



University of Chicago

CLINICAL RESEARCH UPDATES

A Newsletter from the IRB & OCR

Volume 2 Issue 1

February 2008

OCR Monthly Workshops

Put them on your calendar

- 1st Friday Sept–June
- 12–1pm Dora De Lee
- CME & CNE available
- Lunch Provided

3/7/2008 Dr. Stuart Rich

“FDA Drug Approval Process—Buyer Beware”

Past workshops can be viewed on the OCR Website:

http://clinicalresearch.bsd.uchicago.edu/faculty_staff/presentations/index.shtml

Fundamentals in Clinical Research

Series 12: begins 1/8/2008

Registration forms can be found:

http://clinicalresearch.bsd.uchicago.edu/faculty_staff/training_education/documents/fundamentals_reg_form.pdf

Fundamentals of 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 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: Updates

Announcements

- Supplemental Form H has updated language from the RADRAC. New version date is December 2007

This issue is devoted to the cornerstone of protecting human subjects—The Informed Consent Process. All IRB policies can be found on the IRB website. Guidance on informed consents can be found towards the bottom of the IRB Forms & Guidance website: http://ors.bsd.uchicago.edu/IRB/Forms_news.htm

Informed Consent Defined: The knowing consent of an individual, his/her legally authorized representative (LAR), who is able to exercise free power of choice without undue inducement, force, fraud, deceit, duress, or other form of constraint..

Informed Consent is a process, not just a form to be signed. It is an educational process that takes place between the research team and potential subjects.

Informed Consent Process— There are three main points to the informed consent process:

1. **Information—** Written Informed Consent forms must be approved by the BSD IRB and version number and IRB approval date must be included on all pages. Research staff delegated to obtain the informed consent must inform the subject of ALL aspects of the trial. Language should be as non-technical as possible. Advertising is part of the informed consent process and therefore also needs to be reviewed by the IRB prior to its use.
2. **Comprehension** The informed consent is not valid unless the subject or LAR understands the information provided. It is the responsibility of the investigator and his/her research staff to ensure that each potential subject comprehends the information. Tools for documenting comprehension include Informed Consent Checklists and narrative notes, examples of which can be found on the OCR's website: http://clinicalresearch.bsd.uchicago.edu/faculty_staff/templates_tools/documents/informed_process_checklist.doc
3. **Voluntariness** Subjects should be free to participate without undue influence. To that end, financial compensation must be considered reasonable and commensurate with the study risks. Language of the Informed Consent cannot cause a subject to waive or appear to waive any of their legal rights, and they must have the option to terminate participation at any time throughout the study.

Types of Informed Consents:

- **Waiver of Informed Consent-** An Investigator can apply for a waiver of consent if their study meets the following guidelines: no more than minimal risk to subjects; waiver of informed consent will not adversely affect the rights and welfare of subjects; and the research would be impracticable to carry out without the waiver or informed consent. Supplemental Form W submission to IRB <http://ors.bsd.uchicago.edu/IRB/SuppFormW0806.pdf> must be submitted.
- **Oral Consent—** The only record linking the subject and the research would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality and can only be used if the protocol presents no more than minimal risk.
- **Assent—** The assent of all participating children with the capacity to understand the research, risks & benefits and alternatives to research should be obtained. The IRB typically views age 7-18 to be appropriate age for assent however each case is specific.
- **Proxy—** IRB amendments for the use of proxy consent must document the subject lacks decisional capacity and not have an operative and unrevoked living will, durable attorney for healthcare or declaration for mental health treatment. <http://ors.bsd.uchicago.edu/IRB/Proxy0307.doc>
- **Written Informed Consent : BSD IRB Approved Informed Consent Templates**

The IRB informed Consent Template can be found:

<http://ors.bsd.uchicago.edu/IRB/UofCCFTemplate0307.doc>

Spanish Informed Consent Template:

<http://ors.bsd.uchicago.edu/IRB/SpanishUofCConsentFormTemplate0307.doc>

Enrollment of Non English speaking subjects. For research where PIs expect to enroll non-English speakers, a consent must be translated into the native language and submitted to the IRB with the original submission or as an amendment. Proof of the certified translations should be submitted with the IRB documents. Guidance can be found: <http://ors.bsd.uchicago.edu/IRB/Policies.html#Non-English>. If a non English speaker presents for a study in which there is no certified translated informed consent, and the PI could not have foreseen enrollment of a subject who speaks this language, a “short form” may be used which is written in the potential subject’s native language, the English consent is verbally translated with the translator’s signature on the documents. Short form consents are available on the IRB website in the following languages: Spanish, Arabic, Serbian, Macedonian, Polish & Portuguese.

Cost Language: Informed consents must have clear statements as to what is provided free of charge in the study (research related) and what the patient or his/her insurance will be responsible for (standard of care).

Best Practices: Encourage subjects to initial and date each page of the informed consent. Ask subject to state in his/her own words the purpose of the study, the stated risks and why they are choosing to

participate. Document the informed consent process using a checklist or narrative note. In this narrative, document the subject’s questions, who was present and any other pertinent details of the encounter. Send a copy of the signed informed consents with the subject’s medical record number to Medical Records. Provide the subject with a copy of the informed consent signed by the person obtaining consent & the Principal Investigator.

