

Washington University School of Medicine Digital Commons@Becker

ICTS Newsletters

Institute of Clinical and Translational Sciences

1-1-2008

Institute of Clinical and Translational Sciences News, Vol. 1, Issue 6

Follow this and additional works at: http://digitalcommons.wustl.edu/icts_newsletters

 Part of the [Medicine and Health Sciences Commons](#)

Recommended Citation

"Institute of Clinical and Translational Sciences News, Vol. 1, Issue 6" (2008). *ICTS Newsletters*. Paper 6 Washington University in St. Louis Institute of Clinical and Translational Sciences.
http://digitalcommons.wustl.edu/icts_newsletters/6

This Newsletter is brought to you for free and open access by the Institute of Clinical and Translational Sciences at Digital Commons@Becker. It has been accepted for inclusion in ICTS Newsletters by an authorized administrator of Digital Commons@Becker. For more information, please contact engeszer@wustl.edu.

ICTS NEWS

CENTER FOR BIOMEDICAL INFORMATICS: CLINPORTAL & cATISSUE SUITE

INSIDE THIS ISSUE:

| | |
|-----------------------------|---|
| <i>Program Highlight</i> | 2 |
| <i>Funding Programs</i> | 2 |
| <i>Bander Lecture</i> | 3 |
| <i>Last Month</i> | 3 |
| <i>Events/Announcements</i> | 3 |
| <i>In The News</i> | 4 |
| <i>Have You Met?</i> | 4 |

Special points of interest:

- Recruitment Action Plan: REC Can Help
- Two New ICTS Funding Programs Announced
- Dr. Ezekiel Emanuel Lecture November 6
- Have you met Dianne Oliver?

Embedded weblinks are designated by blue text and can be accessed in the online version of ICTS News on our website at icts.wustl.edu.

The ICTS Center for Biomedical Informatics (CBMI) offers industry-standard hardware infrastructure and software tools to store, integrate, query, analyze, and visualize complex clinical and molecular data sets. Director Rakesh Nagarajan, MD, PhD, Assistant Professor of Pathology & Immunology, has successfully assimilated the infrastructure and personnel to support investigators in managing their clinical and translational research data through ClinPortal and tissue samples through caTissue Suite.

ClinPortal allows investigators and study coordinators to describe the data capture components of a clinical study using controlled vocabularies. For example, drop-down menus containing data entry options can be defined by the investigator. ClinPortal then automatically generates the back-end database schema as well as the forms to enter the data and conduct queries. Using this tool, data for clinical studies can be managed without IT personnel intervention.

Although additional setup time may be necessary to map the data for a specific study to the controlled vocabularies in ClinPortal, the advantages are well worth the effort for several reasons:

- By default, data stored in ClinPortal is available for sharing while following all HIPAA regulations, although the investigator that owns the data may turn off sharing if so desired. As a result, once an investigator has established their study within the ClinPortal system, there is potential for sharing relevant data with and from other

studies.

- Data access is controlled both by regulatory (ex. IRB) and investigator permissions.
- Future phases include automated access to clinical data from systems such as ClinDesk and TouchWorks. Assuming appropriate release by the patient and access rights for the researcher, investigators using ClinPortal will eventually have access to clinical data for their study participants.

Tissue Suite, a web-based biospecimen inventory, tracking, and annotation tool, may be used for study-based biospecimen collection efforts and by other non-study investigators interested in identifying existing biospecimens throughout the medical campus that may be available for translational research. The ICTS Translational Pathology and Molecular Phenotyping (TPMP) Core supports the physical storage of biospecimens while caTissue Suite is the application supported by both the CBMI and the TPMP to provide the informatics to manage data about those biospecimens. Investigators who are managing their own biospecimen collection efforts outside of the TPMP Core may still make use of the caTissue Suite application to manage their inventory with caBIG-compliant standards.

Web accessibility, the ability to share biospecimens and biospecimen-related data, advanced search functionality, and capture of clinical, pathological, and quality assurance data for collected (Please see **ClinPortal**: page 4)

MESSAGE FROM THE DIRECTOR

DR. KENNETH S. POLONSKY

The ICTS has recently reached its one year anniversary, and since we are a relatively new program, some investigators have not yet realized the benefit of ICTS membership. As a registered ICTS member you have access to our various Cores and services. For example, the Research Design and Biostatistics Group provides FREE consultations on protocol development. Services provided by specialized Cores such as Human Imaging Unit and the Brain, Behavior and Performance Unit are subsidized by the ICTS.

