Among the many goals of the DoCTR is for our Department to excel in the responsible and ethical conduct of research, and to be outstanding in the scientific conduct of research and implementation of research protocols. Washington University conducts both random and for-cause audits of clinical research, to assess and improve quality, and determine compliance with all applicable regulations.

The goal of DoCTR is for our Department to be viewed as the WUSTL exemplar in this regard. Recent WUSTL audits have shown some Anesthesiology studies to be in significant need of improvement. Others have been found to be outstanding. Indeed, some studies were recently cited as examples of institutional excellence and our Department was asked to share its practices and templates with others. Congratulations to those investigators and to our excellent DoCTR staff!

The role of investigator and staff education in achieving such excellence cannot be overstated. In this edition of the newsletter you will find important information regarding University required training for human subjects research involvement, as well as University and DoCTR recommended trainings. Programs in Good Clinical Practice in Research, and the Necessary Elements in the Fundamentals of Human Subject Research are great introductions to clinical research. It is highly recommend that individuals who have not taken the courses register for an upcoming session.

There is also some financial news. The ICTS is changing its financial model, and new charge-back rates will become effective June 1, 2012 for using WUSTL clinical research facilities. These changes will be applied to existing and new studies. Therefore, currently funded grants will be under budgeted for these expenses. If you have a study utilizing the DoCTR coordinator pool the nursing charges will not affect your study unless a patient requires an overnight stay in the Clinical Research Unit. And, in this newsletter is the announcement of funding opportunities from the Foundation for Anesthesia Education and Research. Go for it! In the “Your Questions Answered” section you will find a brief overview of the steps to submitting a research protocol.

We are always interested in your feedback. If there are topics you wish to see addressed in the newsletter, please contact Sherry McKinnon.
The DoCTR is committed to providing investigators and research staff with the most current, up-to-date, and reliable information and resources pertaining to the regulatory and ethical conduct of clinical research. DoCTR Circulation is aimed, in part, to deliver the newest information from regulatory agencies and from within WUSTL. You will find on the following pages of this newsletter information from the Vice Chancellor of Research, HRPO, Research News, Gov-

NEWS IN BRIEF

NIH Salary Cap
Effective December 24, 2011 the NIH cap has been reduced from $199,700 to $179,700. Our understanding is that the new salary cap WILL NOT be applicable to FY2012 NIH funds awarded on or between October 1, 2011 and December 23, 2011. However, if these awards continue into FY2013, the new salary cap limitation will become applicable. Watch for Research News items to address further guidance releases from NIH addressing these changes. To sign up for Research News emails go to: http://research.wustl.edu/Offices_Committees/REI/Communications/Pages/researchnews.aspx

NIH Launches National Center for Advancing Translational Sciences
December 23, 2011

President Barack Obama has signed the Fiscal Year 2012 spending bill enabling the National Institutes of Health to establish the new National Center for Advancing Translational Sciences (NCATS). This action marks a major milestone in efforts to revolutionize the science of translation. NCATS provides our nation with an opportunity to forge a new paradigm for translational research that involves government, academia, industry, philanthropy, and patient advocacy groups. Through partnerships that capitalize upon our respective strengths, I believe we can work together to achieve our common goal: speeding the movement of scientific discoveries from the lab to patients.

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

Reminders:

- Residents/Fellows cannot be the PI of a research study due to the transient nature of their positions. A full-time faculty member must be named as the PI of the study.

- **Document the consent process**— Consent is not just signing a consent form; it is process of exchanging information. The process needs to be documented in the research chart that the consent form was discussed with the participant and that they understand what was explained and agree to participate. It should be documented that they signed the consent form and were given a copy. 21 CFR 50.27
  http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm#documentation
Policy Information

Prior to conducting human studies research there are several required training modules. Sherry McKinnon can assist with insuring the appropriate training modules are competed. When a research proposal is submitted to DoCTR for scientific review and/or approval for IRB submission, the trainings listed below are verified for each research team member.

University Required Training

HIPPA training
The first modules are the HIPPA modules. These modules must be taken by all employees that will have access to protected health information (PHI); regardless of their research involvement. These modules must be taken within seven days of an employees hire date.

CITI Human Subject Training (CITI)
CITI training is required by the University for anyone involved in human subject research. CITI training must be completed prior to any research involvement. There are 9 modules covering history and ethical principles, Institutional Review Board regulations, Informed consent, social and behavioral research for Biomedical researchers, records based research, genetic research, and research with protected populations. The training modules are accessed through the Research Gateway https://research.wustl.edu/pages/researchgateway.aspx.

