

Human Subjects Highlights

*Institutional Review Board-Health and Behavioral Sciences
University of Michigan*

Special points of interest:

- The IRB-HSBS website is getting an update with an anticipated release date in April. In addition to a new look and feel, the site will enable IRB-HSBS staff to make our own updates to the content.
- By completing their PEERRS certification prior to submitting IRB applications, U-M investigators and their collaborators can keep the review process moving.
- IRB approval may be required for program evaluations depending on the purpose of the evaluation, and the extent to which the findings are generalizable.
- Researchers who use lotteries or sweepstakes as incentives must follow State of Michigan law.

What's new . . .

The IRB-HSBS staff has settled into our new offices at the NCRC, and we are enjoying the close proximity to our IRBMED and UMOR compliance team colleagues, which allows many opportunities for collaboration. Beginning in May, all IRB-HSBS full committee meetings will be held at the NCRC. IRB-HSBS staff members are still available for consultation on central campus at our On-the-Road sessions (please see the schedule at: www.irb.umich.edu/education/otr-current.html) or ad hoc meetings, and researchers are always welcome to visit us at the NCRC.

IRB-HSBS would like to thank long time board member and Vice Chair, Jorge Delva, Professor of Social Work, for his many years of service. Jorge stepped down from his role with the IRB at the end of February. Ray Bingham, Research Professor, UMTRI, began his appointment as IRB Vice Chair in March. We are grateful to both of them, and to all our IRB members, for their commitment to the protection of human subjects at the University and to their service in support of the institution's research mission. We also welcome Janie Slayden, former IRB-HSBS board member and research project manager, as a part time member of the IRB-HSBS staff to assist with quality assurance activities and other special projects.

The University is in the process of renewing its accreditation with the [Association for the Accreditation of Human Research Protection Programs, Inc. \(AAHRPP\)](#). We expect a site visit from the AAHRPP team some time in the fall. The accreditors will interview institutional leadership, IRB members and staff, and principal investigators and study coordinators as part of this visit. Expect more communication from the IRB and from the Human Research Protection Program (HRPP) as we prepare for this visit.



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Proposed changes to human subjects research regulations

Changes to the Common Rule (45 CFR 46), the regulations that govern the protection of human subjects in research, are in process. On February 24, a Notice of Proposed Rule Making entitled "Human Subjects Research Protections: Enhancing Protection for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators" was submitted by the Department of Health and Human Service to the Office of Management and Budget's Office of Internal Regulatory Affairs (OIRA) for review. Once this review is completed, the NPRM will be released for public notice and comment. An [Advance Notice of Proposed Rulemaking \(ANPRM\)](#) encompassing over 70 proposed changes to the current regulations was published in 2011. At the time of this writing, the changes that are included in the final proposed rule are unknown.

PEERRS human subjects certification requirement

U-M investigators and key research personnel are required to complete one of the “Humans Subjects” modules of the Program for Education and Evaluation in Responsible Research and Scholarship (PEERRS) before IRB approval can be issued. PEERRS (<http://my.research.umich.edu/peerrs/>) is a web-based instruction and certification program that covers the ethical and regulatory responsibilities of investigators conducting human subjects research. PEERRS certification is obtained by passing a short quiz, and it is granted for three years.

Engaged external collaborators who are listed as study team members on eResearch applications for projects initiated at U-M must also demonstrate completion of human subjects training by requesting access to PEERRS (<http://my.research.umich.edu/peerrs/non-um-users.php>), or by submitting a request for a certification waiver (http://my.research.umich.edu/peerrs/waiver_request_form.php) along with proof of equivalent training completed within the last three years to: peerrs@umich.edu.

For PEERRS course content, requirements, or access questions, please email peerrs@umich.edu.

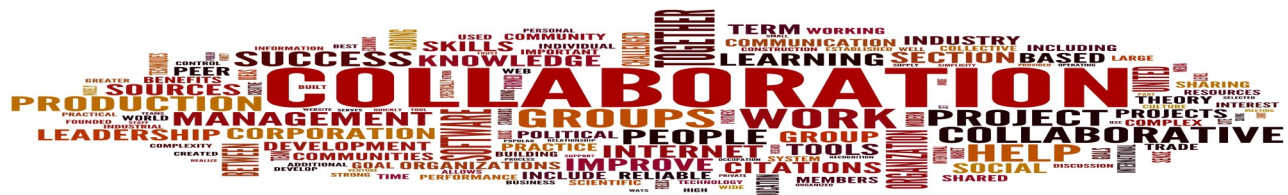
IRB oversight for collaborative research projects

When investigators from separate institutions collaborate on research involving human subjects, all engaged study team members must have appropriate IRB oversight. This applies to regulated, non-exempt studies. Individuals are considered “engaged” when they receive a direct award from HHS, obtain consent, collect data through interaction/intervention, and/or access individually identifiable private information for research purposes.

