THE UNIVERSITY OF IOWA

IRB Connection

HUMAN SUBJECTS OFFICE

Volume 3, Issue 4
August 2015

Human Subjects Research in the News:

Drug Companies Quietly Funnel Funds to Doctors
The Boston Globe
August 6, 2015

Just One All-Nighter Can Alter Your Genes, Possibly For Years To Come
Popular Science
July 24, 2015

Can a Longtime Fraud Help Fix Science?
Chronicle of Higher Education
June 22, 2015

Mad Men: Testosterone, Cortisol, Predict Risky Trading
Medpage Today
July 7, 2015

When Researchers State Goals for Clinical Trials in Advance, Success Rates Plunge
Chronicle of Higher Education
August 5, 2015

Trainings & Presentations

New Project Application
September 4, 2015 9-11:30 AM
October 8, 2015 2:30-5 PM

Continuing Reviews, Mods…
September 15, 2015 8:30-10 AM
October 21, 2015 1-2:30 PM

New IRB Procedures: Separate HawkIRB applications for IRB-01 and IRB-03
September 9, 2015 10-11 AM

Navigating the IRB Review Process: An Overview
September 25, 2015 11-12 PM

HSO Office Hours
Wednesdays 2-4 PM
101 Hardin Library
(through Aug 31st)

No appointment necessary!
For Fall Schedule updates, see our website.

Back to School Special: Faculty Advisor Responsibilities

As we gear up for a new semester, it is a good time to revisit some best practices for faculty advisors (FAs) and student researchers. When FAs and students collaborate in research, each person signs the Assurance Document; this outlines the agreements s/he makes with the IRB about their respective FA and student PI roles and responsibilities in oversight and conduct of the study.

Prior to taking on the role of FA, the advisor should consider the following: 1) the amount of work the study will involve, 2) the time and availability s/he will have to devote to the project, and 3) whether s/he shares common research interests and combined human subjects research experience with the student.

The FA is expected to:

- assist the student with the HawkIRB Application;
- be available as a resource;
- meet with the student on a regular basis (weekly when possible) to monitor the study progress;
- guide and oversee the research upon, and throughout the duration of, IRB approval; and
- refer students to additional, appropriate references.

Many student researchers are first time or fairly new researchers. Accordingly, FAs are expected to work closely with the student to plan and conduct the research, and to analyze the data.

The coordinating student researcher often assumes a majority of the responsibility for the conduct of the research and reports to the FA. The student researcher is expected to:

- ask questions and use available resources;
- and work closely with the FA & keep him/her informed about the study.

The student and FA should work together to ensure the project goals are manageable and to assess the risk to subjects.

The FA has oversight responsibility for the student and the research project. S/he is ultimately responsible for the legal and ethical performance of the project.

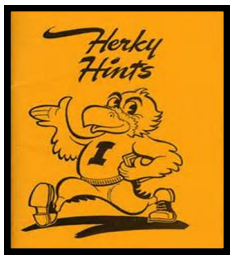
The Compliance Staff monitors FA/student PI research projects to ensure that both parties are adhering to the agreements outlined in the Assurance Document. The monitoring allows each individual an opportunity to ask questions and provide comments to the IRB/HSO.

As FA/student PIs begin their research studies this semester, be sure to keep these guidelines in mind to help your project runs smoothly. As always, if you have questions, contact the HSO at 319-335-6564 or email irb@uiowa.edu . *Written by Leona Ryan.*

Attention Biomedical Researchers (IRB-01): New Type of PRMC Notice

Studies that involve any resources or patients of the Holden Comprehensive Cancer Center (HCCC), which is indicated by a 'yes' to HawkIRB question V.22, may see a new type of review notice coming out of the Protocol Review and Monitoring Committee (PRMC). Beginning in August, at the discretion of the PRMC, certain types of translational and observational research projects involving the HCCC will have a review notice attached designating the project for "PRMC notifications only". What this designation means is that the PRMC will receive notices from HawkIRB about your project for NCI accrual reporting purposes, but PRMC will not conduct scientific reviews of the protocol. The response to V.22 will remain yes. If you have further questions, contact the HSO at 319-335-6564. *Written by Laura Dallas.*

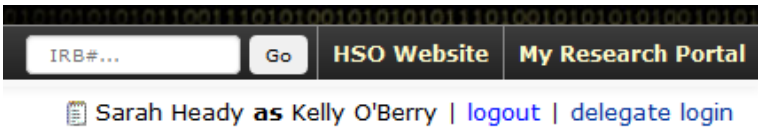
Herky Hints: New Project Landmarks—Finding Your Way in HawkIRB



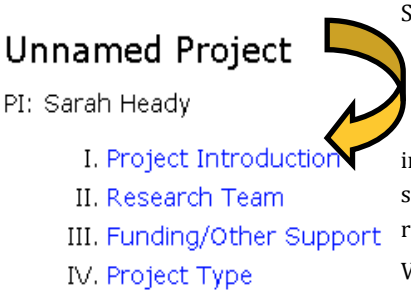
The **INBOX** tab is your home base—if you get lost in a project and aren't sure where to go next, head to your inbox (see below). Your HawkIRB inbox can always be found in the upper left corner of HawkIRB screen, directly under the application logo.

Ready to create a new project? Just click the tab, but don't forget—HawkIRB will create a new project draft form every time you click new project—you can wind up with several extra drafts in your inbox. From your inbox under 'drafts', click 'remove' on the right side of the screen to prune any unnecessary drafts.

On the right side of the HawkIRB screen, you can always see your **LOGIN STATUS**. If you are drafting an application for someone else, make sure you are taking advantage of the delegate permission system. HawkIRB assumes the person creating the draft is the PI, and there is no efficient way to change this. Not only can you see I'm logged in as a delegate in the screenshot to the left, but there are additional HawkIRB resources: the IRB ID # search, and links to the HSO website and the UI Research Portal. For more info about delegate permissions, see here (page 2).



The **INDEX** (shown below to the left and the right) can change depending on your responses. HawkIRB will open, close, or skip other sections, so you may not see everything listed here. For example, Section V *Other Committee Review* won't show up if IRB 02 (Social & Behavioral Sciences) is selected in Section I.



Section VII *Project Description* gives you 5 options for project details:

VII.A includes project locations and other research sites, VII.B collects information on interventions, VII.C asks about genetic research, VII.D gathers a description of the recruitment and consent procedures, and VII.E asks you to describe everything that happens post-consent .

If you're tempted to start with consent documents, resist! HawkIRB will pull template language into the consent from your application. And if you get lost, head back to your inbox . *Written by Sarah Heady.*

UI names Northwestern's Gipson Assistant VP for Research Compliance

The Human Subjects Office welcomes Heather Gipson!
We look forward to working with her and to the expertise she will provide.
For more information and additional changes involving the Office of the Vice President for Research and Economic Development (OVPRED), click the title of the article above.

Human Subjects Office

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Herky Hints cover, new student orientation manual, $5^3 9^3$ [Subject Vertical File Collection (RG 01.15.03), Miscellaneous category, folder "Freshman orientation," University Archives, Department of Special Collections, University of Iowa Libraries]