Department and University Recommended Training

CITI Good Clinical Practices Training
Good Clinical Practice training is not a University requirement; however, it is highly recommended. There are 14 modules to this training. The modules cover the International Conference on Harmonization, FDA regulated research, Investigator-initiated studies, Investigator obligations, Investigational agents, medical devices, informed consent, Adverse events, audits and inspections and monitoring by industry sponsors. These modules are available in the CITI system and are accessed through the Research Gateway https://research.wustl.edu/pages/researchgateway.aspx.

PERCSS
PERCSS is a web-based learning module to proved education in ethics and responsible conduct in research. There are 8 modules: Introduction to Ethical and Responsible Research, Authorship and Publication - Collaborative Research, Conflict of Interest, Data Ownership, Acquisition, Sharing, and Management, Mentor-Trainee Relationships, Peer Review, and Research Integrity. The Department highly recommends completion of these modules prior to individuals conducting research. http://percss.wustl.edu

Necessary Elements in the Fundamentals of Human Subjects Research
“Necessary Elements” training is offered twice a year and is conducted by the Human Research Protection Office (HRPO). Necessary Elements provides and introduction to the conduct of human research. The next available session is in February; see page 8 for more details. Necessary Elements is highly recommended for Clinical Research Coordinators and Clinical Investigators. http://research.wustl.edu/Offices_Committees/hrqaqi/education/Pages/default.aspx
**Implementation of CARS CRU and PCRU Service Charges – June 1, 2012**

_The following new charges will be implemented effective June 1, 2012 for all investigator-initiated research studies using the CRU and/or the PCRU._

_These charges will apply to all (both existing and new) studies._

_It is important to begin including these charges in all new grant applications and study budgets._

_Industry-funded and industry-initiated studies will continue to pay full charges for services and/or space._

1. **Nursing Services - CRU and PCRU**
   a. Study visits lasting ≤ 1 hour: $10.00/visit
   b. Study visits lasting > 1 hour but do not require an overnight stay: $15.00/visit
   c. Overnight study subject visits in the CRU: $25.00/night

   Note: There will not be a charge for those WU investigator-initiated research studies that use Unit space only and that do not require nursing or other CARS personnel support.

2. **Lifestyle Intervention Research Core (LIRC)**
   Investigators need to contact Cathy Anderson Spearie, RD to determine exact charges, based on workload and meal costs, for the services listed below.
   (362-7627; Anderson_C@wustl.edu)
   a. Study design: i) protocol development, ii) diet methods, iii) diet orders
   b. Nutrition education: i) nutrition assessment, ii) diet and weight management counseling
   c. Dietary services: i) recipe, menu and formula development and testing, ii) research diets, iii) packed out meals
   d. Nutrient analysis: i) food record analyses, ii) computerized dietary analyses
   e. For meals or dietary/nutritional services on the PCRU, contact Libby Beach (454-6221; beach_l@kids.wustl.edu).

3. **Body Composition Analysis**
   There is no plan at this time to adjust the current charges.

4. **Clinical Trials Unit (CTU)**
   There is no plan at this time to adjust the current charges.
   **For general questions regarding the implementation of the additional charge-backs, please contact Courtney Sutherland at 362-6916 or Yi Zhang at 362-6864.**

These charges will apply to all (both existing and new) studies. It is important to begin including these charges in all new grant applications and study budgets.
Technology Spotlight

REDCap Database:

REDCap (Research Electronic Data Capture) is a secure, web-based application designed exclusively to support data capture for research studies. REDCap provides: 1) an intuitive interface for data entry (with data validation); 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages (SPSS, SAS, Stata, R); 4) procedures for importing data from external sources; and 5) advanced features, such as branching logic and calculated fields.

REDCap 4.8 should be available in February 2012. The new version will include; improved API functionality, expanded field validation types, Data quality module (data queries), external links functionality, REDCap Plugin capabilities and a data search tool. Also, the new version will have the ability to support multi-site trials. A slide set containing all of the new changes is located on the Biostat website, the link is below.

The REDCap project was initiated at Vanderbilt University and includes more than 130 active institutional partners from CTSA, GCRC, RCMI funded institutions, through a collaborative international consortium. REDCap services are available at no cost through Research Design and Biostatistics Group (RDBG) and SCC Biostatistics Core to research teams using support from Institute of Clinical and Translational Sciences (ICTS) at Washington university in St. Louis. This information was taken from the website where you can find out more about REDCap: http://www.biostat.wustl.edu/redcap.

