



# Clinical Research Updates



December 2008 / Volume 2: Issue 3

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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 Series of 10 modules repeated 5 times / year**

Winter 2008 Session Begins: 01/06/09

[Registration forms](#)

[karrigo@bsd.uchicago.edu](mailto: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

Lunch Provided

1/9/09 - Phoenix Project Overview for Research

(\*2<sup>nd</sup> Friday and Room Change P117)

2/6/09 ---Olufunmilayo Olopade

Breast Cancer and Genetic Links to African American Women

3/6/09 - Carol Zuiches

Conflict of Interest Management

Past workshops can be viewed [here](#)

## New Postings on the OCR Website:

[Adverse Event and Serious Adverse Event Guidance](#)

[Vendor Registration and Clinical Trial Monitors](#)

[OCR IRB Newsletter - September 2008](#)

[Regulatory Support for PI Held IND & IDE](#)

[IND Templates](#)

[Protocol Development Guidelines](#)

[Protocol Template with Guidance](#) ([MS Word](#))

[Administrative Resources](#)

[Manual of Operations \(MOP\) Development Guidelines](#)

[Clinical Research Toolkit](#)

**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:** Human Subject Training and new Principal Investigator training have been merged through Collaborative Institutional Training Institute, CITI. This web based training saves new faculty from checking out DVDs from the IRB & the OCR and integrates the exams. In addition to the Human Research Learning Suite, all staff can take the Good Clinical Practice Course. Completion of these web based trainings are tracked electronically and certificates can be printed for filing in your research training logs. To login to the [CITI training program](#), affiliate with the University of Chicago, BSD.

**Precertification for Research:** When precertification is required for authorizing a research related service, please email [respre-certs@bsd.uchicago.edu](mailto:respre-certs@bsd.uchicago.edu). If a procedure is denied from a 3<sup>rd</sup> party provider because it is deemed "investigational" send documentation of the denial to: [resdenials@bsd.uchicago.edu](mailto:resdenials@bsd.uchicago.edu).

**Monitor Registration:** Recently the University of Chicago Medical Center instituted additional registration requirements for their vendors. [Instructions for Monitors](#) is posted on the OCR Website. Please advise your monitors to obtain a badge from the Vendormate system in the Mitchell Lobby and sign in with the Clinical Trial Monitor Proxy. 1) You will be prompted to enter an email address. All Clinical Trial Monitors should sign in with the [monitor@uchicago.edu](mailto:monitor@uchicago.edu) email address. 2) Then select the "UCMC Monitors" as the firm/company name. 3) In the "Purpose of Visit" field, please enter your name and company name and/or who you are here to see. Then print the Badge.

## 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://bsdird.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 be taken down shortly so please update your favorites!

**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.

**Revisions to IRB Policy and Procedure Manual—** The IRB Committees have approved minor revisions to the IRB Policies and Procedures manual. The new IRB Policies and Procedures Manual will be available on the IRB website ([bsdird.bsd.uchicago.edu](http://bsdird.bsd.uchicago.edu)) on Tuesday, December 2. The changes to the Policies and Procedures manual include clarification regarding the IRBs consideration of conflict of interest issues, updates to the IRB record retention policy, and the availability of the new on-line training program for training in Human Subjects Research (see CITI announcement above). If you have any questions regarding these changes, please contact a member of the IRB staff

## Office of Clinical Research Updates:

**New Policy & Guidance Statements—** The [Quality Assurance Auditing Policy](#) was recently passed by the Clinical Research Policy Board 10/20/2008. The purpose of this policy document the BSD adherence to federal, state and local regulations and policies that govern human subject research. Routine audits also provide investigators and research staff an opportunity to make corrections or adjustments to research procedures and practices to improve the quality of the research program. Guidances have been posted on [Adverse Event Reporting](#), [IND/IDE Regulatory Support](#) and [Good Clinical Practice](#).

**Administrator Round Table (ART)**- To facilitate better communication related to clinical administration the OCR will resume quarterly ART meetings on 10/10/08. Feedback from this meeting led the OCR to post [Administrative Resources](#). The next ART meeting will be scheduled for February 2009.

**Velos eResearch**

our choice for clinical trials management systems

**IRBwise**

future electronic IRB management system

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