



University of Chicago

CLINICAL RESEARCH UPDATES

A Newsletter from the OCR & IRB

Volume 1 Issue 2

April 2007

IRB: Complete List of Revised Forms

New forms can be found at <http://ors.bsduchicago.edu/IRB/Forms.html>.

- Claim of Exemption
- Protocol Submission
- Amendment Submission
- Continuing Review Submission
- Termination Report
- Internal Fatal/Life-threatening Adverse Event
- Internal Serious/Unexpected Adverse Event
- External Adverse Event
- Deviation Report
- Supplemental Form A,B,C,E,G & R
- Waiver of Authorization for Screening

OCR Recruitment Strategies

Ten ways to recruit for free (or very little):

1. UCH clinical trials site
2. Register with the OCR
3. Craigslist.com
4. UCMarketplace.com
5. UCH This Week
6. UCH Intranet
7. Medical center/campus Fliers
8. Partner with other specialists or primary care providers for referrals
9. Health fairs and other community events through the Office of Community Affairs
10. Partner with advocacy groups specific to your disease of interest

IRB Updates

The Office of Research Services (ORS) has moved to McGiffert Hall (5751 S. Woodlawn Avenue; immediately north of the Robie House). This move was necessitated by the critical need for clinical and research space for faculty within the Medical Center complex. All materials currently submitted to ORS should be submitted to the second floor of McGiffert Hall beginning April 25, 2007.

The forms have been revised to reflect the new address and the following form changes.

New Submission form:

- inclusion of Pathology Specimen Utilization Committee query
- reformatting and editorial corrections

Continuing Review form:

- inclusion of Scientific Accrual Monitoring Committee (SAM) query
- for clinical trials, request for submission of protocol schema

For details about the schema requirement contact the Office of Clinical Research (OCR) at 834-9799.

In addition, the IRB Policies and Procedures Manual has been revised to reflect the new address and to implement the following changes:

- Include the need for reviews by the Pathology Specimen Utilization Committee and the Scientific Accrual Monitoring Committee (SAM), as applicable.
- Revise the description of the Clinical Trials Review Committee (CTRC).

The Revised Policies and Procedures Manual is posted at <http://ors.bsduchicago.edu/IRB/Policies.html>.

Please be sure to use the most recent version of all IRB forms when submitting to the IRB. Effective July 1, 2007, outdated versions of these forms will no longer be accepted.

All existing written consent forms and all new consent forms must now indicate the new IRB office address under the "Who Do I Call if I Have Problems Or Questions?" section. Currently approved written consent forms can be revised via an amendment or during the continuing renewal process.

OCR Updates

Do you need help meeting your enrollment goals?

Are you aware of the University of Chicago Medical Center Trials site?

<http://www.uchospitals.edu/clinical-trials>

This site provides the opportunity to communicate clinical trial information to potential research subjects, the OCR, and medical center faculty & staff. Don't forget to update your postings regularly! It is a simple and free opportunity to highlight all of your open protocols. Use Supplemental Form I (<http://ors.bsduchicago.edu/IRB/SuppFormI0406.pdf>) with your IRB Application to post your study on the UCH Clinical Trials site.

Contact the Office of Clinical Research to evaluate your recruitment plan and to take advantage of: lessons learned from other research teams about strategies and success rates; special rates & deals from third party vendors for media and recruitment materials; basic phone screening services; advertising with the research hotline; and referrals from the research hotline. Shahnaz Kazi (4.2736) and Pamela Gonzalez (4.8992) are the primary contacts in the OCR for recruitment and retention efforts. If you have interest in this field, consider joining the recruitment/retention steering committee.

UPCOMING TRAINING:

OCR

Fundamentals of Clinical Research

A free course on the core competencies of clinical research management.

Monthly OCR Workshops

Free and available to all Medical Center clinical research faculty and staff.

For more details regarding either of these training courses contact Pam Gonzalez at 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

Bi-monthly Brown Bag Training

Free bi-monthly training sessions available to all Medical Center clinical research faculty and staff designed to provide researchers with guidance on IRB processes, answer questions, and provide a working relationship between IRB administrators and researchers.

Upcoming session: May 25, 2007 12p-1p in J103 Understanding the IRB Review Process. Specifically covering the IRB timeline from deadline date to approval.