

HUMAN SUBJECTS HIGHLIGHTS

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

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Since the Last Issue

We are happy to announce several of the latest developments within our office and beyond. Judy Birk, IRBMED Director, and Cindy Shindledecker, IRB-HSBS Director, have been appointed as Associate Directors of the UM HRPP. We welcome Debra Schneider, who, in addition to her role as IRB Dearborn Administrator, now serves as Assistant Full Board Administrator for IRB-HSBS. Elaine Kanka has returned to her role as Application Specialist, and Wendy Peebles has been promoted to Research Compliance Specialist. Congratulations all! In other news, IRB Flint recently supported a campus-wide reading of *The Immortal Life of Henrietta Lacks* and hosted a lecture on the Tuskegee Experiments, which contributed to a 20% increase in the number of UM Flint affiliates with PEERRS certification.

New Demonstration Project

To provide flexibility and minimize regulatory burden for investigators and the institution, IRB-HSBS will launch a new demonstration project, UM "Exemption 2a", this spring.

Under current federal regulations for human subjects research, exemption category #2 is defined as: Research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. 45 CFR 46.101(b)(2)

Thus, OHRP's position is that exemption #2 cannot be applied to projects involving an intervention of any kind. However, many studies under consideration for exemption by IRB-HSBS involve a minimal risk intervention (such as watching a video, reading a news story, playing an economics game, using a computer program, etc.). Consequently, the new UM demonstration project will expand the definition of exemption #2 and apply "Exemption 2a" to minimal risk research that involves a non-invasive intervention followed by data collection via survey, interview (including focus groups), or observation.

To qualify for Exemption #2a, a study must pose no more than minimal risk to subjects and must *not* include any of the following elements:

- Federal funding or federal training grants
- FDA regulated components
- Sponsor or other contractual restrictions
- Clinical interventions (including clinical behavioral interventions)
- Prisoners or minors as subjects
- Receipt of an NIH issued Certificate of Confidentiality to protect identifiable research data

IRB-HSBS will review new or renewing applications that meet the above criteria to ensure that subject protections are equivalent to those required by federal regulations. If so, and there are no extenuating circumstances, the new exemption 2a will be issued. All other regulatory requirements pertaining to exemptions will remain unchanged.

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Reminder for Students Conducting Summer Research Projects

Students who plan to conduct research projects over the summer are reminded to allow sufficient time for IRB review and approval. This is especially true for students who are new to the IRB application process, and students whose projects involve federal sponsorship, non-UM collaborators, and/or international research. In general, student investigators should allow 4-8 weeks (depending on review path) for the preparation, submission, revision, and approval of IRB protocols. In addition, students who plan to travel abroad should visit the UM Global Michigan travel registry at: <http://global.umich.edu/going-abroad/planning/registry/>

The Faculty Advisor's Role in Research Conducted by Students

Faculty advisors serve as active mentors to student investigators and share responsibility for the ethical conduct of research carried out by students. In fulfilling this important role, faculty advisors at UM:

1. *Complete the PEERRS human subjects research training module* – Faculty advisors are familiar with ethical and regulatory requirements for human subjects research, and they discuss research ethics with their students. Advisors remind students that IRB approval must be obtained before they interact or intervene with human subjects or access private identifiable information for research purposes.
2. *Assist students in designing and planning research studies* – Student research projects must be appropriate for their level of training and experience. Studies conducted by undergraduates at UM must pose no more than minimal risk to subjects.
3. *Guide students in the preparation of IRB applications* – Knowing that a clear, complete, consistent application will facilitate the IRB review process, faculty advisors ensure that students attach informed consent documents, recruitment materials, and data collection instruments to their applications as appropriate.
4. *Accept their role and submit IRB applications in eResearch* – By clicking the "Accept Role" button before submitting applications in eResearch, faculty advisors acknowledge their responsibility for students' projects. This allows IRB-HSBS to copy advisors on communications with student investigators; it also allows direct communication with advisors should an application reflect a need for faculty involvement.
5. *Support students as they conduct research in field and international settings* – For the safety of human subjects and student investigators, faculty advisors ensure that students are aware of local customs and regulations. In addition, advisors help students establish local contacts or sponsorship, as well as communication and data security plans.
6. *Monitor student research* – Faculty advisors check in with students to ensure that (a) research is being conducted as approved, (b) study modifications are submitted for IRB approval via an amendment, and (c) adverse events or other research-related problems are reported to IRB-HSBS.

