



University of Chicago

# CLINICAL RESEARCH UPDATES

## *A Newsletter from the OCR & IRB*

Volume 1 Issue 4

October 2007

### OCR Monthly Workshops

- 1st Friday Sept—June
  - 12—1pm Dora De Lee
  - CME & CNE available
  - Lunch Provided
- 11/2 Clinical Research Update  
 12/7 M. Wynia "Race, Trust & Tuskegee—Professional Ethics"  
 1/4 P Gonzalez—The Code is the Code  
 2/1 Minsky & Currell "Quality Initiatives"  
 3/7 S. Rich "FDA Drug Approval Process—Buyer Beware"  
 4/4 B. Rehman "GCRC"  
 5/2 J. Sollway "CTSA—Implementation at UCMC"  
 6/4 C. Farr "Qualitative Studies—Religion and Medicine"

### New Staff Contact Information:

Gloria Ortiz 4. 8953  
 Gloria.ortiz@uhospitals.edu  
 Dionisia Sander 2.2270  
 Dionsia.Saner@bsd.uchicago.edu

### IRB: Updates

### Announcements

- IRB Meeting Dates and Deadline Dates for 2008 are now posted on the IRB website
- Deadlines for New Submissions and Amendments have been moved to **Tuesdays** for 2008

### IRB Updates

#### Meeting Dates and Deadline Dates through June 2008

#### Change in New Submission and Amendment Deadline to Tuesdays

- The 2008 Meeting Dates and Deadline Dates through June have been posted on the IRB website. <http://ors.bsd.uchicago.edu/IRB/Dates.html>
- For all new submissions and amendments for 2008, the new deadlines will now fall on **Tuesday**. Please take note that this change for new submissions and amendments begins in January 2008.
- As a reminder, new submissions are due by 5 PM on the deadline date, unless otherwise noted. Late submissions of new protocols and amendments will be reviewed at the next scheduled meeting. The IRB cannot guarantee that late submissions of renewals will be reviewed. Incomplete protocol submissions will not be reviewed until all necessary materials have been received regardless of the date the initial submission was received.

### OCR UPDATES

#### New Faces in the OCR— We'd like to introduce you to new staff and new roles in the OCR:

- **Gloria Ortiz** joined us as a Research Reconciliation Specialist. She will be assisting with all research related bill inquiries, clarifications and corrections, especially those sent to [resbilling@bsd.uchicago.edu](mailto:resbilling@bsd.uchicago.edu).
- **Dionisia Saner** joined the team as the OCR Informatics and Technology Specialist. Di will be launching Velos and helping to develop informatics organizational structure to help with clinical research activities.
- **Amanda Nunez**—Research Program Coordinator will be returning to her original task to champion the financial clinical trial audits, Medical Device oversight and IND/IDE risk analysis.

**Investigator Initiated Protocols**—With the prestige of authoring a protocol comes the additional responsibilities and regulatory oversight requirements. The Investigator is also effectively the sponsor for these trials. Responsibilities that fall to sponsor/investigators include: protocol development;s, submit IND/IDE application & required documents to FDA; register the trial on Clinicaltrials.gov ; select qualified investigators, sites and monitors; provide all information needed to conduct investigation; ensure that study sites get appropriate IRB approval; develop Case Report Forms and data collection tools; provide investigational drug or device; monitor and ensure study conducted according to protocol and good clinical practice; ensure compliance with regulations; provide study supplies and/or investigational product; inform FDA and PIs regarding adverse events and safety reporting; monitor data for safety and efficacy - Data Safety Monitoring Plan (DSMP); perform data analysis and report findings; final reports; and disposition of study article - assure return or destruction of any unused investigational drug. If work with a PI who holds an IND or IDE, please feel free to contact the OCR for additional guidance. 4.8922 or 4.9799

**OCR Website**— If you are looking for copies of the most recent Clinical Research Policy Board policies and guidance, electronic copy of an OCR workshop presentation, site delegation of authority log template, or other trial related resources, please visit the OCR Website:

<http://clinicalresearch.bsd.uchicago.edu/> If you have additional needs, or want to share some of your tools, please contact the OCR at [clinicresearch@bsd.uchicago.edu](mailto:clinicresearch@bsd.uchicago.edu)

### 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.

##### Required and Recommended Training:

**Human Subject Protections**— Required for all NIH protocols. The IRB suggests that all new researchers complete this training, either by checking out the DVD from the IRB or attending a training session. This training is not mandatory for IRB submissions. However, please note that human subject protection training **is** required for any NIH funded project. The NIH provides an on-line training program to fulfill this requirement ([Http://cme.cancer.gov/c01/](http://cme.cancer.gov/c01/))