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Institute of Clinical and Translational Sciences News, Vol. 2, Issue 8

Institute of Clinical and Translational Sciences NEWS

Features

2 Implemetation Research Institute

3 Research-Match.org

3 ASPIRE Request for applications

4 Comparative Effectiveness Research at the CTSAs

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ICTS Items

2 In the News

5 Have You Met?

6 Events & Announcements

Send comments or article suggestions to icts@wustl.edu

Washington University in St. Louis

ICTS Announces New Dissemination and Implementation Research Core

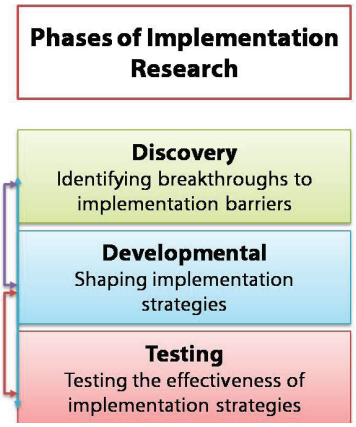
by Sally Haywood, MPH, Director of Administration, Center for Mental Health Services Research

ICTS investigators wishing to pursue dissemination and implementation research have a new resource: the Dissemination and Implementation Research Core (DIRC). This core was funded effective June 1, 2009 under the BJHF/ICTS Clinical and Translational Research Funding Program.

Led by researchers from Washington University's School of Medicine, Brown School of Social Work, and Institute for Public Health, the DIRC provides methodological expertise for research that can inform the translation of research findings into best practices, reducing the time from treatment discovery to community benefit and accelerating the public health impact of the University's clinical and services research. The launch of DIRC is timely. On December 1, the National Institutes of Health released three program announcements related to dissemination and implementation in health (PAR-10-038). In addition, many clinical and translational RFAs are now including a requirement to address dissemination and implementation plans.

Offerings: The ICTS supports the DIRC in its efforts to equip investigators with tools to conduct T2 research (translation to agency or practice-delivered care) and T3 research (broad scale implementation into a standard of care). Investigators tapping into DIRC will have access to:

- Technical assistance on grant applications; specifically, the DIRC can help shape research aims in the area of D&I, advise on grant narrative dealing with D&I outcomes to be assessed, as well as shaping and testing D&I strategies to help implement evidence-based treatments into new settings of care
- Design and analysis expertise including use of mixed methods, stakeholder assessment, and multi-level analysis
- Social System Design Lab to build conceptual models and help model effects of change at the organization and system levels
- Database of researchers and grant information to help identify funding opportunities and collaborators
- Seminars, podcasts, and information guide



These services address a wide array of disciplines and can be applied to the three phases of dissemination and implementation research:

1. Discovery – Aims to inform the shaping of implementation strategies. Discovery studies identify barriers and—more importantly—pathways to break through those barriers to the delivery of evidence-based health care. They assess setting and provider readiness to implement evidence supported treatments (ESTs), the acceptability of a specific EST to the providers, and the fit of ESTs to community preferences / beliefs, institutional history, population characteristics, and policy context.

2. Developmental – Aims to design new implementation strategies, and to adapt existing strategies for local context, toward integration of evidence based treatments. These studies tackle questions such as: What implementation models are most efficient, safe, and affordable? Developmental studies map pathways to EST uptake, penetration, and sustainability.

3. Testing - Examines the effects of an implementation strategy on implementation outcomes (vs. clinical outcomes). The results are evidence-based approaches to introducing and sustaining ESTs in specific

(See DIRC: page 2)

DIRC, from Page 1

service settings. Testing studies may compare an implementation strategy to implementation as usual, the long term effects of a strategy, or compare the effects of different strategies. These studies may also examine mediators and moderators of implementation strategies. Studies at this phase ensure readiness for full experimental tests of implementation.

For More Information:
Enola Proctor, PhD serves as the DIRC's Director. Co-Directors include: Ross Brownson, PhD; Graham Colditz, MD; Doug Luke, PhD; and Peter Hovmand, PhD. For more information, contact Enola Proctor or Sally Haywood, Director of Administration, at DIRC@wustl.edu, or (314) 935-5741 or through the ICTS website at http://icts.wustl.edu/cores/dirc.aspx.


