PRIM&R PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

2017 Social, Behavioral, and Educational Research Conference

November 5 ★ San Antonio, TX

Sunday, November 5: 2017 SBER Conference

7:00 AM — *Hall 4 West Lobby*

On-Site Check-In Opens

Breakfast on your own.

8:00-8:15 AM — *Room 217*

Welcome from the SBER17 Co-Chairs

Elizabeth A. Buchanan, PhD, Endowed Chair in Ethics; Director, Center for Applied Ethics, University of Wisconsin Stout
Julie F. Simpson, PhD, Director, Research Integrity Services; Affiliate Assistant Professor of College Teaching and Education, University of New Hampshire

8:15-9:00 AM — *Room 217*

Keynote Address: Social Black Holes: The Ethics of Research on Illicit or Morally Compromising Market Actors

Kimberly Kay Hoang, PhD, Assistant Professor of Sociology, University of Chicago

CIP

Didactic Sessions and Workshops Series A, 9:15-10:30 AM

A1 — *Room 210*

Recruitment, Incentives, and Compensation in SBER

CIP Basic

Michelle DuBois, Andrea R. McDowell, Linda Petree

Methods used to recruit and compensate research participants must be free from coercion or undue influence, respect the privacy rights of prospective participants, and provide for fair and unbiased selection. As with the informed consent process, researchers and IRBs must consider the content, comprehensibility, and voluntariness of the methods used to recruit and compensate participants. During this session, speakers will:

- Review considerations for ensuring the equitable recruitment of potential research participants (e.g., selection methods, including the use of existing data or social media, recruitment plans and incentives, and compensation components)
- Outline the difference between incentives and compensation, as well as considerations for compensation in vulnerable populations (e.g., substance abusers, minors, individuals living in developing countries, etc.)
- Share best practices for designing recruitment advertising materials
- Address federal tax reporting requirements and participant privacy considerations with consent documentation waivers and certificates of confidentiality
- Discuss the pros and cons of compensation using lotteries/raffles and college course credit

A2 — *Room 213*

The Use of Internal and External IRBs as a Potential Solution to Reducing Administrative Burden

★ CR CIP

Erica J. Heath, Patricia Seymour

- Every year, the number of regulations and oversight requirements for ensuring science advances increases. This is especially true this year with the revised Common Rule and the NIH Policy on the Use of a Single IRB of Record for Multi-Site Research. This session will focus on the regulatory impact of the revised Common Rule and new policies, strategies for adjusting to a changing research climate, and the use of internal and external IRBs as a solution for reducing administrative burden. During this session, speakers will: Review the findings and recommendations from new human subjects protections regulations and policies
- Identify actions and strategies recommended at the federal and institutional levels to help reduce administrative burden
- Share how internal and external IRBs can help reduce administrative burden

ICON KEY

Didactic session
Interactive workshop
★ Call for Session Proposal
CIP CIP eligible
CR Reviews changes to the Common Rule
Recorded session

Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.

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A3

Room 208

Basic

Certificates of Confidentiality (CoCs) and National Institute of Justice (NIJ) Privacy Certificates

Petrice Brown-Longenecker, Elonna Ekweani, Mary Ramirez, Leslie E. Wolf

CoCs and NIJ Privacy Certificates often cause confusion for investigators and IRBs. Both require protection of subjects' information, but differ in their requirements; particularly with regard to compliance with mandatory reporting laws. Furthermore, the 21st Century Cures Act will bring changes to the CoC system. During this session, speakers will:

- Review the scope of legal protection and privilege afforded to researchers under a CoC and a Privacy Certificate, including a review of the applicable regulations and federal guidance
- Discuss implications for informed consent, and how CoCs and Privacy Certificates interface with other protective laws and possible disclosures
- Explore the differences between CoCs and Privacy Certificates
- Outline changes to the CoC system under the 21st Century Cures Act

Note: this session is also on the AER17 agenda (session E16)

