THE UNIVERSITY OF IOWA

IRB Connection

HUMAN SUBJECTS OFFICE

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Additional Requirements for Department of Defense Research

Investigators who conduct human subjects research sponsored by the Department of Defense (DoD) should be aware of additional requirements when planning their research projects. Research conducted or supported by the DoD, including its separate components (i.e., the Army, Navy, Air Force and Marine Corps), requires compliance with additional federal regulations, directives and instructions. The DoD has adopted 32 CFR 219, a version of the Common Rule that mirrors 45 CFR 46. The *Department of Defense Instruction* 3216.02 (DoDI 3216.02) establishes policy and assigns responsibilities for protecting human subjects in DoD-supported research. The Principal Investigator (PI), IRB and institution involved in DoD research must be knowledgeable about these obligations in order to adhere to them. UI investigators conducting DoD sponsored research should also expect to meet with an IRB Education and Compliance Specialist to discuss and document DoD compliance. Investigators are encouraged to work closely with their DoD component contact to insure all the necessary information and documentation is obtained for the UI IRB review process.

Additional requirements for DoD-sponsored research

Requirements include but are not limited to the following:

- Specific training (Department of the Navy (DON))
- The assignment of a research monitor (for studies determined to be greater than minimal risk by the IRB)
- Unique limitations on waivers of informed consent
- DoD approval of surveys or interview questions administered to DoD personnel and their families
- DoD component review, approval and oversight of the study
- Additional protections for vulnerable subject populations
- Additional considerations for the recruitment of military and DoD personnel (specifically recruitment in a group setting)

Where is this "CITI" of which you speak, and what does it have to do with me?

That would be the '**C**ollaborative **I**nstitutional **T**raining **I**nitiative' at the University of Miami—found online anywhere, anytime on the HSO website.

What is CITI?

CITI is a collection of online courses, used to provide a foundation in the history and ethics of human subjects research. You'll review the basics of ethical oversight, and develop an understanding of why IRBs exist, and why human subjects require protection. The courses required by the UI take between 90 minutes and three hours to complete, but you don't have to complete everything in a single sitting. And the UI certification does not expire so you only have to complete the courses once. CITI also offers refresher courses—occasionally sponsors or external funding agencies may require these refreshers. Not to be confused with the UI IRB's human subject protections training via CITI, the University of Iowa's Responsible Conduct of Research (RCR) program also requires undergraduates and professional-degree students who are supported by select federal grants to complete RCR training via CITI. Visit their website for more information.

Why Do I Need to Complete CITI Courses?

During the 1960s-70s, the U.S. government took a proactive role in strengthening regulations for the protection of human research subjects. This was largely in response to revelations of unethical research and abuse (e.g. Human experimentation conducted by the Nazis, the publication of Henry K. Beecher's article, and research conducted by the U.S. Public Health Service). There's also the important matter of the eternal balancing act between advancing scientific understanding and protecting the individuals who participate in the project that lead to those advances.

When Should I Take CITI Training?

Before you submit your research project application in HawkIRB, before you begin research procedures, and before you leave the country to interview subjects in Tibet. It takes 24-48 hours for UI databases to be updated and without a valid certification date, HawkIRB will not accept your application submission.

How Do I Complete CITI Training?

Links and instructions can be found by clicking on the **CITI Program** icon located on the HSO website here.
We're here to help, so call us if you have questions!

- Sarah Heady
IRB Education and Compliance Specialist

Human Subjects Research in the News:

Secrets From Belfast
The Chronicle of Higher Education
January 26, 2014

Give the Data to the People
NYT, The Opinion Page
February 2, 2014

Vast Study Casts Doubts on Value of Mammograms
NYT, February 11, 2014

NIH Makes Wary Return to India
Nature
February 11, 2014

Review: "Please Continue"
The Scientist
February 11, 2014

Cat Bites are Linked to Depression
Popular Science
February 19, 2014

Brain Scans Show Striking Similarities Between Dogs and Humans
Wired Science
February 20, 2014

