

HUMAN SUBJECTS HIGHLIGHTS

FALL



HEALTH SCIENCES &
BEHAVIORAL SCIENCES IRB
UNIVERSITY OF MICHIGAN

2016

U-M Receives Full Reaccreditation from AAHRPP



In June 2016, U-M was awarded full reaccreditation from The Association for the Accreditation of Human Research Protection Programs (AAHRPP), which reviews academic and other institutions with the goal of ensuring ethically sound research. This important achievement affirms the institution's commitment to excellence in human subjects research, and it denotes a high-quality program that promotes compliance with ethical and regulatory standards. We are particularly grateful to the researchers from our community and to our IRB members for their contributions to this effort. Congratulations to all!

Update on Proposed change to the Common Rule



To date, the federal Office of Human Research Protections (OHRP) has not yet issued the final rule implementing changes to the human subject protection regulations proposed last September in its Notice of Proposed Rulemaking (NPRM). The agency received over 2000 comments to the proposed rule changes. The agency has indicated publicly that it still intends to promulgate a final rule before the end of the year.

NIH Policy on Single IRB Review of Multi-site Research



In an effort to enhance and streamline the IRB review process for multi-site research, the National Institutes of Health has issued a formal policy requiring the use of a single IRB of record for nonexempt, NIH-funded human subjects research studies that implement a single protocol at more than one site within the United States, primarily clinical trials. The policy applies to all competing grant applications (including new, renewal, revision, or resubmission applications) with receipt dates on or after May 25, 2017. Ongoing, noncompeting awards are not expected to comply until the grantee submits a competing renewal application. The applicant is responsible for submitting a plan describing the use of a single IRB. An authorization or "reliance" agreement documents respective roles, responsibilities, and communication between the institution providing single IRB review and the sites participating in a multi-site research study. The NIH policy can be found at: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html>.

In preparation for this requirement, the IRBs are working with the eResearch team to develop a new application type (Multi-Site Research) to manage projects where a Michigan IRB is the IRB-of-record for multi-site projects. This new application type will be made available to the research community on October 17, 2016. Investigators are cautioned to contact the IRB before selecting this new application type, as we anticipate that this new NIH mandate will apply to a limited number of projects under IRB-HSBS jurisdiction.

The IRB-HSBS continues to recommend investigators who are working with external investigators on other types of collaborative research to contact us to determine whether an agreement to cede IRB oversight or serve as IRB-of-record is appropriate. For more information about collaborative agreements, see <http://research-compliance.umich.edu/authorization-agreement-process>.

IRB review of pilot and pretest research activities



The IRB-HSBS frequently receives questions about the requirement for IRB review of pilot/pretest activities, including cognitive interviewing. The answer depends on the definition of *research development* (as it appears in the regulatory definition of research, ". . . a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" [45 CFR 46.102(d)]), and *human subject* (" . . . a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information" [45 CFR 46.102 (f)]). Although OHRP has not issued formal guidance on this topic, correspondence with the agency confirms that it considers research development activities such as piloting study procedures or testing instruments to assess psychometric properties to require IRB oversight if such activity would not take place if it were not for the research. Thus, pilot studies and pre-testing activities are subject to IRB review at U-M. Have questions? Please contact IRB-HSBS to discuss your circumstance.

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An invitation for prospective IRB members



Interested in the work of the IRB? The IRB-HSBS encourages interested faculty members from Central Campus to contact us regarding service as an IRB member.

IRB membership involves attendance at one board meeting per month. We have two separate panels: IRB "Blue" (first Wednesday of each month from 1:30-4:30 pm) and IRB "Maize" (third Thursday, 9 am-12 noon). Members are typically appointed as a member of one board and an alternate to the other. The time commitment may vary from month to month. Members are assigned reviews based upon the scholarly expertise; a few hours may be necessary to review an IRB application, informed consent documents, and other study materials in preparation for a board meeting. Often, members are not assigned individual reviews and only need to complete a general review of materials on the agenda so they can participate in the discussion and vote. The IRB-HSBS staff provides regulatory and eResearch training for board members at the beginning of their service. Contact Cindy Shindledecker, IRB-HSBS Director, at cshindle@umich.edu for more information.

Mitigating risk: Sensitive identifiable data



Studies that involve the collection of personal identifiers along with sensitive information may elevate the reputational or legal risk to research participants, either through potential breach of confidentiality, or the risk of compelled disclosure by way of a subpoena. Best practices for mitigating risk where data are both personally identifiable and sensitive include the following:

- Collect only the data necessary to address the research question
- Do not collect identifiers if they are not absolutely necessary for the research
- If collecting identifiers, such as to forward subject payments, do not include a linking mechanism between the data and the identifiers
- If a linking mechanism is necessary, limit who has access to the identifiers, data, and key(s), and do not store these items together in the same location. Keep them separate from the data (with no linking mechanism)
- Deconstruct or recode identifiers as soon as it is feasible to do so
- Reword sensitive questions to ask about individual perspectives or attitudes rather than individual behaviors

IRB Education Opportunities



IRB-HSBS staff members are available for consultation on central campus at our "On-the-Road" sessions (<http://research-compliance.umich.edu/irb-hsbs-road-schedule>) and through in-class or unit presentations tailored to the needs of your group. In addition, U-M faculty, staff, and students are cordially invited to attend our Fall education series (<http://research-compliance.umich.edu/irb-hsbs-road-schedule>), which includes several newly developed sessions. Please contact the IRB Office at (734) 936-0933 or irbhsbs@umich.edu to learn more.

Ethics Education for Community Partners



The HHS Office of Research Integrity has made a resource available (http://ori.hhs.gov/education/products/mass_cphs/training_staff/RCReng/RCRHome.htm) to help community members (such as those who collaborate on studies with U-M investigators) understand the ethical and regulatory responsibilities that come with the conduct of human subjects research. The content is tailored for front-line research workers and their supervisors, and it presents issues and scenarios in four sections: (1) The Research Protocol, (2) Recruiting Participants, (3) Confidentiality, and (4) Professionalism. The website can be used individually or in groups.

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IRB-HSBS Staff and Assigned, Schools, Colleges or Units

Mary Donnelly (mardonne@umich.edu)

- Full Board

Elaine Kanka (mekanka@umich.edu)

- Anthropology
- Architecture and Urban Planning
- Business
- Communication Studies
- Linguistics
- Misc. LS&A (including History)
- Nursing
- Population Studies
- Sociology
- UMTRI

Wendy Peebles (wpeebles@umich.edu)

- Center for the Education of Women
- Center for Human Growth and Development
- Institute for Research on Women and Gender
- Psychology
- Research Center for Group Dynamics
- Center for the Development of Language and Literacy
- Women's Studies

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- School of Public Health
 - Biostatistics
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 - Epidemiology
 - HBHE
 - Human Genetics
 - Nutrition

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- Dentistry
- Economics
- Education
- Engineering
- Ergonomics
- Institutional Research
- Kinesiology
- Law School
- Music
- Pharmacy
- Political Science
- Public Policy
- School of Information
- School of Natural Resources
- Social Work
- Survey Research Center/ Institute for Social Research