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Institute of Clinical and Translational Sciences News, Vol. 2, Issue 5

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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
KL2 RR024994
or
TL1 RR024995

ICTS Items

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Send comments or article suggestions to icts@wustl.edu



Translational Pathology and Molecular Phenotyping Core Services Enhancements

The ICTS Translational Pathology and Molecular Phenotyping (TPMP) Core facilitates the collection, processing, storage, and genomic analysis of clinical specimens. The Core is directed by Mark A. Watson, MD, PhD, Associate Professor, Pathology and Immunology.

Among the various types of genomic analyses offered, microarray-based gene expression profiling, genotyping, and genome copy number analyses are performed using the Affymetrix GeneChip® system. Together with the Siteman Cancer Center, the ICTS has supported several new enhancements to the facility to better integrate genomics with translational and clinical research. These include:

- **Added instrumentation for higher assay throughput.** With a total of 28 array processing stations and two array scanners, the facility is able to process the larger number of arrays required for conducting larger cohort, genome wide association studies.
- **Implementation of policies and procedures for CAP accreditation and CLIA registration of assays.** The facility has completed all necessary steps for College of American Pathologist (CAP) laboratory accreditation and has already registered one assay (Affymetrix SNP6.0 Genotyping Array) for clinical use in association with the Washington University Clinical Cytogenomics Laboratory. Similarly, other microarray- and non microarray-based assays can be developed and validated in a CLIA-registered, clinical laboratory environment for use in specific, investigator-initiated clinical trials.
- **Improved gene expression assays.** The facility has discontinued the use of the standard Affymetrix in vitro transcription (IVT) assay for performing gene expression array analysis using 3' expression arrays
(See TPMP: page 2)

Message from the Director: Kenneth S. Polonsky, MD

I am pleased to announce that the Barnes-Jewish Hospital Foundation (BJHF) and the ICTS have issued the second annual call for proposals for the joint Clinical and Translational Research Funding Program. Letters of Intent are due October 1st and proposals are due November 16th. See the ICTS website (http://www.icts.wustl.edu/funding/bjhf_icts_funding_program.aspx) for full details. This year, as noted in the article on page 5, we will host a Town Hall meeting on Monday, September 14th to provide investigators the opportunity to discuss their questions with the pilot program directors, but you can also email your questions to icts@wustl.edu.

The ICTS News is a key method of distributing information about the ICTS to our members, but in the last few months we have also been developing other communication channels. We have added a calendar to our website (<http://www.icts.wustl.edu/calendar/>) that includes events such as the 2009 – 2010 Ethics Lecture Series and the events supported through our Clinical Research Training Center.

We will also be distributing our new brochure to all ICTS members in the next month. The brochure folds out into a poster that illustrates how all of our cores support the research cycle as well as easy reference contact information for each. In addition, in an effort to remind you to cite the CTSA grant in publications, the mailing will also include a magnet with the CTSA grant number for easy reference. As we move into our third program year we continue to explore new avenues for increasing awareness about the value our cores can provide in supporting clinical and translational research, but communication is most productive if it is two way. We are receptive to your comments and ideas and encourage you to provide feedback either through email to icts@wustl.edu, by calling the Administrative Core at 314-362-9829 or through the anonymous Feedback Forum available directly under the “News” updates on the front page of our website.