A4

Room 206

Basic

SBER IRBs Respond to the Revised Common Rule

Jennifer A. Graf, Julie Kaneshiro (OHRP resource person), Alison S. Orkin

IRBs need to begin implementing the changes to the Common Rule. However, what does that mean for SBER IRB operations, policies, processes, or procedures? How will SBER IRBs effectively educate IRB members and researchers about these changes? How will they implement these changes? What will be the impact on staffing? During this session, speakers will:

- Provide an overview of the major changes in the revised Common Rule
- Identify key considerations when planning an institutional response to the revised Common Rule
- Share approaches to responding to the revised Common Rule on an institutional level, implementing changes, and educating IRB members and researchers

A5

Room 205

Research Data Security in Mobile and Cloud Environments

Adarsh K. Gupta

This session will address research data security issues in cloud and mobile environments, including questions IRBs need to ask to assess the risk involved in using cloud and mobile data storage and retrieval. During this session, the speaker will:

- Discuss ways IRBs can assess the research data risk in cloud and mobile environments
- Review the regulations that pertain to securing research data

A6

Room 211

Basic

Research With Native American Populations: Ethical and Regulatory Perspectives

Jyoti Angal, Heather L. Larsen

This session will provide attendees with an overview of tribal IRB processes, based on the work of Sanford Health and the Collaborative Research Center for American Indian Health. The speakers, from a research organization and from a tribal IRB, will address common challenges in navigating the regulatory landscape of research with Native American populations and on tribal lands, and provide examples of successful collaborations. The Tribal IRB Toolkit will be discussed. During this session, speakers will:

- Provide an overview of the research and collaborative initiatives of the Collaborative Research Center for American Indian Health
- Discuss specific and unique ethical and regulatory aspects to conducting research with Native American populations and on tribal lands
- Reflect on the revised Common Rule changes affecting tribal sovereignty and IRBs
- Review the Tribal IRB Toolkit

ICON KEY

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Interactive workshop
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Didactic Sessions and Workshops Series A, 9:15-10:30 AM

A7

Room 212

Advanced

Scientific Merit in SBER

Julie Slayton, Matthew D. Stafford

Review for scientific merit is a perennial and often thorny issue. Is scientific merit something IRBs should engage in? What are the different perspectives regarding this issue? Attendees should have an understanding of SBER, including methodology and methods, and study challenges related to risk assessment, risk mitigation, and informed consent, as well as a working knowledge of 45 CFR 46 before attending this session. During this session, speakers and attendees will:

- Review the concept of scientific merit in SBER
- Examine and discuss whether review for scientific merit is an IRB obligation (e.g., If not, should it be conducted by someone else at an institution? Who should do it and under what circumstances? If it is, what do IRBs need to review and evaluate scientific merit in a study?)
- Share strategies for assessing scientific merit and training resources for IRB members

A8

Room 209

Advanced

Informed Consent in Mobile Technologies: Exploring Strategies for Participant Engagement

Megan Doerr, Sara Meeder

Big data and mobile technology studies are adding complexity to an already problematic process of making sure participants are fully informed before obtaining consent for study participation. This added complexity is due, in part, to participants' lack of familiarity with technology and the potential risks. Researchers in these fields are using previously tested consent process interventions in an attempt to better engage and inform participants. This session will explore current innovations and results from these consent process interventions. Attendees should have an understanding of 45 CFR 46, informed consent for research, and basic consent processes before attending this session During this session, speakers will:

- Provide a review of tested consent interventions and limitations of consent process research
- Outline what some large cohort studies have incorporated into their consent processes
- Discuss efficacy and feasibility of interventions for studies of differing scales

Tower View Foyer; Park View Foyer

10:30-11:00 AM

Beverage Break

Join us for coffee.

