THE UNIVERSITY OF IOWA

IRB Connection

HUMAN SUBJECTS OFFICE

Volume 1, Issue 8
November 2013

NEWS FLASH!

Due to staff continuing education, the HSO will have the following reduced hours:

November 7, 2013
Open 9AM-1PM

November 8, 2013
Open 10AM-1PM & 2:30PM-4PM

Normal business hours will resume on November 11th.

Human Subjects Research in the News:

Stanley Milgram and the Uncertainty of Evil
The Boston Globe,
September 29, 2013

The Death and Afterlife of Thalidomide
NYT, September 23, 2013

Proposed Treatment to Fix Genetic Diseases Raising Ethical Issues
NPR, October 9, 2013

HAWKIRB

Upcoming Training Sessions

How to Complete a New Project Application
November 5, 2013: 11-1:30PM and
December 2, 2013: 2-4:30PM
Hardin Information Commons EAST

After IRB Approval...
November 11, 2013: 9-10:30AM
HP Smith Conference Room (W256 GH)

Genetic Research 101: The Regulatory Perspective
November 20, 2013: 3-4PM
Braley Auditorium (01136 PFP)

All Aboard for AAHRPP (Re-) Accreditation
December 5, 2013: 2-3PM
Braley Auditorium (01136 PFP)
and
December 6, 2013: 11-12PM
3026 Seamans Center

The Informed Consent Process

Informed consent is more than just a signature on a form. It should be an active process of sharing information between the investigator and the prospective subject. Obtaining informed consent is a basic ethical obligation for researchers. The exchange of information can occur via various modes of communication including face-to-face contact, postal mail or email, telephone, video, or fax. In all circumstances, individuals should be given the opportunity to discuss the study and have their questions/concerns addressed individually. After the initial exchange of information and indication of consent to participate in the study, an ongoing dialogue should continue throughout the duration of the subject's participation. The amount of information provided and the manner of presentation is generally related to the complexity and risk involved in the research study.

The informed consent process involves three key features:

1. *Disclosing to potential research subjects information needed to make an informed decision*
2. *Facilitating the understanding of what has been disclosed*
3. *Promoting the voluntariness of the decision about whether or not to participate in the research*

The informed consent process begins with the initial approach of an investigator to the potential subject (e.g., through a flyer, brochure, or any advertisement regarding the research study) and continues until the completion of the research study. Informed consent must be legally effective and prospectively obtained. To obtain IRB approval for a research study at the UI, investigators must describe a detailed consent process for each subject population in the HawkIRB application. Sections VII.D.29-30 of the HawkIRB application ask the investigator to provide a description of the enrollment and consent process for adult subjects and/or the parents or legal guardians for child/minor subjects. A common problem with responses to these questions noted by IRB reviewers is lack of sufficient detail. Descriptions of the consent process will vary study to study depending on the nature of the study and the subject population. However, the response should always provide information beyond "consent will be obtained."

HSO Mainline Questions: Flavors of Waivers

Imagine the following scenario: You would like to administer a survey and ask participants about a specific experience. Participants will rate option A compared to option B. Your study involves collecting opinions on innocuous, common experiences, and your survey will not ask sensitive questions (for example, about drug use or sexual behaviors). Should you ask the IRB for a waiver of consent or a waiver of documentation of consent? Are you wavering on how to answer that question? (pun intended). It is common to confuse a *waiver of consent* with a *waiver of documentation of consent*, but you can think of it this way: if you will prospectively interact with subjects, whether through online surveys, in-person procedures, or follow-up phone calls, a full waiver of consent is likely not appropriate because it is possible to conduct a consent process with these individuals. But when you request a waiver of documentation of consent and the IRB approves the waiver, the subject is not required to sign a document. There is still a consent process, but your online survey might present a screen describing the study and consent is indicated when a subject selects the "click here to consent and continue" button. Alternatively, you might provide potential subjects with an Exempt Information sheet (for studies with Exempt status) or consent might be described and indicated during a phone conversation. Section VII.D.16 is the place in HawkIRB to request a waiver of documentation of consent and VII.D.17-18 is where you will provide the justification for this request.

