

# Human Subjects Highlights

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



## AAHRPP Site Visit March 30 - April 1

U-M is in the process of seeking 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. AAHRPP accreditation affirms an institution's commitment to excellence in human subjects research, and it denotes a high-quality research protections program that promotes compliance with ethical and regulatory standards.

UM began its most recent re-accreditation process in June 2015 by conducting a self-assessment. The next step is a site visit from AAHRPP, which will take place March 30 through April 1. During the visit, AAHRPP representatives will interview institutional leadership, IRB members and staff, principal investigators, and research staff. Individuals who have been selected for an interview will be notified in advance by the UM site visit coordinators and provided with additional information. If you are selected, it is essential that you prepare for the interview. Knowledge is key, so it is never too early to begin preparing. Specifically, you should re-familiarize yourself with human subjects protections policies and procedures that relate to your role. For example, ensure that you are familiar with practices related to recruitment, informed consent, vulnerable subject populations, privacy and confidentiality, the reporting of noncompliance and adverse events, and conflicts of interest.

AAHRPP representatives will ask specifically about human subjects protections at UM, so make sure you understand the structure of the U-M HRPP. Be prepared to summarize its main components and explain how your research activity follows HRPP policies and procedures. As part of your preparation, take a moment to review the HRPP Operations Manual (<http://research-compliance.umich.edu/operations-manual-contents-page>), as well as the IRB-HSBS website (<http://research-compliance.umich.edu/irb-health-sciences-and-behavioral-sciences-hsbs>). Finally, be prepared to describe the education and training you have received concerning human subjects protections. For example, in addition to completing the PEERRS training modules (<http://my.research.umich.edu/peerrs/>), perhaps you have attended courses, seminars, and/or consultations offered by IRB-HSBS.

If you have questions, please contact: AAHRPPvisit@umich.edu, or visit the U-M AAHRPP reaccreditation website for further information:

<http://research-compliance.umich.edu/human-subjects/aahrpp-re-accreditation>



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## Which IRB should I submit my application to? IRB-HSBS or IRBMED?

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Each IRB at U-M is constituted to review and oversee research within a prescribed scope of jurisdiction. As part of the IRB administrative review process, elements of studies are assessed to ensure that applications are assigned to the appropriate IRB.

Investigators with primary appointments in the U-M Ann Arbor schools, colleges, units, or programs should submit their applications to IRB-HSBS (U-M Central Campus IRB). Studies may be referred for transfer to IRBMED (UMHS and Medical School IRB) for review and oversight when (a) the PI is affiliated with a department or unit of the Medical School, Taubman Health Care Center (UMHCC), or Dental School, (b) any aspect of the research is FDA-regulated, and/or (c) the research utilizes UMHCC facilities, UMHCC PHI/medical records, and/or restricted medical registries or databases. Other conditions may apply depending on the specific application.

Recently, IRB-HSBS has been reviewing some of the Exempt applications (under categories #1, #2, and #2A) submitted to IRBMED by UMHS and Medical School faculty. However, all research involving UMHS PHI remains under IRBMED oversight. Default jurisdiction for UMHS faculty is not changing; if you normally submit to IRBMED, please continue to do so.

For a complete description of each IRB's scope of jurisdiction, please refer to the [HRPP Operations Manual \(OM\), Part 5, IRB Jurisdiction and Cooperative Research](#). To discuss any questions you might have about IRB-HSBS jurisdiction, contact Mary Ramirez, Assistant Director, IRB-HSBS ([mramirez@umich.edu](mailto:mramirez@umich.edu) or 615-9464).

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## Studies Involving Mobile Technology

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U-M investigators whose research involves mobile technology (including mobile applications) should consult with the U-M Office of Technology Transfer for guidance on institutional policies, regulatory issues, licensing requirements, and commercialization processes that might apply to their projects. For example, the use of mobile technology might call for the inclusion of specific language in an informed consent document. Importantly, studies involving mobile applications that meet the definition of a medical device require oversight by the FDA, and must be reviewed by IRBMED. For further information, please contact Jessica Soulliere, Licensing Specialist, Digital Technology at (734) 647-9926 or [jdsoul@umich.edu](mailto:jdsoul@umich.edu).

