UIC
2008 Bringing Administrators Together Conference

Demystifying the Institutional Review Board (IRB) Process

March 6, 2008 – 10:45 a.m.

Workshop Presenters

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Please…

- Turn off cell phones.
- Avoid side conversations.
- Please hold questions to the end of the presentation.
- Sign the attendance roster.
- Complete the evaluation at the end of the workshop.

Workshop Objectives

- Explain the process
- Understanding the Application(s)
- Appendix A through Z – When is it required?
- Informed Consent
- HIPAA Authorization
- Recruitment Materials
- Version Control – Why this is important.

Beginning the Application Process

- OPRS Newsletter
- OPRS Website

  http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/index.shtml
  - Meeting Deadlines
  - Forms
  - Education and Training Requirements
  - Policies and Guidance
  - Conducting Research at JBVAMC
  - FAQs
  - Links to Online Resources
  - Link to RiSC Web
  - OPRS Contacts

Application Forms and Instructions

- Exempt
- Expedited / Convened
- Development / Center / Training Grant
- Amendment
- Continuing Review
- Final Report

Application Forms

- Appendices A through Z
  - Appendix A – Use of Drugs, Devices and/or Biologic Products in Research
  - Appendix B – Involving Children as Subjects in Research
  - Appendix C – Involving Prisoners as Subjects in Research
  - Appendix D – Databases/DNA/Tissues/Sample Banks
  - Appendix E – Investigational Drug Service Drug Study Registration Form
  - Appendix F – Unit/Departmental Review Committee
  - Appendix H – HIPAA Compliance Application
  - Appendix I – Use of International Performance Sites for Human Subject Research
  - Appendix J – Debriefing for Research Involving the Use of Deception
  - Appendix K – Performance Sites
  - Appendix P – Additional Co-Investigators/Key Research Personnel
  - Appendix S – Use of Classroom as a Performance Site
  - Appendix Z – Additional Funding Sources for Human Subjects Resarch

Preparing the Application

- Consistency
- Detailed Explanation
- Read before submitting (or have someone else review)
- Follow the instructions
- Request a Pre-Submission Review
- Contact OPRS with Questions

Managing Documents

- Practice Version Control
- Use a Brief Title, Version # and Date in the footer on all documents.
- Keep a hard copy of what is submitted.
- Keep an electronic copy for future edits.

Managing Documents

- Edits
  - Strikethrough all deletions
  - Highlight all additions
    - Utilize track changes in Word
    - Unlock the Application

    (Forms Page – Tips: Editing Previously Entered Information in IRB Forms)
  - When revising documents, use the most recently approved document.

Tracking Protocols

- Track submission determinations using RiSC Web
- Allow sufficient time for review
  - Expedited Review = outside of an IRB meeting. Not *FAST* review.
  - Convened Review = at an IRB meeting.
- Allow sufficient time to process the submission.

The Consent Form

Informed Consent is a *process* that begins with subject recruitment and continues throughout the subject's participation.

However, except under certain circumstances, *written*, *prospective* informed consent should be obtained for all subjects prior to participation.

The Consent Form

Several consent templates are available on the UIC OPRS website, including:

- Biomedical Research – English
- Biomedical Research – Spanish
- Behavioral Research
- Biomedical Consent for minimal-risk research with HIPAA elements

The Consent Form

It is recommended that an appropriate UIC template is used, rather than a sponsor's template or model consent, to ensure that subjects receive pertinent local information about their participation.

The Consent Form

What should be considered when writing a consent document?

- The description of the research procedures, risks, benefits, privacy and confidentiality, payment, compensation for injury, etc., in the consent must be *consistent* with the description in the protocol and application.

"Consistent" does NOT mean the consent language should be word-for-word from the protocol. Consider…

The Consent Form

…who is your intended subject population?

- The consent must be written so that it is *understandable* to subjects.

  "Understandable" may refer to:

  - Language used: Will subjects be able to read and understand English?
  - Reading level: Are technical terms explained in lay language? We generally recommend a 6th-8th grade reading level for adult consent forms.

The Consent Form

PLEASE DO NOT

Make all of your text **bold,** *italicized,* underlined or CAPITALIZED.

- Text should be consistent throughout the document, generally in a 12-point font.
- Use of enhanced text beyond what is already in the template should be limited, so as not to emphasize any one section of the document (e.g., text describing risks should be the same as **TEXT DESCRIBING PAYMENT!!!)**

The Consent Form

Please *proofread* your document!

- Although poor grammar and punctuation may not seem like a big deal, it can be a distraction!

  - A well-written form shows the subject AND the IRB that you pay attention to detail.

  Wood you has much comfidense in an researcher who's consent from that looks like these?

The Consent Form

More than one subject group?

- Be precise in your language.

  - A “Consent” is for adult participation. A “Parent Permission” is used when asking a parent to permit his/her child to participate. Children under age 18 provide “Assent” in most cases.

- Keep the description of the research geared toward the right subject group.

  - e.g., You don’t have to include the side effects of a drug in the control group consent if the drug will only be given to the treatment group.

The Consent Form

More than one subject group? (cont'd)

- Please use a *unique identifier* in the footer of each document.

  - At first glance, many documents look the same. If we can't tell the difference, look-alikes may be overlooked.

The Consent Form

Modifying your form:

- All consent revisions should be marked so it is easy to identify what changes have been made.

