



University of Chicago

CLINICAL RESEARCH UPDATES

A Newsletter from the OCR & IRB

Volume 1 Issue 5

December 2007

OCR Monthly Workshops

Put them on your calendar

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

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”

Past workshops can be viewed on the
OCR Website:

http://clinicalresearch.bsd.uchicago.edu/faculty_staff/presentations/index.shtml

Fundamentals in Clinical Research

Series 12: begins 1/8/2008

Registration forms can be found:

http://clinicalresearch.bsd.uchicago.edu/faculty_staff/training_education/documents/fundamentals_reg_form.pdf

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 pgonzalez@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

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

Happy New Year from the OCR and the IRB!

To start the New Year off right, we wanted to take this opportunity to focus on Adverse Event Reporting All UCMC IRB policies can be found on the IRB website. Guidance on adverse event reporting to the IRB can be found: http://ors.bsd.uchicago.edu/IRB/Forms_AE.html. If a sponsor's reporting requirements differ from the UCMC AE reporting policy, please communicate our local policies with the CROs and Sponsors.

Adverse Event Definitions:

Adverse Event: an undesirable and unintended, although not necessarily unexpected, result of therapy of other intervention.

Unexpected Adverse Event: Any Adverse Event which is not described in: 1. Investigator Brochure; 2. Detailed Protocol; 3. Risk information in the consent form; or 4. The reasonably expected natural history and progression of the underlying disease or condition.

Serious Adverse Event: Any Adverse Event is that results in any of the following outcomes: 1. Death; 2. A threat of death; 3. Inpatient hospitalization or prolongation of existing hospitalization; 4. Persistent or significant disability or incapacity; 5. Congenital anomaly or birth defect; 6. Causes cancer, 7. is an overdose.

Fatal: death

Life Threatening: The subject is at substantial risk of dying at the time of adverse event or it is suspected that the use or continued use of the investigational drug/device/ or intervention would result in the subject's death.

Related: An adverse event which is related to the use of the study drug, device or intervention for which there is a reasonable possibility (or strong temporal relationship) that the adverse event may have been caused by the drug, device or intervention.

Possibly Related: An adverse event which is possibly related is one that may have been caused by the study drug, device or intervention, however there is insufficient information to determine the likelihood of this possibility.

IRB Reporting Timeframes:

Internal Adverse Events:

Fatal/Life-threatening: must be reported in writing to the IRB within **48 hours** after discovery regardless of whether the event was expected

Drug/ Biologics Studies: Any adverse event that occurs on a research study investigating drug/biologics and is both serious and unexpected must be reported to the IRB. In addition, an adverse event may occur which is moderate in severity, not necessarily serious and unexpected, but which, in the investigators opinion, should be considered by the IRB due to a possible relationship with the drug/biologic being studied. In both cases the AE should be reported to the IRB **within 10 working days**.

Device Studies: any unexpected adverse event that occurs on a device trial (regardless of the seriousness) must be reported to the IRB **within 10 working days**

External Adverse Events: It is the Sponsor's responsibility to submit an FDA Medwatch form to assist PIs in completing the IRB external adverse event form.

Drug/ Biologics Studies: Serious and unexpected and related or possibly related to the research should be reported to the IRB **within 30 working days** of knowledge of event.

Device Studies: any unexpected adverse event (regardless of seriousness or causality) must be reported to the IRB **within 10 working days** of the knowledge of the event.

**Not all adverse events need to be reported to the IRB. Adverse events that do not meet the reporting requirements, both internal and external, can be summarized at the time of continuing review.*

Investigator Initiated Trials

FDA Adverse Event Reporting: For those investigators that hold the IND/IDE for a trial, they assume all responsibilities of a sponsor/investigators in addition to the IRB reporting policies, must report adverse events to the FDA.

IND studies: Fatal or life threatening adverse events must be reported to the FDA as soon as possible and no longer than 7 calendar days from knowing the of the event. Serious and associated with the investigational agent must notify the FDA **within 15 calendar days**. 21CFR312.32

IDE Studies: All serious or unanticipated adverse device effects must be reported to the FDA within **10 days**.

All other adverse events should be summarized with the FDA annual reports for IND/IDE.

Link to FDA Medwatch Forms: http://www.fda.gov/medwatch/safety/FDA-3500A_Fillable_10-25-07.pdf

