

Human Subjects Research in the News:

New Studies Show Promise for Brain Training in Improving Fluid Intelligence
The Atlantic, April 7, 2014

Social Circuits That Track How We Like People, Ideas
Science Daily
April 7, 2014

Top US Scientific Misconduct Official Quits in Frustration With Bureaucracy
Science Insider
March 12, 2014

Ethical Quandaries Raised by Cluster Randomized Trials
Ruth Macklin, Ph.D.
March 21, 2013

"Big Data" and a Dose of Common Sense
Mimi Kim, Sc.D.
February 4, 2014

HAWKIRB

Upcoming Training Sessions

After IRB Approval...
May 12, 2014: 10-11:30AM
HP Smith Conference Room
(W256 GH)

Spring Office Hours
Held through May 29th

Mondays 10-12PM in
N186 Lindquist Center

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

Summer 2014 Office Hours
Begin June 4th

Wednesdays 2-4PM
101 Hardin Library

IRB Review of Qualitative Research – Just Jumping Through the Hoops?

While federal regulations for the protection of human subjects focus largely on quantitative research in the biomedical sciences, it follows that many of the regulations are a poor fit for the circumstances of qualitative research. As a result, many researchers whose projects involve qualitative aspects express frustration "getting their project through the IRB review process". The IRB is not concerned with whether the research is qualitative or quantitative, or in the biomedical or social science realm; their focus is on the nature of the interventions or interactions and the characteristics of the subjects in a given study. Regardless of the research methods, the IRB is charged with applying certain regulatory criteria, located at 45 CFR 46.111, to all non-exempt human subjects research, and ensuring that investigators conduct ethical research and minimize risk to subjects. By addressing the following ethical issues in the HawkIRB application, the Principal Investigator (PI) can facilitate a smooth review process and reduce the feeling that s/he is just jumping through the hoops to get the project approved!

Informed Consent – Investigators must recognize that participants are autonomous individuals who will often share information willingly. Mere ac-

cess to information or behavior is not justification for collecting data without consent from subjects. Unless research meets the regulatory criteria for a waiver of consent (at 45CFR46.116(d)), informed consent must be sought and documented. Section VII.D.29 must describe a consent process that fully explains possible risks associated with research participation.



Privacy and Confidentiality – Qualitative researchers often keep detailed interview notes, audio or videotapes and photographs; and typically hope to publish or disseminate results. If identities are poorly disguised or proper care is not taken by the researcher to protect the confidentiality of the data, subjects can risk embarrassment or more serious harms. An example of such harm stemming from a breach of confidentiality can be found in Vidich and Benman's book, *Small Town in Mass Society*.

Section X must explain specific details of record storage, transport and destruction. If the data will be transcribed, a description of the person who will transcribe must be included. If s/he is a non-research team member, documented agreements demonstrating measures to protect subject confidentiality must be included on the Attachment page.

Data generation and analysis – A description of the possible risks to subjects resulting from data generation and analysis and plans for minimizing risks associated with publication of the data or final outcomes must be described. This is especially important if the subject population is vulnerable or if the research topic is of a sensitive nature and the subjects can be readily identified.

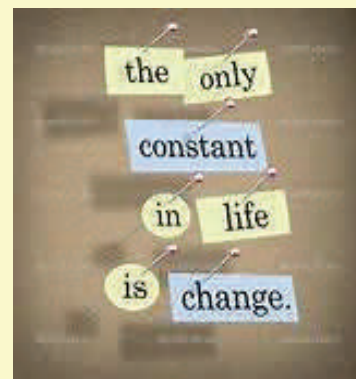
Researcher/participant relationships – Investigators seeking to develop a non-judgmental relationship with their subjects in order to earn the trust and participation of the groups or communities they want to study may inadvertently validate inappropriate behaviors. Section VIII.1 must explain possible risks that result from researcher's effort to establish a rapport with subjects and VIII.2 must outline plans to minimize these risks, and address unique ethical concerns regarding trust and disclosure.

A Change in Your Summer Plans? - Let us Know!

As summer rolls around, some research team members will leave the University of Iowa to embark on new adventures. If this applies to your study, you must notify the IRB. As with any change in the IRB-approved research plans, revising the research team requires the submission of a HawkIRB Modification Form and approval by the IRB, prior to implementation of the change. The research team member change section is readily found on the 'Frequent Mods' tab on a HawkIRB Modification Form.

You must also update any attachments affected by the change, e.g., the Informed Consent Document. If the Principal Investigator (PI) is the individual leaving, the new PI must complete an Assurance Document and obtain the signature of the Department Chair. Follow the 'To edit a current attachment' instructions on the Attachment Changes Tab to upload it 'on top' of the previous assurance document. As PI, if you would like to take data from the UI to your new institution, please review the

guidelines outlined in the [May 2013 IRB Connection](#).



NEWS FLASH!

Our respected IRB Connection editor, Cena Jones Bitterman, has taken a new position in the Holden Comprehensive Cancer Center (HCCC).

While in the HSO, her title was “Education and Compliance Specialist,” but she was IRB Connection Editor; HawkIRB Trainer; policy writer; Mentor Extraordinaire.

Par excellence, crème de la crème, raison d'être – even the fanciest of French words are not enough to describe what an amazing asset you are. Farewell Cena, you will be missed!

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Need help with  
HawkIRB?

HawkIRB is a “smart” web program—stop laughing. Truly, the system is designed to respond to the way questions are answered. Various sections will open and close in reaction to your choices, which is incredibly useful if say, you request a consent waiver—half of the application disappears. If instead, you intended to request a waiver of documentation of consent, (very, very easy to confuse if this is your first HawkIRB rodeo) you will be baffled because you will be missing half of the application and will have no space to describe a consent process. HawkIRB does present many, many advantages over hard copy research applications—researchers can access the system anywhere, anytime; live links provide guidance documents and instructions, workflow questions document the review process from submission to approval to project closure, and the various committees involved in project approvals can coordinate reviews. All that being said, it is not a flawless system.

This column will be a recurring feature in the HSO newsletter, providing common trouble-shooting suggestions and solutions.

HawkIRB sends automatic email notifications to Principal Investigators (PI), research team contacts, and delegates. These notifications include notice of project submission, workflow questions from HSO staff, and reminders of the annual continuing review deadlines. All of these messages are important communications, and can be critical to staying ahead of deadlines. If IRB approval lapses, that is, an annual continuing review form has not been submitted AND approved, all research activity must cease until the continuing review is approved.

These helpful messages can be overwhelming in number, especially if several projects are involved. If not all research team members have a clear idea of their role regarding a particular project (who submits the continuing review, for example), it can be human nature to assume someone else is taking care of the issue.



### Tips for Researchers

- Limit research contacts to those team members who need to respond to required actions for specific projects: PIs, staff able to answer questions about the project from Human Subjects Office (HSO) staff and the IRB, and faculty advisors supervising student PIs
- Research team contacts listed on Informed Consent Documents do not need to be listed as contacts in Section II of the HawkIRB application
- Have a clear discussion about how individuals should respond to email reminders for each project
- Take advantage of the [HawkIRB Delegate permissions](#) option

*Research is to see what everybody else has seen, and to think what nobody else has thought.*

*Albert Szent-Gyorgyi*

## 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]