IRB-HSBS Office

Cindy Shindledecker, BA, CIP
Director

Mary Ramirez, MA, CIP
Assistant Director

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

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Asst Full Board Administrator

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Research Compliance Specialist

Deborah Schild, Ph.D.
Research Compliance Specialist

Elaine Kanka
Application Specialist

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Secretary

IRB-HSBS Leadership

Thad Polk, Ph.D.
Chair

Jorge Delva , Ph.D.
Vice Chair

Richard Redman, Ph.D.
Vice Chair

HUMAN SUBJECTS HIGHLIGHTS

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

FALL 2013

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Since the Last Issue

Summer 2013 was a period transition for the IRB-HSBS. After four years of service as IRB chair, **Dick Redman**, stepped down to focus on his work as Director of the Doctor of Nursing Practice (DNP) program and other commitments in the School of Nursing. Dick served as chair during the transition from two separate central campus IRBs, IRB Health and IRB Behavioral Sciences, to the unified IRB-HSBS which combined membership to provide IRB oversight for all non-Medical School research on the Ann Arbor campus. The IRB and IRB staff will miss his able management of IRB meetings and his fine sense of humor. He has graciously agreed to continue as an alternate member and vice chair of the board.

We are very pleased to announce the appointment of **Thad Polk**, an Arthur F. Thurnau Professor of Psychology and Professor of Electrical Engineering and Computer Science, as chair of the IRB-HSBS. Thad is the director of the Computational and Cognitive Neuroscience Laboratory. Thad has served as a member of the IRB and as an expediting reviewer for the last four years. When asked to comment on taking on this new role, he reflected, “Although the task of filling Dick Redman’s enormous shoes is daunting, I’m comforted to know I will be working with the same terrific staff.”

As we look toward the new year, we would like to invite readers of this newsletter to offer any suggestions they might have for topics that would be useful to include in future editions. Please feel free to contact us at irbhsbs@umich.edu

IRB Staff Members Earn the Certified IRB Professional (CIP) Credential

IRB team members Mary Donnelly, Mary Ramirez, Deb Schneider and Cindy Shindledecker earned the CIP designation this fall. The CIP is a nationally-recognized certification for IRB administrators developed by Public Responsibility in Medicine and Research (PRIM&R) to promote standards for professional knowledge and understanding of research ethics, federal regulations, and best practices for the protection of human subjects.

Updates from the Office of Human Research Compliance Review

The Office of Human Research Compliance Review (OHRCR) reports to Lois Brako, who is Assistant VP for Research – Regulatory Oversight and Compliance, and Director of the Human Research Compliance Program. Following the retirement of Ron Maio, Terry Vandenbosch has been promoted to OHRCR Managing Director. Terry will be responsible for strategic planning, staff, and budget issues, in addition to her post-approval review activities and special projects. Sana Khoury-Shakour joined OHRCR as Project Manager in October 2013. After working as an epidemiologist in a community health department in Israel, Sana came to U-M in 2007 as a postdoctoral fellow in the Division of Molecular Medicine and Genetics. After completing her U-M fellowship, Sana served in several research-related positions in the U-M Cancer Center. Ted Hamilton continues in his role as Research Compliance Associate. Ted just celebrated his 30th anniversary of employment at U-M. Congratulations Ted! Kathy Rogers provides excellent support as OHRCR’s Administrative Assistant. Brandy Byrd has joined OHRCR as an undergraduate assistant.

Investigators Required to Register certain Studies with ClinicalTrials.gov

ClinicalTrials.gov is a web-based resource developed by the FDA and NIH, and maintained by the National Library of Medicine, that provides public access to information on publicly and privately supported clinical studies on a wide range of clinical conditions and diseases conducted in the United States and abroad. Researchers can use ClinicalTrials.gov to search and download records on registered studies and to submit and manage records for their own studies. Although most records refer to clinical trials (including behavioral intervention studies), observational studies and programs are also described. Each study record includes a summary of the protocol, including the purpose, recruitment status, and eligibility criteria. Study locations and specific contact information are listed to assist with enrollment. In some cases, findings are submitted to the ClinicalTrials.gov results database, including information on study participants and a summary of outcomes and any adverse events.

Sponsors or investigators of certain clinical trials are required by U.S. law to register their clinical trials and submit summary results to ClinicalTrials.gov. Guidance provided by the Regulatory Affairs office at the Medical School advises: "If a study is strictly observational, it is not required to register in ClinicalTrials.gov. If it is prospective and measures a health outcome, it must be registered before enrollment of participants to protect the researcher's ability to publish later." (http://www.med.umich.edu/medschool-regulatory/policies/Clinicaltrials-gov.html).

In addition to this regulatory requirement to register certain clinical trials, investigators who hope to publish research results in journals that follow International Committee of Medical Journal Editors (ICMJE) requirements, including the Journal of the American Medical Association, New England Journal of Medicine, and The Lancet, must also register studies which "prospectively assigns human participants or other groups of humans to one or more health-related interventions to evaluate the effects on health outcomes."

While most research requiring ClinicalTrials.gov registration is conducted by investigators under IRBMED jurisdiction, there may be some projects reviewed by IRB-HSBS that should be registered. In the case of NIH-sponsored projects, it is likely that awardees will be informed if registration is required.