Members can also apply for funding through the ICTS Funding Programs. We rolled out the BJHF/ICTS Clinical and Translational Research Funding

Program in September and we are now pleased to be able to offer 2 additional opportunities. The [Just-In-Time Core Usage Funding Program](#) is designed to give investigators quick access to smaller dollar amounts for ICTS Core usage and the [Bander Business Ethics in Medical Research Funding Program](#) is intended to fund specialized research concerning business ethics.

While we have accomplished much in one year, we still have many opportunities ahead of us to help advance clinical and translational research activities. Access our [website](#) or contact our Administrative Core (icts@im.wustl.edu) to see how the ICTS can support your research efforts.

RECRUITMENT ENHANCEMENT CORE: RECRUITMENT ACTION PLAN

BY CHARLES RATHMANN

With the goal of providing a metrics-driven recruitment methodology that delivers consistent dependable outcomes and bolsters campus-wide enrollment in Washington University clinical trials, the ICTS Recruitment Enhancement Core (REC) has developed and tested a highly successful recruitment paradigm. This paradigm involves creative brainstorming and best practice sharing between a REC recruitment specialist and the study team to determine how the study population may be attained. From this session, a study-specific Recruitment Action Plan is developed and implemented. The study plan outlines action items with associated timeline and accountability for each. This approach fosters collaboration and clarity of goals and responsibilities while giving each member of the study team a heightened sense of accountability and accomplishment. Additionally, the REC recruitment specialists continually search for new recruitment venues and opportunities to better assist PIs in hitting their enrollment targets.

The REC piloted the recruitment paradigm in 25 different trials over three main therapeutic areas, specifically pulmonary/critical care, human nutrition and neurology. As of November 2007, after 12 months of measurable data, 664 potential participants were enrolled into the REC pilot trials. This number translates into an achievement of **125% of the enrollment target**. By contrast, the data captured in a previous En-

rollment Enhancement Project showed that the median trial protocol was achieving only 60% of the target enrollment goal for all Washington University studies that were closed in 2005. This vast improvement in enrollment suggests that the proactive, targeted and collaborative recruitment methods being used by the REC can have a positive impact on achieving enrollment goals.

A few takeaways from the REC pilot:

- Having a Recruitment Specialist on a trial or group of trials within a department offers a tremendous return on investment, from an enrollment standpoint.
- It should come as no surprise that no two trials are the same. Even trials that are similar in protocol or potential participant population can be drastically different in which recruitment methods foster the greatest return.
- You have never exhausted all avenues for recruitment – there are always more ways and they don't always need funding!

For more information on how the REC can assist you, please contact Charles Rathmann at 314-362-0897.

“Health Care Band-Aids: How to Fix America’s Ailing Health Care System”

Lecture by
Ezekiel Emmanuel
NIH Dept of Bioethics

November 6

See attached flyer

Proposals for the BJHF/ICTS REA are due by 5 pm, Monday, November 17.

“Best Practices in University Technology Transfer”

Special Address and
Open Forum by
Katharine Ku
Stanford University

November 24

See attached flyer

ICTS FUNDING PROGRAMS BUSINESS ETHICS & CORE USAGE

The ICTS announces two additional funding opportunities to complement the BJHF/ICTS Clinical & Translational Research Funding Program.

Bander Business Ethics in Medical Research Funding Program

The intent of this program is to promote innovative research that examines an ethical issue arising from the business or financial dimension of medical research, especially insofar as this dimension affects the quality of research or the well-being of patients enrolled in clinical trials. Anticipated awards will range from \$10,000 and \$20,000 for 1 year. One or 2 proposals will be funded in 2008.

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

This program is intended to provide quick access to funding to use the ICTS Cores for research

advancing medical knowledge that can improve human health. A Letter of Support from the Director of the ICTS Core that will provide the requested service(s) is an essential part of the application and must corroborate the service(s) to be provided and the scientific relevance of the research. Applicants may request up to \$10,000 for up to 1 year for use of ICTS Core services. Applications will be accepted on a monthly basis with an initial due date of December 10, 2008. The ICTS expects to make available approximately \$100,000 for this program annually.

