Fall 2015

Human Subjects Highlights

Institutional Review Board-Health and Behavioral Sciences
University of Michigan

what's new!

IRB-HSBS is preparing for a busy academic year. The University has completed the initial requirements for 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 this winter. The accreditors will interview institutional leadership, IRB members and staff, principal investigators, and study coordinators as part of their visit. Expect more communication from the U-M Human Research Protection Program (HRPP) and IRB-HSBS as arrangements are finalized.

The IRB-HSBS website (http://research-compliance.umich.edu/irb-health-sciences-and-behavioral-sciences-hsbs) has been redesigned with a new look and feel as part of the U-M Office of Research (UMOR) web upgrade. Our new site appears under the UMOR Ethics and Compliance page and features key resources such as IRB meeting dates and deadlines, guidance documents, informed consent templates, and educational materials including access to online presentations created by the U-M IRB Collaborative (U-MIC), a collaboration between IRB-HSBS and IRBMED.

Finally, we would like to recognize the service of long time IRB-HSBS members Dr. Cleo Caldwell and Dr. Dick Redman, both of whom stepped down at the end of their terms this summer. We will miss their presence and contributions at our meetings. We would like to welcome Dr. Brian Zikmund-Fisher as a new IRB-HSBS member. For those interested in learning more about serving as an IRB member, please contact Cindy Shindledecker, IRB-HSBS Director, at cshindle@umich.edu or (734) 615-9466.

Changes to the Common Rule: Notice of Proposed Rule Making

On September 8, 2015, a Notice of Proposed Rule Making (NPRM) entitled "Human Subjects Research Protections: Enhancing Protection for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators" was published by the Office of Human Research Protections (OHRP) in the Federal Register https://www.federalregister.gov/articles/2015/09/08/2015-21756/federal-policy-for-the-protection-of-human-subjects. The NPRM is the next step in a process initiated by the Advance Notice of Proposed Rule Making, which was published in 2011. Public comment is sought on the proposed changes, the most significant of which pertain to informed consent requirements for future use of biospecimens and personally identifiable data, as well as calibration of IRB review so that it is proportional to the potential risks associated with a study. If implemented, some studies that currently require IRB review would become exempt and others considered exempt would become "excluded", or not regulated, and therefore would not require IRB review.

There are plans to release several webinars that will explain the changes proposed in the NPRM, as well as a town hall meeting planned for October in Washington, D.C. The OHRP summary of the proposed Common Rule revisions can be found at http://www.hhs.gov/ohrp/humansubjects/regulations/nprm2015summary.html . OHRP will accept public comments on the NPRM until December 7, 2015. Researchers are encouraged to submit their comments.

In this issue:

Research using student education records

The Family Educational Rights and Privacy Act (FERPA) is a federal law that protects the privacy of personally identifiable information contained in a student's educational record. FERPA pertains to all schools (K-12 and post-secondary institutions) that receive funds from the U.S. Department of Education. In practice, this means almost all schools, colleges, and universities (public or private) are subject to FERPA. FERPA defines "education records" as records containing information that directly relate to a student that are maintained by the school including data about the student's grades, test scores, and GPA , as well as individual student work. Investigators must consider FERPA requirements when planning research studies involving student data.

Generally, schools must obtain written permission from students (K-12 students over the age of 18 and post-secondary students) or their parent (for K-12 students under 18) in order to release personally identifiable information from student educational records. This requirement is typically met if a student (or parent) signs and dates a consent document and authorizes the release of his/her educational record for research purposes. The consent document must identify the records to be disclosed, the purpose of the disclosure, and the parties to whom the disclosure is made.

Under certain circumstances, FERPA allows schools to disclose educational records *without* written permission:

- Information released is limited to *directory information*
- Student records are *deidentified* prior to release to an investigator
- The research is being conducted for, or on behalf, of the disclosing institution, referred to as the *study exception*. In order to qualify for the study exception, the purpose of the research must be to improve instruction, develop predictive tests, or administer student aid programs. The research must be carried out in a way that does not allow individual students to be identified by persons who are not involved in conducting the study. Further, the disclosing institution and investigator must enter into a written agreement that includes the (a) purpose, scope and duration of the study, (b) information to be disclosed, and (c) specific period of time in which PII will be destroyed once it is no longer needed for the research.