Useful Resources and Links

Food and Drug Administration (FDA) http://www.fda.gov

Human Research Protections Office (HRPO) http://hrpo.wustl.edu/
  myIRB system https://myirb.wusm.wustl.edu
  Categories for Expedited Research http://hrpohome.wustl.edu/study_team/forms/ExpeditedCategories.htm
  Forms Locator http://hrpohome.wustl.edu/study_team/forms/all_forms.aspx

National Institutes of Health http://www.nih.gov/

Office for Human Research Protections (OHRP) http://www.hhs.gov/ohrp


Helpful WUSTL links to funding opportunities.

http://research.wustl.edu/PGC/Funding/Pages/Subscriptions.aspx

http://internalcompetitions.wustl.edu/

Strategies for Recruitment and Retention of Participants in Clinical Trials

Recruitment and Retention in clinical trials is a current struggle. Drs. Probstfield and Frye have identified barriers and suggestions to improve recruitment and retention in clinical trials. The barriers to successful recruitment they identified were: the importance of health care professionals working as gatekeepers for clinical trial participation; estimating the funding of clinical trials accurately; and challenges of administrative burdens and regulatory requirements. Their suggestions to improve recruitment and retention are; a national campaign to increase awareness about clinical trial participation, more funding opportunities to educate health care professionals about clinical research, and establishing a federal working group to facilitate translational science by promoting best regulatory and oversight practices.

The authors reviewed recruitment experiences and identified successful approaches to facilitate recruitment. Some of their identified approaches are: provide metric-driven recruitment strategies with clear measures of success; use electronic medical records information technology to identify potential participants for specific trials and alert their physicians; and stream-lining follow-up or develop searchable databases that would include general consent to permit a clinical data search for preliminary identification of eligible patients and to develop a budget tool that could accurately estimate trial costs and eliminate underestimation of workforce and funding.

They believe the NHLBI must take a leading role in developing this infrastructure. Knowledge about clinical trials needs to be enhanced among potential participant populations and investigators. Combining Clinical trials with clinical practice requires the help of the academic community, medical associations and the caregivers in private practice. Probstfield, JL, Frye, RL, Strategies for Recruitment and Retention of Participants in Clinical Trials. JAMA 2011;306(16):1798-1799.

Research Grant Applications - Now Open

The Foundation for Anesthesia Education and Research is now accepting research grant applications for the 2012 grant cycle.

Application Website
Please share the following URL with applicants interested in applying for a FAER grant. Application website: www.faer.org/programs/grants/application

Submission Deadline: The submission deadline is February 15.

Grant Opportunities
The types of research grants available include:
- Mentored Research Training Grants - Basic Science
- Mentored Research Training Grants - Clinical and Translational
- Research Fellowship Grants

Research in Education Grants
In 2011, FAER awarded eight Mentored Research Training Grants, four Research in Education Grants and two Research Fellowship Grants. These awards totaled $1.76 million.

For more information and requirements on each grant type, visit the grant description page on FAER.org.

Questions? If you have questions about FAER research grants or the application process, contact Carol Demulling, program director, at 507-538-7879 or CarolDemulling@faer.org.
Registration is now open:

Necessary Elements
In the Fundamentals of Human Research

Wednesdays, February 15, 22, and 29, 2012 8:15 AM – 5:00 PM
Held in the Northwest Tower 10th Floor Conference Room (10A)

This course provides an introduction to the conduct of human research.

Session 1: An Introduction to Human Subject Research
TOPICS: Overview of Research at WU; COI/Research Integrity; Research Ethics/Behavioral Research; Living with HIPAA at WU; Introduction to Research Ethics and the IRB

Session 2: Good Clinical Practice
TOPICS: Protocols, Case Report Forms and Study Phases; Case Studies in Compliance; Informed Consent; Preparing a Study and Developing a Study Budget; Study Billing and the Billing Matrix, Investigational Devices; Recruitment, Retention and Advertising

Session 3: Institutional and Investigator Responsibilities
TOPICS: Writing a Protocol; Risk Assessment; Audits

Online Registration available at HRMS self service under Training and Development

Cost of Course: $150

Includes textbooks and other materials distributed throughout course.
Continuing Nursing Education credits have been applied for.

