THE UNIVERSITY OF IOWA

IRB Connection

HUMAN SUBJECTS OFFICE

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'I Didn't Think it was Human Subjects Research because…'

"I didn't have funding." "My subjects were patients." "My survey was anonymous." These are explanations researchers give for conducting human subjects research (HSR) without submitting a HawkIRB application.

If you are unsure whether you need to submit a HawkIRB application, the first step is to determine if your project meets the definition of 'research' as outlined in the federal regulations. The Department of Health and Human Services (HHS) at 45 CFR 46.102(d) defines research as a "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge" and the Food and Drug Administration (FDA) defines it as "any experiment that involves a test article and one or more human subjects." [45 CFR 56.102(c)]

If your project is 'research', the next step is to determine whether the research activity involves human subjects. The HHS at 45 CFR 46.102(f) defines this as obtaining identifiable private information or data through interventions or interactions with the individual; whereas, the FDA at 45 CFR 56.102(e) defines a human subject as "an individual who is or becomes a participant in research, either as a recipient of the test article or as a control."

Whether your research is funded or unfunded, involves patients or healthy volunteers, is a paper or online survey, if you use living people in a project that is an organized attempt to contribute to, or change a body of knowledge, you are probably doing human subjects research.

If you are still unsure, submit a Human Subjects Research Determination form (HSRD) in HawkIRB. An IRB Chair will make a determination based on the responses you provide. If the project is determined to be HSR, a DRAFT New Project Application will automatically be initiated on your behalf. Note that you still need to complete the application and submit it for IRB review and approval before beginning your research. If your study is determined not to be HSR, there is no additional action required on your part. A formal memo from the IRB Chair stating the project does not require IRB review or approval will be attached to the Form Approval Tab of the HSRD application.

If you are a student conducting a class-related project that involves human subjects, please refer to the Course-Related Student Project Policy and Checklist.

When in doubt, contact the HSO at (319) 335-6564 or email irb@uiowa.edu.

We are happy to work with you!

University of Iowa Policy on Mandatory Reporting of Physical and Sexual Abuse of Children: The Research Perspective

EDITOR's NOTE: This article was originally published in February 2015.

As of April 2016, the Operations Manual has been updated , including information about if there is a "research exception". Please see Chapter 15 of the UI Operations Manual for further information:

http://opsmanual.uiowa.edu/community-policies/physical-and-sexual-abuse-children

Human Subjects Research in the News:

How Do You Quantify Panic?
The Atlantic Jan 21, 2015

Blood Test Forecasts Concussion Severity
Scientific American
Dec 15, 2014

Personality outsmarts intelligence at school: Conscientiousness and openness key to learning
Science Daily Dec 17, 2014

Coffee May Protect Some Against Some Skin Cancers
Live Science Jan 20, 2015

Running Faster by Focusing on the Finish Line
The Atlantic Jan 20, 2015

Trainings & Presentations

New Project Application
March 6, 2015 9-11:30AM

Continuing Reviews, Mods…
February 16, 2015 2-3:30 PM
March 25, 2015 2:30-4 PM

Navigating the IRB Review Process for Human Subjects Research
Feb 11 & Feb 13, 2015

Best Practices and Resources for Faculty Advisors
Feb 19 & Feb 27, 2015

Central (External) IRB Models
March 9, 2015 2:30-3:30

HSO Office Hours

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

Mondays 2-4PM in 304 Lindquist Center

NEWS FLASH!

HawkIRB Updates

Enhancements to Section VII.A have been made to provide guidance when the Principal Investigator is the lead investigator for a multi-site study. Please refer to our website for additional information!

A Warm Welcome

Brian Brotzman joined the Human Subjects Office in December. He has previous research experience and is ready to apply this knowledge to the world of human subjects regulation at the University of Iowa. Brian, we bid you welcome!

A Fond Farewell

Ms. Logan Ahmann has joined the UIHC's radiology department as a Clinical Trials Research Associate. Logan will take her knowledge of 21 CFR 50 to a new level in this research position. Logan, we wish you luck and much success!

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Conflict of Interest in Research—Implications for Investigators

Conflicts of interest are common at research universities. Researchers, universities and companies have a long history of collaborating, and these collaborations can provide mutual benefit by contributing to the university's research mission and promoting the development of products and applications that benefit society. Researchers are encouraged to make discoveries, and The University of Iowa is committed to commercializing those discoveries to established companies or companies started by our researchers.

These situations can create opportunities for researchers to receive financial rewards related to their research. With the opportunities come risks --

- the direction of research could be affected
- the objectivity of the data could be compromised
- the interpretation of research results could be skewed

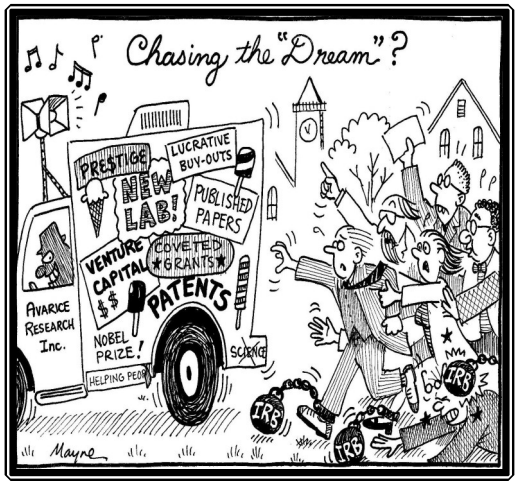
As a researcher, you might not consider that your financial interest would pose these risks, but it can create that perception. *This perception of bias can be as damaging to the researcher and the university as actual bias.*

It is the University's responsibility to determine when a financial interest intersects with research. The *e*COI system allows the Conflict of Interest in Research Office to review all financial interests in the context of research that is proposed, via either an IRB application or a sponsored research application on a routing form. It is University of Iowa policy that investigators complete a disclosure in the *e*COI system. If an investigator fails to comply with this requirement, he/she cannot be named on a routing form or on a Hawk IRB application. Further, it is the responsibility of the investigator to update his/her disclosure within 30 days of any changes.

When the Conflict of Interest in Research (COIR) Office identifies an intersection between an investigator's financial interest and research conducted at the University, it triggers a series of events. The COIR Office will monitor the feasibility of the funding and/or the IRB application submission process. If the funding becomes imminent, or the IRB application moves forward into the review phase, the COIR Office will present the case to the Conflict of Interest in Research Committee (CIRC), much like a primary reviewer in an IRB meeting. The CIRC will review the case and, if it determines the financial interest is manageable, will recommend a management plan to the Vice President for Research and Economic Development to implement.

A conflict of interest is not an inherently bad thing, but it requires transparency. Transparency is the foundation of all management plans, and includes actions such as disclosing the financial interest to journals, audiences, students and human subjects.

Please contact the COIR Office if you have questions or would like us to come and present information on conflict of interest in research to your team or department. For more information, please visit coi.research.uiowa.edu.



Human Subjects Office

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