



University of Chicago

# CLINICAL RESEARCH UPDATES

## A Newsletter from the OCR & IRB

Volume 1 Issue 3

August 2007

### OCR Monthly Workshops

- 1st Friday Sept—June
  - 12—1pm Dora De Lee
  - CME & CNE available
  - Lunch Provided
- 9/7 W. Stadler “Translational Medicine—Future of Clinical research.”
- 10/5 G. Langan “Overview of the Animal Resource Center”
- 11/2 E. Semmes “Investigational Pharmacy”
- 12/7 M. Wynia “Race, Trust & Tuskegee— Professional Ethics”
- 1/4 J. Sollway “CTSA— Implementation at the University of Chicago”
- 2/1 Minsky & Currell “Quality Initiatives”
- 3/7 S. Rich “ FDA Drug Approval Process— Buyer Beware”
- 4/4 B. Rehman “GCRC”
- 5/2 C. Farr “Qualitative Studies—Religion and Medicine”

### IRB: Updates

### Announcements

- IRB Chair/Vice-Chair Updates
- IRB Staff Updates

### Reminders

- Use latest forms

<http://ors.bsd.uchicago.edu/IRB/Forms.html>

- Adverse Event Policy update
- Provide summary of changes for all amendments

### OCR UPDATES

**New Associate Dean of Clinical Research** Walter Stadler, M.D., has been appointed as Associate Dean of Clinical Research, effective July 1, 2007. He succeeds Richard Schilsky, M.D., who will be devoting time to his leadership duties as President of the American Society of Clinical Oncology (ASCO) this year. In addition to his new duties, Dr. Stadler is a Professor of Medicine, Director of the Genitourinary Program and Chairman of the Cancer Research Center’s Clinical Trials Review Committee. He specializes in prostate, kidney, bladder and testicular cancers. Dr. Stadler began his service at the University of Chicago in 1991, when he arrived for a hematology/oncology fellowship. He began working here as an instructor in 1995, followed by time as a research associate, assistant professor and associate professor. In 2006, he was promoted to professor.

**Correct Email Addresses** Please use the correct email alias as different people are on each distribution list::

- [resoutpt@bsd.uchicago.edu](mailto:resoutpt@bsd.uchicago.edu) to create research guarantor accounts or change IRB/ Policy numbers (no billing corrections)
- [resinpt@bsd.uchicago.edu](mailto:resinpt@bsd.uchicago.edu) to create research guarantor accounts for inpatient research subjects
- [resbilling@bsd.uchicago.edu](mailto:resbilling@bsd.uchicago.edu) for billing errors and corrections.

**Radiology Requisitions** Please be sure you are using the correct Radiology requisition as they have recently been updated. <http://pacs.uchospitals.edu> If radiology services are being provided within a clinical trial, please use the **Clinical Trials Radiology Consultation** requisition. Check off the appropriate box- RES or SOC and make sure your encounter is linked correctly and the charges will post correctly. If you don’t use this form, or designate RES or SOC, the charges will likely be billed to research and sections/departments will be responsible. Questions or concerns, Please call Amanda Nunez 4-3192 or Beth Martell 4-9799

### IRB Updates

#### New IRB Chair:

After 10 years of exemplary service [Jonathan Moss M.D., Ph.D.](#) has stepped down as IRB Chair. Effective July 1, 2007 the new IRB Chair is [Christopher Daugherty, M.D.](#) Dr. Daugherty is an Associate Professor in Hem/Onc in the Department of Medicine. He was a previous acting IRB Vice-Chair since 2000 and has been on the IRB since 1996. Dr. Daugherty specializes in research ethics, particularly in the area of cancer care.

#### New IRB Vice-Chairs:

Effective July 1, 2007 [Elizabeth McNally M.D., Ph.D.](#) has become a new IRB Vice-Chair for Committee A. Dr. McNally is a Professor of Cardiology in the Department of Medicine. She has been an active IRB member for over 8 years. Effective July 1, 2007 [M. Kelly Nicholas M.D., Ph.D.](#) has also become a new IRB Vice-Chair for Committee C. Dr. Nicholas is an Assistant Professor in the Department of Neurology. He was an active IRB member at UCSF as well as an active member for the U of C IRB for the last 3 years.

[Marc Garfinkel M.D.](#) continues to serve as the Vice-Chair and has been Vice-Chair for the IRB for a number of years. Dr. Garfinkel is now the Vice-Chair for Committee B.

#### New IRB administrators:

[Nell Thompson](#) was promoted to the Assistant Director of IRB Operations. She now reviews all expedited new protocols, exempt protocols, as well as oversees the day to day operations of the IRB. Please welcome [Milda Plioplys](#) as the newest IRB administrator. Her main focus will be to continue to work on the upcoming electronic IRB submission process (IRBWISE).

#### Adverse Events Policy Update

The IRB has recently revised its reporting policy for adverse events not occurring at this site. External adverse events meeting the reporting requirements of (1) serious (2) unexpected and (3) related or possibly related to the research should now be reported within **30 working days of investigator knowledge of the event**. Note that any unexpected adverse event that occurs on a device trial (regardless of seriousness or causality) must continue to be reported to the IRB within 10 working days of the investigator’s knowledge of the adverse event. As a reminder please be sure to use the updated adverse event forms when submitting any adverse events. The latest external adverse event forms are dated MAY 2007; while the latest internal adverse event forms are dated APRIL 2007

### UPCOMING TRAINING:

#### OCR

##### Fundamentals of Clinical Research

A free course on the core competencies of clinical research management. Open to all research faculty and staff Series of 10 modules repeated 5 times / year [pgonzale@bsd.uchicago.edu](mailto:pgonzale@bsd.uchicago.edu) or 4-8992

##### Principal Investigator Training Program

A self-administered training program required for all new Principal Investigators focusing on the responsibilities of conducting a clinical research study contact Linda DeSouza at [ldesouza@bsd.uchicago.edu](mailto:ldesouza@bsd.uchicago.edu) or 2-6277.

#### IRB

##### Bi-monthly Brown Bag Training

Free bi-monthly training sessions available to all Medical Center clinical research faculty and staff designed to provide researchers with guidance on IRB processes, answer questions, and provide a working relationship between IRB administrators and researchers.

Upcoming session: October 12, 2007

Understanding the IRB .