Deadlines, complete instructions and application forms for both of these programs are now available on the [ICTS website](#).

“HEALTH CARE BAND-AIDS: HOW TO FIX AMERICA'S AILING HEALTH CARE SYSTEM”.

The ICTS Bander Program in Business Ethics in Medical Research is pleased to welcome Ezekiel Emanuel, MD, PhD, for our first Bander Lecture on November 6. Dr. Emanuel's lecture is entitled “Health Care Band-Aids: How to Fix America's Ailing Health Care System”. The lecture will be held at 6 pm in Clopton Auditorium (lower level of Wohl Clinic at Washington University School of Medicine). Appetizers will be served at 5:15 pm. An RSVP will be appreciated but is not required. Please reply to Mary Favazza at mfavazza@im.wustl.edu or 454-8224.

Dr. Emanuel is the Chair of the Department of Bioethics at the National Institutes of Health, and an internationally known bioethicist and breast oncologist. He graduated from Amherst College in 1979, and received his M.Sc. from Oxford University in Biochemistry. He received both his MD and his PhD in political philosophy from Harvard University. In 1987-1988, he was a fellow in the Program in Ethics and the Professions at the Kennedy School of Government at Harvard. He completed his internship and residency in inter-

nal medicine at Boston's Beth Israel Hospital and completed an oncology fellowship at the Dana-Farber Cancer Institute, where he later joined the faculty. He has published extensively on the ethics of clinical research, advance care directives, end of life care issues, euthanasia, health care reform, the ethics of managed care, and the physician-patient relationship. In addition to receiving numerous distinguished awards, he served on President Clinton's Health Care Task Force, on the National Bioethics Advisory Commission (NBAC), and on the bioethics panel of the Pan-American Healthcare Organization.

Dr. Emanuel has also published multiple books, including his latest *Healthcare, Guaranteed: A Simple, Secure Solution for America*, in which he outlines his innovative approach to comprehensive healthcare system reform, an approach he developed together with Victor Fuchs, professor of Economics at Stanford University.

WHAT HAPPENED LAST MONTH?

HIGHLIGHTS FROM OCTOBER

-October 14: *Center for Clinical Research Training* Career Development Seminar Series, “NIH Public Access Policy” by Cathy Sarli, MLS, and “Basic Functions of Endnotes” by Kim Lipsey, MLS.

-October 18: *Center for Community-Based Research* Linda Cottler, Ph.D., professor of epidemiology in psychiatry, Catina O'Leary, project manager and Amy Hepler, research patient coordinator, gave a presentation entitled “The Washington University Center for Community-Based Research: A Model for the Successful Integration of Community, Service and Research” at the Missouri Campus Compact conference Saturday, October 18. Campus Com-

pact is a national coalition of more than 1,100 college and university presidents dedicated to promoting community service, civic engagement and service-learning in higher education.

-October 29: (12-4:30 PM) *Center for Clinical Research Training*, Research Training Symposium and Poster Session. Located in the Farrell Learning & Teaching Center, the symposium included oral presentations and a poster session showcasing research projects performed by junior faculty, fellows, and students in Washington University School of Medicine research training programs.

EVENTS & ANNOUNCEMENTS

- November 6: (4 – 5 pm): *Human Imaging Unit*: Dr. Juhani Knuuti, MD, PhD will give a presentation “Multi-tracer and Multimodal Imaging Services for Pharma: Experiences at Turku PET Centre” in the Scarpellino Auditorium, MIR Building. See attached flyer for additional information.

-November 6: (6:00–7:00 pm) ICTS Bander Lecture. See article above for details.

-November 24 (3:00–5:30 pm): *Business Development Core*: Katharine Ku, Director of the Office of Technology Licensing at Stanford University will present “Best Practices in University Technology Transfer”. Holden Case Study Room, First Floor of

the Farrell Learning and Teaching Center. An open forum will follow the lecture to capitalize on this opportunity to collaborate with another CTSA site (Stanford Center for Clinical & Translational Education and Research)

-November 24 (3:30–4:30 pm): *Center for Clinical Research Ethics*: Ana Iltis, PhD, Assistant Professor in the Department of Health Care Ethics at Saint Louis University will present a lecture entitled “Participants' understanding of risks: Improving communication” in Farrell conference Room #1 of the Center for Advanced Medicine Building.