HRPO SWAT TEAM
The HRPO Office has created a SWAT team. They now have a dedicated staff member on-call and ready to answer questions between 8 and 4:30 each day. Call the main office number (314-633-7400; ask for the SWAT on-call person. The on-call person will assist investigators, administrative staff, and students with questions about any IRB review issues. Another resource available is consultation. Consultation is available in the Farrell Teaching and Learning Center, Room 602; Tuesdays 1-4 pm and Fridays 8-11 am.

The HRPO SWAT Team is offering consultation on myIRB submissions and education about the IRB process. There are computers available so the SWAT team can look through applications or contingencies with you. (There will be an alternate location for Feb 3 - Apr 17, please visit http://hrpohome.wustl.edu/ for more details on these dates.)
(Research News email 10/24/2011)
How do I submit a research study?

A: The first step in submitting a research study is completing the appropriate training. The University requires HIPPA and Human Subjects Training. The Department also strongly recommends training in Good Clinical Practice, the Ethical and Responsible Conduct of Research (PERCSS), and the basics of clinical research (Necessary Elements in the Fundamentals of Human Subject Research) course.

The next step for the PI to create a study protocol. DoCTR has educational materials to help investigators with this step, and Jane Blood can provide assistance. Protocols need to have statistical validity. DoCTR will provide resource for PIs to obtain a consult from a biostatistician. DoCTR will provide resource for PIs to obtain a consult from a biostatistician. The next step is to prepare the my IRB application, and if necessary, an informed consent document, Sherry McKinnon can assist with these steps of the process. The study needs to be entered into the myIRB system; this is the IRB’s electronic submission system. The PI of the study, (a full-time faculty member) will need to add Sherry as a delegate in the system before the study can be entered.

Please contact Sherry for the steps to add a delegate. Once finalized these documents along with the DoCTR protocol approval form are submitted to Sherry McKinnon. The DoCTR protocol approval form is located on the DoCTR SharePoint site. All studies must undergo scientific review prior to IRB submission. If the study has not undergone scientific peer review (NIH study section, PRMC, or equivalent), it will need to undergo Departmental scientific review. Sherry will coordinate Departmental Scientific Review and then obtain the necessary Departmental signatures.

The final step is submission to the IRB via the myIRB system. The myIRB system will send email status updates as the study moves through the review process at the IRB.

Some studies may require other approvals such as Protocol Review and Monitoring Committee (cancer studies) or Radioactive Drug Review Committee prior to receiving IRB approval.

This is a brief overview of the process. If you have further questions regarding the study submission process please contact Sherry. Please note if you are seeking funding opportunities for your research project or would like to submit an application for funding, you must contact Kathy Reeves at reevesk@anest.wustl.edu. There are Department and University processes for submitting applications for funding that must be followed. Kathy will help guide you through the process. If you would like your question answered, please email your question to Sherry McKinnon at mckinnons@anest.wustl.edu.
News and Congratulations

Congratulations! The Journal of Anesthesiology highlights the Department of Anesthesiology at Washington University in the December 2011 issue! The Department is the second to be highlighted in this journal. Congratulations to all of the faculty for your recognition is this leading journal.

Congratulations to Zachary Cohen, MD - Dr. Cohen, a second year resident, was awarded a Distinguished Service Teaching Award from the Washington University School of Medicine recognizing him as Resident of the Year.

Congratulations Zhou-Feng Chen, PhD - Professor Chen discovers mechanism of opiate-induced itching.

Recent DoCTR Publications


Fan J, Brown S, Tu Z, Kharasch ED: Chemical and enzyme-assisted syntheses of norburprenorphine-3-$\beta$-D-glucuronide, Bioconjugate Chemistry, 22:752-8, 2011.


**Upcoming DoCTR Seminars**

**Tuesday, February 14, 2012**
**Mark Neuman, MD**  
Assistant Professor of Anesthesiology and Critical Care  
Attending Anesthesiologist, Hospital of the University of Pennsylvania  
Senior Fellow, Leonard Davis Institute for Health Economics  
Robert Wood Johnson Clinical Scholars program

At 4:30 p.m.  
Location: Barnes South, Green Room

**Tuesday, July 24, 2012**
**Douglas Rains, MD**  
Associate Professor Harvard Medical School  
Department of Anesthesia, Critical Care and Pain Medicine

At 4:30  
Location: TBD

**Tuesday, September 18, 2012**
**Monica Vavilala, MD**  
Associate Director, Harborview Injury Prevention and Research Center  
Attending Anesthesiologist, Harborview Medical Center, Seattle, WA

At 4:30 p.m.  
Location: Barnes South, Green Room