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RePAIR Program Offers Options to Address Problem of Wrongdoing in Research

A $500,000 NIH CTSA administrative supplement award to Washington University’s (WU) Institute of Clinical and Translational Sciences (ICTS) will fund the first ever remediation program for researchers who have engaged in wrongdoing or unprofessional behavior. The Restoring Professionalism and Integrity in Research (RePAIR) program is expected to launch in November 2012. The RePAIR program is being developed in partnership with the ICTS Center for Clinical Research Ethics and Saint Louis University’s (SLU) Albert Gnaegi Center for Health Care Ethics. Both centers are directed by James M. DuBois, PhD, DSc, who also serves as the RePAIR Project Director.

“Maintaining the public’s trust and support is critical to the success of research. As the first program of its kind aimed at correcting problematic research practices, RePAIR will provide an important mechanism to support ethical researcher practices and maintain the public’s trust,” said Raymond Tait, PhD, SLU Vice President for Research and member of the RePAIR Advisory Committee.

DuBois and his team kicked off the project in January 2012 with a needs assessment that was sent to 194 medical schools and comprehensive doctoral institutions. Of the 129 institutions that responded, 96 percent had investigated cases of wrongdoing in the past 2 years. On average, these institutions investigated 4 cases per year. Offenses ranged from procedure violations to more extreme cases of data falsification, fabrication, or plagiarism.

“The results of the assessment confirmed that wrongdoing in research is a widespread problem. It also highlighted the fact that institutions have very few options for responding to these cases,” DuBois said. According to DuBois, at one extreme, researchers get a slap on the wrist – the institution issues a letter of reprimand and may increase oversight of the wrongdoer. At the other extreme, researchers are debarred from research for 5 years and employment is terminated. Both extremes can cause new problems, and only 30 percent of institutions responding to the needs assessment indicated they were very satisfied with their current options.

The hope is that the RePAIR program will provide a middle ground with a substantial educational program that addresses the major causes of research wrongdoing and fosters good research practices and decision making skills. No one has attempted development of a formal program like this for researchers, but the RePAIR team is inspired by the success of physician remediation programs at the University of California San Diego and at Vanderbilt University, which have demonstrated that remediation programs can work.

Program Components

The RePAIR program will offer 2 course options:

Option 1: RePAIRing Research Integrity will address a variety of research integrity violations including falsification or fabrication of data, plagiarism, conflict of interest violations, fraud, questionable research practices and mentoring or oversight failures.
Option 2: RePAIRing Human Subjects Protections will address offenses such as informed consent violation, inadequate management of risks, improper recruitment or enrollment, and privacy and confidentiality violations.

Participants in both courses will be required to complete approximately eight hours of online assessment and education as well as participate in a three and a half day onsite workshop that will focus on promoting thinking patterns, decision making skills, and work habits that support ethical research. Each participant will leave the program with an individualized work management plan to implement upon return to their institutions. Participation in the program will be confidential.

The Team

The RePAIR program is being developed by a team of psychologists and ethicists including DuBois and John Chibnall, PhD, Professor of Psychiatry, SLU; Elizabeth Heitman, PhD, Associate Professor of Medical Ethics, Vanderbilt University; and Michael Mumford, PhD, Professor of Industrial-Organizational Psychology and Center for Applied Social Research Director, University of Oklahoma. RePAIR's Advisory Committee, which has played a major role in shaping the program, includes experts who lead remediation training programs with physicians, liaisons from national organizations, lawyers, clinical psychologists and research administrators. Yi Zhang, JD, RN, WU Assistant Dean for Clinical Trials and ICTS Regulatory Support Center co-Director, serves on this RePAIR Advisory Committee.

For more information about the program, visit: www.repairprogram.org or contact the RePAIR Coordinator, Tessa Gauzy, at repair@slu.edu. The RePAIR project is supported by NIH NCRR/NCATS grant 3UL1 RR024992-05S2.