Didactic Sessions and Workshops Series B, 11:00 AM-12:15 PM

B1

Room 209

Basic

Fundamental Issues in Qualitative Research

Julie F. Simpson, Julie Slayton

In qualitative inquiry, researchers study phenomena in their natural settings where the purpose is contextualization, interpretation, and/or understanding the perspectives of others. The role of qualitative researchers in a study is characterized by their personal involvement and empathetic understanding. This session will help IRB members facilitate the review of qualitative research applications by providing a better understanding of this type of research and the challenges faced by researchers using this paradigm, and will educate qualitative researchers on the issues this research paradigm can present during review. During this session, speakers will:

- Examine the foundations of qualitative inquiry, and review its basic characteristics, including nomenclature and common data collection methods
- Identify the ethical issues qualitative research may present to study participants, including recruitment, informed consent, privacy and confidentiality, and conducting research online
- Share strategies for minimizing harm to participants in qualitative research studies

ICON KEY

Didactic session | Interactive workshop | Call for Session Proposal

CIP eligible | CR Reviews changes to the Common Rule | Recorded session

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B2 *Room 206*

SMART IRB for SBER: A National Roadmap to Single IRB Review

Daniel Alderson, Cynthia J. Monahan, Carol Pech

In this session, speakers will discuss the SMART IRB reliance platform and its utility for institutions engaged in and overseeing SBER. SMART IRB is funded by the National Center for Advancing Translational Sciences to serve as a roadmap for single IRB review while ensuring a high level of protection for research participants. SMART IRB's flexible master IRB reliance agreement, standard operating procedures, and complementary tools and resources enable participation by a wide range of institutions and support a broad spectrum of studies, including SBER. During this session, speakers will:

- Define the impacts of the single IRB policy on SBER/institutions
- Review the key elements of the SMART IRB master IRB reliance agreement, standard operating procedures, eligibility requirements, and joinder process
- Discuss how SMART IRB addresses specific needs and concerns related to the use of single IRB review for SBER

B3 *Room 213* Basic

Is it Research? Build a Toolkit for Navigating the "Grey" Areas of Regulated Research and Program Evaluation

Tonya Ferraro, Shannon Sewards

It is a challenge to discern between human subjects research and program evaluation. Elements of both may be present in a project and conversations between IRBs and investigators can be difficult to navigate. This interactive session aims to distinguish and demystify "regulated research" from "program evaluation." During this session, speakers and attendees will:

- Discuss the distinction and key concepts between regulated research and program evaluation
- Share tips, dos and don'ts, and best practices for improving effective dialogue between IRBs and investigators
- Pull it all together by providing advice and assistance to participants to build their own toolkit that bridges the theoretical to the applied

B4 *Room 205* Basic

SBER in the Era of the Revised Common Rule: An Overview of the Most Relevant Regulatory Changes

Yvonne Lau

This session will provide a birds-eye-view summary of the changes to the Common Rule that are likely to have the most impact on SBER. During this session, the speaker will:

- Describe activities that are now excluded from the definition of research
- Review changes to exemptions, expedited review, and informed consent

Note: this session is also on the AER17 agenda (session B24)

B5 *Room 211* Basic

A Guide to De-Identifying Qualitative Data

Laura Henderson, Sharon L. Zack

Although IRBs are charged with protecting human subjects, fundamental resources, such as professional ethical codes, the federal regulations, and even the existing scientific literature, provide little guidance on de-identifying participants' data to protect subject identities engaged in qualitative research. This session will review the existing literature on protecting subjects from re-identification, and the methodology proposed for de-identifying qualitative data to prevent such deductive disclosure. During this session, speakers will:

- Provide a snapshot of the landscape of issues and trends related to de-identifying qualitative data, including opportunities to share de-identified data, and resources for planning the data life cycle
- Introduce the ethical considerations surrounding data de-identification and the unique challenges qualitative data present
- Review the rules for de-identifying quantitative data and discuss whether these rules apply to qualitative data
- Identify the issues of concern at each stage of the research process