Enola K. Proctor, PhD, Frank J. Bruno Professor of Social Work Research, Associate Dean for Faculty, George Warren Brown School of Social Work

Implementation Research Institute (IRI)

New NIMH Funded Training Institute Invites Applications

The Center for Mental Health Services Research (CMHSR) at Washington University in St. Louis invites you to apply to the Implementation Research Institute (IRI). Funded by a five-year R25 grant from the National Institute of Mental Health, this unique interdisciplinary training program will help you launch a research career in implementation science. Over two years, the IRI provides IRI Fellows with experiential learning, didactic training, faculty mentoring, and support for pilot research and NIH grant writing-- all focused on helping participants shape a research project for competitive external funding.

What is the IRI? The IRI was established to advance the field of implementation science in mental health by enhancing the career development of early to mid-career investigators. IRI participants will join a learning collaborative of implementation researchers for two years, spending one week each summer at a week-long institute at the CMHSR, and receiving individualized mentoring to help them shape a research agenda in implementation science and prepare a competitive research grant proposal.

Who should apply? We invite applications from ambitious PhD/MD investigators, with demonstrated experience and enthusiasm in the study of mental health services, who wish to conduct ground-breaking research in the area of implementation science.

Applications must be submitted electronically by February 28, 2010.

For more detailed information and application instructions, including the FAQ page, visit **http://cmhsr.wustl.edu/Training/IRI/Pages/ImplementationResearchTraining.aspx**, or contact Sally Haywood, MPA, Director of Administration at **shaywood@wustl.edu** or (314) 935-5741.

In the News

- "Cancer linked to Alzheimer disease but not vascular dimentia," was published in the December 23, 2009 issue of Neurology. The article was co-authored by C.M. Roe, A.L. Fitzpatrick, C. Xiong, W. Sieh, L. Kuller, J.P. Miller, M.M. Williams, R. Kopan, M. I. Behrens and J. C. Morris, of Washington University. Catherine Roe, PhD, one of the study's authors, is a current post-doctoral scholar in Neurology at the ICTS Clinical Research and Training Center at Washington University. For an online version of the article, visit: http://neurology/org/cgi/content/full/74/2/106 .
- The January 2010 national CTSA newsletter can be found at http://www.ncrr.nih.gov/ctsa/newsletter/currentissue/. Also learn more about upcoming events, workshops, and intra-CTSA university initiatives at the CTSA website at http://www.ctsaweb.org/

ICTS Participating Site in Newly-Launched National Volunteer Recruitment Registry -- ResearchMatch.org

by Charles Rathmann, Director, Recruitment Enhancement Core

Over the last decade, Washington University School of Medicine (WUSM) has been fortunate to have a local, robust, web-based clinical trial recruitment tool - the Research Participant Registry (RPR), powered by Volunteer for Health. A complementary tool to the RPR was recently implemented which allows national web-based participant registration and investigator recruitment. People within the St. Louis region who want to participate in research studies at other Clinical and Translational Science Award (CTSA) affiliated institutions can now connect online with researchers nationwide by joining ResearchMatch. ResearchMatch.org is a not-for-profit website that, in a secure and convenient manner, brings together researchers and people who are willing to learn more about research studies. The national ResearchMatch web-based recruitment database will not replace Washington University's local RPR, but provides an additional tool for researchers to enhance their recruitment efforts.

The WU RPR has enhanced the recruitment efforts of many WU study teams and helped thousands of clinical trial volunteers connect to currently enrolling trials at WUSM, but not all academic medical centers have a recruitment tool like the RPR. The new national ResearchMatch initiative is a direct response to this need. ResearchMatch is the product of the CTSA Consortium, which is led by the National Center for Research Resources (NCRR), a part of the National Institutes of Health (NIH). Washington University is one of the 52 institutions participating in this first national, disease-neutral, volunteer recruitment registry.

How does ResearchMatch work?

ResearchMatch will 'match' any interested individual residing in the United States with researchers who are approved to recruit potential research volunteers through the system. For an interested ResearchMatch Volunteer, registration takes between 5 to 10 minutes at www.researchmatch.org. After an individual has self-registered to become a volunteer, ResearchMatch's security features ensure that personal information is protected until volunteers authorize the release of their contact information to a specific study that may be of interest to them. Volunteers are simply notified electronically that they are a possible match and then make the decision regarding the release of their contact information.