Center for Administrative Data Research (CADR)

By Anita Helstrom

The Center for Administrative Data Research (CADR) resources have grown considerably since last featured in the ICTS News (May-June, 2010). We've added a Lead Programmer (Harini Subramaniam) and Research Coordinator (Anita Hellstrom) to our staff, and by early June will be welcoming 2 additional programmers (Aekyung Lee and Michael Birnbaum) to meet increasing demand.

For ICTS investigators interested in using existing administrative data for clinical epidemiologic, health service and comparative effectiveness research, the big news at CADR is the recent acquisition of the Thomson Reuters MarketScan® Commercial Claims & Encounters Databases consisting of HIPAA-compliant, de-identified, patient-level medical claims data for inpatient and outpatient services and outpatient pharmaceutical claims. This data has just recently arrived so look for more details to be distributed to ICTS members in the near future. A presentation at the ICTS Brown Bag Seminar series is planned for the last week of October. You may also want to check the CADR website to learn about the other available databases. (Note that registration is required for much of the site but it is a quick process for the ICTS community – click here to register).

User Group

Whether you're new to administrative data or an old hand, you may be interested in joining CADR's Administrative Data Users' Group monthly meetings. For more information on future and past topics, click here or access via the 'news' tab from the front page of the CADR website http://cadr.wustl.edu/. If would like periodic updates on meeting topics and dates, contact Anita Hellstrom (286-0850 or ahellstr@dom.wustl.edu).

For more information about the program contact Margaret A. Olsen, PhD, MPH, CADR Director, or Anita Helstrom at CADR@wustl.edu or visit the website at cadr.wustl.edu.

National CTSA Update

Tools for Pre-Clinical and Clinical Researchers

The National Center for Advancing Translational Sciences (NCATS) website highlights various tools that are available to support both pre-clinical and clinical researchers to advance translational science. Many of the clinical research tools were developed by CTSA institutions that are now funded by NCATS. The tools that are open-source and freely available to the scientific community can be found on the NCATS website (http://www.ncats.nih.gov/research/tools/tools.html).

Find research resources and keep up with national CTSA news at: https://www.ctsacentral.org/
The Our Community, Our Health program welcomed a crowd of over 120 people to the Missouri History Museum on April 17, 2012, for an event focused on Improving Health Outcomes in St. Louis: Emerging Research and Strategies to Address Health Disparities. Attendees were welcomed by: Our Community-Our Health co-Director Dr. Consuelo H. Wilkins, ICTS Center for Community-Engaged Research Associate Director and Associate Professor at Washington University School of Medicine; Dr. Edwin Trevathan, Dean, School of Public Health at Saint Louis University; and the WU Institute of Clinical and Translational Sciences Director and Assistant Dean for Clinical and Translational Research, Dr. Bradley A. Evanoff.

Rev. Starksy D. Wilson, President and CEO of the Deaconess Foundation, gave the opening address titled “Caring, Healing, and Teaching: Minority Health as Mission in the Margins.” His talk emphasized the history of health inequities in St. Louis and emphasized a vision of reconciling rather than reducing disparities through a collaborative mix of community efforts and faith-based initiatives.

The balance of the OCOH program featured 4 research presentations:

“The Road to Eliminating Racial Disparities in Health” - Melody S. Goodman, PhD, MS, Assistant Professor, Washington University School of Medicine

“Building Community Partnerships to Address Black Men’s Health” - Keon L. Gilbert, DrPH, MPA, MA, Assistant Professor, Saint Louis University School of Public Health

“Healthy, Wealthy, and Wise: The Case for Economic and Educational Interventions to Address Health Disparities” - Jason Q. Purnell, PhD, MPH, Assistant Professor, Washington University Brown School of Social Work

“Exploring Disparities Through the Preconception Partnership” - Pamela K. Xaverius, PhD, Assistant Professor, Saint Louis University School of Public Health (with contributions from Deborah Kiel, PhD, Assistant Professor, College of Nursing, University of Missouri-St. Louis)

Closing remarks were given by OCOH co-Director, Dr. Darcell P. Scharff, Associate Dean and Associate Professor at the Saint Louis University School of Public Health, taking the opportunity to offer her heartfelt thanks to her Our Community, Our Health co-director Dr. Wilkins, who will be leaving St. Louis to become Executive Director of the Meharry-Vanderbilt Alliance in June 2012.