Please see the Medical School Regulatory Affairs guidance referenced above for more information and for information necessary to register a trial. The Regulatory Affairs team periodically offers training on this topic that is open to anyone on the U-M campus. Additional information is also available at http://clinicaltrials.gov/ct2/manage-recs.

U-MIC (The University of Michigan Educational Collaborative)

The U-M IRBs (IRB-HSBS, IRBMED, IRB-Flint and IRB-Dearborn) have teamed up to provide shared educational resources to the U-M research community. U-MIC ((http://hrpp.umich.edu/education/umic.html) provide brief (3 to 5 minutes in duration) educational tips in the form of PowerPoint slides with voiceover on a variety of topics related to human subject research ethics and IRB processes. Topics include the key ethical concepts of the Belmont Report, eResearch training, information on informed consent and waivers, research lotteries and sweepstakes, deception and concealment, data security tips, and may others. Would you like to suggest a topic for a U-MIC moment? Drop a line to irbhsbs@umich.edu.

Data Security and Use of Mobile Devices Guidelines

Given the increasing use of mobile devices, both university-owned and personal, to store, access and transmit data, it is vitally important for researchers to be up-to-date on the requirements for security of data and devices in order to protect the confidentiality and integrity of institutional and personal data. U-M researchers should be familiar with the ITS Safe Computing website (http://www.safecomputing.umich.edu/) provides a wealth of information regarding data security tip and requirements for University and personal devices, such as information about encryption. The Sensitive Data Guide provides information on how and where sensitive data, including sensitive human subjects research data, can be safely stored and shared using IT resources available on the Ann Arbor campus. For example, researchers may not be aware that personally maintained services, such as Drop box, that are not under university oversight should never be used to store or share sensitive research data. The site also provides information regarding device/data security when traveling outside the United States.

In addition, IRB-HSBS has posted a data security checklist for PIs (http://irb.umich.edu/policies/Data%20Management%20and%20Security%20PI%20Checklist.pdf), which describes the minimum core data security procedures that should be in place for the protection of subject data. The nature of a particular study and the sensitivity of data determine whether core security procedures are adequate or whether additional steps should be taken to ensure data secuirty. The PI checklist also outlines sections of the eResearch application where data management and security procedures should be described, and includes a table that lists sources of protected health information, personal identifying information, and other sensitive information.

Students and Employees are Potentially Vulnerable as Research Subjects

Human subjects are considered vulnerable when their capacity to make autonomous decisions in their own best interest is compromised. Students and employees are among special classes of subjects who may be vulnerable in terms of their research participation, perhaps as a result of undue influence or coercion. Undue influence/inducement refers to offers of "excessive or inappropriate reward" that are made to secure an individual's participation in a research study. Such offers may lead individuals to participate in studies that they would otherwise object to based on their personal values, preferences, or risk tolerance. The possibility of undue influence is a concern for IRBs, especially when studies pose risk of harm and offer considerable incentives to participants who have limited means or opportunities. Whereas undue influence refers to an offer of reward, coercion involves a "threat of harm or reprisal" in order to obtain compliance with a request to participate in research. Coercion occurs when someone is in a position to make potential subjects worse off if they don't participate. This power imbalance may interfere with a potential subject's capacity to choose or act voluntarily.

There a number of safeguards IRBs can recommend and researchers can employ when studies involve special classes of subjects. For example, where students are involved, the instructor (researcher) should arrange to have data collected by an independent third party so that they do not know who participated and cannot access identifiable data until course grades have been assigned. Data collection during regular class meetings should be avoided as loss of instructional time may be considered a loss of benefit. When course credit is issued for research participation, students should have the option to complete an alternate assignment that is comparable in terms of time, effort, and educational benefit.

In work settings, researchers must ensure employees understand that participation is not required as a condition of employment. Employees should not be recruited or consented directly by a member of their current department, and supervisors and peers should not be informed of an employee's decision to participate. When supervisors or administrators are part of the research team, they should only review aggregate data that has been stripped of identifiers.

IRB Staff and Assigned Schools, Colleges, or Units

Mary Donnelly (mardonne@umich.edu)
Debra Schneider (dschnei@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
Exempt, Not-Regulated

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
SRC/ISR (except HRS and PSID)
Exempt, Not-Regulated

Debra Schneider (dschnei@umich.edu)
Dentistry
Engineering
Ergonomics
Kinesiology
Pharmacy

Calendar of Events

Full Board 2013 -2014

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

IRB "On the Road"

Unit	Dates/Time	Location
Business	11/15, 2 - 4 p.m.	4020 R-BUS
Education	11/14 & 12/12, 9 a.m. - 12 noon	3002 SEB
School of Information	11/13 & 12/11, 12:30 - 2:30 p.m.	4445 NQ
Nursing	11/26, 2 - 4 p.m.	4320 SON
Psychology	11/4, 11/18, 12/2, & 12/16, 2:30 - 4 p.m.	1343 EH
Public Health	11/27 & 12/18, 3 -5 p.m.	1623 SPH I
Social Work	11/1, 12/5,12 noon - 2 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