

Human Subjects Research in the News:

[Crowdsourcing medical decisions: Ethicists worry Josh Hardy case may set bad precedent](#)

Health, Science & Environment, March 23, 2014

[Is It Good For Kids To Have A Pet?](#)

Jason G. Goldman
April 17, 2014

[Here's Why The FDA Is Regulating E-Cigarettes](#)

Popular Science
April 24, 2014

[Not Just for Sex: Why the Y Chromosome Hasn't Vanished](#)

LiveScience, April 23, 2014

[How Does IQ Relate to Personality?](#)

Scott Barry Kaufman
April 21, 2014

HAWKIRB

Upcoming Training Sessions

[How to Complete a New Project Application](#)

June 12, 2014: 1:30-4:00PM
Hardin Information Commons
EAST

[After IRB Approval...](#)

June 20, 2014: 10:00-11:30AM
HP Smith Conference Room
(W256 GH)

[HSO Office Hours
Summer 2014](#)

Wednesdays 2-4PM
101 Hardin Library

No appointment necessary

A More Flexible IRB on the Horizon

A nationwide effort of human research protection programs to streamline IRB review processes, improve efficiency and quality, and reduce regulatory burden led to the creation of [The Flexibility Coalition](#) in 2011. This organization consists of over 50 research organizations, including the University of Iowa, (UI) and the [Association for the Accreditation of Human Research Protection Programs](#) (AAHRPP). The Coalition's goals are to identify additional areas of flexibility that research institutions can implement while remaining compliant with federal regulations and without reducing the protection of human subjects.

Efforts to identify and implement flexible IRB policies stem largely from the ability of institutions to "uncheck the box" on their [Federalwide Assurance](#) (FWA). "Unchecking the box" means the institution has elected not to extend all the requirements of the federal regulations to unfunded and non-federally funded projects. This limits the scope of the FWA, and thus HHS oversight, to federally funded research. Unfunded or non-federally funded research projects have

the same requirements for the protection of human subjects, but the unchecked box gives an institution more flexibility in how it oversees these studies.

While the UI unchecked the box on its FWA a decade ago, current UI IRB policy requires the IRB to apply the federal regulations to all human subjects research, regardless of the funding source.



Utilizing existing flexibility in the regulations has allowed the UI IRB to:

- Actively work with investigators to identify new and ongoing projects that are eligible for exempt status. In the last six months (October 2013-March 2014) there was a 35% increase in exempt determinations under IRB-02.

- Approve waivers of documentation of consent, even for minimal risk studies that involve face-to-face contact with subjects.
- Implement the [Course-Related Student Project Policy](#). Under this policy, projects conducted as a course requirement are excused from IRB review and approval if they meet eight criteria outlined in the policy.
- Continue to utilize a Chair designee to approve research that qualifies for expedited review. Four HSO staff members serve as IRB Chair designees and have authority to approve a range of modifications.
- Use college- or department-level IRB liaisons. The UI has identified four departmental liaisons from the College of Business, College of Education, and the VA Health Care System. The roles and responsibilities vary, but all are available to assist investigators with the IRB application and review process. Efforts are underway to expand the IRB liaison program.



Tips to Protect and Secure Information When Using Mobile Devices

While the Department of Health and Human Services (DHHS) provides these [tips](#) to protect the health information of patients, investigators can apply the same measures when using portable or mobile devices in their research. We've listed a few below.

1. Install and enable encryption.
2. Install and activate remote wiping &/or remote disabling to erase the data on your device if it is lost or stolen.
3. Disable and do not install or use file sharing applications.
4. Install and enable a firewall.
5. Install and enable security software.
6. Keep your security software up-to-date.
7. Research mobile applications (apps) before downloading.
8. Use adequate security to send or receive health information over public Wi-Fi networks.



NEWS FLASH!

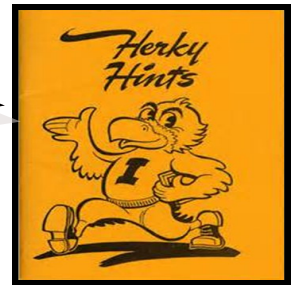
Relocation of the Conflict of Interest in Research Program

Since the majority of the financial conflicts of interest at the University of Iowa involve aspects of human subjects research, the Conflict of Interest in Research Program will be moving its operations to co-locate with the Human Subjects Office.

The purpose of this realignment is to foster synergy and build a stronger partnership with the HSO/IRB. Martha Hedberg, Conflict of Interest in Research Coordinator, will be relocating the COIR program office from the Office of the Vice President for Research suite in University Capitol Center to HSO's suite in the Hardin Library for the Health Sciences the week of June 9th.

Martha's contact information will remain the same. Questions should be directed to martha-hedberg@uiowa.edu or (319) 384-4256.

Need help with
HawkIRB?



The Assurance Document is one of the final pieces of your HawkIRB application – it is uploaded into the last category you will find on the Attachment Page. Arguably the most important attachment, it includes a list of commitments the Principal Investigator (PI) agrees to abide by for the course of the study; essentially, it is an agreement to conduct ethical research in accordance with federal regulations and UI policies. There are a few common mistakes researchers make when submitting this document.

Signatures

The Principal Investigator must sign the document—and it must be an authentic signature. The Human Subjects Office cannot accept electronic signatures, and cutting and pasting in a signature image might be convenient, but it's convenient forgery (not generally advised). The Departmental Executive Officer (DEO or Department Chair) also must sign the assurance document, confirming that the PI has the experience and resources to conduct the research. If a PI is classified as both "Faculty/Staff and Student" in UI human resources records, the HawkIRB application will be returned with a workflow question, requesting clarification.

Editing

If a new investigator is assuming PI oversight, the Assurance Document must be updated - in addition to the HawkIRB application. Follow the steps in this order:

1. Modify Section II of the HawkIRB application.
2. From the "Consent Forms & Other Attachments" page, generate a new Assurance Document. HawkIRB will automatically update the new assurance document with the new PI name.

Assurance Document Attachment

i You must attach a SIGNED Assurance Document before submitting your application. Follow the steps below:

1. Click on the button to "Generate Assurance Document"
2. Print the page
3. Obtain ALL necessary signatures
4. After all signatures are obtained, scan the document and attach it in this Assurance Document Attachment section

[Generate Assurance Document](#)



3. After all required signatures are in place, use the "EDIT" link (below) to add the new version.

| Attachment Name | Category | Ver | Size | Attached |
|--|--------------------|-----|--------|--|
| Assurance Document.pdf | Assurance Document | 1 | 89 k E | 10/23/13 delete EDIT |



You don't have to worry about removing the previous version—HawkIRB will add the updated copy 'on top' of the previous version. This is true for all attachments in HawkIRB, not just the Assurance Document. It is a feature that helps track modifications as projects evolve.

Have a question or concern about how HawkIRB works? Let me know, and I'll try to address it in Herky Hints. Email sarah-heady@uiowa.edu, or give me a call at 319-384-1736.

Human Subjects Office

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Herky Hints cover, new student orientation manual, 1959 [Subject Vertical File Collection (RG 01.15.03), Miscellaneous category, folder "Freshman orientation," University Archives, Department of Special Collections, University of Iowa Libraries]