ICON KEY

Didactic session | Interactive workshop | Call for Session Proposal

CIP eligible | CR Reviews changes to the Common Rule | Recorded session

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B6 *Room 210*

Data Protection in International Settings: Legal and Security Considerations

Edward E. Bartlett, Adarsh K. Gupta

This session will address the considerations for data management when conducting research abroad. During this session, speakers and attendees will:

- Review the pertinent major regulations and laws that affect research data in studies conducted abroad
- Address the implications of countries' privacy laws for consent and data sharing across boundaries
- Discuss best practices for data security when collecting data outside the United States
- Explore the intersection of export control compliance and data security
- Outline the challenges and considerations for IRBs and researchers when designing and reviewing studies conducted outside the IRB, particularly with regard to risk to participants

B7 *Room 208*

Bridging the Gap: How Biomedical IRBs and SBER IRBs Can Effectively and Successfully Work Together

Advanced

Melissa Beck, Krista T. Kenney

In the world of research, biomedical and SBER IRBs are often seen as two separate entities. There are times, however, when these IRBs collaborate in the review of research. This session will discuss the steps an institution that reviews biomedical research and a university that reviews SBER can use for successful and effective research review. Attendees should have a basic understanding of reliance agreements and what it means to rely on another institution, and the functions of a SBER IRB and a biomedical IRB before attending this session. During this session, speakers will:

- Review the major differences between a biomedical and SBER IRB
- Discuss a course of action to begin an effective collaboration between biomedical and a SBER institutions
- Share how to facilitate an effective and successful research review process between a biomedical and a SBER institution

B8 *Room 212*

FDA Oversight, SBER, and the IRB

Jeffrey M. Cohen, Patrick J. McNeilly, Robin S. Tyndall

Social science research is increasingly incorporating techniques and devices that are more traditionally found in biomedical research, creating challenges for SBER IRBs in determining when a study falls under FDA oversight. The FDA's authority extends beyond just drugs and devices to mobile medical applications and other innovations, which can create challenging regulatory questions as to whether a study falls under FDA jurisdiction. This session will provide an overview of the FDA's authority and provide considerations for SBER IRBs when determining whether a study might fall under FDA oversight. During this session, speakers and attendees will:

- Discuss concepts the IRB should consider when a study may be FDA-regulated
- Review the basic regulatory requirements that apply to FDA regulated research, in addition to the Common Rule
- Describe the basic distinctions among terms such as "drug," "dietary supplement," "medical device," and "mobile medical app"

12:15-1:30 PM *Room 214*

Networking Lunch

Time to connect...over lunch! Meet peers for conversation and networking.

1:45-3:15 PM *Room 217*

Plenary Session: Research Ethics in Tech Companies: Similarities, Differences, and What IRBs Need to Know About Research Collaborations

Moderator: *Elizabeth A. Buchanan*

Panelists: *Brenda L. Curtis, Lauri Kanerva, Kambria Tabor*

A considerable amount of SBER takes place in industry settings, especially in fields like big data, computer-human interaction, internet based research, and others. Since industry researchers do not typically receive federal funding, they are not required to go through an IRB. This plenary session will discuss the ethics review processes at tech companies: What are the similarities between their reviews and IRB review? What are the differences? What are best practices for ethics review in environments where IRB regulations may not apply? In addition, this session will identify issues that industry research teams frequently face, including privacy, ethics, and legal considerations. Finally, speakers will discuss what universities should be aware of when researchers collaborate with industry partners in human subjects research, and the questions university IRBs should ask about these collaborative projects.

ICON KEY

Didactic session | Interactive workshop | Call for Session Proposal

CIP eligible | CR Reviews changes to the Common Rule | Recorded session

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3:15-3:45 PM
Tower View Foyer; Park View Foyer

Beverage Break
Join us for coffee and cold drinks.

