

HUMAN SUBJECTS HIGHLIGHTS

IRB-HSBS Office

Cindy Shindledecker, BA
Director

Mary Ramirez, MA
Assistant Director

Mary E. Donnelly, BBA
Full Board Administrator

Adam J. Mrdjenovich, Ph.D.
Senior Research Compliance
Specialist
Education Coordinator

Wendy Peebles, MSW
Application Specialist

Deborah Schild, Ph.D.
Research Compliance Specialist

IRB-HSBS Leadership

Richard Redman, Ph.D.
Chair

Jorge Delva, Ph.D.
Vice Chair

University of Michigan

Institutional Review Board Health Sciences & Behavioral Sciences (IRB-HSBS)

FALL 2012

Since the Last Issue

Congratulations are in order. Judy Nowack has begun a phased retirement after 15 years of service to OVPR. We welcome Professor James A. Ashton-Miller as Judy's successor in the role of Associate Vice President for Research. Cindy Shindledecker has been appointed to the position of IRB-HSBS Director. Since joining the IRB-HSBS staff in 2005, Cindy has held virtually every position in the office. Institutionally, she has been involved with HRPP, including eResearch governance committees and the AAHRPP accreditation process. We are also very happy to announce Mary Ramirez's appointment as Assistant Director, and Mary Donnelly's appointment as Full Board Administrator. All of us look forward to continued collaboration with the UM research community to ensure that human subjects research is conducted ethically, respectfully, and in compliance with regulations. Finally, we congratulate Nancy Skurka, who has accepted a position with the regulatory affairs Clinical Trials Office of the UM Comprehensive Cancer Center. We are very sorry to see Nancy go, but wish her all the best in her new job.

Tips for Preparing and Submitting Your IRB Application

IRB-HSBS staff are happy to answer your questions about the application and review process. We offer a variety of seminars throughout the fall and winter semesters (<http://www.irb.umich.edu/education/workshops-current.html>). In addition, we hold office hours "On the Road" at units across campus. This provides an opportunity for you to ask questions and discuss your projects on an individual basis. If your unit is not listed on our current schedule (page 4) and you would like to arrange office hours, please contact us. You may also contact us to request a presentation for your unit, program, class, or group. For more information, please visit <http://www.irb.umich.edu/education/>.

Through our educational activities, we are often asked about best practices for preparing and submitting IRB applications. We offer the following tips as a starting point.

General Information

- Allow 2-4 weeks for expedited review and 4-8 weeks for full board review.
- Use resources on our website, including informed consent templates (<http://www.irb.umich.edu/>).
- Contact ITS if you're unsure how to use eResearch (764-HELP, 4Help@umich.edu)
- Call the IRB if you have questions about the content of the application or the process (734-936-0933)

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IRB Application Tips (continued)

- Key study personnel must complete PEERRS "Human Subjects" module (<http://my.research.umich.edu/peerrs/>).
- Review the application before submitting to ensure that responses are consistent and that all required materials are provided (e.g. letters of support, recruitment flyers, consent document, surveys, etc.)
- Read requested changes carefully and make revisions or offer clarifications. Click "submit changes" when you're ready to return your application to us.

Application-specific (the numbers in parentheses represent a relevant section of the eResearch application)

- Student PIs, including post-docs, must include a faculty advisor on study team (1.3).
- Provide current CVs for key members of the study team (1.4).
- For externally-sponsored projects, provide the link to the ePAF (2.7).
- All research activities conducted by UM affiliates are UM study functions regardless of performance site (3.1).
- The Performance Sites section captures two types of information: 1) sites where research will be conducted; 2) collaborating institutions. (3-1)
 - Performance sites are not engaged unless an individual at the site is engaged (<http://www.hhs.gov/ohrp/policy/engage08.pdf>) (3-1).
 - IRB approval or an IRB authorization agreement is required for engaged collaborators. (3-1)
- Describe your study clearly, completely, and consistently. The reviewer should be able to replicate your design based on the information you provide (5).
- Distinguish benefits and risks to subjects from societal or community risks and benefits (<http://med.umich.edu/irbmed/guidance/risk-guide.html>) (6).
- The number under 8.1. should match the sum in table 8.2.
- Select a population only if your study specifically targets it (9-1).
- Use informed consent templates (<http://www.irb.umich.edu/policies/consent/>) (10).
- Waiver of consent refers to the consent process (10-3); waiver of documentation means that a signed consent document will not be obtained(10-4).
- Know the difference between "anonymous", "confidential", and "deidentified" (<http://www.irb.umich.edu/policies/anonymous.pdf>) (11).