Evaluations from attendees were quite positive with respondents noting high satisfaction with the relevance of presentations and the length and other logistics of the program. In addition, 100% of evaluation respondents either “strongly agreed” (85%) or “somewhat agreed” (15%) that they would encourage others to attend future OCOH programs.

To read coverage of the event visit the St. Louis Beacon.

SAVE THE DATE
Department of Anesthesiology and the Institute of Clinical and Translational Sciences Present:

“Adventures in Drug Development in Academia”

Douglas E. Raines, MD
Associate Professor
Harvard Medical School

Tuesday, July 24, 2012
4:30-5:30pm

Connor Auditorium
Washington University Farrell Learning and Teaching Center

For questions, contact Kathy Reeves at REEVES@WUSTLE.DU or the ICTS at ICTS@WUSTLE.DU
BJHF/ICTS Clinical & Translational Research Funding

The 4th annual Barnes-Jewish Hospital Foundation/ICTS RFA was issued in August 2011 resulting in 142 letters of intent, 118 invitations to investigators to submit full applications, and actual receipt of 95 applications. After consideration of the outcomes from the 3 study sections held in December, the ICTS Executive Committee and the Barnes-Jewish Hospital Foundation Committee approved funding for 17 applications, each for one year beginning June 1, 2012. Out of the 17, 10 will be funded through BJHF and 7 through the ICTS. The list of awardees can be found at http://www.icts.wustl.edu/funding/current_awardees.aspx. Plans are underway to issue a BJHF/ICTS RFA again in mid or late summer of 2012.

Pilots Across the SPIRiT (PATS)

SPIRiT, the Sharing Partnership for Innovative Research in Translation has awarded its first grants under the Pilots Across the SPIRiT (PATS) program that supports pilot research projects representing collaborations between investigators from at least 2 of the SPIRiT sites. Twenty-one applications were submitted by ICTS members and a total of 55 applications were submitted across the 5 SPIRiT Consortium partners. The 4 WU ICTS awardees include Dr. David A. Hunstad (Pediatrics), Dr. Catherine Lang (Physical Therapy), Dr. Audrey R. Odom (Pediatrics) and Dr. Daniel S. Ory (DOM-Cardiology). Each awardee will receive one year of funding for up to $25,000 beginning June 1, 2012, as will their partner PI at another PATS site.

The SPIRiT Consortium members supporting this program include Johns Hopkins University, University of Chicago, University of Pennsylvania, University of Pittsburgh, Washington University in St. Louis, and Yale University – all members of the NIH Clinical and Translational Science Award (CTSA) Program. A similar review process was followed at each of the organizations. Since each proposal included a principal investigator (PI) from at least 2 of the SPIRiT partners, in order to be selected for funding, the applications had to be highly scored by the home institution for each PI. This was the first RFA under this program. Details can be found at http://icts.wustl.edu/funding/spirit_funding_program.aspx.

Questions about the ICTS funding programs can be addressed to Jaimee Stagner (jstagner@dom.wustl.edu) or Becky Evans (revans@dom.wustl.edu).

Research Navigator

Inquiries directed to the ICTS Research Navigator, via e-mail or phone, are currently being monitored by the ICTS Administrative Core staff and triaged to the appropriate expert.

To learn about services, visit the ICTS Cores and Resources website or contact the ICTS at 314-362-9829 or ICTSNavigator@wustl.edu for assistance.

Attention ICTS LINC Members:
The next LINC meeting will take place from 12:00 to 1:00pm in BJCIH Room 10A/B on June 29th. Hope to see you there!