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2009

## Institute of Clinical and Translational Sciences News, Vol. 2, Issue 3

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## Features

- 2 CTSA Pharmaceutical Portal Survey
- 3 Reporting Back: The Center for Community Based Research
- 3 Business Development Advisory Committee Meets
- 4 Subject Enrollment Reporting is Key

## Grant Citation

Investigators using ICTS cores and services to support their research should acknowledge the CTSA Grant  
**UL1 RR024992**

ICTS scholars and trainees should acknowledge the CTSA linked grant  
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## ICTS Items

- 2 In the News
- 4 Have you-Met?
- 5 Past Events & Updates
- 5 Events & Announcements

Send comments or suggestions to  
[ICTS@wustl.edu](mailto:ICTS@wustl.edu)



## Translating Research: ICTS Business Development Core

Exploring research questions and potential inventions, commercializing research discoveries and evaluating community benefits are three aspects of translation that are supported through various ICTS programs. To uncover commercial opportunities and promote investigator awareness, the ICTS offers the services of the Business Development Core (BDC). The BDC is an important contributor with a core objective of actively pursuing industrial relations for the translation and commercialization of ICTS funded and ICTS member-developed technologies. The BDC is integrated into the Washington University Office of Technology Management (OTM). Co-Directors Bradley J. Castanho, PhD and Michael T. Marrah, JD have cultivated relationships with business leaders in the St. Louis community to better understand how to work more effectively in the transfer and licensing of intellectual property (IP) from WU to private companies to promote translation of research to the community.

A key aim of the BDC is to identify the clinical and translational research projects that have significant potential to lead to diagnosis or treatment of disease at an early stage, and to provide the necessary expertise and administrative support to realize this potential through commercialization. To achieve this aim the BDC is proactive by offering educational opportunities to the faculty on how to manage IP opportunities and contacting individual investigators to discuss commercial potential of their projects. In addition, the BDC serves as a matchmaker between investigators and industrial partners.

Toward this goal of being proactive, three fellowships were recently established in BDC under an award received by the WU Skandalaris Center. These fellows contact faculty to discuss projects and the importance of, not only protecting the IP from their research, but also the subsequent translation work of that IP into commercial licenses. This effort is funded in part by a National Science Foundation grant and is coordinated with local St. Louis community incubators – i.e. Biogenerator, Angel Network, Nidus Center and Center for Emerging Technologies. The BDC staff is also available to provide educational sessions at department or center meetings.

(See Translating Research: page 2)

## Message from the Director: Kenneth S. Polonsky, MD.

During the last 20 months since the CTSA grant was funded, more than 650 investigators have become members of the ICTS. Those members have benefited in a variety of ways. The ICTS has awarded over \$2.4 million to members through the three ICTS funding programs. During our 02 year of funding, 386 investigators received services from the ICTS Cores and those investigators were associated with 185 NIH grants that benefited from the services. In our recently submitted annual progress report we also noted over 1350 services that were delivered by ICTS Cores during the Institute's second year.

The ICTS infrastructure was designed to provide needed resources and expertise for the various phases of clinical and translational research projects. The ICTS Tracking and Evaluation Group, in collaboration with the Siteman Cancer Center (SCC) administration, recently issued a User Satisfaction Survey to ICTS and SCC members to help us gauge where we are succeeding in meeting member needs and what areas still need attention. We received responses from 203 members and are currently evaluating those responses. As we move into our third year of funding, we will continue to work toward enhancing service delivery as well as turning attention to longer term initiatives. For example, ICTS Program Directors submitted 8 CTSA administrative supplement proposals to the NCR for funds made available under the American Recovery and Reinvestment Act. If these applications are successful, not only will it strengthen collaborations with some of our CTSA cohorts, but also further our translational initiatives locally. Despite the current economic challenges, I am increasingly encouraged by the opportunities for innovative, collaborative research programs that the ICTS creates.

## Translating Research, from Page 1

### ICTS Pilot Application Commercial Potential

The BDC/OTM Fellows specifically play a role in evaluating the commercial potential of the projects submitted to the ICTS pilot funding program. The Fellows met with each of the investigators of the 15 funded proposals from the 2008 ICTS Pilot and Novel Methodologies Funding Program to evaluate each project for its potential commercial opportunity. Such meetings will also be conducted with the investigators of the 2009 ICTS funded pilot projects. In addition, even if not chosen for funding through the BJHF/ICTS pilot program, if the proposed project was flagged by either the applicant or reviewer as having commercial potential, the BDC will contact the investigator. The Principal Investigator is interviewed to provide BDC staff with a better understanding of the project and promote investigator awareness of the nuances related to commercialization opportunities such as licensing, copyright and patents. For the first round, investigators of 40 unfunded projects were contacted and 18 meetings were held with investigators to evaluate options and build awareness.

