



University of Chicago

CLINICAL RESEARCH UPDATES

A Newsletter from the OCR & IRB

Volume 1, Issue 1

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Policies from the Clinical Research Policy Board

Details can be found at http://clinicalresearch.bsd.uchicago.edu/faculty_staff/policies/index.shtml

- Registration Policies
 - For billing
 - Outpatient registration
 - Enrollment registration
- Study Monitoring Visits: Scheduling and Access
- Distinction of Charges (Schema Review Memo)

Policies from the IRB

- New Written Consent Form Template dated 1/18/07 now available
- New guidance for "Costs" section language
- New Claim of Exemption, Supplemental Form O, and Supplemental Form W dated 1/18/07 now available

OCR: Updates

Training of all clinical research faculty & staff should be documented and archived to verify qualifications to perform designated functions. In addition to institutional requirements, the FDA requires all Investigators to maintain documentation of the qualifications and training of all members of their research team. To assist in these documentation requirements, a Site Delegation of Authority/ Responsibility Form can be used. A template for this form and additional details can be found on the OCR website at

http://clinicalresearch.bsd.uchicago.edu/faculty_staff/documents/source/site_delegation/site_delegation_authority_log.doc.

The OCR website contains many resources, tools, templates, instructions, contact information, that may help you to achieve your clinical research goals. If you have trouble finding what you need or are aware of additional resources that could be included for the use of others, please contact the OCR at 2-6277 or ldesouza@bsd.uchicago.edu.

Are you looking for healthy volunteers for your studies? Potential subjects often call the Medical Center regarding research participation. If they don't remember the contact information of the research team from an ad, or are just looking for healthy volunteer studies, their calls generally forwarded to the OCR. To help ensure potential subjects are connected with appropriate research studies, please contact the OCR at 2-6277 or ldesouza@bsd.uchicago.edu to provide a summary of your study and contact information.

IRB: Updates

The Biological Sciences Division Institutional Review Board has revised the written consent form template to include suggestions in the "What Are the Costs?" section with the help of the Office of Clinical Research (OCR). While this language is not required, it is suggested that investigators preparing clinical trial submissions in particular consult this language when writing consent forms. The new template can still be found under the Guidance section on the IRB website.

http://ors.bsd.uchicago.edu/IRB/Forms_newsub.html

Please note that the new Written Consent Form Template is dated 1/18/07 and should now be used as a template for all new IRB submissions. The template was revised to provide further guidance on what costs are associated with a subject's standard medical care versus the costs that are associated with the research study. Subjects have the right to know what costs are associated with the research and who is responsible for those costs; e.g., whether it is the responsibility of the research sponsor, subject's insurance provider, or the subject themselves. Other key points include guidance on language for volunteer studies, pre-certification from insurance companies, and instructions on how to clearly delineate the clinical costs associated with the research from costs associated with standard of care.

UPCOMING TRAINING:

OCR

Fundamentals of Clinical Research

A free course available to all Medical Center faculty and staff focusing on the core competencies of clinical research management. . To register, please contact Pam Gonzalez at pgonzale@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. To obtain materials, please contact Linda DeSouza at ldesouza@bsd.uchicago.edu or 2-6277.

Monthly OCR Workshops

Free monthly workshops available to all Medical Center clinical research faculty and staff. For upcoming dates and topics, please contact Pam Gonzalez at pgonzale@bsd.uchicago.edu or 4-8992.

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: March 9, 2007 12p-1p in J103

Submitting grants that involve human subject research to the IRB.