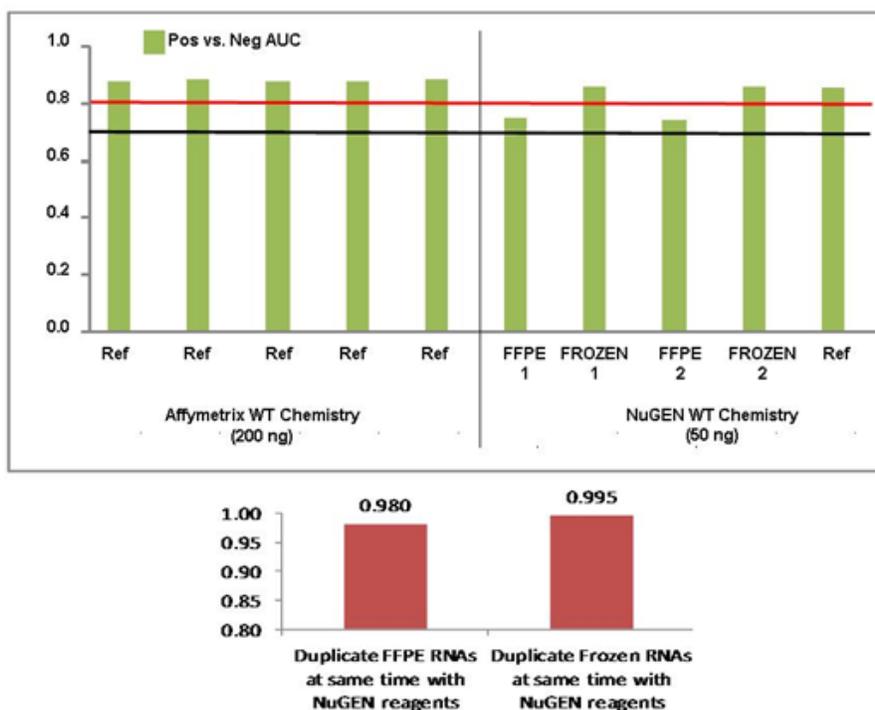
TPMP, from Page 1

(e.g. Human U133Plus2). The assay has been replaced by a new method (3' IVT Express) which is faster, cheaper, more robust, and can be used with as little as 25 ng of total cellular RNA without further molecular amplification.

- **Whole transcriptome gene expression assays.** Using the 'next generation' of Affymetrix GeneChip® microarrays (Gene and Exon arrays) and NuGen® nucleic acid amplification chemistries, quantitative and qualitative (i.e. exon splicing) data can be reliably obtained from as little as 10 ng of total cellular RNA. All new assays have been validated in the facility for robustness and reproducibility, and representative results comparing new and existing methods have been documented.

- **Gene expression analysis from fixed or degraded biospecimens.**

The facility has also tested and validated the use of Affymetrix GeneChip® Exon and Gene arrays with NuGen® chemistry to obtain reliable and reproducible gene expression data from small quantities of degraded RNA, such as often obtained from formalin fixed tissue specimens, flow cytometry cell preparations, or other suboptimally collected clinical biospecimens. As shown in the accompanying figure, standard Affymetrix chemistry (left) generates repro-



ducible and high quality data (reflected in array AUC values > 0.8) from a 200 ng reference RNA sample. The NuGen® assay (right) produces similar data from only 50 ng of the same reference sample. Furthermore, using fixed (FFPE) and snap frozen pairs of two different tissue specimens, nearly comparable quality data was obtained (average array AUC of 0.85 vs. 0.75). While data from fixed and frozen specimens is not directly comparable, technical reproducibility within frozen specimens ($r=0.99$) and fixed specimens ($r=0.98$) as a group was almost indistinguishable, demonstrating that reproducible array-based gene expression profiling studies can be performed on fixed and embedded tissue specimens, which are readily available in hospital surgical pathology departments.

- **miRNA analysis.** The facility has tested and validated the Affymetrix GeneChip® assay for miRNA expression analysis. The Affymetrix array provides probe sets to detect miRNAs from human, mouse, rat, and monkey genomes in addition to other human small nuclear RNAs, using as little as 0.1 ug of total cellular RNA.

Additional information regarding assay performance, costs (which are subsidized for ICTS members), and sample requirements can be found on the facility's website: <http://pathology.wustl.edu/research/lcgicts.php> or by contacting the facility by email (genechip@pathbox.wustl.edu) or phone (314-454-8520).

The Pediatric C-STAR Program Announces First Scholars

The Pediatric Community Scientist Training and Research program, or C-STAR program, at Washington University and St. Louis Children's Hospital is a new pediatric residency elective in clinical sciences training. C-STAR is part of the ICTS initiative in interdisciplinary career development and translational research in pediatrics supported by the NIH CTSA grant. By providing pediatric residents the opportunity to perform clinical research under the guidance of a faculty mentor and advisory committee, the program seeks to narrow the gap between clinical trials and the pediatrician's office and thus further the prevention and cure of pediatric disease.