### New Quick-Material Transfer Agreements (MTA) and National CTSA Consortium Influence

Material Transfer Agreements have become increasingly onerous barriers to the free and open exchange of scientific information and materials. The new WU Quick-MTA tool has been developed by OTM in an effort to simplify the process of sending basic research tools from Washington University to other academic and non-profit researchers. In addition, Dr. Castanho sits on the national CTSA Public and Private Partnership (PPP) Key Function Committee and has been able to influence some of the 39 other CTSA institutions to adopt this specific tool or adopt similar less onerous processes. The new WU Quick-MTA form and instructions will soon be available on the OTM website and in the meantime can be obtained by emailing [mta@otm.wustl.edu](mailto:mta@otm.wustl.edu).

For additional information about the Business Development Core services refer to the ICTS website (<http://icts.wustl.edu/cores/bdc.aspx>) or contact Brad Castanho at 747-0927 or [bjcastanho@wustl.edu](mailto:bjcastanho@wustl.edu).

### CTSA Pharmaceutical Assets Portal Survey

The National Center for Research Resources (NCRR) has funded a pilot project to build a portal that would match academic researcher needs for investigational compounds with pharmaceutical assets for research and clinical treatment. To lay the foundation for this portal, the study partners are asking all CTSA researchers to take a survey that will:

- Identify whether discontinued investigational compounds are available for your research;
- Identify potential researchers for collaboration and form clusters of expertise for future multi-disciplinary and multi-institutional investigations.

Take the survey at: [www.ctsapharmaportal.org](http://www.ctsapharmaportal.org)

The information you provide will contribute to a better understanding of industry barriers such as transferring or in-licensing of compounds. The larger Portal Project hopes to forge relationships between researchers and pharmaceutical companies to provide access to assets and request compounds directly from companies. Translational researchers would gain access to drugs with an established safety profile that may benefit approval of licensing for new indications or for commercial use.

## In the News

Three ICTS members -- Drs. Randall J. Batemen, David M. Holtzman, and John C. Morris -- participated in HBO's *The Alzheimer's Project*. This multi-platform media series examines recent research about Alzheimer's by our country's leading scientists, including those working through the Alzheimer's Disease Research Center at Washington University. The entire project includes four documentaries, 15 supplemental films, an extensive resource website, and a nation-wide community outreach campaign. All the films can be viewed at <http://www.hbo.com/alzheimers/>. The project is a partnership between HBO Documentary Films and the National Institute on Aging of the National Institutes of Health in association with the Alzheimer's Association®, Fidelity® Charitable Gift Fund, and Geoffrey Beene Gives Back® Alzheimer's Initiative.

## Reporting Back to the Community: Center for Community Based Research

The activities of the Center for Community Based Research (CCBR) are part of Washington University's ongoing effort, through its Clinical and Translational Sciences Award and the ICTS, to increase the relevance of research to community needs, further expand community participation, and disseminate more research findings back to the community.

The CCBR and the Siteman Cancer Center's Program for the Elimination of Cancer Disparities (PECaD), in partnership with the St. Louis American Foundation, hosted a poster session during a reception held before the St. Louis American Foundation's Annual "Salute to Excellence in Healthcare" Luncheon. The event was held April 25, 2009 at the Hilton St. Louis at the Ballpark.

"The poster session provided a unique opportunity for those who attended the Salute to become more knowledgeable about some of the promising research that is conducted locally. The information was especially relevant to our community and the presentation was



Photo courtesy of CCBR

well-received and enhanced the learning experience for our attendees." says Donald M. Suggs, President, St. Louis American Foundation. Ten posters were selected by a formal community and academic review process based on their relevance to community needs and interests from posters originally presented at the opening event launching the Washington University Institute for Public Health.

The posters reported on a range of topics including sickle cell disease, obesity, STDs and more. "We wanted to share with community members and providers the findings of the research being conducted that impacts them and their surrounding community," says Victoria Anwuri, MPH, PECaD Project Manager and Salute awardee.

Guests provided positive feedback about the posters and indicated that they would like to see them again in other venues. "Feedback from the exhibit will help us find better ways to deliver on the promise of research: to improve the health and wellness of all people," says Dr. Katherine Mathews, CCBR Co-Director. "In the future, we hope to expand the exhibit to new locations and include additional research projects that can benefit the St. Louis community. Through this project and other similar initiatives, we hope to continue an important dialogue with the community about how research can best benefit the community at large."

## Business Development Advisory Committee Meets

The Business Development Advisory Committee (BDAC), working with the ICTS Business Development Core, is chaired by John McDonnell, Chairman of the Board of BioGenerator and Vice-Chairman of the Washington University Board of Trustees. The BDAC met on April 20th and was attended by representatives from 7 St. Louis companies, Saint Louis University, and Washington University.

