

Clinical Research Updates

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Patient Complaints- Should Research Staff receive a complaint from a patient/subject or their spouse regarding potential billing errors, they should forward them onto Amanda Heinze (4-3192) via email (aheinze@bsd.uchicago.edu / or interoffice mail (MC 1108) for us to review and make a determination on the complaint.

ClinicalTrials.gov Registration Update ClinicalTrials.gov offers up-to-date information for locating federally and privately sponsored clinical trials for a wide range of diseases and conditions. The goal of registration is public access to a clinical trials registry that includes descriptive information about trials as well as clinical trial results. The registry allows investigators to make available information to a broad array of potential subjects and for patients to find potential research enrollment opportunities.

Why Register? It's required by law if you are the sponsor/author of a protocol. Section 113 of the FDA Modernization Act mandates registration with ClinicalTrials.gov of investigational new drug (IND) efficacy trials for serious diseases or conditions. It's required for journal publication. The International Committee of Medical Journal Editors (ICMJE) requires trial registration as a condition for publication of research results generated by a clinical trial (N Engl J Med 2004;351:1250-1).

Updating Your ClinicalTrials.gov Registered Study – Once a trial is registered, both the FDA and the ICMJE require that registrations be updated. **Posting basic study results for completed studies has also become mandated.** Please see [OCR's website](#) for details.

Institutional Review Board Updates:

New Policy & Guidance Statements—In accordance with the new Medical Center policy entitled, "[Treatment of Research Related Injuries](#)", the IRB has recently revised their "Research Related Injury" policy. Please review this policy available on the [IRB website](#). In addition, please note that this new policy affects the statements regarding compensation in the event of research related injury in the "What are the Costs" section of the consent forms and removes the requirement for separate sponsor statements regarding reimbursement for such injuries. This new language will be required to be included for all new protocol submissions submitted after February 28. In addition, for existing protocols, you will be asked to update the verbiage in the "What Are the Costs" section during the time of continuing review. If you have any questions regarding this policy, please contact Millie Malekar at 2-1472.

Office of Clinical Research Updates:

Administrator Round Table (ART)— To facilitate better communication related to clinical research administration the OCR will resumed their quarterly ART meetings this past fall. Feedback from this meeting led the OCR to post [Administrative Resources](#). The next ART meeting will be scheduled for February 27, 2009 from 1:30 – 3pm. Along with other updates, the topic will be operationalizing concurrent routing.

Velos – Version 8 of Velos, the electronic data platform for clinical research trials management, will be available this spring with advanced functionality. The next Velos training session for subject registration is scheduled for March 17, 2009. If your section/department has not fully implemented the Velos system for your research data needs, please contact Dionisia Saner in the OCR to assist with group / individualized training. (dionisia.saner@bsd.uchicago.edu) and complete a [Velos Access Request Form and Contacts form](#).

Reminders:

The OCR Has Moved! Effective 12/17/08 the OCR is now conveniently located next to the IRB on the second floor of McGiffert Hall, 5751 S. Woodlawn. **Contracts** should be delivered to the OCR and signed in next to the IRB log. **DP's** should be delivered to Gloria Ortiz in room 210 A.

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

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

3/6/09 – Linda Triemer

Conflict of Interest Management

4/3/09 – Rules that Govern Clinical Research

Past workshops can be viewed [here](#)

New Postings on the OCR Website:

- § [Treatment of Research Related Injuries Policy](#)
- § [Concurrent and Centralized Routing \(CCR\)](#)
- § [FDA IND/IDE Templates](#)
- [Adverse Event and Serious Adverse Event Guidance](#)
- § [Vendor Registration and Clinical Trial Monitors](#)
- § [ClinicalTrials.gov Protocol Registration Information](#)

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

Precertification & Denials for Research: When insurance precertification is required for authorizing a research related service, please email respre-certs@bsd.uchicago.edu. If a procedure is denied from a 3rd party provider because it is deemed "investigational" or "experimental" send documentation of the denial to: resdenials@bsd.uchicago.edu.

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.

Velos eResearch

our choice for clinical trials management systems

IRBwise

future electronic IRB management system

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