THE UNIVERSITY OF IOWA

IRB Connection

HUMAN SUBJECTS OFFICE

Volume 2, Issue 1
January 2014

Human Subjects Research in the News:

Surgeons Eye Google Glass for Use in the Operating Room
The Sacramento Bee, November 26, 2013

Opinion: On Dying After Your Time
NYT, November 30, 2013

Pfizer to Expand Clinical Data Access to Researchers, Patients
Reuters, December 4, 2013

Overhaul Recommended for Gene-Therapy Review
Nature, December 5, 2013

23andMe Remains Optimistic Despite FDA Issues
Venture Beat, December 7, 2013

Faculty Push for Independent Research Review
Minnesota Daily, December 9, 2013

Medicine's Problem of 'Incidental Findings'
The Atlantic, December 12, 2013

HAWKIRB

Upcoming Training Sessions

Spring HawkIRB training sessions and topical presentations are being scheduled now. Check the HSO website for the Spring schedule.

HSO Office Hours will resume the last week of January. Check the HSO website for hours and locations.

A Letter from the Editor

Goodbye 2013 and hello to 2014! As we start the new year, I would like to take advantage of this opportunity to thank our readers for all of your feedback and suggestions regarding the content of IRB Connection. I would also like to acknowledge my fellow HSO staff members who have written great articles, provided valuable feedback, and creative ideas for this newsletter over the past year. My goal, as this newsletter's editor, has been to provide its readers with interesting and useful information related to human subjects research and the protection of research participants. In 2013, we saw a lively debate within the human subjects research protections field surrounding risk and informed consent when research involves standard of care interventions. We also read about revisions to the Declaration of Helsinki, a document that recently turned 50 years old! Last spring, an advisory committee to the U.S. Department of Health and Human Services endorsed a 20-point set of recommendations regarding the conduct of Internet-based human subjects research, the first of its kind. This past fall, we read about the federal government enacting significant changes to HIPAA. At the institutional level, we have used this newsletter to disseminate information on everything from how to use the delegate permission system in HawkIRB, IRB policies regarding informed consent when minors "age-up" during the course of a longitudinal study, to the Course-Related Student Project policy revision. Looking to 2014, we intend to cover more topics related to ongoing discussions of internet-based human subjects research, genetic research, as well as disseminating useful information on UI IRB policies, news, and much more! As always, if you have questions, comments or suggestions about IRB Connection, please do not hesitate to share those at irb-monitors@uiowa.edu. I greatly appreciate your feedback and aim to provide the UI research community with useful and helpful information related to human subjects research protections.

- Cena Jones-Bitterman
IRB Education and Compliance Specialist

Should I Submit a New Project Application or a Modification?

New project or modification? That is the question. Whether 'tis nobler to change an existing study in HawkIRB or 'tis better to start fresh? You may not be in a Hamlet-like crisis over this issue, but if you engage in research long enough, at some point you face this quandary. While there is no absolute rule to follow, here are a few questions that can help guide your decision.

⇒ ***Does the revision alter my research hypothesis?***
If the basic research question remains intact, then a new application might not be warranted. If the new aspect involves a new focus or research question, even if it builds on the knowledge learned in an existing study, a new application may be needed.

⇒ ***How substantially will my procedures change?***
The more your new procedure(s) deviate from the original research plan, the more you should consider submitting a new application. Don't let your study become unwieldy with multiple add-ons that blur the focus of your research and prevent others from comprehending study procedures.

⇒ ***How long has my study been open?***
If your application was approved by the IRB 7 or more years ago, it may include outdated aspects, and in this case, a new application would allow you to refresh your hypothesis, your procedures, and ensure that all aspects of the application align.

⇒ ***Will I utilize a new grant?***
New funding may point to new directions for your research, and a new application will cleanly delineate this new focus.

It is a fallacy to think that adding a modification to an existing study will be easier than submitting a new application. In fact, a modification which results in an overly long application with many inconsistencies and inclusion of information and documents that are no longer relevant, can be much more confusing to reviewers than a new, shorter "clean" application which is current and consistent. The HSO/IRB will scrutinize a major revision to an existing study with the same diligence that a new application receives, and we tell investigators who submit major changes to their study that a new application is needed instead. The new application can reference the "parent" study, and can utilize the same subjects (when appropriate). If in doubt, call us! HSO staff or an IRB Chair would be happy to discuss proposed changes with you!