Research Using U-M Student Data

U-M investigators planning to conduct research that will use student education records must first submit an IRB application for the project, including a description of the specific student records to be used in the research and the process for obtaining written informed consent to access those records. Some research projects conducted by the University to study learning and teaching (e.g. Learning Analytics, CLRT, etc.) may fall within the FERPA study exception. In order to obtain data from the Registrar's Office, Office of Undergraduate Admissions, or Office of Financial Aid, investigators must first obtain IRB approval with contingencies, and then submit a data request to student.data.request@umich.edu. The unit receiving the request will prepare a Memorandum of Understanding (MOU). Investigators must provide the IRB with an executed copy of the MOU for final approval. It should be noted that IRB approval does not mean that the data steward must or will release the data. The responsibility for ensuring compliance with FERPA lies with the data steward. For further information about FERPA and research, please contact the IRB office or Maya Kobersy in the Office of General Counsel: mkobersy@umich.edu.

IRB-HSBS Review of Studies using the Routine fMRI Master Protocol

Previously, all research projects involving the use of functional magnetic resonance imaging (fMRI) have been reviewed by the IRBMED. The IRB-HSBS, IRBMED and U-M fMRI Laboratory have worked together to formalize a new system in which all standard fMRI studies conducted by any eligible investigator are covered under a single, recently approved IRBMED protocol (HUM93760 "Routine Functional Magnetic Resonance Imaging of the Brain"). As a result, such standard fMRI studies only require IRB approval for the behavioral component of the study (task, stimuli, responses, etc.), which can now be reviewed by IRB-HSBS rather than IRBMED, so long as the following criteria are satisfied:

- The Principal Investigator must be associated with a unit that is typically subject to IRB-HSBS jurisdiction (not the U-M Medical School or University Health System). Undergraduate students may not serve as PI on an fMRI study.
- Participants must be healthy adults age 18 or older.
- The project must be limited to the use of routine scans:
  - No contrast agents (e.g., gadolinium) may be used.
  - The MRI pulse sequences cannot use gradients that exceed 120 mT/m/s ,or RF pulses that exceed 1 Watt/kg. No other scanning protocols may be used.
- Other limitations:
  - The study may not involve any drugs or medical interventions.
  - The study sample may not include UMHS patients.
  - UMHS patient medical records may not be used in the study.
  - The study may not utilize transcranial magnetic stimulation (TMS) or other external methods of disrupting brain function.
  - The study may not involve the use of unique or unusual equipment not already in use in the fMRI Laboratory.

Any projects not meeting the criteria for review by IRB-HSBS must still be reviewed and approved by the IRBMED. For further information about this new review process, please contact Cindy Shindledecker, IRB-HSBS Director, at cshindle@umich.edu

IRB-HSBS 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 invited to attend our Fall 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 to learn more.

The Michigan Nutrition Obesity Research Center's Human Phenotyping Core (MNORC)

MNORC provides research services for studies involving dietary, physical activity/exercise, body composition, and/or metabolic measurements or interventions in human subjects. MNORC services include consultation services to investigators , standardized and sophisticated assessment and physiological testing , and other services to assist researchers in conducting nutritional and/or exercise interventions in human subjects. For more information, visit the MNORC website or contact Sarah Ball, Research Manager, sjcball@umich.edu.

IRB Staff and Assigned, Schools, Colleges or Units

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- Full Board

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- Anthropology
- Architecture and Urban Planning
- Business
- Communication Studies
- Linguistics
- Misc. LS&A (including History)
- Nursing
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- Center for the Education of Women
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- Education
- Institutional Research
- Law School
- Music
- Political Science
- 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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Submission due	**Meeting date**	**Submission due**	**Meeting date**
October 12	November 4	October 26	November 19
November 9	December 2	November 23	December 17
November 30	January 13	December 21	January 21
January 8	February 3	January 22	February 18
February 5	March 2	February 19	March 17
March 11	April 6	March 25	April 14
April 8	May 4	April 22	May 19
May 6	June 1	May 20	June 16
June 10	July 6	June 24	July 21
July 8	August 3	July 22	August 18
August 12	September 7	August 19	September 15
September 9	October 5	September 23	October 20
October 7	November 2	October 21	November 17
November 11	December 7	November 18	December 15