Michael DeBaun, MD, MPH, the Ferring Family Chair in Pediatrics and Professor of Biostatistics and Neurology, directs the program. Together with program co-directors Jane Garbutt, MB, ChB, FRCP (C), Director of the WU Pediatric and Adolescent Ambulatory Research Consortium (WU PAARC), and Katie Plax, MD, Medical Director of Pediatricians in Community program, they guide the scholars in planning their curriculum and creating a research project proposal. C-STAR participants have a specially designed schedule during the summer and fall of their third year of residency, including a two month community advocacy rotation.

The C-STAR scholars for 2009-2010 are Rebecca Papez, MD (pictured below, left), and Lisanne Palomar Newton, MD (pictured below, right).



Dr. Papez studied biochemistry as an undergraduate and attended medical school at the University of Nevada, where she was awarded the Roland W. Stahr Award for Excellence in Clinical Pediatrics. In 2007 she began her residency in pediatrics at St. Louis Children's Hospital. Her current research is part of the Childhood Obesity Project, in which she studies the consumption of sugar-sweetened beverages by adolescents and the role that community pediatricians play in implementing limited consumption of these products during health maintenance examinations.

Dr. Palomar Newton studied biomedical engineering science, biology, and English at Washington University as an undergraduate. She attended Dartmouth Medical School and then came to Washington University Medical School, where she was awarded the Wynder Prize for Preventive Medicine in 2007. Her current research works to identify early signs and symptoms of asthma exacerbations in children and the barriers to treatment.

After their residency, C-STAR alumni will be encouraged to join WU PAARC and will have the opportunity to use the Department of Pediatrics' Patient-Oriented Research Unit (PORU) and be part of the vibrant community of researchers within the Department of Pediatrics. For more information about the C-STAR program and its requirements, please see the ICTS website (<http://icts.wustl.edu/cores/cdtrp.aspx>).

Have You Met?**Yi Zhang**

Yi Zhang, JD, RN, returned to Washington University July 1st as Assistant Dean for Clinical Trials, Operations Officer for the Center for Applied Research Sciences (CARS), and Co-Director of the ICTS Regulatory Support Core (RSC). CARS staff provide access to specialized clinical research services for investigators and, in conjunction with the RSC, assist investigators and their research teams in developing and conducting efficient, safe, and ethical studies. In her new roles, Zhang plans, directs, and oversees clinical trial activities at the School of Medicine.



CARS is directed by Samuel Klein, MD, the William H. Danforth Professor of Medicine and Nutritional Science who helped recruit Yi to the position. “We are very fortunate that Yi Zhang agreed to be the Operations Officer for CARS. Yi has a diverse background in law, business, clinical care and clinical research that make her exceptionally well-suited for this complex and challenging position. It is impressive how quickly she has grasped the major issues that need to be addressed in the CARS, and is developing creative and efficient approaches for how we conduct our business.”

Yi is returning to Washington University after leaving in 2008 to take a position in a large Chicago law firm where she specialized as a clinical research expert, advising clients such as Harvard and the University of Pittsburgh Medical Center. “I thought a law firm environment would enable me to work for a more diverse group of clients, academic medical centers and regional hospitals alike, and felt I needed to do that for awhile.” This spring WU was able to recruit Yi back. “I am so happy to return to Washington University. I missed the operational side of the business. It is one thing to draft a comprehensive or bullet-proof contract or policy, but it is quite a different thing altogether to steer the ship. The challenge is not conceptualizing the process but choreographing and operationalizing it.”

Yi attended Saint Louis University Law School, where she focused on health law, attending classes at night while running clinical trials, for example, a mitral valve replacement trial and a heart bypass surgery trial, at Washington University during the day. After graduation she secured a position with Husch & Eppenberg, LLC, and her first assignment was to join a team of attorneys working with WU’s School of Medicine to negotiate clinical trial contracts and develop compliance processes. “It must have been fate,” Yi says now. After a year she accepted the position as the Director of Operations and Development for the Center of Clinical Studies.

