



University of Chicago

CLINICAL RESEARCH UPDATES

A Newsletter from the IRB & OCR

Volume 2 Issue 3

September 2008

OCR Monthly Workshops

Put them on your calendar

- 1st Friday Sept—June
- 12–1pm Dora De Lee
- CME & CNE available
- Lunch Provided

10/3/08– Linda Triemer & Bob Gross
HIPAA Regulations for Clinical Research

11/7/08–Stacy Lindau—

Sexual Health of the Aging

12/5/08—Matthew Wynia

Pharmaceutical Impact on Clinical Research

Please RSVP to

clinresearch@bsd.uchicago.edu

if you'd like to attend.

Past workshops can be viewed on the [OCR Website](#):

Fundamentals in Clinical Research

Fall 2008 Session Begins: 10/7/08

[Registration forms](#) are on the OCR Website.

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 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 or 2-6277.

IRB: Updates

Reminder—The members of IRB Committee C have asked that we remind everyone of the importance of providing complete information on the Continuing Review Form.

Websites

Office of Clinical Research:
<http://clinicalresearch.bsd.uchicago.edu/>

IRB:
<http://bsdirb.bsd.uchicago.edu/>

IRB/OCR Merger— The administrative support for the BSD IRB has become a part of the Office of Clinical Research. The goals for this merger are: streamline protocol review of human subject studies; decrease duplicity of effort from Principal Investigators; & increase institutional knowledge of research. The IRB Counsel and IRB Committees will remain independent entities as they need to be free of any conflict of interest. What this means for you: centralized and concurrent routing of IRB and Contract documents to be rolled out Fall 2008; & increased communication between protocol reviewers in the IRB & OCR.

Concurrent Routing - This fall the OCR/IRB will begin rolling out a concurrent routing process. This will eliminate the research staff from duplicity of effort. Providing the clinical trial budget in concurrence with the IRB submissions will facilitate a more complete review .

Institutional Review Board Updates:

New IRB Website— 9/5/08 The BSD IRB launched a new website to help facilitate researchers in quickly finding the appropriate forms and guidance: <http://bsdirb.bsd.uchicago.edu/> We welcome your feedback. Content has remained the same, but the new format reflects the partnership with the OCR. The former IRB website will only remain live for a short time, so please set your favorite bookmarks with the new site.

Online Electronic IRB submissions— IRBWISE— a web based IRB submission platform will be implemented in the BSD IRB. It's benefits: paper free system; PI has access to all IRB submissions and status; & once data is entered it pre-populates for amendments, AEs, Continuing Renewals etc. **Preliminary Timetable:** pilot—Fall 2008 for selected programs; early adoption—January 2009; & Full Roll Out tentatively scheduled for March 2009.

Reminder—The members of IRB Committee C have asked that we remind everyone of the importance of providing complete information on the Continuing Review Form. **In particular, the "Progress of the Research"** section oftentimes describes accrual at the U of C, but does not consistently provide information regarding the progress of the research study at all sites or the status of subjects enrolled at the U of C. Please provide as much detail as possible in response to this query to describe not only the status of subjects and accrual at the U of C, but relevant information for the study in general, including any results of interim analysis, if applicable.

The continuing review form (page 6) requests a summary of the adverse events that have occurred at all study sites in the past year. The IRB has been receiving lists (or logs) of external adverse events from the sponsor which provide very minimal information and the IRB Committee members have expressed concern that this is not providing the necessary information (in many cases, the logs do not even provide the description of the adverse event, but only the adverse event #). Thus, we are asking your assistance in working with the PIs to summarize the adverse events that have occurred at all study sites since during the past year. It may be helpful for you to utilize the logs from the sponsor (if they are adequately detailed) in preparation of the summary. What we are really looking for is trends in adverse events - often similar to what is often explained in a DSMB report

Office of Clinical Research Updates:

New Policy & Guidance Statements— The Research Billing Auditing Policy for Clinical Research was approved 7/30/08. This fall we also expect to publish the Research Injury Policy and approve the Quality Auditing Policy. In addition, Draft Guidance Documents on IND/IDE Registration, Clinical Trial Budget Guidance & Scientific Review can be found on our website:

New Tools— The Office of Clinical Research has designed new electronic tools and templates to assist you in conducting clinical research. The Research Tool Kit contains: Summaries of Research Roles & Responsibilities; Research Conduct Guidance; Research Regulatory Administration Guidance; UCMC Research Forms; FDA Forms; Templates; Source Documents; Research Finance Resources; Study Management Aids; & Audit Tools. The protocol template has been redesigned to assist in study design. All tools can be found on the **OCR Website**.

If there are additional tools that you need or items that you'd like to share, please send your comments and suggestions to the OCR. To assist with management for IDE/IND regulated trials where the PI is also the sponsor, the following tools have been posted: Regulatory Requirements for IND/IDE; Sponsor/Investigator Checklist & PI Responsibility Checklist.

Administrator Round Table (ART)- To facilitate better communication related to clinical administration the OCR will resume quarterly ART meetings. The fall meeting is scheduled for Friday 10/10/08 1:30—3 pm. Please RSVP to: clinresearch@bsd.uchicago.edu if you'll be attending. Thank you.