- Becka Simpson
Senior IRB Application Analyst

Sign up for the IRB Connection's distribution list by sending an email to listserv@list.uiowa.edu

NEWS FLASH!

With both sadness and warm wishes, the HSO announces that Andy Bertolatus, our Executive Director, will be stepping down from his directorship duties in July 2014 as he enters phased retirement. Dr. Bertolatus will retain his IRB Chair responsibilities. OVPRED and the HSO are currently in the process of conducting a nationwide search for an applicant to fill the HSO Executive Director position. Best wishes to Dr. Bertolatus on all of his future endeavors!

HSO Executive Director/
Primary IRB Chair

J. Andrew Bertolatus (Andy)

Back to School Reminder: Submit Your HawkIRB Application

As student investigators return to classes this spring semester, the HSO would like to offer a friendly reminder to those conducting human subjects research to start the HawkIRB application submission process sooner rather than later. It is important for students conducting human subjects research, particularly time sensitive or semester projects, to submit applications to the HSO/IRB and any materials to the applicable UI committees and programs that review research involving human subjects as soon as possible.

International Research

This is especially important for students conducting international research, which requires additional documentation (e.g. translated consent documents, documented permission from the site where research procedures will occur, a completed International Research Local Context Review Form, etc.). Certain funding entities may also require additional documentation. For example, International Programs has specific requirements of Stanley Undergraduate Award recipients that may necessitate additional planning on the part of the student investigator and their faculty advisor.

Allow for Enough Time

Investigators should plan for IRB review to take approximately 6-8 weeks for a new study, regardless of whether it receives expedited or full board review. Allowing for a sufficient amount of time to receive IRB review is particularly important for researchers who need to make travel arrangements to conduct international research.

Submitting a HawkIRB application 1-2 weeks before a scheduled international research trip with an expectation of receiving quick IRB approval is not advised. Investigators should allow themselves ample time to discuss their research plans with their faculty advisor or class instructor, visit HSO Office Hours (resuming at the end of January), or contact the HSO to ask questions and receive guidance on submitting the application. Starting the review process as early as possible helps ensure that the study is approved with plenty of time to complete the research, but also allows time for the investigator to consider and/or correct any issues that may delay the research.

Course-Related Student Projects

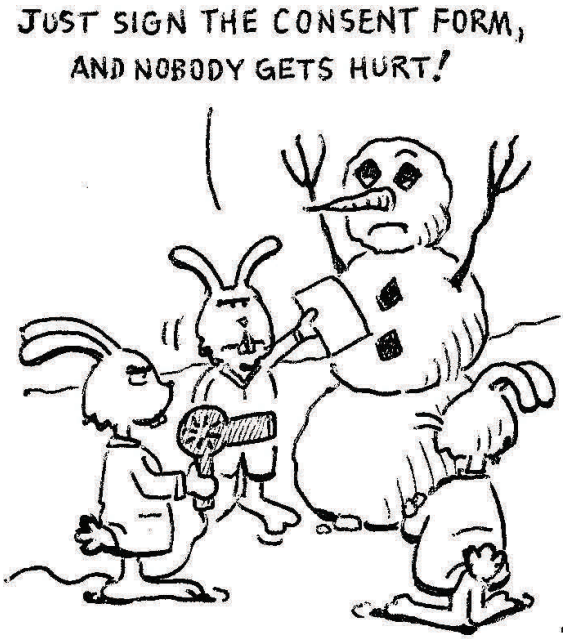
For course-related research projects, students conducting human subjects research as part of a course requirement, or faculty members/ class instructors assigning these projects should refer to the Course-Related Student Projects policy to help determine if the project will require IRB review and approval.

Research in Public Schools

Investigators planning to conduct research in public schools may want to consult with the Cooperating Schools Program (CSP) to receive assistance in obtaining and documenting permission to conduct research in Iowa schools and school districts.

Is it Human Subjects Research?

Those who are unsure as to whether a proposed project requires IRB review should submit a Human Subjects Research Determination (HSRD) form in HawkIRB to receive a documented determination from an IRB Chair.



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