Issues in Clinical Research
Saint Louis University

PREDOCTORAL TRAINEE SYMPOSIUM 24 GIVE FINAL PRESENTATIONS

On Tuesday, July 29, 2008, trainees in the Clinical Research Training Center Pre-doctoral Program Summer Cohort gave their Final Presentations in Connor Auditorium at the Farrell Learning and Teaching Center. Eighteen Washington University School of Medicine (WUSM) predoctoral students, five students from the St. Louis College of Pharmacy, and a WUSM summer intern from Case Western Reserve University in Cleveland, Ohio pre-

sented summaries of their various research projects.

The students worked with faculty mentors from a variety of WUSM departments and divisions including Emergency Medicine, Geriatrics and Nutritional Science, Internal Medicine, Neurology, Obstetrics and Gynecology, Occupational Therapy, Otolaryngology, Psychiatry, Pediatrics, and Surgery.

In addition to being a requirement for the completion of the summer training pro-

gram, the Final Presentations are an opportunity for trainees to share their research with other trainees and mentors, and to receive feedback from Dr. Jay Piccirillo and Ms. Karen Dodson on their presentation skills.

After the twenty-four five-minute presentations, the trainees, their mentors, and program instructors enjoyed a box lunch social, bringing the summer semester to a close.

RECRUITMENT TIPS: CORRESPONDENCE & ADVERTISEMENTS

The Recruitment Enhancement Core (REC), one component of the Regulatory Support Center, is designed to help ICTS investigators establish and meet study recruitment targets (including adequate participation by women and underrepresented minorities) while helping to ensure regulatory compliance and the highest ethical standards in recruitment. As the REC develops innovative ways to facilitate recruitment, recognition of the need to maintain the process to protect potential participants is of the highest priority.

ICTS News will periodically

include this feature on Recruitment Tips as a reminder on how certain strategies MUST play out. The topic for this feature is: Correspondence and Advertisements:

- Recruitment correspondence, such as letters to physicians and recruitment flyers, must be approved by the WU IRB. In some cases, the trial sponsor may have templates to build on or, conversely, may want right of approval also.

- Any advertisement with outside vendors must be approved by the WU IRB. Even when a sponsor provides an advertisement or flyer that

has met their internal approval, the WU IRB must approve before the advertisement is placed.

- Pre-screening tools, including those used when potential participants call in to inquire about trials, must be WU IRB approved. This ensures that interactions researchers have with potential participants has the participant's privacy and safety at the forefront.

For more information on how the REC can be a recruitment resource for your clinical trials, contact Charles Rathman, Director, at 362-0897 or rathmann@wusm.wustl.edu.

WHAT HAPPENED LAST MONTH?

HIGHLIGHTS FROM LATE JUNE & JULY

- June 21: Ana Iltis, PhD, Assistant Professor in the Department of Health Care Ethics at Saint Louis University presented the first of the Ethics Series Lectures "Payments for Research Participants"

- June 23 and 24: NCRR hosted the Clinical Research Management Workshop in Bethesda, MD. Representa-

tives from the WU ICTS included: 1) Jim Moran, JD, CPA, Program Director of the ICTS Regulatory Support Center; 2) Denise McCartney, Associate Vice Chancellor for Research Administration; 3) Brad Evanoff, MD, MPH, Associate Professor of Medicine and Co-PI of the CTSA and 4) Diane Clemens, DC, CIP, eIRB

Education Specialist for WU HRPO. Two new regulatory taskforces were formed. One will work on developing common metrics for measurement of IRB and contracting performance. The second will work on common processes and process improvement that can be applied to IRBs and research contracts.

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.

- 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 aebers@im.wustl.edu or 314-454-8255.

- October 31: Applications for the Goldfarb Patient Safety and Quality Fellowship Pro-

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

Ongoing ICTS Meetings

- August 8 (3–4:30 PM) ICTS Governing Council Meeting: Center for Advanced Medicine.

