‘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!

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
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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