Fall
2014

INSTITUTIONAL REVIEW BOARD-HEALTH SCIENCES AND BEHAVIORAL SCIENCES
UNIVERSITY OF MICHIGAN

Human Subjects Highlights

IRB-HSBS has moved to NCRC

The IRB-HSBS office has relocated to the North Campus Research Complex. Phone numbers for our office (734-936-0933) and individual staff members remain the same. Our new address is:

Institutional Review Board -
Health Sciences and Behavioral Sciences
2800 Plymouth Rd., Building 520, Room 1169
Ann Arbor, MI 48109-2800

This address should be used for the IRB contact information on informed consent documents in all new applications, as well as amendments to previously approved consent documents. Our general informed consent template has been updated to reflect our new address (www.irb.umich.edu/policies/consent/templates/Template_ConsentGeneral_2014.pdf).

As of the date of this newsletter, IRB-HSBS board meetings will still be held in the Liberty Center conference room.

As always, IRB-HSBS staff are available to provide face-to-face consultation for UM investigators. IRB "On the Road" (please see schedule at http://www.irb.umich.edu/education/otr-current.html) and general education sessions (please see schedule on page 2) will continue to be offered on central campus . In addition, office hours are available at our former location (540 E. Liberty, Ste #202) on Wednesday afternoons from 2:30-4:30 on the following dates: 10/8, 15, 22, 29; 11/12, 19; and 12/10. To schedule an appointment, please send an e-mail to irbhsbs@umich.edu.

IRB obligations: A reminder for study teams

The IRB-HSBS would like to take this opportunity to remind our readers about the obligations researchers have in terms of protecting human subjects.

Investigators must ensure that activities which meet the definition of human subjects research undergo IRB review and approval (or are determined to be exempt) before studies are initiated (this includes enrollment, interaction, collection or analysis of identifiable data, and expenditure of federal grant or contract funds for research purposes). Any amendments to approved protocols must be reviewed in advance by the IRB unless changes are necessary to eliminate apparent immediate risks to subjects. A Scheduled Continuing Review (SCR) application must be submitted in advance of the expiration date for approved studies. Any ORIOs, adverse events, and/or unanticipated problems involving risks to subjects or others, as well as any disapprovals, suspensions, or terminations of a project, must be reported to the IRB promptly.

To begin a new IRB application, please login to Regulatory Management within eResearch (the web-based system that centralizes the review and approval process for human subjects research at U-M):
http://www.eresearch.umich.edu/
A pre-application checklist is available as a resource for investigators at
http://www.umich.edu/~eresinfo/errm/start/preappchklist.html

Inside this issue:

Special points of interest:

- *IRB-HSBS has been a leader in the implementation of flexibility when applying the federal regulations for human subjects research.*
- *UM faculty, staff, and students are invited to attend the IRB-HSBS Fall education series.*
- *IRB-HSBS provides individual consultation for investigators at central campus locations.*

IRB-HSBS Flexibility Initiatives

The University of Michigan strives to take full advantage of the flexibility provided in the federal regulations governing human subjects research. Thus, the IRB-HSBS has introduced and implemented a number of innovative practices that have significantly reduced application turn-around times without sacrificing the protection of human subjects including:

- Using alternative processes and procedures for the review of non-federally funded human research studies.
- Regulating only those projects that meet the regulatory definition of human subjects research
- Granting exemptions via IRB staff review
- Utilizing and streamlining expedited review
- Utilizing waivers or alteration of informed consent and waivers of documentation of informed consent
- Establishing cooperative research review arrangements to avoid duplicate review
- Providing two year approvals
- Expanding or reinterpreting the exempt review categories for adult participants

Did you know . . .

- *Since 2007, U-M has launched several demonstration projects to provide additional flexibility and reduce administrative workload for investigators.*
- *Approximately 25% of the currently approved studies at IRB-HSBS have two-year approvals.*
- *For minimal risk research with adults, U-M Exemption #2a allows investigators to precede a survey, interview (including focus groups) or observation with a non-invasive intervention.*
- *U-M Exemption #7 provides appropriate review and subsequent exemption from regulatory oversight (continuing review) for minimal risk studies where research activity is limited to analysis of identifiable data.*

General education sessions

September 30, 2014 - Introduction to the IRB: This session covers the ethical principles that guide the work of an IRB and provides an overview of the IRB review process at UM.

October 7, 2013 - Fundamentals of Informed Consent: This session reviews regulations involving informed consent and consent waivers, and offers strategies for writing informed consent documents.

October 28, 2013 - Exempt, Not-regulated, and Secondary use: This session outlines (a) activities that are *not* subject to IRB oversight, (b) differences between not-regulated and exempt determinations, (c) specific categories of exemption, and (d) circumstances under which a "secondary use" application is appropriate.

November 11, 2013 - Working with Collaborators: This session addresses the issue of ensuring that all collaborating researchers (non U-M affiliates) have appropriate IRB oversight while avoiding duplicate reviews. IRB Authorization, Individual Investigator, and Collaborating Institution Agreements are described.

November 18, 2013 - Students and Employees as Research Subjects : Protections for potentially vulnerable subject populations are discussed.

**Sessions are held from 3:30-4:30 pm in the Liberty Center Conference Room, 540 E. Liberty, Suite 202*

To register, please send an e-mail to irbhsbs@umich.edu indicating your desire to attend. Please include your name and department.

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)

- 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
- University Center for the Development of Language and Literacy
- Women's Studies

Debra Schneider (dschnei@umich.edu)

- Full Board
- Dentistry
- Engineering
- Ergonomics
- Kinesiology
- Pharmacy

Deborah Schild (drsw@umich.edu)

- Economics
- Education
- Institutional Research
- Music
- Political Science
- Public Health
- Public Policy (includes Law School)
- School of Information
- School of Natural Resources
- Social Work
- Survey Research Center/Institute for Social Research

Board Meeting Dates 2014-2015

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Submission due	**Meeting date**	**Submission due**	**Meeting date**
December 22	January 22	December 1	January 7
January 26	February 19	January 12	February 4
February 23	March 19	February 12	March 4
March 23	April 16	March 9	April 1
April 27	May 21	April 13	May 6
May 25	June 18	May 11	June 3
June 22	July 16	June 8	July 1
July 27	August 20	July 13	August 5
August 24	September 17	August 10	September 2
September 21	October 15	September 14	October 7
October 26	November 19	October 12	November 4
November 23	December 17	November 9	December 2