For the first year of the project, only researchers affiliated with participating CTSA institutions will be eligible to utilize the recruitment tool, but plans exist to ensure the recruitment tool will be available beyond the CTSA by 2011. If you are a researcher who is interested in using ResearchMatch as a recruitment tool, please complete the Researcher Interest Form so you may be notified of your options to utilize this resource.

ResearchMatch is accessible at www.researchmatch.org. For additional information, contact Charles Rathmann in the ICTS Regulatory Support Centers' Recruitment Enhancement Core at rathmannc@wustl.edu or (314) 362-0897.

ICTS Advanced Summer Program for Investigation and Research Education (ASPIRE)

Request for Applications

The ICTS Clinical Research Training Center (CRTC) is launching a summer program for high school and college students with the purpose of introducing research to young investigators and to further their existing interest in clinical research. The Advanced Summer Program for Investigation and Research Education (ASPIRE) is led by two WU School of Medicine clinician-researchers, Jay F. Piccirllo, MD, and Victoria J. Fraser, MD, and is funded by a CTSA administrative supplement. The short summer program includes didactic sessions, seminars, and mentored research experiences. **The application deadline for students interested in applying is February 15, 2010.**

To learn more about eligibility requirements and what materials to submit for application, visit the program website at http://ccrt.wustl.edu/aspire.php. You may also contact Rachel Driskell, Program Coordinator, at (314) 362-8719 or rdriskel@dom.wustl.edu.

Comparative Effectiveness Research at the CTSAs

by Pamela Owens, PhD, Research Assistant Professor of Medicine and Co-Director, Center for Adminitrative Data Research

The American Recovery and Reinvestment Act (ARRA) of 2009 has dedicated $1.1B to bolster new comparative effectiveness research (CER): $300M for Agency of Healthcare Research and Quality (AHRQ), $400M for National Institutes of Health (NIH), and $400M for the Department of Health and Human Services (DHHS). ARRA provided this money in an effort to evaluate the relative effectiveness of different healthcare services and treatment options and encourage the development and use of clinical registries, clinical data networks and other forms of electronic data to generate outcomes data.

A June 2009 Institute of Medicine (IOM) report entitled, "Initial National Priorities for Comparative Effectiveness Research," states that CER "compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor clinical conditions or to improve the delivery of care." The purpose of CER is to "improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision makers [e.g., purchases, policymakers], responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances."[1]

The CTSA Consortium's Strategic Goal Committee #4 recently developed a White Paper detailing the potential role of the CTSA in facilitating CER.[2] The paper notes that the CTSAs offer a strong infrastructure for furthering the national effort towards CER, including extensive clinical research infrastructure, formal education, training and career development programs, community engagement, medical informatics expertise and capacity, and leadership in cross-disciplinary research. To encourage the development of CER in CTSAs, the Consortium formed a Key Function Committee (KFC) focused on CER, whose task is to bring together individuals from each of the CTSAs interested in addressing the expanded role of CER. The ICTS would like to organize a network of investigators interested in CER to enhance collaborations across departments as well as disseminate relevant information from other CTSAs nationally or from key federal agencies (see Table 1 for CER funding opportunities found at www.grants.gov). If you are interested in CER or learning more about CER opportunities, please contact Pamela Owens, PhD at powens@dom.wustl.edu or (314) 747-5684. Dr. Owens is the ICTS representative on the new CTSA KFC.

Table 1: Current American Recovery and Reinvestment Act (ARRA) limited competition funding opportunities related to comparative effectiveness research

