

HUMAN SUBJECTS HIGHLIGHTS

University of Michigan

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

SPRING 2012

IRB-HSBS Office

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Application Specialist

IRB-HSBS Leadership
IRB-HSBS Chair:
Richard Redman, Ph.D.

IRB-HSBS Vice Chair:
Jorge Delva, Ph.D.

Since the Last Issue ...

HHS Proposes to Change the Common Rule for Human Subjects Research

As a first step in the process of updating the Common Rule, regulations that govern the conduct of human subjects research (in place since 1991), the federal department of Health and Human Services (HHS) issued an Advance Notice of Proposed Rulemaking in July of 2011. The document entitled “Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators” sought commentary from the research community on topics including (1) single IRB review for multi-site studies, (2) mandatory data security and information protection standards for research involving identifiable data, (3) calibration of review framework to risk level, (4) enhancement of the informed consent process, (5) collection of data for adverse events and unanticipated problems, (6) extension of federal regulatory requirements to all research at US institutions receiving federal funds, and (7) the provision of unified guidance on federal regulations. U-M was among several hundred institutions to submit comments for consideration by HHS before the agency issues a formal Notice of Proposed Rulemaking to announce the specific, proposed changes. The timetable for HHS to complete this process and implement any regulatory change is unknown. For more information, including access to comments submitted, please see

<http://www.hhs.gov/ohrp/humansubjects/anprm2011page.html>.

Topic	Page
Turnaround time	2
Full Board Corner	2
ORIOs	3
Calendar of Events	4
IRB Staff & Units	4
Helpful links	4

IRB-HSBS Staff Changes

Several staff changes have occurred at IRB-HSBS since our last issue. Former Assistant Director, Mona Moore, and Education Coordinator, Nancy Birk, have moved to new positions with the Medical School. Cindy Shindledecker now serves as Assistant Director. Elaine Kanka, a long time IRB staff member, and IRB secretary, Connie LaBumbard, are now enjoying retirement. Recently, we welcomed two new administrative reviewers, Deb Schild and Nancy Skurka, and we are finalizing the hiring of a new secretary. Please see page 4 for a list of IRB office staff members and the schools, colleges, and units for which they are responsible.

Turnaround time for expedited review down by 4 days

IRB-HSBS continually strives to enhance efficiency, streamline processes, and reduce regulatory burden. As part of these efforts, Adam Mrdjenovich, Ph.D. joined the IRB-HSBS staff as “in-house” expedited reviewer in January 2011 after working for ten years as a practicing psychologist, research associate, and adjunct faculty member in psychology and health behavior/health education. Since Adam began functioning in this newly designed role, the average turnaround time for expedited reviews conducted through IRB-HSBS has decreased by four days. “Although the expedited process involves an evaluative component of scientific review, I really see it as a collaborative process [in which] I can apply my own experience as a researcher to support the design and conduct of sound research, and facilitate the IRB approval process for investigators at UM.” In an additional role as IRB-HSBS Education Coordinator, Adam develops, delivers, and evaluates general education sessions and classroom presentations on a variety of topics related to research ethics and human subjects protection. “It’s really been a pleasure meeting with faculty and students through our educational outreach efforts on campus, and a privilege to read about much of the research that takes place at the University of Michigan. More than anything else, I appreciate the opportunity to help people by protecting the rights and welfare of human subjects.” When asked “What cool thing would you want people to know about you?”, Adam replied “I’m married to the love of my life, Wendy. I have two healthy parents, five siblings, four nieces, and seven nephews. My hobbies and interests include music, cooking, and aquarium keeping, which reminds me of the warm climate and sunshine in my second favorite state of Florida!”.

What kinds of studies require review by the full board?

IRB-HSBS is frequently asked about criteria used to determine whether a study must be reviewed by the full board. The primary point of assessment is the risk level as indicated by the study team. According to federal regulations, research studies that involve *more than minimal* risk to human subjects **must** be reviewed by a convened IRB. Among other types of studies that require full board review are those involving prisoners as subjects or the collection of individually identifiable data on sensitive topics (e.g., illegal behavior, substance abuse, sexual behavior, health history) that may require a study team to obtain an NIH Certificate of Confidentiality, which protects subject data from compelled disclosure. *Minimal* risk research **may** be referred to the full committee when studies involve complex designs that would benefit from interdisciplinary review by the breadth of expertise represented at the full board. Additionally, an expediting reviewer may choose to refer an application to the full committee for any reason. The Maize full board and Blue full board each meet once per month. Applications must be submitted to the IRB-HSBS office three weeks prior to the full board meeting in order to be placed on the agenda. Please see the full board meeting schedules on page 4 for submission deadlines.

ORIOs

What is an ORIO? “ORIO” stands for Other Reportable Information or Occurrence. An ORIO is a reporting tool used by researchers to share important information with the IRB. The term “ORIO” is unique to the University of Michigan. ORIOs are different from adverse events (AEs). AEs result in *actual* harm to subjects. ORIOs, on the other hand, might represent events that increase the *potential* for harm to subjects.

