THE UNIVERSITY OF IOWA

IRB Connection

HUMAN SUBJECTS OFFICE

Volume 1, Issue 7
October 2013

Human Subjects Research in the News:

How to Share Scientific Data
NYT, August 12, 2013

US Brain Project Puts Focus on Ethics
Nature, August 14, 2013

Subject to Question
Nature, August 21, 2013

Study Affirms Benefit of Back Braces as Scoliosis Treatment
NYT, September 19, 2013

How Physical Fitness May Promote School Success
NYT, September 18, 2013

Tufts Bans Professor from Research on Human Subjects
Inside Higher ED
September 19, 2013

HAWKIRB

Upcoming Training Sessions

How to Complete a New Project Application
October 10, 2013: 2-4:30PM
Hardin Information Commons EAST

After IRB Approval...
October 17, 2013: 9:30-11AM
HP Smith Conference Room (W256 GH)

Don't Get Lost in Regulation Land: New IRB Compliance Monitoring and Educational Resources
October 24, 2013: 2-3PM
Braley Auditorium (01136 PFP)
October 25, 2013: 11AM-12PM
SC 3315

HSO Office Hours
Wednesdays 2-4PM and Thursdays 10AM-12PM in 101 Hardin Library
Fridays 10AM-12pm in N186 Lindquist Center
No appointment necessary

Coercion and Undue Influence: What is the difference?

Federal regulations require investigators to obtain the voluntary consent of research subjects under conditions that are free of coercion and undue influence. However, the terms *coercion* and *undue influence* are not clearly defined and are often mistakenly used interchangeably. Coercion is frequently used to describe all situations in which subjects may be pressured or receive what is perceived to be an excessive reward for their participation in research. Coercion and undue influence are in fact two distinct concepts. The Belmont Report defines coercion as an overt threat of harm intentionally presented to obtain compliance. Undue influence, by contrast, is an offer of an excessive, unwarranted, or inappropriate reward in order to obtain compliance. Coercion requires a threat or the perception of a threat. To be coerced, a potential subject must be made worse off or made to feel they may be worse off for declining enrollment. Contrary to its frequent association with excessive payment, receiving payment for research is never coercive. No one is ever made worse off or perceives to be made worse off by receiving payment for participation. Incidents of undue influence can be difficult to recognize as there is often uncertainty in applying the definition. Threats are typically verifiable, but this is not always the case for undue influence as it relies on interpretation. What may be perceived as excessive by one individual may not be excessive to another person. Related to subject compensation, it is UI IRB policy that subject compensation be a form of recognition for the investment of the subject's time or other inconveniences incurred. Therefore, subjects should not be compensated for the level of risk assumed in the study. Undue inducements are cause for concern because offers that are too attractive may blind prospective subjects to the risks or impair their ability to exercise proper judgment and may prompt subjects to conceal information that, if known, would disqualify them from enrolling or continuing as participants in a research study.

HSO Mainline Questions: Alphabet Soup

You mean the HSO is not the IRB? Who are these people? Most researchers are familiar with the acronym "IRB," but may not know what it means. Although, I have heard it defined as the "Iowa Review Board," (no, we aren't really the IRB of record for every research project in Iowa). You might even have a mental image of the IRB at work—a conference of strangers gathered to discuss and vote on human subjects research projects. But wait: you're supposed to call the HSO with questions about your IRB application? Confused yet? The central purpose of any Institutional Review Board—protecting human subjects—is consistent, yet institutions vary in their regulatory interpretations and requirements. No IRB can function without administrative support. Someone has to coordinate all of those meetings, answer all of those emails, and review all of those projects. The HSO (Human Subjects Office) provides critical support to the three UI IRBs. You can think of the HSO as the skeleton supporting the energy and activity of the IRB muscles. Different institutions give the administrative support skeleton different names (no orderly Linnaean taxonomy here), so your previous experience may not always translate. At the UI, the HSO serves as the human research protection program (HRPP) under the oversight of the Vice President for Research and Economic Development. The HSO aims to protect human research participants. It also has a team dedicated to outreach; the Education and Compliance staff work to educate investigators and research staff about protecting research participants, ethical responsibilities, and regulatory requirements. Together, the HSO and the IRBs help move the body of human subjects research at the University of Iowa.