Kenneth S. Polonsky, MD, Director of the ICTS provided a general overview of the ICTS activities, including a description of current funding programs and the Center for Biomedical Informatics initiatives. Bradley J. Castanho, PhD, Co-Director of the BDC, described three initiatives of the BDC:

- **Interactions with the CTSA Public & Private Partnership (PPP) initiative:** The PPP is a committee consisting of representatives from the 39 CTSA organizations focused on streamlining the process for developing public/private partnerships.
- **Bear Cub Fund:** This WU funding program is made up of endowment income and capital from private sources and is designed to promote commercialization of local research discoveries.

- **FastTrac Training:** This entrepreneurial training is sponsored by the Kauffman Institute and is made available to invited faculty with interest in exploring the possibility of starting a company based on their research discoveries.

The committee agreed on some initiatives to explore during the next year, including fund raising opportunities and ways to leverage local business efforts in promoting translation of research into commercial practice.

### Just In Time (JIT) Core Usage Funding Program

The maximum amount for JIT Core Usage awards is now \$5,000.

In the case of requesting services from the Human Imaging Unit, the maximum allowable request is \$10,000 due to the availability of matching funds from the WU Mallinckrodt Institute of Radiology (MIR).

For more information visit the ICTS website page:  
[http://icts.wustl.edu/funding/jit\\_core\\_usage\\_funding\\_program.aspx](http://icts.wustl.edu/funding/jit_core_usage_funding_program.aspx)

## Subject Enrollment Reporting is Key

By Charles Rathmann

Recruitment of potential participants into clinical trials at Washington University continues to be a major challenge for investigators and research coordinators tasked with the execution of these trials. Fortunately, the ICTS has two groups dedicated to helping study teams meet and even exceed their recruitment and enrollment targets:

- The Recruitment Enhancement Core (REC) in the Regulatory Support Center, which includes the Research Participant Registry, powered by Volunteer for Health, and
- The Center for Community Based Research (CCBR) which connects underrepresented volunteers to clinical research through a community based site called HealthStreet, as well as a community outreach van.

When recruitment services are requested, the REC and the CCBR provide referrals of potential participants who are interested in and who may qualify for the clinical trials. Most referrals are even prescreened against the inclusion and exclusion criteria of those trials.

In order for the REC and the CCBR to measure the impact they have on enrollment for trials they support, as well as the impact on the overall vision of the ICTS, it is imperative that they track the referrals they send to study teams. Both ICTS cores send inquiries by e-mail and call to find out if the potential participants were enrolled, randomized, screen failed, not qualified, etc. The feedback provided about the referrals is critical for the REC and the CCBR to evaluate what strategies lead to maximizing enrollment and what strategies need to be adjusted. It cannot be emphasized enough how important this information is so that study enrollment yield can be measured in order to improve core services to meet the needs and expectations of the investigators and the participants.

**PLEASE DO YOUR BEST TO RESPOND TO REQUESTS AND ACCURATELY REPORT THE ENROLLMENT INFORMATION THAT IS BEING REQUESTED BY THE REC and CCBR.**

If you have any questions or comments, please contact Charles Rathmann, Director of the REC, at 314-362-0897 or [rathmannc@wusm.wustl.edu](mailto:rathmannc@wusm.wustl.edu) or Dr. Linda Cottler at HealthStreet at 314-531-3034 or [ctsa@epi.wustl.edu](mailto:ctsa@epi.wustl.edu).

## Have You Met?

Michelle Jenkerson, RN, RRT, CCRC, a graduate of the Barnes-Jewish College of Nursing and the Cardinal Glennon Respiratory Therapy School, is the Research Participant Advocate (RPA) for the ICTS Regulatory Support Center (RSC). Upon graduation, Michelle along with a therapist and a pilot, formed a transport response team that traveled by ambulance, helicopter, or jet to transport pediatric patients to Cardinal Glennon for care. “I learned a lot of life lessons during those 13 years. Most importantly life is too short and precious to sweat the small stuff.”



After her response team experience, Michelle worked in the Pulmonary Department at The Jewish Hospital of St. Louis for 6 years and became a Washington University (WU) employee when that department was merged into the WU Pulmonary Lab. She served as a nurse/respiratory therapist for Dr. Mario Castro, Professor of Medicine, until 2001 when she took the job as the Research Participant Advocate in the WU General Clinical Research Center (GCRC). The RPA position was required under the GCRC and Washington University has maintained this activity under the Institute of Clinical and Translational Sciences.

As the Research Participant Advocate, Michelle reviews research protocols and consent forms that request CARS resources. She also interviews a randomized subset of subject participants and is responsible for ensuring participant rights are safeguarded on any of the CARS units.