Announcement Number	Title	Issuing Org	Release Date	Receipt Date
RFA-HS-10-005	PROSPECT Studies: Building New Clinical Infrastructure for Comparative Effectiveness Research (R01)	AHRQ	12/8/2009	2/17/2010
RFA-OD-10-008	Comparative Effectiveness Research on Upper Endoscopy in Gastroesophageal Reflux Disease, Eradication Methods for Methicillin Resistant Staphylococcus aureus and Dementia Detection and Management Strategies (RC4)	NIH	12/28/2009	2/26/2010
RFA-OD-10-009	Methodology Development in Comparative Effectiveness Research (RC4)	NIH	12/28/2009	2/26/2010
NOT-OD-10-037	Administrative Supplements for Comparative Effectiveness Research Workforce Development	NIH	1/4/2010	3/1/2010
RFA-HS-10-015	Scalable Distributed Research Networks for Comparative Effectiveness Research (R01)	AHRQ	1/21/2010	3/10/2010
RFA-AE-10-001	Accelerating Adoption of Comparative Effectiveness Research Results by Providers and Patients (R18)	NIH	1/11/2010	3/11/2010
RFA-OD-10-005	NIH Directors Opportunity for Research in Five Thematic Areas (RC4)	NIH	12/28/2009	3/15/2010
RFA-OD-10-002	Behavioral Economics for Nudging the Implementation of Comparative Effectiveness Research: Pilot Research (RC4)	NIH	12/28/2009	3/19/2010
RFA-OD-10-011	Recovery Act Limited Competition: Institutional Comparative Effectiveness Research Mentored Career Development Award (KM1) (NIH)	NIH	1/13/2010	3/25/2010
RFA-HS-10-020	Enhanced Registries for Quality Improvement and Comparative Effectiveness Research (R01)	AHRQ	1/21/2010	3/29/2010
RFA-OD-10-001	Behavioral Economics for Nudging the Implementation of Comparative Effectiveness Research: Clinical Trials (RC4)	NIH	12/28/2009	4/7/2010

[1] US Department of Health and Human Services. June 30, 2009. Federal Coordinating Council for Comparative Effectiveness Research: Report to the President and Congress. Washington, DC.

[2] Selker HP, Strom BL, Ford DE, et al. CTSA White Paper on CTSA Consortium Role in Facilitating Comparative Effectiveness Research. September 23, 2009.

Have You Met? Phyllis Klein

Phyllis Klein, RN, BSN, CCRC, combines her expertise in clinical studies with a love of numbers to meet the demands of her role as Director of the Regulatory Core. One of three Cores within the ICTS Regulatory Support Center, the staff of the Regulatory Core specialize in assisting investigators with developing budgets and negotiating contracts with clinical study sponsors. As Director, Phyllis says "My job is to get the best ethical, fair and balanced budget for each PI."

Phyllis manages a team of dedicated professionals eager to help researchers in three distinct areas: budget, regulatory, and billing compliance. The team also works collaboratively with the Center for Applied Research Center (CARS) units and the Center for Clinical Studies (CCS) staff. Phyllis understands the value of the Regulatory Core to researchers. "PIs and their coordinators are freed up to focus on patients rather than on the paperwork." Currently she and her team are providing services for approximately 150 studies.

The Regulatory Core staff assists ICTS investigators in navigating the regulatory process, from project planning and initial submission of an IRB through the life of the clinical study. The Regulatory Core offers the following services:

- Project Planning Consultation
- IRB submission, follow up & other regulatory committee submissions as required
- Per patient study budget preparation/review
- Assistance with pre-study site initiation activity

Phyllis came to Washington University after working in the Special Care Nursery at BJH. She was hired by the CCS in 1998 as a coordinator for the "Women's Card" pilot project that studied use of a smart card that stored limited prenatal and health data and offered access to the full patient chart for pregnant women in an effort to aid physicians in coordinating and improving prenatal care. After the pilot ended, she remained with the CCS to work on other studies. In 2002, she was promoted into a directorship position working in the industry sponsored clinical trial process. During those years she gained the expertise she now uses to assist investigators with the development and negotiation of clinical trial budgets.

Phyllis is married with five children--four sons and one step-daughter. One son is married, and another will marry in June 2011. She lives in St. Charles and rides the Metro to work, which allows her time for one of her passions, reading mysteries, especially enjoying the Alex Cross mysteries by James Patterson.

To contact Phyllis email her at kleinp@wustl.edu or phone (314) 747-4289. To learn more about how the Regulatory Support Center can assist you with a clinical research project, email reg_sup_ctr@wusm.wustl.edu.