New International Research Portal

OVPR has announced a new International Human Research website: <http://www.hrpp.umich.edu/policies/international.html>, which provides guidance and resources for UM investigators and IRB members on international research laws and ethics panels, informed consent, ethics training, investigator and staff training materials in five languages, international clinical trials, and more. The content was developed by OVPR's Office of Human Research Compliance Review with assistance from a broad community of UM faculty and staff engaged in international research. Dr. Terry Vandenbosch spearheaded the project, and Karin Teske created the web site.

UM School of Public Health Conducts “exFLU” Study

By way of our newsletter, IRB-HSBS wishes to highlight the breadth and significance of the research studies we oversee. Given that flu season is upon us, it seems especially appropriate to feature the “ex-FLU” study, which is lead by UM-SPH faculty Drs. Allison Aiello and Arnold Monto and examines the transmission of influenza among students living in UM residence halls. Findings will inform recommendations concerning the length of time students should stay home when they have the flu.

Aspects of the ex-FLU design are notable from a human subjects perspective. For example, some participants who report flu symptoms are asked to remain in their dorm for three days. To determine whether this prevents transmission of the flu, it is necessary to recruit subjects in such a way that their social networks can be constructed. (When students enroll in the study, they nominate social contacts living in one of several UM residence halls. Enrolled students and nominees who agree to participate are then considered to be social contacts in the study population). For this reason, subjects must consent to reveal their participation to any other enrolled individual and respond to surveys regarding their social interactions with other participants. Such procedures, which would traditionally present privacy and/or third-party concerns, serve as excellent examples of considerations that arise as IRBs review study designs involving social networks, including those accessed via internet and social media. IRB-HSBS keeps abreast of related issues and works together with study teams to ensure that human subjects are protected as contemporary research tools are utilized to their maximum benefit. We wish the ex-FLU study team continued success with their research!

Amazon Mechanical Turk “Workers” are not anonymous

Researchers at the School of Information recently notified the IRB-HSBS of an issue involving Amazon Mechanical Turk, a crowd sourcing site that is currently being used as a survey tool by many social and behavioral researchers. It has generally been believed that “workers” responding to task or research requests on mTurk were not individually identifiable, identified only by a fifteen character alphanumeric Worker ID. A team of researchers has discovered that the Worker ID is used throughout the Amazon site to identify an individual and it may be possible to ascertain their identity via a simple search, depending on the security settings set by that individual.

Blog post: <http://crowdresearch.org/blog/?p=5177>

Paper: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2228728

Because the Worker ID can be considered a personal identifier, there may be IRB implications for research projects using Amazon mTurk as a data collection tool. Please contact the IRB for more information if you are using this tool.

Exemption “Wizard”

IRB-HSBS is participating in an evaluation, sponsored by the Federal Demonstration Partnership (FDP), of an electronic “wizard” designed to allow investigators to “self-determine” whether their project meets the regulatory criteria for exemption or requires standard IRB review. Participating institutions were asked to have investigators re-review projects that received exemptions, as well as projects that have undergone expedited review, to evaluate whether the wizard produces the same determination as the IRB review process. All investigators receiving an exempt determination have been invited to participate.

If you have questions or wish to participate in wizard testing, please contact Adam Mrdjenovich at amrdjen@umich.edu or Cindy Shindledecker at cshindle@umich.edu. For more on the Federal Demonstration Partnership Human Research Subcommittee, please see http://sites.nationalacademies.org/PGA/fdp/PGA_060999.

IRB Staff and Assigned Schools, Colleges, or Units

Mary Donnelly, Debra Schneider

Full Board
A-STARRS
HRS/PSID

Elaine Kanka

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

Wendy Peebles

Exempt, Not-Regulated
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)

Calendar of Events

Full Board 2013

IRB "On the Road"

IRB-HSBS Blue:		IRB-HSBS Maize:	
Meeting date	Submission due	Meeting date	Submission due
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	4/19, 5/17; 2 - 4 p.m.	3010 R-BUS
Communication Studies	4/10; 2 - 4 p.m.	5356 NQ
Economics/Linguistics	4/15; 2 - 4 p.m.	301 LORCH
Education	4/18, 5/9; 9a.m. - 12 noon	3002 SEB
School of Information	4/10, 5/8; 12:30 - 2 p.m.	4446 NQ
Nursing	4/2; 2 - 4 p.m.	4320 SON
Psychology	4/8, 4/22, 5/6, 5/20 2:30 - 4 p.m.	1343 EH
Social Work	4/3; 12 - 3 p.m.	2773 SSWB

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