International Research

IRB-HSBS has oversight for research conducted by UM investigators, even when studies take place outside the United States. We consider the local context and population in order to assess risks to subjects. The key is that protections for subjects abroad must approximate those provided for subjects in the U.S.

Differences in language, religion, cultural history, social mores, national policies, or legal systems may deem procedures for human subjects research set forth by U.S. federal regulations as inappropriate. For example, a study might involve societies where no written language exists, or where signatures represent something different from what signatures represent in the United States. Therefore, IRB-HSBS does not impose standards of informed consent *documentation* on other cultures. We do, however, endorse a meaningful consent *process*. Study teams should give special attention to local customs and norms when drafting consent forms or scripts, or when proposing alternate consent procedures. For non-English-speaking subjects, translated consent documents or the use of an interpreter is necessary to ensure full understanding on the part of subjects.

Study teams are asked to provide IRB-HSBS with assurance that international research proposals are consistent with local regulations for human subjects research. If review by a local government agency or ethics board is required, documentation of that review should be provided as part of the IRB-HSBS application process. In cases where no equivalent IRB or ethics review is required, study teams may be asked to provide the name of a context expert who could serve as consultant to IRB-HSBS in the review process. Ideally, the consultant would have experience conducting human subjects research in the country or area under study.

Key Points - When preparing applications involving international research:

- Provide information about the local research context as part of your assessment of risks to subjects. Describe your knowledge of the community (have you lived or conducted research there, studied the region extensively, etc?).
- Plan a consent process that is appropriate for your subjects. IRB-HSBS may waive some of the standard elements of informed consent. Requests for waivers should describe cultural norms or explain conditions that call for the waiver.
- If you will conduct your study in a language other than English, provide translations of research materials or describe plans for use of an interpreter.
- Local IRB/ethics review or expert consultation may be required.
- If local residents will assist with your research, individual investigator agreements may be necessary.
- Develop a plan for data management and security while traveling.

Adapted in part from the Human Subjects Office newsletter (<https://research.uiowa.edu/hso/?get=news>) with permission of The University of Iowa.

IRB Staff and Assigned Schools, Colleges, or Units

Mary Donnelly

Full Board, A-STARRS, HRS/PSID

Wendy Peebles

Center for the Education of Women
 Center for Human Growth and Development
 Engineering
 Ergonomics
 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

Deborah Schild

Exempt Not-Regulated
 Economics
 Education
 Institutional Research
 Kinesiology

Music
 Political Science
 Public Health
 Public Policy (includes Law School)
 School of Information
 School of Natural Resources
 Social Work
 SRC/ISR (except HRS and PSID)

TBD

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

Calendar of Events

Full Board 2012 - 2013

IRB On the Road

IRB-HSBS Blue:		IRB-HSBS Maize:	
Meeting date	Submission due	Meeting date	Submission due
September 5	8/13	September 20	8/27
October 3	9/10	October 18	9/24
November 7	10/15	November 15	10/22
December 5	11/12	December 20	11/26
January 9	12/3/12	January 24	12/13/12
February 6	1/14	February 21	1/28
March 6	2/11	March 21	2/25
April 3	3/11	April 18	3/25
May 1	4/8	May 16	4/22
June 5	5/13	June 20	5/27
July 3	6/10	July 25	7/1
August 7	7/15	August 15	7/22
September 4	8/12	September 19	8/26
October 2	9/9	October 17	9/23
November 6	10/14	November 21	10/28
December 4	11/11	December 19	11/25

Unit	Dates/Time	Location
Business	9/21, 10/19, 11/16, 12/14 2- 4 p.m.	3010 R-BUS
Communication Studies	9/12, 10/10, 11/14, 12/12 2- 4 p.m.	5356 NQ
Education	9/13, 10/11, 11/15, 12/13 9 a.m.-12 noon	TBA
Information	9/12, 10/10, 11/14, 12/12 12:30 - 2 p.m.	TBA
Nursing	9/11, 10/9, 11/6, 12/4 12:30 - 2:30 p.m.	4217 SON
Psychology	Every other Monday 8/27-12/10 2:30 - 4:00 p.m.	1343 EH
Public Health	9/25, 10/23, 11/13, 12/4 12:30 - 2:30 p.m.	1623 SPH
Social Work	9/18, 10/16, 11/6, 12/12 12 noon - 2 p.m.	2733 SSW

Helpful Links

Office for Human Research Protection
www.hhs.gov/ohrp

UM Human Research Protection Program
www.hrpp.umich.edu

eResearch
eresearch.umich.edu

UM Office of the Vice President for Research
www.research.umich.edu/ovpr

PEERRS
my.research.umich.edu/peerrs/

IRB-HSBS
www.irb.umich.edu