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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IN THE NEWS:

- A new journal called "CTS: Clinical and Translational Science" from Blackwell Publishing "highlights investigative work bridging the gap between laboratory discovery and practice", according to their website at <http://www.blackwellpublishing.com/cts>. Among the editorial board for the CTS are WU faculty Monica Bessler, MD, PhD; Associate Professor of Medicine; Mario Castro, MD, MPH, Associate Professor of Medicine; John DiPersio, MD, PhD, Professor of Medicine; Michael Holtzman, MD, Seldin Professor and Director, Pulmonary & Critical Care Medicine; Alan Schwartz, MD, PhD, Harriet B. Spoehrer Professor of Pediatrics and Chairman, Department of Pediatrics; and J. Philip Miller, Professor of Biostatistics and Director of the ICTS Research Design and Biostatistics Group.

- Michael R. DeBaun, MD and ICTS Program Director for Career Development and Translational Research in Pediatrics has been named Ferring Family Chair in Pediatric Cancer and Related Disorders at the School of Medicine and St. Louis Children's Hospital. See the July 17 Record for the full [article](#).

- Robert W. Thompson, MD, Professor of Surgery and Program Director of the ICTS Pilot & Novel Methodologies Program, was featured in the July 15th edition of the St. Louis Post Dispatch. Specializing in surgery to relieve Thoracic Outlet Syndrome, he has operated on several athletes, including former Cardinals pitcher Kip Wells. Last year Dr. Thompson performed 130 of the surgeries. For the full [article](#) see: <http://www.stltoday.com/stltoday/news/stories.nsf/sciencemedicine/story/B314DE6CFCC99160862574870011DB12?OpenDocument>

HAVE YOU MET? MAE O. GORDON, PHD

One of the first thoughts to come to mind when you meet Dr. Mae O. Gordon is that she is passionate about everything she does. One of the last thoughts is that she is passionate about whitewater kayaking and karate – and very good at the latter, with trophies galore, including one for her intermediate-level Grand Championship at a recent Budweiser National Karate Tournament.

Dr. Gordon, who has a PhD from the University of Wisconsin, is a Professor in the Department of Ophthalmology & Visual Sciences, with a joint appointment in the Division of Biostatistics. She is a co-Director of the Research Design and Biostatistics Group (RDBG) of the ICTS. She believes strongly that biostatisticians can make a decisive difference in the scientific rigor of research protocols, the competitiveness of grant applications, and the acceptance rate of manuscripts for publication. Every NIH grant application she has submitted as PI has eventually been funded – and "eventually," she points out, is what really matters.

Dr. Gordon and her collaborators at WU and other medical centers have received a number of awards, including the 2002 Lewis Rudin Prize for outstanding glaucoma research from the New York Academy of Medicine and the International Glaucoma Society Award (pictured) for "daring, breakthrough, creative, original research in glaucoma." In 1994 she helped establish one of the first NIH-funded coordinating centers at WU. With the center's support, she currently directs two major multi-center clinical studies, involving over 50 sites and 2800 participants. Both multi-center studies required completion of pivotal pilot studies to define eligibility criteria, to develop new outcome measures and to estimate treatment effect.

Along with J. Philip Miller, Professor of Biostatistics, and Kenneth B. Schechtman, PhD, Associate Professor of Biostatistics and Research Associate Professor of Medicine, Gordon provides expertise to achieve the aims of the RDBG. Specifically, they provide consultation on hypothesis development, study design



and implementation, data analysis and publication. In addition, she supervises PhD-level biostatisticians and staff in conducting data analyses and creating data management systems.

All of this, of course, with the same passion and dedication she brings to kayaking and karate.

For further information, contact Dr. Gordon at mae@wubios.wustl.edu or 362-3716 or the RDBG at rt-rdbg@rt.biostat.wustl.edu. Biostatistics open clinic hours are Tuesdays 9 am to noon and Thursdays 1-4pm in Barnard 3349. Website: <http://icts.wustl.edu/cores/rdbg.aspx>

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