THE UNIVERSITY OF IOWA

IRB Connection

HUMAN SUBJECTS OFFICE

Volume 2, Issue 6
April 2014

Human Subjects Research in the News:

Crowd-Funded HIV Vaccine Project Sparks Debate
Nature, February 10, 2014

Whole-Genome Growing Pains
The Scientist
March 11, 2014

NIH Rethinks Psychiatry Trials
Nature, March 14, 2014

Contagious Yawning a Mystery: May not be Linked to Empathy After All
Science Daily
March 14, 2014

Seattle Research Explores Adult Lives of Gang Members
Tim Haeck
March 17, 2014

HAWKIRB

Upcoming Training Sessions

How to Complete a New Project Application
April 8, 2014: 1-3:30PM
Hardin Information Commons EAST

After IRB Approval...
April 16, 2014: 1:30-3PM
HP Smith Conference Room (W256 GH)

Federal Regulations Subpart Spectacular Part II
April 24, 2014: 1-2PM
HP Smith Conference Room (W256 GH)

HSO Office Hours
Wednesdays 2-4PM and Thursdays 10-12PM in 101 Hardin Library

Mondays 10-12pm in N186 Lindquist Center

No appointment necessary

Describing Risk to Research Participants

All human subjects face some risk when they participate in research. UI researchers are advised in the Informed Consent Document (ICD) template that "there is no such thing as a 'risk-free' study." In the context of human subjects research, "risk" is the probability of harm a subject could reasonably encounter from participating in a study. Federal regulations for the protection of human subjects do not define *risk*, but do include a definition of *minimal risk*.

Minimal Risk

A study is considered minimal risk when "the **probability** and **magnitude** of harm or discomfort are not greater in and of themselves than what subjects ordinarily encounter in their daily life or during the performance of routine physical or psychological examinations or tests." The level of risk to subjects (minimal or more than minimal risk) is the basis for determining the type of IRB review the study receives; either full board or expedited review. The probability (likelihood) and magnitude (severity) of risk can also influence a potential subject's decision about whether or not to participate in a study.

UI IRB Policy

The UI IRB requires researchers to:

- Describe potential risks from study participation in the ICD. UI IRB policy categorizes research risks as physical, psychological, social or economic and privacy issues.
- Provide information about the risks associated with the study and what the research team will do to minimize those risks in Sections VIII.1 and VIII.2 of the HawkIRB application.

When describing risks, researchers should consider emotional, psychological, financial, legal or social risks, as well as physical risks. Some risks may be better described as "things that could make the subject uncomfortable," such as fatigue from repetitive study procedures or embarrassment from disclosure of private information. To describe how research risks will be minimized, specific procedures (in some cases) can be followed, such as sterile procedures for a blood draw or use of a lead apron during an x-ray. Studies that involve looking at a computer screen may include short breaks so that subjects can rest their eyes. Investigators should also describe how subject safety will be monitored (e.g. through follow up phone calls, visits, safety lab testing, etc.).

Risk in Social/Behavioral Research

While serious harm to subjects is less common in the conduct of social or behavioral research (IRB-02), investigators should describe any physical discomforts (such as fatigue or embarrassment). However, some social/behavioral research carries more risk of harm to subjects. For example, studies collecting information about illegal drug use or underage drinking could put subjects at risk for social or legal harms. Additionally, studies of social support or past traumatic experience may cause psychological harms that could be extreme for some subjects.

Disclosing the Probability and Magnitude of Physical Risk

For biomedical research (IRB-01/03), the ICD should typically disclose the probability (likelihood) and magnitude (severity) of physical risks. Instructions in the risk section of the ICD template provide two options for presenting the likelihood and severity of physical risks; a bulleted list OR a table. Both formats provide percentages for risks that are rare (less than 10%), less likely/less common (10%-35%) or likely/common (more than 35%). For drug studies, information about probability and magnitude of risk from study medication can often be found in the package insert for FDA approved medication or in the Investigator Brochure (IB). The terminology alone may not be enough to convey the frequency or likelihood of the risk. What is "common" to some people may not be "likely/common" to others, so the percentages are an additional way to convey the likelihood of physical risks. It is important to note that subjects with limited education or a lower reading ability may not understand the percentages. A verbal description of the study, including a description of risks, can greatly enhance subject understanding of the likelihood and severity of physical risks. It is important to consider the subject population to evaluate whether risk information is presented in a way that subjects can understand. The IRB will also consider the description of the consent process provided in the HawkIRB application to evaluate how risk information will be presented to subjects.