Yi grew up following in her parents footsteps. Both her mother and father were physicians in Shanghai, China, where Yi spent her childhood. Her father, who had taught himself English by listening to the Voice of America radio program during the tumultuous times of the Cultural Revolution, sought an opportunity through a government grant to work in Norway. He then made his way to England and connected with a Washington University physician who would go on to sponsor him and bring him to St. Louis. At 17, with very little skill in English besides “book knowledge,” Yi found herself attending high school here. Given she was still struggling with the language, she felt becoming a doctor would be a difficult path, so she entered nursing school at the University of Missouri-St. Louis. After graduation, she worked at several area hospitals eventually becoming a cardiothoracic surgery ICU nurse. “I loved it,” Yi said, “When we were fully staffed we were a well-oiled machine and the position gave me the autonomy and responsibility I desired.” Yi crossed over to the corporate side of health care during the dot.com days, when she worked for a Mountain View, California medical device company and managed medical device clinical trials. When the company’s venture funding faded, Yi decided to attend law school.

Yi is married and has two children, a son -- her “strong-willed” child -- who is five, and a baby girl who is just three months and is happily the opposite -- “sweet and easy-going.” Their family was happy to return to St. Louis to be near her parents again and be working at WU. For now, she is focused on streamlining business processes in CARS and working with our hospital partners to enhance our clinical trial compliance programs that will not add another layer of complexity and bureaucracy to the conduct of clinical research at the medical school.

For questions about the Center for Applied Research Sciences (CARS) or to reconnect with Yi, contact her at 314-362-6864 or yzhang@wusm.wustl.edu.

In the News

**Want to know what lectures or events are coming up?
Visit the new ICTS calendar**
<http://icts.wustl.edu/calendar/>

Announcing the 2nd Annual BJHF/ICTS Clinical and Translational Research Funding Program

The Barnes-Jewish Hospital Foundation (BJHF) and the ICTS have again partnered to issue the second RFA for the Clinical and Translational Research Funding Program. The primary purpose of this program is to fund high-quality, innovative proposals that have the potential to advance human health. Principal Investigators applying for this funding must be members of the ICTS. Member eligibility information and registration is available at www.icts.wustl.edu.

Applications will be accepted in two categories:

- **Planning Grants:** Provide up to \$25,000 direct costs for 1 year to facilitate the planning of a new clinical or translational research project
- **Research Grants:** Provide up to \$75,000 direct costs per year for 1-2 years to support a clinical or translational research project

A town hall meeting to provide investigators the opportunity to ask questions of the ICTS pilot program directors (Robert W. Thompson, MD, FACS, and Bradley A. Evanoff, MD, MPH) and obtain assistance in developing a competitive proposal will be held on Monday, September 14, 2009, from 2:00 – 3:00 p.m. in the classroom of the Clinical Research Training Center, 2 Wohl Clinic.

The full RFA can be accessed on the ICTS website at http://icts.wustl.edu/funding/bjhf_icts_funding_program.aspx.

Important Dates:

- **RFA Issue Date:** August 3, 2009
- **Town Hall Q&A Meeting:** September 14, 2009 (2:00-3:00 p.m., CRTC Classroom)
- **Letters of Intent Due:** October 1, 2009
- **Applications Due:** November 16, 2009
- **Proposal Peer Review:** January, 2010
- **Award Start Date:** June 1, 2010

Questions may be addressed to icts@dom.wustl.edu, Becky Evans at 314-362-9386, Jaimee Stagner at 314-362-6325 or Pamela Jayne at 314-286-0349.

Events & Announcements

September 3 (8:00 a.m.) The Rena Schecter Memorial Lecture in Cancer Research, “*Clinical and Translational Studies in Head and Neck Cancer at the University of Chicago*,” with Everett E. Vokes, MD, Professor of Medicine, Chairman, Department of Medicine, University of Chicago. Clopton Auditorium, Wohl Hospital, Lower Level, 4960 Children’s Place. Sponsored by the Siteman Cancer Center, Barnes Jewish Hospital and WU School of Medicine.