  - Additions and deletions should be marked on the SAME form.

  - Remember to update the version number and date so OPRS staff can ensure that the most recent version is being used.

HIPAA Authorization

When is an Authorization needed?

Research using or disclosing health-related information that is considered Protected Health Information (PHI) may be subject to the HIPAA Privacy Rule requirements. Health-related information **is considered to be PHI** if any of the following apply:

- the researcher obtains it directly from a healthcare provider, a health plan, a healthcare clearinghouse or an employer (other than records relating solely to employment status);
- the records were created by any of the entities noted above and the researcher obtains the records from an intermediate source which is NOT a school record or employment record related solely to employment status; **OR**
- the researcher obtains it directly from the subject in the course of providing treatment/health care to the subject.

HIPAA Authorization

Generally speaking, research involving:

- Existing medical records
- Creation of medical records
- Procurement of tissue samples or data that contain PHI

This will include most Biomedical research conducted in any of the health sciences colleges at UIC (College of Medicine, College of Pharmacy, College of Dentistry, College of Nursing, and sometimes the School of Public Health).

HIPAA Authorization

What's the difference between Authorization and Consent?

- Subjects "consent" to participate in a research study. Subjects "authorize" the use and disclosure of their protected health information for research purposes.
- In some cases, a subject can consent to participate in research without providing authorization.

HIPAA Authorization

As far as mechanics go, keep in mind the consent form tips when writing the Authorization:

- Use the UIC template
- Information should be consistent with other documents (particularly Appendix H)
- Language should be understandable
- Keep text/font consistent
- More than one subject group? You may need more than one Authorization.
- Proofread, mark your revisions, and maintain version control!

HIPAA Authorization

Are there options for obtaining Authorization?

- OPRS has separate Authorization form templates available in both English and Spanish.

  - This form can be used for any study that requires written authorization.

HIPAA Authorization

Options? (cont'd)

- When biomedical research is minimal risk and both consent and authorization are required for participation, the "Biomedical Consent for minimal-risk research with HIPAA elements" can be used.

  - Since this is a combined consent/ authorization document, this should not be used when subjects may refuse Authorization.

HIPAA Authorization

Options? (cont'd)

- OPRS also offers HIPAA drop-in language for consent forms for research that is greater than minimal risk, and that requires both consent and Authorization to participate.

HIPAA Authorization

Note:

- When psychotherapy notes will be used, a separate HIPAA Authorization form is required. An Authorization for use/disclosure of psychotherapy notes cannot be combined with a consent form.

Waivers

What if you plan to request waivers?

- Consider whether your planned activity qualifies for a waiver(s). Criteria that need to be met are outlined in the Initial Review application (waivers of consent) and Appendix H (waivers of HIPAA Authorization).

Waivers

- When reviewing medical records without prospective written consent or Authorization, you MUST request waivers of informed consent AND HIPAA Authorization.

- This applies to waivers for recruitment purposes as well as retrospective chart reviews!

Recruitment Materials

When writing recruitment materials, the same general guidelines can be followed as for consent and Authorization.

Recruitment Materials

The IRB DOES look for specific content:

- Research project title or identifier (i.e. smoking cessation).
- A description of the type of research and purpose of the research.
- The word "research" must be included in the description.

Recruitment Materials

- Name of the person or office to contact and the number to call for further information.
- The UIC research protocol number and the fact that the research is being performed at UIC.
- The Principal Investigator's name, department, and address.

Recruitment Materials

- The specific location of the research.
- A footer with version # and date.
- Space for the UIC IRB approval stamp (approximately 2.5 x 1.5 inches).

Additional information can be included in the recruitment materials as desired, such as

- the subject population being sought

- a more detailed description of the procedures

- an estimate of the time commitment needed for participation.

Recruitment Materials

The IRB does accept professionally developed recruitment materials provided by sponsors.

However, the IRB may require that UIC requirements are still met, such as including local investigator name and contact information or providing a version number and date.

Consent, Authorization and Recruitment Help

Please visit the OPRS website for additional requirements, guidelines and forms:

Forms –

http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/forms/index.shtml

Policies & Guidance –

http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/index.shtml

Helpful Hints

- IRB = Institutional Review Board not research protocol.
- When calling OPRS:
  - For status regarding your research protocol please have your protocol number available. Dr. Research may have more than one protocol.
  - For simpler questions, explain the document in which you are having difficulties. Letter, Application, other document.
  - For multiple questions or more complex questions, it is best to outline the issues in an email to the individual who signed the letter.

Helpful Hints

- OPRS staff provides assistance based on UIC policy and procedures. Any one individual within OPRS will be able to answer your questions.
- Understand that calling multiple individuals multiple times for status slows down the process.
- Please be patient with the OPRS Staff. They are knowledgeable and will assist you in any way they can.

Helpful Hints

- Use of Protected Health Information (PHI) requires Appendix H – HIPAA Compliance.
- Retrospective vs. Prospective
  - Retrospective = existing, available at the time of submission.
  - Retrospective requires Waiver of Informed Consent, Waiver of HIPAA Authorization.
  - Prospective = to be collected.
  - Prospective requires Written Informed Consent, Written HIPAA Authorization.

Workshop Summary

- OPRS Website
  http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/index.shtml
  - Updates
  - Forms
  - Templates
  - Policy and Guidance
  - OPRS Newsletter
  - Contacts

Questions / Concerns?