NEWS FLASH!

Changes with HawkIRB and the CRU

The IRB is no longer requiring the overall CTSA grant be referenced in the funding source section (Question III.1) of the HawkIRB application or the Informed Consent Document if you are using the Institute for Clinical and Translational Science (ICTS) Clinical Research Coordination Core services, REDCap, or the Clinical Research Unit (CRU). This policy change is due to changes in the way ICTS tracks studies using its resources.

The IRB is not requiring modifications for studies referencing the CRU or REDCap in either the consent document or Section III of the HawkIRB application. This modification will be at the discretion of the PI. If the PI would like to remove this reference, please complete and submit a modification in HawkIRB reflecting these changes.

What We Did Last Month...

Submitted an application for AAHRPP Re-Accreditation!

During the month of March, the HSO was busy putting the finishing touches on its re-accreditation application to the Association for the Accreditation of Human Research Protections Program (AAHRPP). Readers may recall we introduced AAHRPP in the December 2013 newsletter. AHHRPP is an independent, non-profit accrediting body that promotes high-quality research through an accreditation process that helps organizations (such as the UI) strengthen their human research protection programs (HRPPs). AAHRPP uses a voluntary, peer-driven, educational model to ensure that HRPPs meet rigorous standards for quality and protection. To earn accreditation, organizations must provide tangible evidence of their commitment to scientifically and ethically sound research and to continuous improvement.

The UI HRPP initially received full accreditation in 2003 and was the first academic medical center in the U.S. to receive AHHRPP accreditation. The UI's HRPP (which is much bigger than just the HSO/IRB) was re-accredited in 2006 and 2009. The re-accreditation application process is a lengthy endeavor, requiring submission one year in advance of the actual review by the AAHRPP council. The application is approximately 1000 pages long and includes all of the HRPP's documented policies, procedures, and practices to demonstrate adherence to AAHRPP standards. On March 13, 2014, the HSO submitted its re-accreditation application for the 2014-2015 review cycle. Application submission is just the first step in a four step process. The steps are as follows:

1) AAHRPP reviews the application and provides feedback. Next, the HRPP makes requested changes and provides clarifications, as needed.
2) If the reviewers believe it is necessary, the HRPP generates revised content (policies and procedures) and supplies additional information that was not included in the application.
3) A site visit of the HRPP is conducted by members from AAHRPP accredited organizations. As the accreditation process is a peer-driven review, the site visitors typically include 2-4 individuals from other HRPPs with a variety of experience. The site visit is conducted over 2-4 days; records are reviewed and HRPP staff and investigators are interviewed.
4) Finally, the AAHRPP Council on Accreditation (a body of 9 members) meets to review the application and information collected during the site visit. The HRPP is then notified of accreditation status: Full approval or pending approval. The HRPP may or may not need to respond to the council.

AHHRPP accreditation is an important accomplishment for the UI HRPP and the University as a whole. Accreditation demonstrates the University's commitment to scientific and ethical human subjects research, holds the institution accountable to others, and accreditation is an important consideration among sponsors and funding agencies in deciding where to support research.

This Month in Human Subjects Protection History

On April 18, 1979, the Belmont Report was published in the Federal Register. Created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the Report was developed largely in response to public outcry over revelation of the U.S. Public Health Service Syphilis Study at Tuskegee. The Belmont Report summarizes ethical principles and guidelines for research involving human subjects. Three core principles are identified: respect for persons, beneficence, and justice. Three primary areas of application are also described: informed consent, assessment of risks and benefits, and selection of subjects. The ethical principles and applications of the Belmont Report guide all human subjects research conducted at the University of Iowa. The publication of the Belmont Report was an important event in the history of human subjects protections in the U.S., providing a moral framework for the basis of current regulations governing the conduct of human subjects research and ethical standards.

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