PRIM&R's
2019 Social, Behavioral, and Educational Research Conference
November 17 • Boston, MA

2019 Advancing Ethical Research Conference
November 17-20 • Boston, MA

Sunday, November 17: SBER19

7:00 AM- 5:30 PM — *Pre-Function Hall C*
On-Site Check-In Open
Breakfast on your own.

8:00-8:05 AM — *Ballroom B*
Welcome from the Conference Co-Chairs

8:05-9:00 AM — *Ballroom B*
Keynote Address: Katie Shilton, MLIS, PhD, Associate Professor, Information Studies, University of Maryland College Park

Breakout Session Series A, 9:15-10:30 AM

A1: Academic Ethics–How Social Science Researchers Operationalize and Exercise Research Ethics
(Hot Topics Track)

New CIP Basic

This session will examine how academic SBE researchers understand research ethics as it relates to federal regulations governing human subjects research. Empirical data of academic SBE researchers providing expert opinions on federal regulations will be used to demonstrate how academic SBE researchers come to understand and interpret regulatory language into their IRB submissions. During this session, speakers and attendees will:

- Review the literature on academic research ethics, institutional and organizational theory, and theories on occupations and professions
- Explore data that demonstrate how academic SBE researchers understand and interpret the federal regulations
- Discuss how academic SBE researchers view their work and what perspectives, attitudes, and beliefs they bring when submitting IRB applications

A2: Clinical Trials in SBER (NIH and OHRP Overview)--Part I *(Advanced Track)*

I/II CIP Advanced

NIH has implemented policies designed to improve stewardship, accountability, and transparency of clinical trials, including some research characterized as basic science. SBER IRBs (and their research communities) need to understand the special NIH requirements for clinical trials. The revised Common Rule also imposes additional requirements for projects identified as clinical trials. Attendees should have a basic knowledge of NIH clinical trial policies and 45 CFR 46 before attending this session. During this session, speakers and attendees will:

- Consider the similarities and differences between NIH and OHRP requirements related to SBER clinical trials, including the requirements associated with "basic research"
- Discuss NIH and OHRP requirements related to SBER clinical trials
- Provide examples of SBER studies that fall under these requirements

***Note**: Part II of this session will take place on from 3:15-4:30 PM (Session C4).*

A3: Scientific Merit and SBER *(Advanced Track)*

CIP Advanced

Review for scientific merit is a perennial and often thorny issue. Is assessing scientific merit something IRBs should engage in? What are the differing perspectives regarding this issue? Attendees should have an understanding of SBER methodology 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:

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

ICON KEY

Pre-registration required	Recorded session	New Breakout sessions new for 2019
I/II Sessions span two time periods	CIP CIP eligible	Call for Session Proposal

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Breakout Session Series A, 9:15-10:30 AM

A4: OHRP's Guidance on the Revised Common Rule: A Question and Answer Session *(Basic Track)*

New Basic

OHRP staff will provide a brief summary of the draft and final guidance they have issued on the revised Common Rule, and attendees will have the opportunity to comment or raise questions about this guidance. During this session, speakers and attendees will:

- Review OHRP's draft and final guidance on the revised Common Rule
- Clarify the policies and interpretations of the revised Common Rule that are proposed in draft guidance or included in final guidance
- Engage in a discussion about the draft or final guidance

A5: Optimizing Openness in Human Subjects Research: Balancing Transparency and Human Research Protections *(Hot Topics Track)*

New CIP

Trends toward increased research transparency have heightened the expectation that researchers will share primary data, while recent technological advances have allowed for an increase in the amount of human subjects data that can be safely shared. The goal is to make research data "as open as possible, but as closed as necessary." Various actors in the academic research landscape play a role in this process, with data repositories and IRBs being of primary importance. At the same time, there is little formal interaction among them, and many IRBs might not yet be familiar with these developments or the new solutions that exist for responsible data sharing. This session will give the audience an update on a National Science Foundation funded research project that investigates the gap between modern options for safely sharing sensitive data and IRB practices. Work under the grant aims to establish socio-technical infrastructure to support a sustained dialogue and productive partnerships between data repositories and IRBs, and future work will include other relevant actors (funders and journal publishers in particular). Strong collaboration among these institutions should accelerate the emergence of a new consensus on the sharing and long-term re-use of sensitive data generated through research with human subjects. Speakers will review broad developments in academia, and their research on current IRB practices, and attendees will have an opportunity to discuss how to align model guidance for data management plans and consent scripts related to sharing data in different scenarios. A draft glossary of terms relating to the topic will be provided. During this session, speakers and attendees will:

- Review new developments and challenges in expectations for data sharing and research transparency
- Examine the interaction between data repositories and IRBs in protecting research subjects while facilitating data availability
- Share model study documents (e.g., template consent language that enables appropriate data sharing under different scenarios, data management plan, etc.) for endorsement and/or adoption

A6: Reviewing Exercise Science Research at Primarily SBER Institutions *(Basic Track)*

New CIP Basic

This session will offer IRB administrators, chairs, and members a comprehensive review of issues related to reviewing exercise science research in primarily SBER institutions. This session will describe key ethical and regulatory issues related to exercise performance, sports nutrition, and related interventions, and differentiate these issues from similar questions encountered in SBER. Best practices for IRB applications, review processes, risk minimization, data and safety monitoring, informed consent documents, and postapproval monitoring (PAM) will be provided through case study discussions. During this session, speakers and attendees will:

- Describe key ethical and regulatory distinctives of exercise science research relative to SBE-oriented research
- Review best practices for the review, approval, and documentation of interventions unique to exercise science research
- Identify practical solutions for effective review of exercise science research in the SBER environment through enhancements to IRB applications, review processes, informed consent materials, PAM, and related human subjects protections

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Breakout Session Series A, 9:15-10:30 AM

A7: Continuing Review or No Continuing Review, That Is the Question *(IRB Policy/Operations Track)*

Under the revised Common Rule, continuing reviews are no longer required for minimal risk research. This specifically applies to projects reviewed under expedited authority or by full board, including studies that progressed to long-term follow-up or data analysis (even with identifiers), unless the research is FDA-regulated. Formally, the IRB is still responsible for oversight on research conduct and human subjects protections, but, informally, researchers want to know what's going on with their projects (e.g., how recruitment is progressing). Without formal, ongoing monitoring of project status, notification the project is over could be the only time, aside from the initial review, the IRB hears from a researcher. Without a check-in mechanism, will investigators forget about on-going responsibilities (e.g., human subjects training, reporting incidents, changes to consent forms, unanticipated problems, and changes and additions to previously approved research)? During this session, speakers and attendees will:

- Discuss procedures for determining when projects receive continuing review or a status check-in review (e.g., introducing checklists and forms)
- Review how to roll out changes to using new procedures and forms, and educate researchers and research staff
- Share data on investigator satisfaction of the process

A8: May the Revised Common Rule Force Be With You: How to Become a Review Jedi *(Basic Track)*

There is little instruction on how to become an efficient and compliant IRB reviewer. Often, IRB review is taught through experience on the job and by learning from others. Why are best practices not shared? Why has a comprehensive overview on how to review IRB protocols not been developed? Why is it important to know if it is an "and" versus an "or"? And, why does "it depend"? During this session, speakers and attendees will:

- Discuss how to establish best practice review methods for new and existing staff
- Explore how to teach staff the best way to approach difficult research methodologies
- Learn creative approaches while staying compliant and being consistent

Basic

Boylston Street Hallway, Level 3

10:30-11:00 AM
Beverage Break

Breakout Series B, 11:00 AM-12:15 PM

B1: From Flexible to More Flexibility: What's Left to Review? *(Advanced Track)*

At institutions that already implemented extensive flexibility for non-federal minimal risk research, the 2018 regulatory revisions had limited impact in many ways. However, with limited IRB review, navigating whether projects previously triaged to greater than minimal risk could be reviewed at the exempt level pose new challenges for the IRB. Attendees should be familiar with federal requirements and flexibility afforded to institutions who conduct some research that is not formally regulated by the common rule or FDA regulations before attending this session. During this session, speakers and attendees will:

Advanced

- Explore the range of flexibility for minimal risk research pre- and post- the 2018 regulatory changes
- Learn to differentiate the nuances of proposed projects relative to their institutional policies for triage and review
- Assess the risks to subjects and develop recommendations to minimize risk to subjects while reducing burden on IRBs and principal investigators

B2: The European General Data Protection Regulation (GDPR): Oversight and Impact *(Hot Topics Track)*

GDPR went into effect in May 2018. Although its primary purpose is to moderate intrusions by companies like Google and Facebook, GDPR is also having far-reaching effects on human subjects research conducted in Europe and elsewhere. This session will provide an update on the evolving implementation of GDPR, how research organizations are responding, and what approaches researchers can consider to ensure their work is compliant with and unhindered by the regulation. During this session, speakers and attendees will:

- Describe the most important concepts and provisions of GDPR
- Discuss strategies how to effectively manage GDPR requirements
- Explain how research projects are being affected

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Breakout Series B, 11:00 AM-12:15 PM

B3: Informed Consent in SBER *(Basic Track)*

Basic

The new informed consent requirements in the revised Common Rule can present a challenge in SBER. For example, it can be tricky to determine when the key information requirement (46.116(a)(i)) is needed in already simplified consent documents. Adding this information can result in unnecessary redundancy of content and added length to the informed consent process, without added value to the subject experience. This session will offer guidance to IRBs and researchers on this, as well as will discuss using flexibility in implementing other common informed consent regulations relevant to SBER (e.g., waivers of informed consent, waiver of documentation, electronic consent). During this session, speakers and attendees will:

- Review the informed consent regulations in the revised Common Rule
- Discuss ways IRBs can navigate the key information requirement
- Offer guidance and strategies for IRBs and researchers for satisfying the informed consent regulatory requirements, including documentation waivers, while ensuring an efficient and concise informed consent discussion

B4: Challenges and Opportunities for Small IRB Offices at Small Research Programs

(IRB Policy/Operations Track)

IRB professionals at small research programs (fewer than 200 open protocols) usually have limited resources and work alone or with few (one to two) staff. While challenges such as time, budget, and bandwidth may seem constraining, smaller programs often have more possibility for flexibility and responsiveness to researchers due to flatter organizational structures and greater decisional authority. This interactive session will address common constraints that small to mid-sized academic IRBs face and discuss strategies not only for remaining compliant and handling these concerns, but also creating prospects for reducing administrative burden, building relationships, and increasing the IRB's voice on campus. During this session, speakers and attendees will:

- Discuss various challenges facing smaller IRBs offices
- Offer strategies and tools from different institutional viewpoints
- Consider benefits and opportunities of a smaller research program
- Network with fellow small-office professionals

B5: Exempt or Not? Don't Get Psyched Out By the Benign Behavioral Intervention Research Exemption

(Basic Track)

Basic

This session will review the draft guidance issued by OHRP on the exemption at 104(d)(3) concerning benign behavioral intervention research. It will review what kind of studies fall within the scope of the exemption, and what counts as prospective agreement, including prospective agreement and deception research. During this session, speakers and attendees will:

- Understand the key terms that define the scope of the exemption
- Explore what is meant by "prospective agreement" in the exemption
- Use case studies to further explore concepts

B6: Reliance: SBER Specific Issues *(Hot Topics Track)*

This session will review regulatory considerations, as well as the specific ethical issues that arise when negotiating and executing reliance agreements in SBER contexts between ceding institutions and central or single IRBs. During this session, speakers and attendees will:

- Discuss issues of local context and institutional knowledge as it pertains to ceding review to another IRB in SBER studies
- Review what an institution is responsible for when it is not the IRB of record, but remains charged with ensuring proper conduct of the study at their site and without the benefits biomedical research boards often receive from other oversight bodies (e.g., Data and Safety Monitoring Boards, Contract Research Organizations, etc.)
- Outline the issues that arise when ancillary reviews are required outside of IRB review, and learn strategies for handling them
- Learn about the challenges that arise when SBER and biomedical institutions collaborate in a ceded review arrangement

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Breakout Series B, 11:00 AM-12:15 PM

B7: Is This "Education Research" Research at All? *(Basic Track)*

Basic

Education research poses unique challenges for IRBs given the often-nebulous nature of the procedures, the inclusion of vulnerable populations, and concerns about impact on the educational experience. In some cases, though, the challenge does not come in reviewing education research, but in determining whether IRB review is needed at all. In conflating entrepreneurship, consultancy, program evaluation, and professional development with human subjects research, education researchers put IRBs in the position to regularly ask, "Is this 'education research' research at all?" Through reviewing cases in which research intersects with a researcher's other academic and professional activities, this session will help attendees identify what activities constitute human subjects research in this field. In making such determinations, the IRB can reduce burden for itself and the research community by ensuring that human subjects regulations are applied only to the appropriate research. During this session, speakers and attendees will:

- Discuss and define regulated research, education research, and activities that often intersect with these (e.g., program evaluation, professional development, community based participatory research, secondary data analysis)
- Identify strategies for sensitively communicating with education researchers about complex regulatory concepts like generalizability and engagement in ways that consider and complement the education researcher's own terminology and field
- Examine situations when human subjects research regulations do and do not apply, focusing on assessment of the education researcher's purpose, motivation, obligations, and role

B8: Understanding and Applying Family Educational Rights and Privacy Act (FERPA) in Higher Education *(Advanced Track)*

Advanced

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 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 revised Common Rule and exemption categories, as well as a foundation in human research protections ethics and principles, including the criteria for approval and definitions from DHHS regulations, before attending this session. During this session, speakers and attendees will:

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

12:15-1:30 PM *Ballroom A*

Networking Luncheon

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

1:30-2:45 PM *Ballroom B*

Plenary Session: Strategies and Solutions for Working With Challenging Principal Investigators (PIs)

This panel will discuss strategies found to be effective in ensuring a productive working relationship with PIs in order to facilitate the IRB review process. Through scenarios and strategies presented by the moderator, panelists will discuss best practices and "insider tips" for how IRB staff and members can work in concert to deliver an effective review process, especially with challenging PIs, while maintaining a smooth running HRPP.

2:45-3:15 PM *Boylston Street Hallway, Level 3*

Beverage Break

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Breakout Series C, 3:15-4:30 PM

C1: Different Minimal Risk Review Models *(IRB Policy/Operations Track)*

CIP

The revised Common Rule provides clear instructions for the conduct of convened meetings, but offers little guidance when it comes to minimal risk review procedures. This session will present two models for minimal risk reviews: a traditional model with designated reviewers and a model of minimal risk review boards. An effective minimal risk research model decreases researcher burden while maximizing protections for research subjects. This didactic session will outline the benefits of each review model while exploring options for streamlining minimal risk review methods. During this session, speakers and attendees will:

- Discuss minimal risk review regulatory requirements
- Explore different minimal risk review models and identify opportunities to streamline minimal risk review
- Consider minimal risk review models for the revised Common Rule (e.g., limited IRB review)

C2: Research in K-12 Settings *(Basic Track)*

CIP Basic

Research conducted with students in elementary and secondary school settings presents specific considerations for IRBs and researchers. Through interactive case studies, speakers will examine various topics as they relate to research conducted in K-12 schools. During this session, speakers and attendees will:

- Review considerations that affect research in K-12 settings
- Discuss consent considerations (e.g., assent, parental permission, possible alternatives)
- Go over the Family Education Rights and Protections Action, the Protection of Pupil Rights Amendment, and common misconceptions about the IRB's role in ensuring investigator compliance with these laws
- Share scenarios that may be encountered in the classroom (e.g., undue influence as a result of teachers as investigators, incidental subjects, how to respect the rights of students who do not wish to participate)
- Explore the potential benefits of "flex policies" for institutions
- Address other IRB considerations (e.g., privacy and protection of data)

C3: The "Nuts and Bolts" of Running an IRB Meeting Online *(IRB Policy/Operations Track)*

★ New CIP

With online organizations and teleworking on the rise, the work of IRB's work in "virtual" spaces is growing. This session will focus on how to run an effective IRB meeting virtually. During this session, speakers and attendees will:

- Learn a step-by-step approach to running an online meeting
- Understand the management of the IRB meeting using a semi-structured approach to IRB reviews
- Evaluate strengths and weaknesses of the online IRB meeting approach

C4: Clinical Trials in SBER (ClinicalTrials.gov Registration)--Part II *(Advanced Track)*

I/II CIP Advanced

NIH-funded research projects meeting the NIH definition of clinical trials must be registered and results reported on ClinicalTrials.gov. For investigators and institutions that do not typically work with clinical trials, meeting these requirements can be challenging. This session is designed to provide an overview and tips for assisting SBE researchers and institutions with ClinicalTrials.gov responsibilities. Attendees should be familiar with the content presented in A2: Clinical Trials in SBER (NIH and OHRP Overview), or have basic knowledge of ClinicalTrials.gov before attending this session. During this session, speakers and attendees will:

- Review requirements for registering a study on ClinicalTrials.gov
- