The Center for Economic Evaluation in Medicine
By Colleen Peters, MA, Research Coordinator

The Center for Economic Evaluation in Medicine (CEEM) is a new ICTS core funded in June 2009 under the BJHF/ICTS Clinical and Translational Research Funding Program. Steven M. Kymes, PhD, MHA, Research Associate Professor in Ophthalmology and Visual Sciences and CEEM Director states that "the focus on comparative effectiveness and health care reform by policy makers has created an awareness of the need for clinical and translational researchers to make the case for the 'value' of their therapies and health programs. We are here to help them do that."

CEEM Staff and Services
The CEEM consists of a staff of economic modelers, statisticians, and research coordinators to support investigators who want to develop proposals for economic evaluation projects, collaborate on the conduct of such projects, or learn more about the methods employed.

CEEM offers a wide range of services for students, investigators, clinicians and policy makers, including:

- Cost-benefit analysis
- Cost-effectiveness analysis
- Modeling of disease processes
- Development of patient decision aids
- Development of clinical decision support tools
- Value of information studies
- Quality of life studies

Plus ça change, plus c’est la même chose.
- The more things change, the more they stay the same.

I am honored to succeed Ken Polonsky as Director of the ICTS. On October 1, Ken began his new position as Dean of the University of Chicago’s Medical School. Under Ken’s leadership since its inception in 2007, our ICTS has made tremendous strides toward achieving its original aims: to provide the infrastructure, resources, and services needed to stimulate and facilitate the performance of outstanding interdisciplinary research; to create a centralized home for Clinical and Translational Research Training and Career Development Programs; and to establish inter-institutional partnerships for clinical research and training with community, academic, health care, and industrial organizations in the St. Louis region. The ICTS has always been an ambitious undertaking: we were tasked by the NIH to transform research and research training in order to accelerate the translation of research findings into health practice. This ongoing transformation is well underway.

Among the challenges in this fourth year of the ICTS is the submission of our competitive renewal in late Spring of 2011. In addition to prompting a detailed evaluation of our current activities, the renewal will require us to articulate our aims for the next 5 years. So how do we keep transforming? Through
Examples of Current Projects
The role of the CEEM is to support investigators who want to compare treatments or health interventions, develop tools for support of clinical decision making, or estimate the burden of disease. Among the projects that CEEM has in-house right now are:

- Economic comparison of methods of stem cell mobilization in people with Non-Hodgkins Lymphoma;
- Estimation of the value of reduction of intraocular pressure in people with glaucoma;
- Identification of the optimal frequency of physician follow-up for patients who undergo knee or hip replacement;
- Evaluation of the cost-effectiveness of pharmacogenetic testing in children with asthma;
- Estimation of the economic burden of hip/spine syndrome;
- Economic evaluation of interventions to prevent clostridium difficile infection in hospitalized patients;
- Comparison of the cost-effectiveness of a method of promoting smoking cessation in disadvantaged communities;
- Evaluation of the cost-effectiveness of genetic identification of biopsy samples prior to testing.

“We have a tool box of economic, statistical, and psychometric tools we can bring to bear on a problem. When we collaborate with investigators who have a clinical or policy question, we can help them to develop answers. This helps to promote dissemination of successful programs by answering objections that treatments or public health interventions are ‘too expensive’ to be considered,” said Dr. Kymes.

CEEM also serves as a resource for medical students, residents, and fellows seeking to learn more about economic evaluation methods. Past students have completed projects that have been published in high impact journals. One example is Dr. David Vollman, Chief Resident in the Department of Ophthalmology this year, who developed an economic model during his first year of residency that was used by the Canadian government to make coverage decisions for people with macular degeneration.

CEEM Educational Opportunities
CEEM held its first “lunch-inar” on September 30 at the Center, which is located at 4547 Clayton Avenue. At the seminar, Dr. Kymes and his team presented some of the basics of economic evaluation. Additional “lunch-inars” will be held in the future and will be posted on our events page at http://ceem.wustl.edu/Events.aspx. This semester CEEM personnel are also teaching the “Decision Analysis for Clinical Investigation and Economic Evaluation” course for students in the WU Master of Science in Clinical Investigation and Master of Science in Population Health Programs (see http://k30.im.wustl.edu/documents/2010_FL_Syllabus_DecisionAnalysis.pdf for more information).

For More Information
To learn more about CEEM, visit the ICTS website at http://icts.wustl.edu/cores/ceem.aspx. To request information about current CEEM services, contact Katie Dalton at daltonc@vision.wustl.edu or if you would like to better understand how CEEM may help you in your research, contact CEEM’s director Steven M. Kymes, PhD, MHA at kymes@vision.wustl.edu or Dennis Lambert, PhD at lambertd@vision.wustl.edu.

Evanoff, from Page 1
The planning retreat in July and the deliberations of our several leadership groups, we have identified areas of strength and need. There are clearly opportunities for improving our mission at both ends of the translational research spectrum: “first in human” research moving basic science discoveries into human applications, and disseminating, implementing, and evaluating treatment and prevention in populations. We need to better engage and interact with our institutions’ tremendous strengths in basic science and human genetics, and use these resources to advance early stage clinical and translational research. At the other end of the spectrum, the past five years has seen an amazing flowering of research and training in public health, population health science, community-based research, and comparative effectiveness research. At the time we wrote our first application for the CTSA in early 2006, we could hardly imagine the exciting and rapid expansion that has occurred in these areas. Continuing momentum while promoting coordination among many players is an ongoing challenge here, as for all areas of the ICTS.

In its short history, the ICTS has seen significant changes in the research environment: a change of directors at the NIH, the brief joy of ARRA funding, the promise of new resources for comparative effectiveness research, and the painful prospect of lower paylines at the NIH over the next few years. Our future work will need to adapt to these changing circumstances while promoting the original aims of the ICTS – promoting excellence in clinical and translational research, research education, and institutional partnerships. Because while some things change, our goals stay the same.
WU PAARC Conducts Needs Assessment of Parents’ Health Concerns for their Children

Reprinted from WU PAARC newsletter (with edits)

The Washington University Pediatric and Adolescent Ambulatory Research Consortium (WU PAARC), a Practice-Based Research Network (PBRN) of community pediatricians which acts as one of three arms of the ICTS Center for Community Based Research, completed a needs assessment to learn about parents’ health concerns for their children. WU PAARC staff visited 12 pediatric practices in the St. Louis area and obtained 1,119 surveys from parents waiting for an office visit. Respondents represented the local St. Louis population (23% African American, 68% Caucasian, 1% Asian, 2% Hispanic). Parents’ health concerns for their children include common chronic diseases and avoiding unhealthy behaviors, as well as concerns about issues that are not always addressed during routine pediatric care. Specific concerns varied by race and by the age of the child.

Overall, more than 50% of parents ranked the following issues as either a large or medium problem for children and adolescents in their community: allergies, lack of exercise, asthma, ADHD, internet safety, obesity, tobacco use, and bullying. For all parents, the top two concerns for their own children varied by age-group: <2 years old, acute respiratory diseases, allergies; 2 to 5 year olds and 6 to 11 year olds, allergies, asthma; and 12 to 17 year olds, illegal drug use, sports-related injuries.

WU PAARC would like to thank the following practices for their participation in the needs assessment project: Children’s Clinic; Crystal City Pediatrics; Esse Health–Creve Coeur; Esse Health–Florissant; Esse Health–Watson; Fenton Pediatrics; Forest Park Pediatrics; Health Care for Kids; Robert H. Strashun, MD; Southwest Pediatrics; St. Louis Pediatric Practitioners; and Tots Thru Teens.

WU PAARC offers consultation about community-based patient recruitment (pediatric and adult) and the formation of Practice-Based Research Networks. In addition, if involved in the planning process, WU PAARC can assist with recruitment of pediatric patients from the community. For more information about WU PAARC, visit the ICTS website at http://icts.wustl.edu/cores/chcp.aspx. You can also contact Jane Garbutt, MB, ChB, FRCP, Medical Director of WU PAARC at jgarbutt@dom.wustl.edu or Shannon Gentry, MS, LPC, Network Coordinator of WU PAARC at gentry_s@kids.wustl.edu.

HRPO Update

New "myIRB" Responds to User Feedback

The Human Research Protection Office (HRPO) is very pleased to announce the release of "myIRB" to the Washington University (WU) research community. This electronic IRB application and data management system was made available campus-wide on October 11, 2010 for submission of New Project applications.

Development of an electronic IRB system on campus has a long history dating back to 2002 when groundwork began with the creation of basic databases to track investigators and adverse events. Ongoing work led to the purchase of a commercial eIRB system that began pilot testing in 2006. However, in the summer of 2009, further development of this system was halted by the eIRB Steering Committee due to a variety of ongoing concerns. At that time, negotiations began to acquire software originally developed at The University of Iowa. The new software arrived in March, 2010 and an aggressive development and customization schedule was implemented. At WU, this new system was dubbed "myIRB" through a campus-wide naming contest.

A key feature of myIRB is the use of “smart form” technology. This technology automates question “skip” patterns and removes the burden from researchers of having to know which form or appendix form needs to be submitted to the IRB for review. Instead, the researcher just chooses to start a New Project form and begins answering questions. Answers to selected questions automatically drive what additional questions are asked. Based on how questions are answered, the application also prompts for additional materials to be attached electronically and begins to build a consent document with suggested language based on what is described in the application. These features should address some of the concerns identified in the recent survey conducted by the ICTS with regard to frustration over use of the HRPO website, and in particular, the paper forms currently in use.

Through myIRB, research teams can track progress of a submitted application by viewing their workflow history and will have ready access to the full description of studies to which they have been named. Because the software is web-based, IRB materials can be accessed from anywhere researchers have internet access.

In addition, you are probably aware that the IRB and HRPO have also undergone some recent changes in leadership. In July of this year, Jonathan M. Green, MD succeeded Philip A. Ludbrook, MD as Associate Dean for Human Studies and Executive Chair of the IRB. Dr. Green, Associate Professor of Medicine in the Division of Pulmonary and Critical Care Medicine has an active NIH funded laboratory and is an experienced clinical investigator. As well, in spring, 2009 Martha Jones, MA, CIP became the Executive Director of HRPO. Martha came to WU from The University of Iowa. The new software arrived in March, 2010 and an aggressive development and customization schedule was implemented. At WU, this new system was dubbed "myIRB" through a campus-wide naming contest.

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Further information about myIRB, including upcoming training sessions, is available on the HRPO website at http://hrpohome.wustl.edu.
The ICTS Clinical Research Training Center (CRTC) launched a summer program for high school and college students with the purpose of introducing them to research and furthering their interest in clinical research. The Advanced Summer Program for Investigation and Research Education (ASPIRE) led by Victoria J. Fraser, MD and Jay Piccirillo, MD, FACS, CPI, is funded by a CTSA administrative supplement.

ASPIRE had a strong response to its call for applications. Two cohorts were formed consisting of 8 high school and 11 college students. Both cohorts began on June 7, 2010 with the high school program lasting 6 weeks and the college term 8 weeks. Students were assigned to a lab or clinical environment for didactic experience and mentored by an experienced investigator. Mentors provided opportunities to learn about their research as noted in the program survey: students were surprised by, and appreciative of, the level of involvement allowed and mentors were impressed with the level of involvement by students and their commitment to their projects. Five students stayed on with their mentor beyond the program term. All of the students said they would recommend the program to others.

Course offerings included “Designing Outcomes and Clinical Research” taught by Dr. Piccirillo and “Analysis of Clinical Data,” taught by Dorina Kallogjeri, MPH. Friday seminar topics included: “Writing an Abstract,” “Developing Successful Mentoring Relationships,” “Effective Presentations,” and “Writing a Grant and Research Training Opportunities.” Students finished the term by giving presentations on a topic related to their research experience. Below are the students who participated, their academic level, institution, research topic, and mentor.

**High School Cohort**
- **Tasha Evanoff** (JR, John Burroughs)  *Minimum Legal Drinking Age Laws and Adult Suicide* – Rick Grucza, PhD, MPE
- **Sarah Huynh** (SR, Affton)  *Severe Asthma Research Program (SARP)* – Mario Castro, MD, MPH
- **Nikita Katta** (JR, Parkway West)  *Processing Speed as an Objective Measure of Tinnitus* – Jay Piccirillo, MD
- **Shelly Koch** (SR, St. Joseph’s)  *Driver Safety in Older Adults in the Emergency Department* – Chris Carpenter, MD, MSc
- **Amanda Miller** (JR, Lafayette)  *RSV Bronchiolitis in Early Life: RBEL & RBEL II* – Mario Castro, MD, MPH
- **Brett Virgin-Downey** (JR, Clayton)  *Effects on Pip2 Binding in the IKS Potassium Channel* – Jianmin Cui, PhD
- **Maeve Woeltje** (JR, Cor Jesu)  *Statistical Brief: Back Pain in the Emergency Department* – Pamela Owens, PhD
- **Eileen Zhu** (JR, Parkway West)  *Do Common Sexually Transmitted Infections Cause Symptoms? An Analysis of the Contraceptive CHOICE Project* – Jeff Peipert, MD, MPH, MHA

**College Cohort**
- **Kelsey Anderson** (SO, Vanderbilt)  *Neurocognitive Testing and Metabolic Syndrome in HIV-Infected Persons* – Turner Overton, MD
- **Andy Chen** (JR, WU)  *Validation of ICD-9-CM Diagnosis Codes for Skin and Soft Tissue Infections and Etiology* – David Warren, MD, MPH
- **Trent Dondero** (JR, WU)  *Diagnostic Bronchoscopies in Mechanically Ventilated Patients* – David Warren, MD, MPH
- **Chris Geiger** (SR, WU)  *The Search for a Biomarker of Parkinson disease Using PET-based Neuroimaging* – Joel Perlmutter, MD, CDE
- **Chelsea Kebodeaux** (JR, WU)  *Correlates of Inconsistent Condom Use in Women* – Jeff Peipert, MD, MPH, MHA
- **Matt Koperwas** (SR, WU)  *Use of Biomarkers to Detect Traumatic Brain Injury* – Larry Lewis, MD
- **Jennifer Lapp** (SO, WU)  *Social Networking and Peer Support (SNAPS) in Children and Adolescents with Type 1 Diabetes Mellitus* – Neil White, MD, CDE
- **Samantha Morley** (SO, Georgetown)  *Total Plasma Homocysteine Concentrations after Nitrous Oxide Anesthesia in Children* – Peter Nagele, MD, MSc
- **Bolu Oladimi** (FR, WU)  *Synosis 115: A Better Treatment for Parkinson’s Disease?* – Kevin Black, MD
- **Benjamin Peipert** (FR, Brown)  *Assessment of Diastolic Dysfunction in Patients with Severe Aortic Stenosis* – Brian Lindman, MD
- **Mark Posnick** (FR, WU)  *Hidradenitis Suppurativa- a Mendelian Trait?* – Peter Nagele, MD, MSc

To learn more about the ASPIRE program, visit the program website at [http://ccrt.wustl.edu/aspire.php](http://ccrt.wustl.edu/aspire.php) or contact Jackie Rice, Program Coordinator, at (314) 454-8255 or jrice@dom.wustl.edu.
Comparative Effectiveness Research Scholars Announced

The ICTS Clinical Research Training Center (CRTC) KL2 program received an ARRA supplement that provides funding to extend the Career Development training program to scholars specifically engaged in Comparative Effectiveness Research (CER). 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, policy makers], responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.”

The ICTS CER Scholars must have a doctoral-level degree in a discipline that can be applied to clinical research as well as a commitment from their department to allow at least 75% of their time to be devoted to didactic and clinical research training. Applications were received during August and two scholars were named with appointments beginning for one year as of September 1, 2010. The new ICTS CER scholars are:

**Christianne Hadi, MD, MPH – Department of Medicine, Division of Infectious Diseases**

**Research Topic:** “Effectiveness of an HIV patient education program in improving clinical outcomes”

**Mentor:** Mario Schootman, PhD, Associate Professor of Epidemiology and Medicine, Chief, Division of Health Behavior Research, and Co-Program Leader, Prevention and Control Program, Alvin J. Siteman Cancer Center

**Elna Nagasako, MD, PhD – Department of Medicine, Division of Medical Education**

**Research Topic:** “Geographic variation in physician supply and health outcomes”

**Mentor:** Pamela Owens, PhD, Research Assistant Professor of Medicine, Infectious Diseases

For more information about the CER program or other ICTS CER activities, contact Rachel Driskell, Program Coordinator, at rdrskell@dom.wustl.edu or 314-362-8719.

BJHF/ICTS Clinical and Translational Research Funding Program Update

The Barnes-Jewish Hospital Foundation (BJHF) and the ICTS Clinical and Translational Research Funding Program is underway. 114 Letters of Intent were submitted by the September deadline and 94 applications by October 18, 2010 at 5:00 p.m. CST. Proposal peer review will occur during December, 2010.

Have You Met?  

**Jae Allen**

When Jae Allen met Becky Evans, ICTS Business Director, through a mutual friend on the Central West End Metro Link platform in the summer of 2006, she agreed to interview for a temporary project manager position to help assemble the resubmission of the CTSA proposal. She had no idea that 4 years later she would be an integral part of the ICTS operations as its Program Manager, and be playing a key role in planning the 2011 competitive renewal for the NIH CTSA grant.

Jae came to Washington University with exceptional qualifications. From the University of Illinois, Urbana she earned a BA in Elementary Education/Physical Education, an MS in Exercise Physiology, and an MBA. And just for fun she also obtained an Associate Degree in Data Processing. Her professional experience includes the following: 1) University of Wisconsin, Milwaukee Portal Administrator responsible for delivery of a production PeopleSoft portal allowing students and faculty access to secure financial and transcript information, 2) Metavante Corporation Director of the Talent Management Center of Excellence working directly with senior management to prioritize and implement initiatives designed to increase personnel effectiveness, and 3) 7 years as a Program Manager and an Associate Director at the National Center for Supercomputing Applications in Champaign, Illinois - one of two supercomputer centers funded by the National Science Foundation.

In September 2007, upon Washington University’s receipt of the CTSA award, Jae accepted a full time position with the ICTS and she, Becky and a newly hired secretary got things up and running. With her broad range of experience she is able to meet the challenging demands of the multi-dimensional ICTS. She manages the day to day activities of the ICTS Tracking and Evaluation Team and applies her project management skills to develop implementation plans for specific administrative projects. Most recently she has taken the lead in working with the ICTS Center for Biomedical Informatics group to design, develop and implement the web based Service Tracker tool reducing the effort needed to meet the NIH requirements for tracking data about services provided by ICTS cores. In addition, it may not be her favorite responsibility, but Jae manages the logistics of the BJHF-ICTS annual RFA which she has down to an art form processing the 100+ letters of intent, followed by the applications, and then assignment of 3 reviewers to each proposal. She admits she has been fully initiated into the world of research administration.

Living in Swansea, Illinois, Jae often spends the 40 minute Metro Link commute reading the next book to discuss with her book club. She enjoys gardening, movies, early morning workouts and traveling. She and her partner of 17 years have recently explored national parks in Hawaii, Maine and Oregon.

For questions related to ICTS activities contact Jae at jallen@dom.wustl.edu or 314-362-9331.
Events & Announcements

ICTS Brown Bag Seminars
October 21 (Noon-1:00 p.m.)
“Maintaining the Trajectory in Research Centers When the Economy Tanks: When Bad Things can Foster Good”
Brian C. Springer, MHA, Executive Director, Research and Business Administration, Alvin J. Siteman Cancer Center

November 30 (Noon-1:00 p.m.)
“The inherent ethical conflict of the physician/clinical researcher”
Jonathan Green, MD, Associate Dean and Executive Chair, WU Human Research Protection Office, Associate Professor of Medicine
Holden Auditorium, Farrell Learning & Teaching Center, WU Medical Center Campus. Registration preferred due to limited seating. WU staff register via HRMS Self Service, Training & Development. Non-WU staff email ICTS@wustl.edu. For more information, call 314-362-9829.

Institute for Public Health 3rd Annual Conference
October 21 (8:00 a.m. - 12:00 p.m.)
What Hurts? What Works? What Have We Learned in Eliminating Health Disparities?
- Breakout Sessions on "Four Winnable Battles in Health Care Disparities: Obesity, Teen Sexuality, Teen Violence, Tobacco.
- Panel presentations: Where does Missouri stand; What’s working in our communities; and How does public policy impact health disparities?
Eric P. Newman Education Center, Washington University Medical Center Campus. Registration is required and there is an administrative fee for CEU (Social Work) credits. For more information, visit the IPH website or email IPH staff at publichealth@wustl.edu.

Clinical Research Training Center (CRTC) Seminars
October 27 (12:30 - 4:30 p.m.)
5th Annual Research Training Symposium and Poster Session
- Keynote Address (Evan Kharasch, MD, PhD, WU Vice Chairman for Research) and Oral Presentations -- 12:30 – 2:30 p.m. (Connor Auditorium)
- Poster Session -- 2:30 - 4:30 (Atrium and Hearth)
Farrell Learning & Teaching Center, WU Medical School Campus. Refreshments will be served during the poster session. For more information about any CRTC event, contact Julie Headrick at jheadric@dom.wustl.edu or call 314-454-8957.

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ICTS Research Navigator Corner

Did you know that ICTS has a core specifically dedicated to the study of the nervous system?

Whether you are interested in collaboration or consultation for designing studies involving the nervous system, the Brain, Behavior and Performance Unit (BBPU) has specialized infrastructure and expertise in the execution of clinical and translational research of the nervous system. Under the direction of Joel Perlmutter, MD, in addition to consultation the other services provided by BBPU are:

- Training for investigators, trainees and research coordinators.
- Performance based measures of activities of daily living.
- Neurologic evaluations including multiple standard rating scales of movement, mental status and mood.
- Structured psychiatric interviews, limited.
- Specialized testing for muscle strength and function.
- Psychometric testing.
- Quantified measures of movement, including gait.
- Quality-of-life measures.
- Key infrastructure support for research studies, including common database collection, retrieval and transfer of research information.
- Consultations for collaborative studies.
- Regulatory document assistance.

Utilizing the services of the BBPU core, Allison Wright Willis, MD, Assistant Professor of Neurology and scholar in the KL2 Career Development Award Post-Doctoral Program of the Clinical Research Training Center has successfully executed and published her study, Geographic and Ethnic Variation in Parkinson's Disease: A Population-Based Study of US Medicare Beneficiaries, (Neuroepidemiology 2010; 34:143-151.9), concluding that Parkinson's Disease is more common in whites, and is nonrandomly distributed in the midwest and northeastern US.

To get started with your idea using BBPU services contact Ling Yan, PhD at 314-362-7148 or yanling@npg.wustl.edu. The BBPU is located at the lower level of McMillan Hospital, 517 S. Euclid Avenue.

Sally Anderson, RN, BSN, CCRC
ICTSNavigator@wustl.edu
(314) 747-8155

ICTS Bander Program in Business Ethics in Medical Research Lecture
November 4, 2010 -- 4:00- 5:00 (Reception at 3:30 p.m.)
“Conflicts of Interest in Medicine”
Marcia Angell, MD
Senior Lecturer, Department of Social Medicine, Harvard University
Connor Auditorium, Farrell Learning & Teaching Center. Find more information on the ICTS website (www.icts.wustl.edu). RSVP to ICTS@wustl.edu or call 314-362-9829.

In the News

Learn more about upcoming events, workshops, and intra-CTSA university initiatives at the CTSA web site at http://www.ctsaweb.org/.