The default scenario is one in which IRB-HSBS covers research activities conducted by U-M investigators, and external collaborators are covered by their own IRB; that is, they provide evidence of IRB approval from their home institution by attaching documentation to the eResearch application. Alternatively, three types of agreements can be used to minimize or eliminate duplicate IRB review where appropriate:

1. *IRB Authorization Agreements (IAA)* involve two or more institutions, typically academic or medical, that have a federalwide assurance (FWA) on file with OHRP, through which institutions ensure HHS that they will comply with regulations for human subjects research. Under certain circumstances, U-M uses IAAs either to become the “IRB-of-Record” (a U-M IRB assumes IRB responsibilities for research conducted at another institution), or to cede IRB oversight (U-M allows another institution's IRB to serve as IRB-of-Record for U-M research). U-M will generally not serve as IRB-of-Record for research in which U-M investigators are not engaged, or in cases where the local context cannot be appropriately addressed or adequate oversight cannot be exercised.
2. *Individual Investigator Agreements (IIA)* are used to provide IRB oversight for investigators who are not affiliated with an assured institution to document their obligations while conducting human subjects research. UMOR and/or the IRB chair determine whether U-M is willing to oversee the work of an individual investigator.
3. *Collaborating Institution Agreements (CIA)* are used to designate a single person at a non-assured institution who is responsible for overseeing the activities of anyone engaged in research at that institution, typically multiple investigators. CIAs can only be used for projects that are *not* federally funded.

IRB staff will alert investigators to these requirements as part of their review, and investigators should keep in mind the possibility that IRB approvals or agreements may be needed for collaborators as they plan studies.



Do program evaluations require IRB approval?

We are often approached by faculty, staff, and students with questions about whether IRB approval is required for program evaluations. The answer depends on the purpose of the project, and the degree to which project activities fit the regulatory definition of “research” (“a systematic investigation . . . designed to develop or contribute to generalizable knowledge”).

In general, IRB approval *is* required for projects that (a) test a new, modified, or previously untested program or service to determine whether it is effective, and (b) generate knowledge and yield benefits that extend beyond a particular program and/or group of participants; for example, findings might contribute to the scientific literature or inform policy development. Additionally, aspects of design such as random allocation of participants to intervention or comparison groups and activities where participants have the ability to opt in or out are more likely to require IRB oversight.



IRB approval is generally *not* required for program evaluations when (a) the purpose is to evaluate the success of an established program or service in achieving its objectives for a specific population, (b) the information obtained will be used to provide feedback solely for the program and/or participants, and (c) the benefits will primarily or exclusively be for the program and/or participants. Although the findings may be published, such evaluations, as well as other quality assurance/improvement projects, will typically not require IRB approval because the focus is on program activities rather than human subjects.

Investigators and evaluators are welcome and encouraged to consult with IRB-HSBS staff about whether a given project will require IRB approval. They may also request a formal determination by submitting an application in eResearch (please select “Activities Not Regulated as human subjects research” as the application type and Quality Assurance/Quality Improvement-Other as the not regulated category). In this way, IRB-HSBS can determine the most appropriate steps based on information about a particular project.

For more information, interested readers may wish to access guidelines provided by the U.S. Department of Health and Human Services at: <http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf>

This resource covers distinctions between activities that are likely to require IRB approval and those activities that would not. Although the document is written in the context of public health, it includes a comprehensive section on program evaluation and examples that are rele-

Using lotteries or sweepstakes as incentives for research participation

When researchers use lotteries or sweepstakes as incentives for participation, they must follow State of Michigan gaming laws. In a research *lottery*, subjects are offered a chance to win a prize (cash, gift certificates, gift cards, merchandise, etc.) in return for their participation. The total cash value of prizes awarded cannot exceed \$100 per day, and second chance drawings are not allowed, meaning that individual subjects cannot be entered into a pool for a prize more than one time. As an example, imagine a study team has \$300 to offer as incentives. They could hold three separate drawings, each for \$100, each on a different day, and each involving a discrete pool of participants. Informed consent documents for studies involving lotteries should include information such as “if you agree to participate, you will be entered into a drawing for one \$100 prize”.

Whereas lotteries limit the cash value of prizes to \$100 per day, *sweepstakes* (called “Game Promotion” in the law) can be used to offer prizes worth more than \$100. However, individuals cannot be required to participate in the research. This means that everyone who is invited to participate must be entered into the drawing, whether they agree to participate or not. In the informed consent document, researchers must disclose the date and location of the drawing, the odds of winning, and the means by which winners will be notified.

IRB Staff and Assigned, Schools, Colleges or Units

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- Full Board

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- Anthropology
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- Music
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- Public Health
- Public Policy
- School of Information
- School of Natural Resources
- Social Work
- Survey Research Center/
Institute for Social Research

Board Meeting Dates 2015 - 2016

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<u>Submission due</u>	<u>Meeting date</u>
April 13	May 6
May 11	June 3
June 8	July 1
July 13	August 5
August 10	September 2
September 14	October 7
October 12	November 4
November 9	December 2

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<u>Submission due</u>	<u>Meeting date</u>
April 27	May 21
May 25	June 25
June 22	July 16
July 27	August 20
August 24	September 17
September 21	October 15
October 26	November 19
November 23	December 17