St. Louis Community/University Health Research Partnerships (CUHRP) Update

Washington University, Saint Louis University and BJC HealthCare have partnered to establish and provide funding for research collaborations between community-based organizations in St. Louis city and county and faculty members at Washington University and Saint Louis University. This program is being coordinated by the St. Louis Regional Health Commission (RHC). 57 Letters of Intent were received for the January 8 deadline. Upcoming events and deadlines include:

• Skills Building Workshop (see page 6 for more info)	February 10, 2010
• Proposals Due	March 26, 2010 (by 5pm)
• Panel Review	April and May 2010
• Anticipated Award Announcement	June 2010
• Anticipated Award Start Date	July 1, 2010

For more information contact Angela Fleming, Community Partnerships Director, St. Louis Regional Health Commission at (314) 446-6454 x1011 or afleming@stlrhc.org or visit the website at http://www.stlrhc.org.

Events & Announcements

Febuary 9 (1:00–3:15 p.m.)
ICTS CRTC Career Development Lecture

- **"*Responding to Wrongdoing in Research*," James M. DuBois**, PhD, DSc, Hubert Mäder Chair of Health Care Ethics, Director, ICTS Center for Clinical Research Ethics and Department Chair and Bander Center Director, Saint Louis University**;**
- **"Use of Administrative Data for Comparative Effectiveness Research: Resources at Washington University," Pamela Owens**, PhD, Co-Director, ICTS Center for Administrative Data Research.

ICTS Clinical Research Training Center (CRTC), Wohl Auditorium, Lower Level Wohl Hospital Building, 4950 Children's Place. Reservations are not required. Contact Julie Headrick at (314) 454-8957 or jheadric@dom.wustl.edu for more information.

February 9 (4:00-6:00 p.m.)
Institute for Public Health Lecture
"Understanding and Eliminating Disparities in Health Care"

- **John Ayanian**, MD, MPP, Professor of Medicine and Health Care Policy, Harvard Medical School, Professor of Health Policy and Management, Harvard School of Public Health
- **Judy Bentley**, MSN, MBA, RN, President and Chief Executive Officer, Community Health in Partnership Services (CHIPS)
- **Bradley Stoner**, MD, PhD, Associate Professor of Anthropology and Medicine, Washington University in St. Louis

For more information, visit the IPH website at http://publichealth.wustl.edu/news/Pages/Events.aspx.

March 1 (4:00-5:00 p.m.)
ICTS Center for Clinical Research Ethics Lecture,
"Human Experiments and National Security"

Jonathan Moreno, PhD, David and Lyn Silfen University Professor of Medical Ethics and of History of Sociology of Science at the University of Pennyslvania.

Scarpellino Auditorium, Mallinckrodt Institute of Radiology, Washington University School of Medicine Campus, 510 S. Kingshighway, St. Louis, MO 63110.

Reservations not required. For information contact Deborah Jaegers at (314) 362-9829 or icst@wustl.edu.

OUR COMMUNITY, OUR HEALTH
and
St. Louis Community/University Health Research Partnerships (CUHRP)

Presents

Partnering for Sustainability: A Skills Building Workshop

Wednesday, February 10, 2010
8:30 a.m. – 12:30 p.m.
Phyllis Wheatley Heritage Center
2711 Locust Street, St. Louis, MO 63103

- Keys to succesful partnerships between community-based organizations and universities
- Grant writing tips
- Responsible conduct in research

REGISTER ONLINE TO ATTEND

For more information, email ocoh@dom.wustl.edu or contact Angela Fleming, St. Louis Regional Health Commission, (314) 446-6454, Darcell Scharff, PhD, Saint Louis University, (314) 997-4009 or Consuelo Wilkins, MD, Washington University, (314) 286-2700

ICTS Center for Biomedical Informatics (CBMI) Training Workshops

Hands-on Data Entry Training for New Users
February 9, 2010
Becker Library, Room 601B

caTissue	12:30-2:30 p.m.
ClinPortal	2:30-4:30 p.m.

ClinPortal Feedback Meeting
February 16, 2010 12:30-1:30 p.m.
Farrell Learning & Teaching Center, Room 209

Demonstrations
February 23, 2010
Farrell Learning & Teaching Center, Room 403 A/B

caTissue	12:30-1:30 p.m.
ClinPortal	1:45-2:45 p.m.

caTissue and ClinPortal descriptions can be found at the CBMI website:
http://cbmi.wustl.edu/html/services.html

Please RSVP to ensure seating.
- For caTissue trainings
- For ClinPortal trainings

If you have questions, please contact Mary O'Brien Uhlmansiek, MA, at the CBMI, at (314) 747-8098 or muhlmansiek@path.wustl.edu