THE UNIVERSITY OF IOWA

IRB Connection

HUMAN SUBJECTS OFFICE

Volume 3, Issue 2
April 2015

Human Subjects Research in the News:

Phineas Gage, Gauging Time
The Atlantic Mar 16, 2015

Robot model for infant learning shows bodily posture may affect memory and learning
Science Daily Mar 18, 2015

Why Are So Many People Nearsighted?
Popular Science
Mar 18, 2015

Getting the message across: Can active symbols on road signs save lives?
EurekAlert Mar 31, 2015

Feeding Peanuts To High-Risk Infants Could Prevent Allergy Development
Popular Science
Feb 24, 2015

Trainings & Presentations

New Project Application
May 4, 2015 1:30-4 PM

Continuing Reviews, Mods…
April 14, 2015 9-10:30 AM
May 8, 2015 9:30-11 AM

IRB Monitoring: Types of visits and common findings from 2013-2014
April 10, 2015 2:30-3:30 PM

Mandatory Reporting of Physical and Sexual Abuse of children: The Research Perspective
May 4 & May 7, 11:30-12:30

HSO Office Hours

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

Mondays 2-4PM in 304 Lindquist Center

No appointment necessary

The Tattletale IRB?

There are specific incidents, called reportable events or REFs, that UI investigators are required to report to the IRB. But have you ever wondered what the IRB does with these reports? All REFs are reviewed by an IRB Chair. If they meet the UI IRB reporting requirements, they are either filed in HawkIRB or sent to the Full Board for additional review. Federal regulations at 45CFR46.103(b)(5) and 21CFR56.108(b) mandate specific reporting requirements for IRBs. Just as Principal Investigators (PI) must report specific events to the UI IRB, IRBs must report the following events to appropriate officials:

- unanticipated problems involving risks to subjects or others (UPIRTSOs)
- serious and/or continuing noncompliance
- suspensions or terminations of research

Per UI IRB policy, HSO staff generate a letter summarizing the study information, the nature and a detailed description of the problem, institutional information, IRB determinations, required actions to address the problem and follow-up plans. The letter is sent, no more than one month following the final determination by the convened IRB, to the following entities.

1) UI Institutional Official
2) Principal Investigator (PI)
3) Division of Sponsored Programs (DSP), if externally funded
4) PI's Departmental Executive Officer
5) Dean of the College of the PI
6) Research Integrity Officer (RIO), if the event involved research misconduct

The IRB will also report to the following entities, as applicable:

- the FDA, if subject to FDA regulations
- the OHRP, if subject to DHHS regulations
- the ACOS and AO, if the study involves the VAHCS.

The IRB does not report these events to penalize PIs. Researchers may view the IRB's reporting of these events as being detrimental to the investigator and the UI; however, NOT reporting is potentially more damaging. OHRP selects institutions for 'not-for-cause' compliance evaluations based on a range of considerations, including whether they have a history of a relatively low level of reporting to OHRP under the HHS regulations requirements previously mentioned. So not only is the UI IRB required to accurately report these events, it is in the institutions best interest to do so.

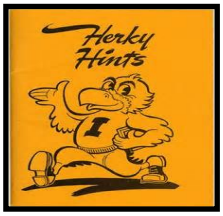
IRB Compliance Staff to attend FDA Audits

Beginning January 2015, IRB Compliance staff began attending Food and Drug Administration (FDA) audits of University of Iowa (UI) investigators. The FDA audits may either be 'study-oriented' (formerly routine) or 'investigator-oriented' (formerly for cause) audits.
The Compliance staff will attend the Opening and the Exit Meetings between the FDA auditor and the research staff.
The goal of this monitoring is two-fold:

1) It provides investigators with assistance in addressing any findings identified in the audit, if necessary
2) It provides the IRB with formal documentation of the FDA audits

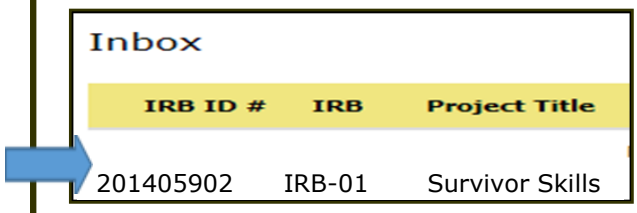
Research staff should notify the Human Subjects Office (HSO) when initial notification is received from the FDA that an audit will occur by emailing irb-monitors@uiowa.edu.

HawkIRB Hints: Best Kept Secret

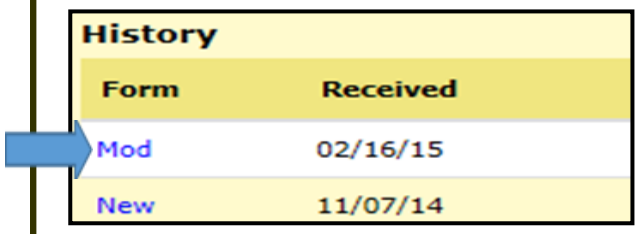


It's no secret the HawkIRB application covers a lot of ground, from research questions to data analysis, and all the details in between—PIs are expected to describe every aspect of a project. The project application isn't just large, it's densely detailed. Each section builds on the previous section, expanding and elaborating item particulars. When it comes time to alter a project, (by submitting a modification for review and approval) remembering exactly where a detail is included in the application can be a daunting task, especially if it's mentioned in multiple locations. Finding specific details in an application can feel like searching for a needle in a haystack. *'Edit / Find' is your metaphorical magnet, a tool that helps you sort through the information and takes you directly to the item(s) you are searching for!*

1. From the HawkIRB inbox, click the project ID number



2. This takes you to the Project Summary page with a brief overview of project details, and a history of the project in the lower section.



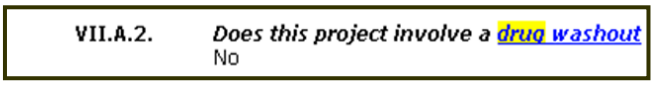
3. Click the form you are looking for—this will vary. You may see 'New, Mod, Mod/CR,' etc.

4. Now, look on the upper, left side of your screen!

5. When you click on this 'Printer Friendly Version' link, a new tab will open that includes all sections and attachments associated with the Form you chose. Just scroll up and down to see it all.

6. The keyboard combination "Ctrl + F" will open a small window; it displays differently depending on your browser, Chrome, Firefox, etc. (The example below is Chrome.)

7. Using the arrow keys on your keyboard will systematically highlight each instance of your term throughout the application, For example:



As always, call us if you have questions: 319-335-6564!

NEWS FLASH!

AAHRPP Reaccreditation Achieved!!

The University of Iowa's Human Research Protection Program has received Full Accreditation status from the Association for the Accreditation of Human Research Protection Programs (AAHRPP) for the 4th time! The five-year accreditation demonstrates the entire research community's commitment to sound and ethical human subjects research.

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]

Content edited by Therese Barenz