

Human Subjects Research in the News:

[Researcher Charged in HIV Vaccine Fraud Case](#)
NBC News, June 24, 2014

[Bionic pancreas controls blood sugar levels in adults, adolescents with type 1 diabetes](#)
Science Daily, June 16, 2014

[What Does Mindfulness Meditation Do to Your Brain?](#)
Tom Ireland, June 12, 2014

[Study: People Who Over-share on Facebook Just Want to Belong](#)
The Atlantic, June 16, 2014

[Having authoritarian parents increases risk of drug use in adolescents, European study finds](#)
Science Daily, June 11, 2014

[What's Lost as Handwriting Fades](#)
NYT, June 2, 2014



Upcoming Training Sessions

How to Complete a New Project Application

July 11, 2014: 9:00-11:30AM
Hardin Information Commons EAST

After IRB Approval...

July 24, 2014: 2:00-3:30PM
HP Smith Conference Room (W256 GH)

HSO Office Hours Summer 2014

Wednesdays 2-4PM
101 Hardin Library

No appointment necessary

Research Misconduct, Prevention Strategies and More

Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. The [Department of Health and Human Services](#) (HHS) has numerous offices responsible for handling misconduct of the research process. Each of these offices has a different role.

The [Office for Human Research Protections](#) (OHRP) responds to allegations of noncompliance with HHS regulations at [45 CFR 46](#) for research supported by Public Health Service (PHS), among others. Indications of research misconduct regulated by the [Food and Drug Administration](#) (FDA) are generally



investigated by the Office of Regulatory Affairs, Bioresearch Monitoring Program.

The [Office of Research Integrity](#) (ORI) handles accusations of misconduct as defined in the Code of Federal Regulations at [42 CFR 93.103](#), that involves research supported by the PHS.

ORI's 'Research Misconduct' section provides an overview of the process for responding to allegations of research misconduct as well as:

- [Prevention Techniques for Researchers](#)
- [Guidelines for avoiding plagiarism, self-plagiarism, and questionable writing practices](#)
- [ORI Responses to Issues Arising from Inquiries and Investigations](#)

For a recent case of research misconduct in Iowa, see the first article in the gold sidebar to the left. To learn more about regulations related to research misconduct, see [42 CFR 93](#).

Changes in IRB Determinations for Studies that Access Protected Health Information for Recruitment

IRB-01 and IRB-03 have revised the review process for studies requesting the use of Protected Health Information (PHI) for recruitment purposes (i.e., reviewing medical information/clinic records to identify potential subjects or any information available to the researchers or their colleagues because the subjects are their patients). However for researchers, no changes are required in the HawkIRB application process as long as HawkIRB Sections VII.D.2-VII.D.7 are thoroughly addressed and provide the IRB with adequate information to apply the regulatory criteria for a Partial Waiver of HIPAA Authorization under [45 CFR 164.512 \(j\)\(1\)\(i\)](#) AND a limited Waiver of Consent for recruitment under [45CFR 46.116 \(d\)](#). A partial HIPAA waiver is a regulatory determination allowing investigators to access a limited amount of PHI related to eligibility prior to consent, in order to identify patients as potential research subjects. If the responses provided in the HawkIRB application satisfactorily address these criteria, the IRB can determine that the waiver that allows the use of PHI to identify potential subjects will not adversely affect the rights and welfare of the subjects. A limited waiver of consent for recruitment will also now be granted. Both of these waivers allow limited access to PHI for the identification of potential research subjects. We are making this change primarily to meet VA requirements. IRB Meeting Minutes, when applicable, the Project Approval tab and a Partial HIPAA Waiver memo issued upon IRB approval will document these determinations.

DID YOU KNOW ?

The Human Subjects Office (HSO) staff are available to give presentations on a variety of topics related to human subjects research.

These presentations provide information on topics of interest to principal investigators, study coordinators, research team members and the University of Iowa research community.

Additionally, classroom presentations can be designed to meet the needs of the students and cover a variety of topics. For more information, visit the [HSO website](#).

Need help with HawkIRB?

Who Should be a Research Team Member?



Principal Investigators (PI)

Deciding on the Principal Investigator is the easy part, as least as far as the HawkIRB application goes. It's like [Highlander](#): there can be only one. Yes, many research projects are collaborative, and might have co-investigators, multiple authors on articles, and that sort of thing, but one person has to accept ultimate responsibility for the project; that's the individual listed as the PI in the HawkIRB application, the person who signs the Assurance Document agreeing to adhere to federal, state, and university regulations.

Research Team Members (RTM)

If PIs are the Highlander, research team members are more an [Avengers](#)-style ensemble, with different roles and talents. Defining some members of the research team is clear-cut: If someone will interact with research subjects directly—recruiting, consenting, answering questions about the research project procedures or aims—that person is definitely a research team member. It's less clear, however, if an individual will be conducting statistical or data analysis—they will never interact with research participants. You may need to include them as part of the team in HawkIRB; it depends on the status of the data. If you will be sharing identified or coded data with others, they should be included in your research team, even if they will never ever interact with a human subject.

The exception that proves the rule

Every rule has exceptions—if a potential non-UI research team member is an employee, staff, student, or faculty member at another institution, *do not* add them to your UI research team. Personnel not affiliated with the UI should obtain approval from their institutions, and send you documentation of IRB approval. Before adding non-UI personnel to your research team, call the HSO at 335-6564 to discuss your situation ([Investigator's Guide pg. 47](#)). If instructed, you should then attach the project approval to your UI HawkIRB application, and describe the non-UI research team members' roles throughout the application.

Why does this matter?

The HSO's research team member policy is rooted in the [Belmont Report](#) (the foundation document for modern human subjects protections in the USA) principles of "[respect for persons](#)" and "[beneficence](#)." Respect for persons states that individuals get to make their own decisions, and this includes deciding who has access to one's personal information. Beneficence obligates researchers to consider minimizing harms, including preserving a subject's privacy and confidentiality of data. When you add people to your research team, the IRB makes sure team members have adequate training in human subjects protections, and checks for potential [conflicts of interest in research](#). You could think of the research team section of Hawk-IRB as your [superhero cape-check](#)—the IRB is protecting research participants, **and** making sure you're covered.

Try Your Hand at Being an IRB Chair

In March 2014, the [Office for Human Research Protections](#) (OHRP) and [The Office of Research Integrity](#) (ORI) released a web-based, interactive training video entitled, [The Research Clinic](#), that is designed to educate clinical and social researchers on protecting subjects and avoiding research misconduct. The video presents four characters and allows the viewer to assume the role of each of the characters: a Principal Investigator, a clinical research coordinator, a research assistant and an IRB Chair. The viewer is presented with various scenarios, must decide between different courses of actions, and thereby, determines the outcome to the story. Following decisions points, the viewer has the option of reading more about regulations and/or guidance pertinent to the that topic.

Previously, ORI released a similar video entitled [The Lab: Avoiding Research Misconduct](#). Focused on biomedical research, this video has been incorporated into training programs at various research institutions. Don a new hat and test your knowledge of regulations and guidance from another researcher's perspective!



Human Subjects Office

Office of the Vice President for Research
and Economic Development
105 Hardin Library for the Health
Sciences

600 Newton Rd.
Iowa City, IA 52242-1098

Phone: (319) 335-6564

Fax: (319) 335-7310

E-mail: irb@uiowa.edu

hso.research.uiowa.edu

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]