

HUMAN SUBJECTS HIGHLIGHTS

WINTER



HEALTH SCIENCES &
BEHAVIORAL SCIENCES IRB
UNIVERSITY OF MICHIGAN

2017

Since the Last Issue



The IRB-HSBS would like to welcome Dr. Riann Palmieri-Smith, Associate Professor of Kinesiology and Orthopedic Surgery, as Vice-Chair for the Maize and Blue boards effective April 1. Riann is a long time board member and we look forward to working with her in this new role.

We also wish to announce the (second) retirement of IRB Application Specialist Ms. Elaine Kanka. Elaine officially retired in December 2011 after a long career at the University, but she missed the IRB so much that she returned to her position in 2012 and stayed for another four years! Elaine's professional and personal contributions to our office will be missed.

We are very happy to announce the arrival of Lisa ("Li") Morrow as Associate Research Compliance Specialist. Li earned a bachelor's degree from U-M and a master's degree from Kent State University. She has a diverse work background in early childhood education, automotive quality, and adult counselling and education. Li recently moved back to Michigan after living in Barrow, Alaska. A list of the units Li serves appears on page 4.

Revisions to the Common Rule

The U.S. Department of Health and Human Services has published a Final Rule to revise the Federal Policy for the Protection of Human Subjects (for a press release, see <https://www.hhs.gov/about/news/2017/01/18/final-rule-enhances-protections-research-participants-modernizes-oversight-system.html>). The revisions are intended to reduce administrative burden for investigators and IRBs. Key changes include the elimination of continuing review (for minimal risk studies that are eligible for expedited review, and studies that have transitioned to analysis of identified data or biospecimens), a single IRB-of-record requirement for cooperative research, and changes to elements of informed consent. Also, the exemption categories have been expanded:

- Exemption #2 now includes studies that collect sensitive identifiable data via surveys, interviews, or observation of public behavior; however, "limited IRB review" is required to ensure adequate protections for privacy and confidentiality.
- New Exemption #3 allows benign behavioral interventions in conjunction with data collection involving adult subjects; however, it *does not permit deception or concealment unless the subject prospectively agrees to participate in deception research*.
- Exemption #4 is no longer limited to existing data; it can now be applied to secondary research use of identifiable private information and identifiable biospecimens for which consent is not required, as well as identifiable health information regulated under HIPAA.
- New Exemption #7 is intended for repositories; it requires limited IRB review to ensure that broad consent for storage, maintenance, and secondary use has been obtained and documented as appropriate.
- Exemption #8 applies to secondary research use of identified private information or biospecimens collected under broad consent and can be issued after limited IRB review.

The implementation date for the new rule is January 19, 2018. *Until then, current U-M IRB policies and procedures remain in effect.* UMOR and the U-M HRPP and IRBs are reviewing institutional policies and procedures involving human subjects research at U-M and evaluating eResearch with the goal of streamlining processes. As a note, under the terms of the Congressional Review Act, there is still a chance that the rule could be nullified.

Communications and training to inform the U-M research community about these significant changes to IRB review processes are forthcoming. Questions about the Final Rule may be directed to IRB-HSBS Director Cindy Shindledecker: cshindle@umich.edu.

HUMAN SUBJECTS HIGHLIGHTS

WINTER



HEALTH SCIENCES &
BEHAVIORAL SCIENCES IRB
UNIVERSITY OF MICHIGAN

2017

New Requirements for NIH-Sponsored Clinical Trials



National Institutes
of Health

U-M investigators conducting behavioral clinical trials subject to IRB-HSBS oversight should be aware of several new requirements for NIH-sponsored clinical trials.

All NIH-funded clinical trial study team members except administrative staff are required to complete GCP training. GCP modules for social and behavioral researchers can be found at: [Social and Behavioral Research Best Practices](#). GCP training does not replace PEERRS.

All new NIH-funded clinical trials (or those receiving a competing renewal) and trials conducted by investigators who wish to publish in [ICMJE](#) journals must be registered on [ClinicalTrials.gov](#). Investigators must mention [ClinicalTrials.gov](#) registration in the informed consent document. They must also submit results of the trial at its conclusion. Administrative liaisons trained to assist investigators have been designated for schools and colleges that expect to obtain NIH funding for clinical trials.

Effective September 25, 2017, the NIH requires the designation of a [single IRB-of-Record](#) for multi-site clinical trials where the same non-exempt protocol will be implemented at multiple sites. A plan designating a single IRB must be included in proposals submitted to the NIH as of the effective date. Investigators planning multi-site studies should check with the IRB when planning such studies.

Please contact Cindy Shindledecker, IRB-HSBS Director, at cshindle@umich.edu or 5-9466 if you have questions.

Screening and Recruitment



Procedures for the initial identification, contact, screening, and recruitment of research participants demonstrate respect for the autonomy of prospective subjects when information is presented by someone who can answer questions about the study, when individuals do not feel obliged to participate, and when investigators protect the privacy of individuals and the confidentiality of information obtained.

All screening procedures are subject to IRB review. Information collected during the screening process should be limited to that which is necessary to determine eligibility. Investigators must indicate in the IRB application whether they plan to collect and/or record any personally identifiable information for screening purposes, and whether such information will be destroyed or retained after screening, and for whom. When eligibility determinations involve the collection of sensitive identifiable information, investigators are encouraged to obtain consent prior to screening and before enrolling individuals in the main study. Alternatively, investigators may request an IRB waiver of consent for screening.

Recruitment materials should include information about how the recipient was identified as a potential research participant; who is conducting the study and why; a summary of eligibility criteria; what participation involves (e.g., location of the research, time commitment); and an overview of any risks or potential benefits of participation. Recruitment materials should also let the recipient know how to inform someone if he or she wants to participate, and where to get answers to questions.

IRB 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 cordially invited to attend our general education series <http://research-compliance.umich.edu/irb-hsbs-educational-sessions-winter-2017>), which include several newly developed sessions. Please contact the IRB Office at (734) 936-0933 or irbhsbs@umich.edu to learn more.

HUMAN SUBJECTS HIGHLIGHTS

WINTER



HEALTH SCIENCES &
BEHAVIORAL SCIENCES IRB
UNIVERSITY OF MICHIGAN

2017

IRB-HSBS Staff and Assigned, Schools, Colleges or Units

Mary Donnelly (mardonne@umich.edu)

- Full Board

Lisa Morrow (hamiltol@umich.edu)

- Anthropology
- Architecture and Urban Planning
- Art and Design
- Business
- Engineering
- Ergonomics
- Linguistics
- Misc. LS&A
- Nursing
- UMTRI

Wendy Peebles (wpeebles@umich.edu)

- Adult Psychological Clinic
- Center for the Development of Language and Literacy
- Center for the Education of Women
- Center for Human Growth and Development
- Communication Studies
- Institute for Human Adjustment
- Institute for Research on Women and Gender
- Psychology
- Research Center for Group Dynamics
- Sociology
- University Center for the Child and Family
- U-M Aphasia Program
- Women's Studies

Debra Schneider (dschnei@umich.edu)

- School of Public Health
 - Biostatistics
 - Environmental health
 - Epidemiology
 - HBHE
 - Human Genetics
 - Nutrition

Deborah Schild (drsw@umich.edu)

- Dentistry
- Economics
- Education
- Institutional Research
- Law School
- Music
- Pharmacy
- Political Science
- Population Studies
- Public Policy
- School of Information
- School of Natural Resources
- Social Work
- Survey Research Center/ Institute for Social Research