A Certified Clinical Research Coordinator (CCRC) herself, Michelle is concerned about improving training and educational opportunities for research coordinators and is actively involved in the WU Research Education Task Force. She believes that up-front training, as opposed to the “learn by doing” technique, enhances compliance, and allows the coordinator to develop expertise and confidence, preventing problems in the long run. She has worked with Sally Anderson, RN, BSN, CCRC, Director of the CARS Clinical Research Services, to develop an extensive training and orientation program for CARS research coordinators and has shared lessons learned with a national audience at the Association of Clinical

See Have you Met?: page 5

## Past Events & Updates

**April 20: Business Development Core:** The Business Development Advisory Committee met. (See article on page 3 for details.)

**April 26: Center for Applied Research Sciences:** The Association of Clinical Research Professionals (ACRP) held the *ACRP 2009 Global Conference* in Denver, Colorado. Sally Anderson, RN, BSN, CCRC, Director of Clinical Research Services at the ICTS CARS and Michelle Jenkerson, Research Subject Advocate for CARS presented a talk entitled "Creation and Implementation of a Clinical Research Coordinator Education and Mentoring Program."

**May 4 and 5: Clinical Research Training Center: 2009 National Predoctoral Clinical Research Training Conference.** Washington University School of Medicine hosted the first national meeting convened for students and faculty involved in NIH-sponsored predoctoral clinical research training programs. The event was held at the Eric P. Newman Education Center. For complete conference information visit <http://t32.im.wustl.edu/predocnational/index.html>. The conference was sponsored by WU School of Medicine, Barnes-Jewish Foundation, The National Institutes of Health, and the ICTS.

**May 19: Center for Applied Research Sciences:** *The Brown Bag Seminar Series*, "Public Relations and Marketing Services for Your Research Studies," was presented by WU Medical Public Affairs staff Joni Westerhouse, Executive Director for Medical Communications, and Donna De Pond, Executive Director, Creative Services and Marketing.

## Have You Met, from Page 4

Michelle Jenkerson (ACRP) Global conference in Colorado in April, 2009. She also teaches the *Fundamentals of Clinical Research Management Courses I and II* as part of the University's Clinical Management Certificate and Bachelors Degree programs.

Michelle's husband, Dennis Jenkerson, has been Chief of the St. Louis Fire Department since November, 2007 and is a third generation firefighter. Having met in kindergarten, they started dating in high school and were married after college graduation. Their daughter, Danielle was married last October and works in public relations and marketing. Their daughter Emily works with the WU Volunteer for Health, and their son, Denny, is a senior at the University of Missouri, Columbia.

## Events & Announcements

**June 25 (Noon-1:00 pm): Center for Applied Research Sciences:** *Brown Bag Seminar*, Holden Auditorium, Farrell Learning and Teaching Center. Speakers include:

- Rakesh Nagarajan, MD, PhD, Center for Biomedical Informatics (CBMI)
- Ken Schechtman, PhD, Research Design & Biostatistics Group (RDBG).

**June 26 (8:00 am-Noon): ICTS Clinical Research Training Center:** The CRTC will host the *3rd Annual Career Development Retreat*, Moore Auditorium.

- 8:30 – 9:30 am -- "Exciting Careers in Clinical and Translational Research: the Perspective of a Department Head," Kenneth S. Polonsky, MD, Aldolphus Busch Professor and Chairman, Department of Medicine, Director, ICTS
- 9:45 – 10:45 am -- "A Career Studying Sex: Follow Your Passion in Academic Medicine," Jeffrey F. Peipert, MD, PhD, Robert J. Terry Professor and Vice Chair of Research, Department of Obstetrics and Gynecology
- 11:00 am – Noon -- "Effective Presentations," Thomas M. De Fer, MD, FACP, Associate Professor of Medicine, Director, Internal Medicine Clerkship and the ACES Program

RSVP by June 19 : 314-454-8244; [mfavazza@dom.wustl.edu](mailto:mfavazza@dom.wustl.edu)

**July 14-15: NCRR Workshop: Efficient Management and Utilization of Core Facilities.** Natcher Center, NIH Campus, Bethesda, MD This workshop will examine the state of existing NIH-funded research core facilities, identify common problems encountered, and discuss solutions to maximize their use. For more information or to register, visit [http://www.ncrr.nih.gov/Core\\_Facilities](http://www.ncrr.nih.gov/Core_Facilities).

Michelle is gracious and well suited to represent Washington University in her interactions with study participants and the City of St. Louis in community events with her husband. With grandparents that immigrated to St. Louis from Italy and a father that served as St. Louis City Assessor for St. Louis, Michelle states, "I've always lived in the city, was educated here and have never had a job outside the city limits." Seems it would be difficult to be more closely connected to St. Louis than that.

For more information about Research Participant Advocacy or clinical research coordinator training opportunities, contact Michelle at [jenkerson\\_m@gcrc.wustl.edu](mailto:jenkerson_m@gcrc.wustl.edu) or 314-362-5626.