Investigators using ICTS Cores & Services to support their research should acknowledge the CTSA Grant

[UL1 RR024992](#)

Scholars and Trainees should acknowledge the appropriate CTSA Linked Grant

[KL2 RR024994](#) or
[TL1 RR024995](#)

The funding acknowledgement [statement](#) is posted on the ICTS website.

Institute of Clinical &
Translational Sciences

Washington University School of Medicine
Box 8066
660 South Euclid Ave
St. Louis, MO 63110-1010

Phone: 314-362-9829
Fax: 314-362-8015
E-mail: icts.im.wustl.edu

We're On the Web!
icts.wustl.edu

IN THE NEWS:

Donna Jeffe, PhD, research associate professor in the Division of Health Behavior Research and Director of the ICTS Tracking & Evaluation Program senior author of "Characteristics and career intentions of the emerging MD/PhD workforce" published in the September 10th issue of the Journal of the American Medical Association. (PMID: 18780845) See the [article](#) in the October 2nd issue of The Record.

The local chapter of the American Parkinson Disease Association (APDA) hosted their 13th annual fundraiser on October 13th. Our own Dr. Joel Perlmutter, director of the Brain, Behavior, Performance Unit, was one of the St. Louis "celebrities" that walked the runway to raise money for research and patient services. For more information about the St. Louis Chapter of the APDA, see www.stlapda.org.

Jeffrey I. Gordon, MD has been elected to the Institute of Medicine of the National Academy of Sciences, one of the highest honors medical scientists in the United States can receive. Dr. Gordon is Co-Director of the ICTS Human Genetics & Genomics Core and the Dr. Robert J. Glaser Distinguished University Professor and director of the Center for Genome Sciences. For more information, see the [article](#) in the October 30th issue of The Record.

CLINPORTAL, FROM PAGE 1

biospecimens are key features of caTissue Suite. Together, ClinPortal and caTissue Suite facilitate collaboration between investigators and data integration across studies. As clinical data becomes available through the ClinPortal tool, biospecimens referenced in the complementary caTissue Suite tool will gain increasing clinical annotation, making them even more valuable for translational research studies.

CBMI provides fully-subsidized support to ICTS members in using both ClinPortal and caTissue Suite. For more information, send an email to help@cbmi.wustl.edu. Dianne Oliver (see article below) is the contact for ClinPortal and can be reached at doliver@path.wustl.edu or 314-362-3185. David Mulvihill, at dmulvihill@wustl.edu or 314-747-6785, can provide assistance with caTissue Suite.

HAVE YOU MET? DIANNE OLIVER?

"I love this job. This is such a fast-paced exciting group and many investigators have said ClinPortal is just what they've been looking for to manage their data." Dianne Oliver, Project Manager of ClinPortal with the ICTS Center for Biomedical Informatics (CBMI), is clearly enthusiastic about her work, the people she works with and the application development she manages. Rakesh Nagarajan, MD, PhD, Assistant Professor of Pathology & Immunology is Director of the CBMI. Dianne credits him with being a "tremendous mentor" as she acclimates to her role.

With an Information Management degree from Washington University and 8 years experience in the Internal Medicine Division of Oncology, Dianne began managing the ClinPortal project in July of this year. She summarizes her job as "leveraging the considerable development talent in this group to best reach the expected end results."

Those end results currently include one investigator study fully supported in ClinPortal and 18 in process and expected to be in production by the end of 2008. Dianne notes that they will be ready to take on additional projects starting in January, although investigators can call now.

To transition existing clinical studies data to ClinPortal or establish electronic forms to input

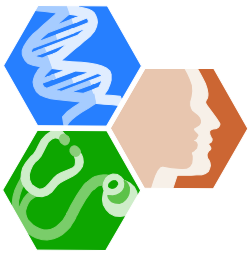
new information, the investigator should first talk with Dianne. Following a demo of ClinPortal, Dianne and the informatics staff work with the user to discuss any existing data collection forms, information workflow and the advantages and potential limitations of automation through ClinPortal. Then the informatics personnel create forms. A short iterative process combining user feedback and forms refinement is used to finalize the study's representation in ClinPortal.

The system uses a standard data dictionary, leveraging existing medical terminologies (e.g. SNOMED-CT and LOINC). Dianne works with technically astute, medically trained staff to assist in creating an appropriate object model and user-friendly data entry forms for each study. The robust query functionality can search on any data element and return de-identified or identified data, depending upon the access rights of the investigator doing the search and the privileges set by the investigator owning the data. ClinPortal will also support single sign-on and data sharing with caTissue Suite (see article, page 1).