-Sarah Heady
IRB Assistant

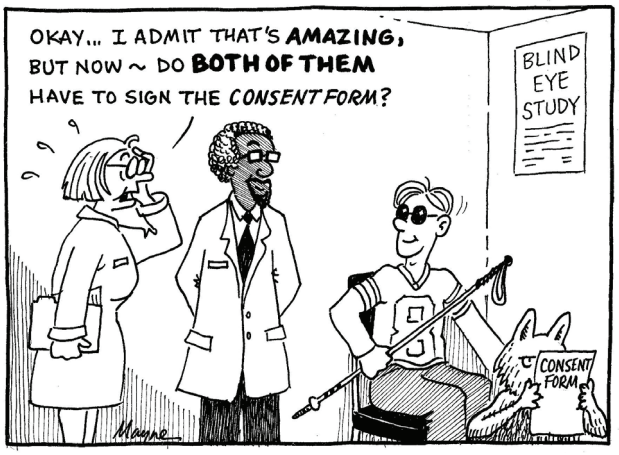
Sign up for the IRB Connection's distribution list by sending an email to listserv@list.uiowa.edu

Use of a Short Form Consent Document for Non-English Speaking Subjects

Federal regulations for the protection of human subjects require that the information given to a potential subject during the consent process is presented in an understandable language (45 CFR 46.116). Additionally, except in specific circumstances, informed consent must be documented by the use of a written consent form. If the study population includes non-English speaking individuals, the informed consent document (ICD) must be translated into the language(s) understandable to prospective subjects. The UI IRB realizes that investigators cannot always anticipate when they will encounter non-English speaking individuals who may be eligible for a study. If an investigator plans to enroll primarily English speaking individuals, but encounters a potentially eligible non-English speaking individual, the regulations allow for the use of a *short form consent document* to obtain written consent. A short form consent document is a written consent document stating that the elements of consent required by the federal regulations have been presented orally to a potential subject or his/her legally authorized representative. The UI IRB allows the use of a short form when all of the following apply:

1) The research team encounters a prospective research participant who does not speak English
2) The IRB has not approved an ICD translated into the potential participant's language
3) The research team does not have adequate time to have the ICD translated into the potential subject's language, reviewed and approved by the IRB before enrolling the subject

Short Forms in several languages are available on Human Subjects Office website. If necessary, the Principal Investigator (PI) is responsible for having the Short Form translated into additional languages. The Person Who Obtains Consent (PWOC), either the PI or a research team member designated as being involved in the consent process, enlists a translator who is fluent in both English and the subject's language. If the medical or technical information contained in the in ICD is complex, the translator must have an understanding of the information and terminology included in the document. The translator verbally presents the information in the IRB-approved English version of the ICD to the potential subject in his/her language, translates any questions the individual may have for the investigator, and provides the potential subject with the investigator's responses. The research team provides the non-English speaking subject with the Short Form written in his/her language to read. An adult individual, fluent in both English and the subject's language, must witness the entire consent process. For more information on the use of a short form, read here.



Obtaining the Required Signatures on the Informed Consent Document

Studies enrolling minors and minor subjects' parents or cognitively impaired adult subjects and their Legally Authorized Representatives (LAR) must be careful to ensure that all the required signatures are obtained on the Informed Consent Document (ICD). Typically, the IRB encourages investigators to have each subject sign separate ICDs; however, sometimes multiple individuals may sign a single document. In these cases, it is important that each individual signs the correct line. For example, if the research team is enrolling a minor (ages 0-17) and the minor's parent, the ICD will have three signature lines: one for the minor to sign for their participation, a second line for the parent to provide consent for their child to participate in the study, as well as a third line for the parent to sign to consent for their own participation in the study. Additionally, for research that is greater than minimal risk and involves minors, the IRB will typically require two parent signatures for the participation of the minor in the study. Investigators can find this determination in the IRB Full Board meeting minutes on the Project Summary page in HawkIRB and will see two parent signature lines on the IRB-approved ICD for the study. Researchers are required to obtain proper documentation of consent by obtaining the signatures of both parents and the minor (if the child is old enough to read and sign an ICD or Assent Document). If investigators are unsure about the purpose or intent of each signature line found on an IRB-approved consent document, they should review the IRB meeting minutes and/or contact the Human Subjects Office to ensure proper documentation of informed consent will be obtained.

Human Subjects Office

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