HAWKIRB

Upcoming Training Sessions

After IRB Approval...
March 13, 2014: 9:30-11AM
HP Smith Conference Room
(W256 GH)

Federal Regulations Subpart Spectacular
March 31, 2014: 2-3PM
HP Smith Conference Room
(W256 GH)

How to Complete a New Project Application
April 8, 2014: 1-3PM
Hardin Information Commons EAST

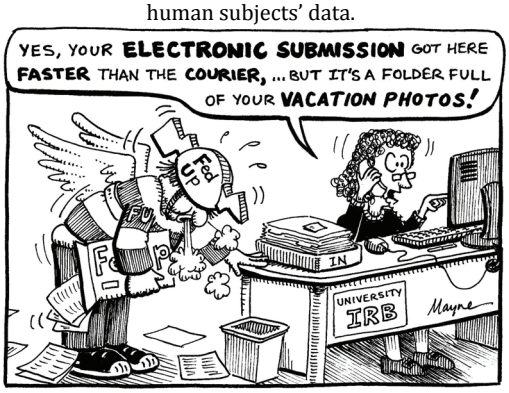
HSO Office Hours
Wednesdays 2-4PM and Thursdays 10-12PM in 101 Hardin Library

Mondays10-12pm in N186 Lindquist Center

No appointment necessary

Spring Break Reminder

Spring break is just around the corner! Many investigators (especially student investigators) use the break as an opportunity to conduct research outside the state or the country. If you intend to use your spring break for this purpose, be sure that you have already submitted your HawkIRB application and received IRB approval or submitted a Human Subjects Research Determination (HSRD) form and received a "not human subjects research" determination from an IRB Chair before you travel to collect human subjects' data.



IRB Policy ~~Reminder~~ Revision

Revised Guidelines Regarding Research Payment and Compensation

Effective January 21, 2014 the requirement to collect Social Security Numbers (SSN) from research subjects for compensation purposes is increasing from any form of monetary compensation greater than $25.00 to greater than $75.00. If your research team provides compensation to subjects in amounts of $75 or less at one time or less than $600 in a calendar year, you no longer need to collect SSN to provide compensation to research subjects. This policy change does not apply to studies conducted at the Veterans Administration Healthcare System. VA researchers should refer to VAHCS policy. In order to adhere to record keeping requirements of the State of Iowa, grantor agencies, and the Internal Revenue Service, researchers will be required to submit a completed substitute W-9 form to Accounts Payable for all research subjects receiving compensation for any amount over $75.00. For investigators who have already begun submitting substitute W-9 forms to Accounts Payable, please note the form was recently updated to add a contact person. **The Research Participant/Substitute W-9 Form should <u>not</u> be attached to the HawkIRB application.** The IRB is requiring that all projects update their HawkIRB application to adhere to these new changes. If this policy change applies to your study, please submit a Modification to update the Informed Consent Document and applicable sections of the HawkIRB application pertaining to the collection and storage of SSN. Read the new Research Subject Payment and Compensation FAQ here. Read the Guidelines for Research Payment and Compensation here.

What's that Mean?: Certified IRB Professional

CIP CERTIFIED IRB PROFESSIONAL

PRIM&R PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

If you have ever corresponded with HSO staff or searched for a staff member's contact information on the HSO website, you may have noticed the acronym "CIP" after their name. Nine HSO staff members are currently Certified IRB Professionals (CIP). The CIP certification program was developed in 1999 by Public Responsibility in Medicine and Research (PRIM&R) to promote standards for professional knowledge and to support adherence to regulatory requirements, best practices, and ethical conduct for the protection of human subjects in research. To obtain certification, applicants must have a Bachelor's degree plus two years of relevant human research protection program (HRPP) experience or three years of relevant HRPP experience. Currently, there are over 2,000 people who have attained certification. Certification is valid for three years, and can be renewed via re-examination or with continuing education credits twice in a nine-year period. Certification for IRB professionals is highly valued and provides formal recognition of an individual's knowledge of IRB functions and human research protection programs.

Human Subjects Office

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