For more information about ClinPortal, contact Dianne at doliver@path.wustl.edu or 314-362-3185.



*Comments about ICTS
News, suggested articles or
questions should be directed
to ICTS@im.wustl.edu or
by contacting Jae Allen at
314-362-9331.*



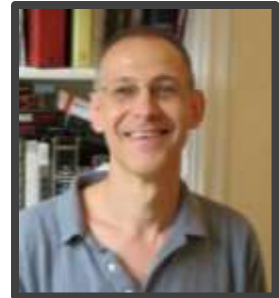
WASHINGTON UNIVERSITY IN ST. LOUIS

Institute of **C**linical and **T**ranslational **S**ciences

BANDER PROGRAM IN BUSINESS ETHICS IN MEDICAL RESEARCH

HEALTH CARE BAND-AIDS: HOW TO FIX AMERICA'S AILING HEALTH CARE SYSTEM

EZEKIEL EMANUEL, MD, PHD
CHAIR, DEPARTMENT OF BIOETHICS
NATIONAL INSTITUTES OF HEALTH



THURSDAY, NOVEMBER 6, 2008

6:00 – 7:00 PM

(APPETIZERS 5:15 – 6:00 PM)

CLOPTON AUDITORIUM

(LOWER LEVEL WOHL CLINIC BUILDING)

RSVP REQUESTED BUT NOT REQUIRED BY OCTOBER 31 TO:
MARY FAVAZZA, 314-454-8224 OR MFAVAZZA@IM.WUSTL.EDU

WWW.ICTS.WUSTL.EDU

ICTS Partner Organizations

Washington University; Saint Louis University –Graduate School –School of Public Health –Doisy College of Health Sciences –School of Nursing; St. Louis College of Pharmacy; University of Missouri at St. Louis College of Nursing; Southern Illinois University Edwardsville School of Nursing; BJC Health System including –Barnes-Jewish Hospital –St. Louis Children's Hospital –Goldfarb School of Nursing; Key organizations promoting community health; Biomedical and pharmaceutical companies in the St. Louis Area.

Primary funding through the NIH/NCRR Clinical & Translational Science Award Program UL1 RR024992





Washington University in St. Louis

Special Address and Open Forum

“Best Practices in University Technology Transfer”



Katharine Ku

Director,
Office of Technology Licensing
Stanford University

Monday, November 24, 2008

3:00 PM–5:30 PM

Holden Case Study Room on the First Floor
—Farrell Learning and Teaching Center, 520 S. Euclid
Washington University Medical School Campus

Open Forum Following the Address

Moderator: Samuel L. Stanley, Jr., M.D., Vice Chancellor for Research

Panelists: Katharine Ku, Director, Office of Technology Licensing, Stanford
Bradley Castanho, Co-Director, Office of Technology Management
Michael Marrah, Co-Director, Office of Technology Management

Reception at 5:30 PM in the
Hearth Room on the Second Floor
—Farrell Learning and Teaching Center

Center for Clinical Imaging Research Seminar Series

CCIR Center for Clinical
Imaging Research

“Multi-tracer and Multimodal Imaging Services
for Pharma – Experiences at Turku PET Centre”



Juhani Knuuti, MD, PhD

Director and Professor of the Turku PET Centre
University of Turku
Turku, Finland

November 6, 2008 • 4:00 p.m. | Scarpellino Auditorium
First Floor | Mallinckrodt Institute of Radiology

Juhani Knuuti, MD, PhD, is the Director and a Professor of the Turku PET Centre, University of Turku, Finland. His main research interests are in the field of noninvasive cardiovascular imaging using PET, SPECT, MRI and CT.

He has published over 200 articles in peer-reviewed journals. He has actively worked in several associations of cardiology and nuclear medicine, arranging international congresses, as well as, editorial boards of scientific journals.

No Admission Fee | Seating is on a first-come, first-seated basis
For further information contact Robin Link at 314 747-0380

This seminar was underwritten in part by unrestricted educational grants from Pfizer, Inc. and Covidien AG. This seminar is also sponsored in part by the Center for Human Nutrition and the Cardiovascular Imaging Laboratory at Washington University.