Didactic Sessions and Workshops Series C, 3:45 PM-5:00 PM

C1
Room 206

College Students and Research: Challenges and Issues for IRBs
Basic

Andrea R. McDowell, Julie F. Simpson

A considerable amount of research takes place on college/university campuses involving students as subjects. This includes research on novel educational strategies and the use of departmental pools of introductory-level students to participate in research studies and other projects for credit (subject pools). This session will review regulatory and legal standards, as well as specific ethical issues, that arise when reviewing research where college students on campus are subjects, and when they may serve as investigators or research personnel. During this session, speakers will:

- Identify different types of issues that frequently arise when conducting research on a university/college campus, including best practices for addressing ethical issues (e.g., instructors using their own students as subjects, students who are minors, etc.)
- Discuss the issues that arise when college students conduct research, either as principal investigators and/or as research personnel
- Outline the issues that arise with the operation of university/college subject pools, and best practices
- Review the role of the HRPP in educating student researchers
- Provide a high level overview of the pertinent laws and regulations affecting this population (e.g., Family Educational Rights and Privacy Act, Title IX)

C2
Room 211

Managing IRBs at Small Institutions
Basic

April V. Baker, Aimee E. Huard

Small institutions face unique challenges with regard to IRB operations, including minimal resources and staff that wear multiple hats and are expected to "do it all." This session will explore the challenges such institutions face. During this session, speakers will:

- Discuss how to garner resources for managing an IRB at an institution with a limited budget
- Review how to determine what needs IRB review
- Share strategies for creating IRB policies and procedures sswith limited resources
- Outline approaches for communicating with the faculty, staff, and students about human subjects protections and the IRB
- Address how to balance issues of human subjects protections with other responsibilities

C3
Room 212

Understanding and Applying Family Educational Rights and Privacy Act (FERPA) Guidelines
Advanced

Tracy Smart Arwood, Casey Mumaw

This session will focus on FERPA-related issues and how they apply to research in higher education. The session will address what is and is not FERPA-protected data, how that impacts research, and how to interpret the FERPA guidelines. Several scenarios will be presented illustrating common pitfalls in research with FERPA-protected data, and the audience will be encouraged to identify problems and come up with solutions. Attendees should have an understanding of the Common Rule, particularly of exempt categories 1 and 4, as well as expedited category 5, before attending this session. During this session, speakers will:

- Review what data is covered by FERPA
- Demonstrate how to safeguard affected data in research
- Share strategies for assisting researchers with FERPA compliance

ICON KEY

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Interactive workshop
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C4 *Room 205*

Limited IRB Review of Exempt Studies With Sensitive Data: How to "Let it Go" With Data Security Plans

Teresa Doksum, Lauren Hartsmith, Daniel K. Nelson, Sean Owen, Katie B. Speanburg

This session will focus on how to interpret and apply the revisions to the Common Rule on exemption categories related to the new type of review, limited IRB review, to "assess the adequacy of provisions to protect the privacy of subjects and the confidentiality of data." Using case studies, speakers will share their experience using a specific review process and a data security plan template. Any additional guidance issued by HHS and the Office of Management and Budget after January 10, 2017, about limited IRB review will be incorporated and discussed. During this session, speakers will:

- Describe how IRBs can develop a limited IRB review for studies that qualify for such a review
- Outline how to develop a review process with institutional partners to ensure the protection of sensitive data
- Review how to classify the sensitivity of data and studies according to the new exemption criteria
- Use case studies to show how to use a data security plan template, including ensuring consistency with other study protocol documents (e.g., consents and data use agreements, etc.)

Note: this session is also on the AER17 agenda (session B18 – also includes information on biospecimens)

C5 *Room 209*

IRB Guidelines and Data Sharing in the Social Sciences: Tensions and Strategies to Address Them

Lynette F. Hoelter, Diana Kapiszewski

This session will address the tension between two scholarly imperatives advanced by federal funding organizations, disciplinary associations, and publishers alike: the longstanding mandate to treat research participants with respect and to minimize the potential risks of participating in research, and the newer expectations of providing access to the results of that research including data generated through interaction with human participants. While IRBs tend to focus on the first concern, their decisions and practices also impact research transparency. This session will present the results of an empirical investigation of the language used in general guidelines and consent script templates that IRBs at 50 major research universities in the United States, discuss how the tension noted above might be resolved, and generate debate and discussion on several proposed models for revisions of consent language and general data management guidelines that individual IRBs might consider adopting. *Additional credit for this session goes to Dessislava Kirilova, Qualitative Data Repository, who could not attend in person*. During this session, speakers will:

- Review the ongoing changes in expectations about data availability as they affect both scholarly communication and the evaluability of research
- Discuss the roles that trusted repositories can play in protecting research participants while facilitating data availability
- Explore models for consent language that assures the protection of human subjects and allows data generated through interaction with them to be shared

C6 *Room 208*

Human Subjects Protections Across Borders

Edward E. Bartlett, John R. Baumann, Byung-in Choe

While there are challenges to human subject oversight of intra-national research collaborations, they pale in comparison to those faced when participating in inter-national research collaborations including, but not limited to those arising from different cultural, regulatory, and institutional contexts. But, then, so do the opportunities. This session is designed to explore the various challenges that HRPP's face when conducting collaborative international research. Speakers will address a variety of issues that may arise regarding protections of human subjects in international research and how they have addressed them. During this session, speakers and attendees will:

- Review how differing definitions of "human subjects" and "identifiability" around the world affect the scope of SBER standards
- Learn which countries have implemented laws, regulations, or guidelines that are specific to SBER
- Discuss the various challenges in human subjects international research collaborations
- Explore the various approaches for the elimination or mitigation of challenging human subjects oversight of international research collaborations
- Identify policy and process best practices for IRBs/Ethics Committees in the review of inter/trans-national human subjects research

Note: this session is also on the AER17 agenda (session B9)

ICON KEY

Didactic session | Interactive workshop | Call for Session Proposal
CIP eligible | Reviews changes to the Common Rule | Recorded session

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C7 *Room 213*

IRBs and Ethnographers: Unpacking the Dimensions of a Challenging Relationship to Increase Mutual Understanding

Advanced

Laura Henderson, Guillermina Gina Núñez-Mchiri, Ivor A. Pritchard (OHRP resource person), Shannon Sewards

Anthropologists' core method of ethnography can be argued to offer the greatest challenges for the IRB review process, for researcher and reviewer alike. These challenges are also appearing more frequently for many IRBs, with increasing numbers of researchers across disciplines adopting ethnographic approaches. This session will present a dialogue across three perspectives: the anthropological view informed by the field and the practice of ethnographic methods, the trenches of IRB review, and the overarching regulations. The conversation aims to identify legacies and trends, patterns of practice, ways that perspectives are articulated, and moments of the struggle for mutual understanding that characterize the IRB-anthropologist relationship, aiming to contribute to an improved IRB-ethnographer dialogue within the review process. Attendees should have working knowledge of the Common Rule, including the use of informed consent in SBER and knowledge of the regulatory flexibility in its implementation, as well as one to two years experience with IRB issues before attending this session. During this session, speakers will:

- Discuss the unique challenges ethnographic research poses for IRBs
- Identify specific areas in research protocols that require special attention in order to capture research methods and achieve regulatory compliance
- Address the assumptions that can impede the review communication process

C8 *Room 210*

Clinical Trials in the SBER Context

Melissa W. Riddle, Cindy S. Shindledecker

In late 2016, NIH released new policies to improve stewardship, accountability, and transparency of clinical trials. SBER IRBs need to understand the requirements expected of a NIH-funded SBER study that meets the NIH's definition of a clinical trial (e.g., Good Clinical Practice (GCP) training, Clinicaltrials.gov registration, single IRB review). During this session, speakers will:

- Review the NIH's definition of "clinical trial"
- Discuss the requirements expected of a SBER study that meets the NIH's definition of a clinical trial
- Outline options for GCP training that is SBER-focused

5:00-6:00 PM *Tower View Foyer*

SBER17 Networking Reception

Join us to celebrate SBER17 and network with your colleagues. Light refreshments will be served.

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