September 8 (1:00–3:15 p.m.) Career Development Lecture, “*An Introduction to Economic Evaluation in Medicine*,” with Steven M. Kymes, PhD. ICTS Clinical Research Training Center (CRTC), 2nd Floor, Wohl Clinic. This presentation will introduce the basic concepts and tools of economic evaluation. Included will be how to construct an analysis, selection of the correct costs and measure of benefit, and construction of the decision models.

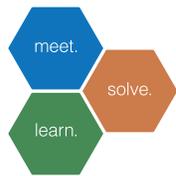
September 23 (1:00–6:15 p.m.) Institute for Public Health Second Annual Conference, “*Multidisciplinary Approach to Eliminate Disparities*.” Eric P. Newman Education Center. Keynote speakers include:

- Dr. Felton Earls, Professor of Behavior and Development, Harvard School of Public Health
- Dean Bruce Lindsey, Dean of the College of Architecture and Graduate School of Architecture & Urban Design, Sam Fox School of Design & Visual Arts, Washington University

The conference will also include a panel discussion on “*Solutions for Children, Youth, and Families*,” and will be followed by a poster session and reception. Visit the IPH website (<http://publichealth.wustl.edu/news/Pages/2009AnnualConference.aspx>) for more information and registration information.

September 30 (4:00-6:00 p.m.) A reception for the Career Development Awards, Postdoctoral, Predoctoral and Doris Duke Programs. Clinical Research Training Center, 2nd Floor, Wohl Clinic. RSVP by September 23 to mfavazza@dom.wustl.edu or 314-454-8224.

October 28 (12:30-4:30 p.m.) *ICTS Clinical Research Training Center 4th Annual Research Symposium and Poster Session*. Connor Auditorium, Farrell Learning and Teaching Center. The symposium will include oral presentations and a poster session.



Fall Conferences

OUR COMMUNITY, OUR HEALTH CONFERENCE

Community-Academic Partnerships to Reduce Health Disparities in St. Louis

Thursday, October 29, 2009

8:30 a.m. – 1:00 p.m.

Emerson Center at Harris Stowe State University

Continental breakfast at 8:00 a.m. and lunch will be provided

Our Community, Our Health is a joint program between Washington University and Saint Louis University that seeks to engage the St. Louis community in partnerships that address local health disparities.

The conference will bring together citizens, community health and cultural leaders, community health professionals, and academic and medical researchers to address health disparity issues in our region and to align academic research priorities with community-identified health priorities. This conference features a multifaceted program including:

- A keynote address, “*Community-Academic Partnerships: Essential to Addressing Health Disparities*” by Gloria Wilder, MD, MPH, nationally acclaimed pediatrician and anti-poverty activist. <http://www.corehealthdc.com/aboutus.html>
- A report on *Community-Identified Health Priorities*
- Presentations from local community organizations and researchers on *Success Stories of Community-Academic Partnerships*

The conference is free and open to the public but registration is requested

[Click Here to Register](#)

Our Community, Our Health is directed by [Consuelo H. Wilkins, MD](#), of Washington University and co-directed by [Darcell P. Scharff, PhD](#), of Saint Louis University.

The series is funded by Washington University’s [Institute of Clinical and Translational Sciences](#) and Washington University’s [Center for Health Policy](#)

For more information about the conference visit the [Our Community, Our Health website](#)

ICTS Bander Program in Business Ethics in Medical Research

Thursday, November 5, 2009 Lecture

3:30-4:30 p.m.

Connor Auditorium

Farrell Learning and Teaching Center

Washington University Medical School Campus

(Reception in Atrium beginning at 3:00 p.m.)

“*Conflicts of Interest in Academic Medicine:*

Where We Were, Where We Are, and Where We Might Be Headed”

William M. Sage, MD, JD

Vice Provost for Health Affairs and James R. Doherty Chair for Faculty Excellence in Law, University of Texas at Austin

RSVP by October 31 to 314-362-9829 or icts@wustl.edu