- Sarah Heady, IRB Assistant

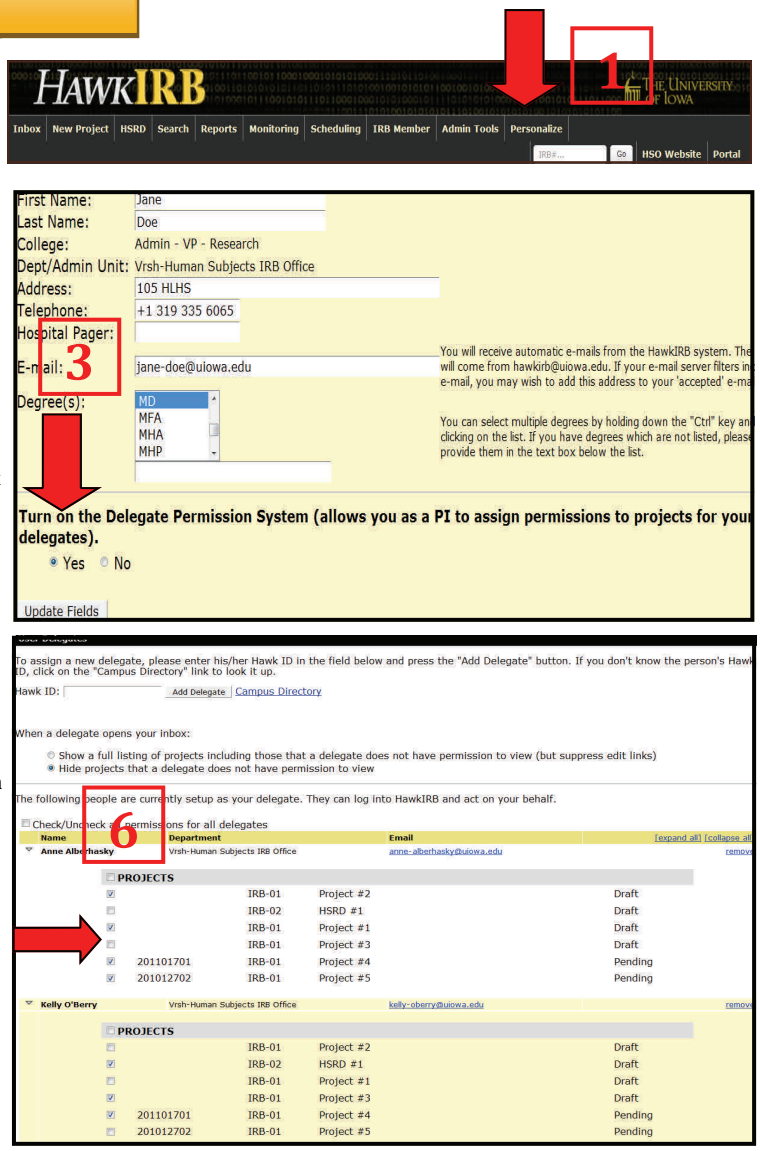
Sign up for the IRB Connection's distribution list by sending an email to listserv@list.uiowa.edu

HawkIRB: How Do I.....

Use the Delegate Permission System?

Principal investigators (PI) may name delegates to act on his/her behalf in HawkIRB. Once named, the delegate may enter, edit, and submit all types of application forms for the PI. However, the Principal Investigator remains responsible for the completeness and accuracy of all submitted forms. If a PI wishes to name a delegate, the IRB encourages the PI to establish documented procedures within his/her research group for reviewing and approving forms prior to their submission. Principal Investigators may also grant and restrict access to delegates on a project by project basis. To use this permission system, PIs will need to manually update their profile and make their designations in HawkIRB. If the permission system is not turned on, all previously named delegates will continue to have access to all of the Principal Investigator's projects rather than access to projects specified by the PI. To turn on the system and assign permissions follow these steps:

1) Log into HawkIRB and click on the **Personalize** tab
2) Click the **Update my profile** link
3) Select **Yes** and **Update Fields**
4) Return to the **Personalize** tab
5) Click on the **Update my delegates** link
6) Check/uncheck permissions for each listed delegate
7) Be sure to click the **Save Permission Information** button located at the bottom of the screen to save your changes



IRB Policy Reminder of the Month

Requirements for Subject Completion of Optional Agreements within the Informed Consent Document

Optional agreements allow subjects to indicate preference for optional research activities or study procedures within the Informed Consent Document (ICD). Optional agreements may be used by investigators who wish to enroll subjects while allowing for individuals to refuse specific aspects of the study. Typically, subjects indicate their preference by placing their initials, checking a box or marking a "yes/no" option. When a subject does not indicate agreement or fails to appropriately mark an optional agreement in the ICD, the optional activity or procedure should not be done. It is the responsibility of the research team to track and honor all optional agreements.

Investigators are encouraged to limit the use of optional agreements in the ICD as it is not always necessary to make certain study procedures optional. Optional agreements must be marked at the time of enrollment (i.e. at the time the subject signs the ICD). Members of the research team should never call subjects to inquire about blank optional agreement and then fill it in based on the subjects' verbal response. A copy of the ICD may be mailed to the subject with instructions for completing blank optional agreements if the research team has IRB approval to do so. If the research team plans to have in-person contact with the subject (e.g. a follow-up study visit), the subject may be asked to complete blank optional agreements at that time.

Human Subjects Office

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