

Clinical Research Updates

April 2009 / Volume 3: Issue 2

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Fundamentals in Clinical Research

A free course on the core competencies of clinical research management. Open to all research faculty and staff. Participants are welcome to join at any time.

[Registration forms](#) [Schedule](#)

karrigo@bsd.uchicago.edu or 4-2740

OCR Monthly Workshops

Put them on your calendar

1st Friday Sept—June
12—1pm Dora De Lee
CME & CNE available

5/1/09 Why the IRB Asks So Many Questions
Jim Lynch & Nell Thompson

6/3/09 Patient enrollment in medical trials: Selection bias in a randomized experiment
Anup Malani JD University of Chicago

Past workshops can be viewed [here](#)

IRBWISE Training: Training sessions have been scheduled for the following dates and times. Certain sessions will be held in rooms with dedicated computer stations, while other sessions will be in conference rooms. Attendees are encouraged to bring their laptops to the conference room sessions in order to have a "hands-on" training session. Sessions in the L026 location are limited to 9 participants on a first come, first serve basis. Sessions will last **one hour**.

Date and Time	Location
4/24/2009 11:30	A109
4/29/2009 11:30	A109
5/6/2009 12:00	A109
5/8/2009 11:30	A109
5/13/2009 12:00	A109
5/20/2009 12:00	A109

Institutional Review Board Updates:

Online Electronic IRB submissions— As per prior communications, the BSD/UCH IRB has been in the process of implementing an on-line submission system, IRBwise for the past few years. As part of the implementation process, the IRB staff identified and piloted this system with a group of users this winter. We have modeled the electronic submission form on the existing paper submission forms as much as possible in order to ease this transition. With useful feedback and participation from the pilot group, we are now moving forward and rolling out online submissions to the entire research community.

NEW submissions of protocols

New protocols submitted on or after **May 1** may be submitted in IRBwise. All new protocols submitted to the IRB on or after **July 1, 2009** **must** be submitted in IRBwise. (The IRB will not accept paper copies of new submissions after July 1.)

CONTINUING REVIEW submissions

In order to renew existing protocols, renewal applications (continuing reviews) submitted on or after **July 1** may be submitted in IRBwise. All renewals submitted for protocols expiring on or after **October 1, 2009** (to be submitted for the deadline of August 21, 2009) **must** be submitted in IRBwise.

For AMENDMENTS, AEs, and OTHER Submissions

For all other types of IRB correspondence for approved **existing** studies, these submissions should continue to be submitted on paper until the continuing review for that protocol is submitted and approved in IRBwise. After a study is **approved in IRBwise**, all future submissions on that protocol should be submitted in IRBwise.

To enter protocols online, users will need a valid CNet username and password. To determine whether you have a valid CNet account, please access the NSIT website at <http://nsit.uchicago.edu/services/cnetid/>. This site also allows you to update your CNet account, including updating your password. If you are a hospital employee and do not have a CNet ID, a UCHAD account may be used.

Users may login to IRBwise at <https://irbwise.bsd.uchicago.edu/> beginning May 1 to submit new protocols. Users must first request that their account be activated by clicking the "Request an Account" link on the IRBwise homepage.

Training sessions will be held periodically throughout the spring and summer in order to acquaint users with submitting online. Training session availability will be posted on the IRB website at <http://bsd.uchicago.edu/irbwise/#Training>. In addition, training materials are also available at the same web address, including a Principal Investigator User Manual, a Research Staff User Manual as well as a document entitled "Quick Q & As for PIs."

We look forward to your assistance with the implementation of this system. If you have any questions concerning this process, please contact Millie Maleckar at 2-1472 or Nell Thompson, the IRB Associate Director at 4-7674.

Office of Clinical Research Updates:

Concurrent and Centralized Routing (CCR)

Starting on May 1, 2009, regulatory documents (schema, budget, contract) should be submitted at the same time as the IRB submissions. We started piloting this process this winter with few problems, but this is a work in progress and your feedback will be very important. For externally sponsored protocols only the timing of the submission is changed. For internally sponsored/unfunded, this will require, at minimum, the submission of a PI reviewed schema and applicable budget documents. The schema has been required since June 2006, but has not been consistently collected until now. The reason for these changes is that this allows protocols to be considered in their entirety both by the IRB and the Regulatory Group rather than separately as in our previously model. If this concurrent model is not

5/27/2009 12:00 A109

5/29/2009 11:30 A109

Sessions may also be arranged with departments or sections, as needed. Please contact James Lynch at jlynch@bsd.uchicago.edu or 834-1613 to arrange a group session.

New Postings on the OCR Website:

[Concurrent and Centralized Routing \(CCR\) Memo](#)

[Concurrent and Centralized Routing Reference](#)

- [Treatment of Research Related Injuries Policy](#)
- [ClinicalTrials.gov Protocol Registration Information](#)
- [Quality Assurance Auditing Policy](#)
- [February 2009 OCR/IRB Newsletter](#)
- [Vendor Registration and Clinical Trial Monitor](#)
- [Regulatory Support for PI Held IND & IDE](#)
- [Protocol Development Guidelines](#)
- [Administrative Resources](#)

feasible for individual groups, submission of the budget/ contract prior to the IRB documents is acceptable, but not vice versa. For assistance please see the attachment labeled "[Concurrent and Centralized Routing Reference](#)" for information on what should be submitted with the IRB documents.

Please note, these concurrent requirements DO NOT apply to protocols eligible for EXPEDITED review.

Additionally, this review process will require all clinical research protocols to comply with the "[Identification and Distinction of Clinical Trial Participants Charges](#)" policy, also known as the Schema Review policy.

If you have any questions or concerns about this new process, please contact Beth Martell at 4-9799 or bmartell@bsd.uchicago.edu

Contest to Clear Accounts Receivable Attention all Bill Payers A.K.A Financial Administrators: The OCR is hosting their first ever bill-paying challenge for all sections. The goal is to get all of your section's research accounts paid that are over 60 days old and as many current accounts as possible by June 30, 2009. If your section achieves this goal, you will be entered in a drawing for the top 3 PRIZES! There are only 3 winners so don't wait—get all your research bills paid today!! The drawing will be held on July 1st.

Reminders:

New Online Trainings: With the merger of the Office of Clinical Research (OCR) and The BSD Institutional Review Board (IRB), the previously required training for new Principal Investigators has been combined. OCR and the IRB will now offer training through the Collaborative Initiative Training Initiative (CITI) on-line training program. New Principal Investigators will be required to complete six core modules and one elective module of their choosing. New Investigators will be asked to register on the CITI home page www.citiprogram.org The CITI training will fulfill Institution-specific requirements as well as Human Subjects Protections requirements. Those who complete the CITI training can print out a certificate of completion to be given to their Department grant administrators to prove to federal funding agencies that they have completed the required training. Furthermore, research with children training is also included so that all required training is now in one central location. We encourage all research staff to complete this training as it offers excellent information on conducting research in human subjects.

More information can be found at the IRB website: <http://bsd.uchicago.edu/training.html>

Questions regarding training should be directed to James Lynch at 4-1613 or jlynch@bsd.uchicago.edu.

Velos eResearch
our choice for clinical trials management systems

IRBwise
future electronic IRB management system

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