When is an ORIO required? Principal investigators must report events or other information that may (a) indicate the possibility of increased risk of harm to subjects or others, (b) alter the risk-benefit assessment for a given study, (c) influence subjects’ willingness to participate in a study, and/or (d) represent a departure from applicable human subjects protection regulations and policies.

What are some different types of ORIOs? **Protocol deviations/violations** involve *purposeful* (i.e., necessary to eliminate apparent or immediate risk to subjects or others) or *accidental* (e.g., over-enrollment of subjects, use of an incorrect consent document or survey) variance in the procedures outlined for a study in its IRB approved protocol. Regulations require IRB approval of all proposed changes to studies *prior* to implementation. ORIOs allow an opportunity for PIs to (a) describe and offer justification for protocol deviations, (b) assess the integrity of data or risk of harm to subjects, and (c) outline ways in which occurrences have been addressed or corrected, or how similar occurrences will be avoided in the future. A **study lapse** occurs when continuing IRB approval is not secured prior to a study’s expiration date. The purpose of this particular type of ORIO is to document the reason for the lapse and report any project activity that has taken place during the period of the lapse. Other examples of ORIOs involve accidents or incidents, loss of data, subject withdrawals, and subject complaints. ORIOs may also be used to update the IRB with information contained in reports sent to or received from an auditing organization or study sponsor.

How do I submit an ORIO? ORIOs are submitted via eResearch (<http://eresearch.umich.edu>) as follows:

- Go to the “parent” record for the study using the ALL SUBMISSIONS or ARCHIVED tab in the home workspace.
- At the bottom left of the screen, click NEW ADVERSE EVENT/ORIO .
- Question 1.2 —Type of Report: Choose ORIO
- Question 1-2.1 — ORIO Type: Answer as appropriate for your project.
- eResearch smart form logic generates necessary sections based on responses to previous items. Answer as appropriate for your project.
- Click FINISH and then SUBMIT.

Detailed guidance and procedures for ORIO reporting are available at: http://www.med.umich.edu/irbmed/ae_orio/. Similar information is referenced within the Help feature of eResearch. Due to possible time criticality associated with ORIOs, a PI may delegate the submission of an ORIO to a co-investigator or faculty advisor; however, the PI is ultimately responsible for the report.

What does the IRB do with an ORIO? ORIOs are reviewed to evaluate patterns that may present concerns in relation to risk assessment, informed consent, research progress, etc. IRB staff conduct an initial review of the ORIO to ensure that it is complete and to assess the expectedness and seriousness of the ORIO. After initial screening, it is routed for review by the IRB Chair, single IRB member, or the convened board. ORIOs are not approved, but are acknowledged.

What are some possible outcomes of an ORIO submission? The possible outcomes vary depending on the nature and circumstances of the particular ORIO, but these could include modifications to the protocol, consent process, or continuing review schedule, and the provision of additional information to past or current participants. The IRB will notify the investigator if additional information is needed in the process of acknowledging an ORIO. Investigators may need to submit an amendment application if review of the ORIO requires changes to the previously approved IRB application.

IRB Staff and Assigned Schools, Colleges, or Units

Mary Donnelly

HRS/PSID
Nursing
Public Health
UMTRI

Wendy Peebles

Center for Human Growth and Development
Psychology
Research Center for Group Dynamics
Women's Studies (includes Center for the Education of Women, and Institute for Research on Women and Gender)

Deborah Schild

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

Nancy Skurka

Architecture and Urban Planning
Business
Communication Studies
Dentistry
Engineering
Ergonomics
Linguistics
Misc. LS&A (including History)
Pharmacy
Population Studies
Sociology
UCDLL

Calendar of Events

Full Board 2012

IRB-HSBS Blue:		IRB-HSBS Maize:	
Meeting date	Submission due	Meeting date	Submission due
March 7	2/13	March 15	2/20
April 4	3/12	April 19	3/26
May 2	4/9	May 17	4/23
June 6	5/14	June 21	5/28
July 11	6/11	July 26	6/25
August 1	7/9	August 16	7/23
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

IRB On the Road

(<http://www.irb.umich.edu/education/otr-current.html>)

Unit	Date/Time	Location
Anthropology	TBA	TBA
Business	3/16, 2-4	R-BUS 3010
Education	3/8, 9-12	SEB 3002
Information	3/14, 12:30-2	TBA
Nursing	3/28, 2-4	TBA
Psychology	3/5, 3/19, 3:30-5	1343 East Hall
Public Health	3/27, 12:30-2:30	SPH I # 1623
Social Work	3/7, 1-3	2733 SSWB

Helpful Links

Office for Human Research Protection

www.hhs.gov/ohrp

UM Office of the Vice President for Research

www.research.umich.edu/ovpr

UM Human Research Protection Program

www.hrpp.umich.edu

eResearch

eresearch.umich.edu

PEERRS

my.research.umich.edu/peerrs/