

Human Subjects Research in the News:

I had my DNA Picture Taken, With Varying Results

NYT, December 30, 2013

Improved Regulations to Protect Human Research Subjects Would Better Protecting Study Participants

Science Daily
January 9, 2014

Teen Concussions Increase Risk for Depression

Science Daily
January 9, 2014

The 16 and Pregnant Paradox: Warning or Endorsement?

The Atlantic
January 13, 2014

Rare Diseases-In Honor of Sam Berns

Judy Stone
January 14, 2014

HAWKIRB

Upcoming Training Sessions

How to Complete a New Project Application

March 12, 2014: 1-3:30PM
Hardin Information Commons
EAST

After IRB Approval...

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

HSO Office Hours

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

Mondays 10-12pm in
N186 Lindquist Center

No appointment necessary

New Compliance Monitoring Programs Coming to a Study Near You

The term “compliance monitoring” may sound a bit scary but really is one component of a larger outreach and educational program that aims to establish relationships with investigators and protect research participants. The [IRB Education and Compliance Program](#) works to educate University of Iowa researchers and the IRB, while also promoting the [UI Human Research Protection Program’s \(HRPP\)](#) commitment to ensuring research compliance. Currently, IRB Education and Compliance Program staff primarily conduct post-approval monitoring and education visits with

investigators of the following:

- 1) Studies selected among all IRB-approved biomedical and social/behavioral projects
- 2) All IRB-approved studies in which an [Investigational New Drug \(IND\) application](#) is held by a UI investigator
- 3) All IRB-approved studies receiving [Department of Defense \(DoD\)](#) funding

Beginning in 2014, the IRB Education and Compliance Program will be launching additional monitoring activities described in the table below. These new activities as well as changes made to existing programs, are the result of

investigator feedback and an effort to place more emphasis on best practices across studies over time and less emphasis on single studies or events.



New Program	Goals	What to Expect
Faculty Advisor/ Student PI Monitoring	<ul style="list-style-type: none"> • Offer individual education and help to student investigators and their Faculty Advisors • Answer questions about the IRB and/or the review process • Address potential concerns or problems before they occur • Provide guidance on Principal Investigator (PI) and Faculty Advisor responsibilities • Establish long term connections with faculty members advising student investigators 	<ul style="list-style-type: none"> • Starts with an online Qualtrics survey sent to the student PI and their Faculty Advisor • The survey will provide information about and document acknowledgment of PI and advisor responsibilities • Establishes a connection between the student PI, Faculty Advisor and an IRB/HSO contact • Unless there are issues or concerns noted in survey responses, or the PI/Faculty Advisor requests an in-person meeting, this monitoring program will not typically involve an in-person component (i.e. no face-to-face meeting with an IRB Education and Compliance Specialist)
Closed to Accrual Monitoring	<ul style="list-style-type: none"> • Close HawkIRB applications that are inactive and not enrolling subjects • Reduce investigator burden <ul style="list-style-type: none"> • Report less information • Fewer applications to keep up on • Start clock on record retention requirements so there are fewer documents to keep • Reduce IRB burden <ul style="list-style-type: none"> • Less information to review • Fewer active applications in HawkIRB 	<ul style="list-style-type: none"> • Targeted e-mails to investigators and their HawkIRB contacts • Directed education for investigators via the newsletter, distribution of fliers and posters, and information provided on the HSO website • Disseminate information on “closed to accrual” verses a “closed study”
Department of Defense (DoD)-Sponsored Research Monitoring	<ul style="list-style-type: none"> • Deliver investigator education on additional DoD regulatory requirements • Document PI and IRB compliance with DoD and DoD component (Army, Navy, Air Force and Marine Corps) regulations, directives and instructions 	<ul style="list-style-type: none"> • All investigators with DoD-sponsored research projects should expect at least one in-person monitoring and education visit with an IRB Education and Compliance Specialist • For investigators with multiple DoD-sponsored projects, rather than holding in-person visits for each project, PIs should expect to receive a Qualtrics survey and assurance materials to complete and return to the IRB Education and Compliance Specialist to document compliance

NEWS FLASH!

New Hours of Operation

Effective February 3, 2014, the HSO will be changing its business hours. HSO staff are available by phone, e-mail, or in-person to answer your questions 8AM-4:30PM Monday-Friday. If you're not sure who to contact, please use the main HSO phone number (319) 335-6564 or send us an e-mail at irb@uiowa.edu.

Please note, HSO staff are not available to answer the main number between 12-12:30PM daily. All voicemails received during this half hour will be returned after 12:30PM.

The HSO staff and IRB chairs are here to assist you. Please don't hesitate to contact us with your questions!

IRB Policy ~~Reminder~~ Revision



Inclusion of Compensation Amount in Recruitment Materials

Readers may recall the IRB Policy Reminder for [June 2013](#) which explained that investigators should not include compensation amounts in their study's recruitment materials (e.g. compensation amount displayed on a recruitment poster). While there are some IRB policies that are not specified in the [code of federal regulations](#), IRBs often rely on guidance documents provided by federal regulatory agencies in the interpretation of regulations and the development of policies. In September 2013, one such agency, the Office for Human Research Protections (OHRP) [revised its response to the Frequently Asked Question \(FAQ\) "When does compensating subjects undermine informed consent or parental permission?"](#) The previous version of the response

stated "In no case should remuneration (payment) be viewed as a way of offsetting risks; that is, it should not be considered a benefit to be weighed against study risks. The level of remuneration should not be so high as to cause a prospective subject to accept risks that he or she would not accept in the absence of the remuneration." In the September revision, the first sentence was struck from the response. However, OHRP still asserts that IRBs should not consider remuneration as a way of offsetting risks. The response was changed to clarify that payment to subjects may include compensation for risks associated with their participation in research and that compensation may be an acceptable motive for some individuals agreeing to participate in research. Under the old guidance, the IRB inferred that

OHRP considered any degree to which compensation was based on research risks unacceptable, and therefore, not appropriate to include in recruitment materials. In light of this change, the UI IRB has revised its policy on the inclusion of compensation amounts in recruitment materials. It is acceptable to include the compensation amount in recruitment materials. However, study materials should not over emphasize the amount of compensation for participation. This policy applies to recruitment materials such as posters or flyers, mass mail or e-mail messages, or newspaper, radio or television advertisements, etc. that provide information about a research study. Read the revised policy [here](#).

IRB Policy Reminder of the Month

Cold-Calling of Potential Subjects as a Recruitment Method



The IRB strongly discourages "cold-calling" potential research subjects. Cold-calling occurs when investigators, who are unknown to potential participants, make contact based on their prior knowledge of private information (e.g. medical or education records). Cold-calling is strongly discouraged because contacting individuals for research based on access to confidential information is a violation of privacy. Investigators who contact potential subjects based on direct access to private information such as name,

address, and phone number may offend potential subjects, especially in research on sensitive topics. The UI IRB does allow the use of random-digit dialing for telephone surveys or polling. This sampling method is acceptable because it uses publicly available information. This method is widely used for statistical surveys, including opinion polling. Random-digit dialing differs from cold-calling in that the call is initiated based on publicly available information rather than prior knowledge of private information. For investigators conducting research at the VA, VAHCS policy [strictly prohibits](#) cold-calling. VA researchers are required to make initial contact with potential subjects either in person and/or by letter prior to any telephone contact. Read the UI IRB policy [here](#).

*Ethics is nothing else than
reverence for life.*

~ Albert Schweitzer

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