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## IRB-HSBS Education Opportunities

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IRB-HSBS staff members are available for consultation on central campus at our "On-the-Road" sessions (<http://research-compliance.umich.edu/irb-hsbs-educational-sessions-winter-2016>) and through in-class or unit presentations tailored to the needs of your group. In addition, U-M faculty, staff, and students are invited to attend our Winter education series (<http://research-compliance.umich.edu/irb-hsbs-educational-sessions-fall-2015>). Please contact the IRB Office at (734) 936-0933 or [irbhsbs@umich.edu](mailto:irbhsbs@umich.edu) to learn more.

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## Deception and Concealment in Human Subjects Research

Since full disclosure of a study design can influence research participants' responses, investigators may utilize deception (whereby participants are told something about a study that is not true) or concealment (when all of the details about a research protocol are not revealed to subjects in advance of their participation). The deception or concealment might be related to the purpose of a study, or the investigator's role in the study. In other cases, subjects may not even be aware that a study is in progress at the time, or they might receive false feedback about themselves or others.

Deception or concealment is necessary for some studies because it allows investigators to control the research environment, elicit spontaneous behavior, and manage problematic responding. However, there are important ethical considerations when it comes to the use of deception and concealment for research purposes. Such considerations primarily involve prospective subjects' ability to provide voluntary and fully informed consent. For this reason, research involving deception or concealment must meet all criteria for a waiver or alteration of informed consent. This means that the (1) study must pose no more than minimal risk to subjects, (2) waiver or alteration must not adversely affect subjects' rights and welfare, (3) deception or concealment (and, therefore, the waiver or alteration of consent) is necessary in order to conduct the study, and (4) subjects are debriefed about the true and complete nature of the study following their participation, at which point they may choose to withdraw their data.

There are several related issues for investigators to consider as they design studies, and for IRBs to consider as they review research protocols:

- Deception and concealment are inappropriate when a study is reasonably expected to cause pain or distress for research participants.
- Deception and concealment must be justified by the knowledge the study could generate. It is important to consider whether a given study could be accomplished without, or with a lesser degree, of deception or concealment.
- When the research and debriefing are complete, it is important to consider the possibility that participants may still perceive the deception or concealment as a betrayal of trust or somehow unfair, or that the deception or concealment could leave participants feeling denigrated in some way. Reasonable steps must be taken to correct misconceptions under these circumstances.
- Particularly in cases where there is a delay between participants' involvement and the debriefing process (IRBs may grant permission for investigators to wait until they have collected all study data before debriefing subjects, so as not to contaminate the research among members of a subject pool, for example, who may communicate with one another in the interim), investigators must ensure that participants do not face undue stress or embarrassment, and they must debrief participants as soon as data collection is complete.
- Perhaps most importantly, if investigators become aware that study procedures have harmed a research participant, they must take reasonable steps to minimize that harm, and they must report the event to the IRB.

## IRB 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)

- Adult Psychological Clinic (MARI)
- Center for Child and Family
- Center for the Development of Language and Literacy
- Center for the Education of Women
- Center for Human Growth and Development
- Institute for Human Adjustment
- Institute for Research on Women and Gender
- Psychology
- Research Center for Group Dynamics
- U-M Aphasia Program
- Women's Studies

### Debra Schneider (dschnei@umich.edu)

- Engineering
- Ergonomics
- Kinesiology
- Public Health

### Deborah Schild (drsw@umich.edu)

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

## Board Meeting Dates 2016

### IRB-HSBS Blue

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

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<u>Submission due</u>	<u>Meeting date</u>
February 19	March 17
March 25	April 21
April 22	May 19
May 20	June 16
June 24	July 21
July 22	August 18
August 19	September 15
September 23	October 20
October 21	November 17
November 18	December 15