

Human Subjects Research in the News:

Guidance Issued for US Internet Research
Nature, April 24, 2013

NIH Stops HIV Vaccine Trial After Immunizations Fail
Emily Mullin, April 26, 2013

Catch-22, Clinical Trial Edition: The Double Bind for Women and Children
Hilda Bastian, April 23, 2013

Neuroscientists Brainstorm Goals for US Brain-Mapping Initiative
Helen Shen, May 6, 2013

Privacy Protections: The Genome Hacker
Nature, May 8, 2013

HAWKIRB

Upcoming Training Sessions

After IRB Approval ...

June 21, 2013
10:30AM-12PM
Braley Auditorium
(01136 PFP)

HSO Office Hours Summer 2013

Wednesdays, 2-4PM
101 Hardin Library
No appointment necessary.

Greetings From the HSO: Mainline Questions

If you have called the HSO, you have likely talked with me. I answer and respond to calls to the HSO main office line along with two of my colleagues, Kelli Wallace and Kathy Beck and our valuable students. The mainline is the first place to start if you have general questions—at the least, we can help you determine which expert you should talk with. In upcoming editions, I'll be using this newsletter space to respond to your questions and discuss some of the frontline

issues people ask about; please call the HSO mainline (319-335-6564) or submit questions directly to me at sarah-heady@uiowa.edu,



or the IRB inbox at irb@uiowa.edu. No questions are too basic, *How do I login to*

HawkIRB? or too obscure, *Who or What is the IRB?* If I don't know the answer, you will be giving me an opportunity to learn more—and we all know our supervisors appreciate staff self-education. Please speak up with questions about the HSO, the IRB, federal regulations, or why we use so many acronyms. (Check out our new acronym glossary [here](#).)

-Sarah Heady
IRB Assistant

New FDA Final Rule: Additional Safeguards for Children in Clinical Investigations

Effective March 28, 2013, the FDA amended its pediatric research regulations. The final rule provides additional protections for children enrolled in clinical investigations and harmonizes FDA regulations with the [Children's Health Care Act of 2000](#). The FDA also provides an updated interpretation of requirements for placebo-controlled studies involving children. According to the final rule, the FDA does not consider

the administration of a placebo to offer a prospect of direct benefit. Therefore, the placebo arm of a study does not meet the requirements under [21 CFR 50.52](#) of Subpart D, which allows research that offers the possibility of direct benefit to subjects even if it poses risks that are more than minimal. For University of Iowa researchers, this revision may have implications for IRB determinations related to whether one or both parents

should provide written consent for their child's participation in FDA-regulated research. The rule made additional revisions to definitions for "guardian" and "permission" to make them more consistent with [Department of Health and Human Service \(HHS\) regulations](#) and clarifies that the exception for emergency research applies to research involving children. Read the final rule [here](#).

NEWS FLASH!

There is a new online registration process for attending HawkIRB training sessions and presentations.

Attendees are asked to pre-register electronically.

Sign-up on the Human Subjects Office website or [here](#).

If you are unable to attend an in-person session, recordings of the HawkIRB training sessions are also posted in Unit 2 of our [IRB ICON Course](#).

IRB Policy Reminder of the Month

Including the Compensation Amount in Recruitment Materials

Recruitment materials that are the initial presentation of information about a research study to potential subjects should not include the amount of compensation for participation. Recruitment materials include posters or flyers, mass mail or e-mail messages, newspaper, radio, or television advertisements that provide information about a study. When the compensation amount is included in recruitment materials, the payment or the dollar amount must not

be emphasized. For print or web-based materials, that means not emphasizing the amount in large or bold type or with any graphic design element (such as dollar signs).



Recruitment materials should not emphasize payment

For verbal recruitment efforts (in-person or over the phone), the compensation amount must not be used as a promotional or "selling" point to encourage individuals to participate in

the study. Recruitment materials may state, "You will be paid for your time and effort," or include the phrases "compensation available," or "compensation provided." If the researcher has had previous contact with potential subjects in the context of prior research, a proposal to include the compensation amount in recruitment letters, e-mail messages or telephone scripts may be included in the description of recruitment procedures in Section VII.D.29 and/or VII.D.30 of the HawkIRB application.

Get to Know.....

The IRB Education and Compliance Program Staff

The IRB Education and Compliance Program staff is charged with providing tools and guidance to the University of Iowa research community to ensure research is conducted according to UI policies and federal regulations for the protection of human subjects. The Program's primary focus is investigator/research team outreach and education. Contact any member of the [Education and Compliance Program](#) if you have questions about regulatory requirements, UI IRB policies, or educational opportunities related to human subjects research at the University of Iowa. Contact the Program's Manager, Anne Alberhasky (anne-alberhasky@uiowa.edu), directly regarding issues related to human subjects research compliance or for more information about the Education and Compliance Program.



Left to right, bottom row: Anne Alberhasky & Kelly O'Berry
Top row: Therese Barenz, Heather Herman, & Cena Jones-Bitterman

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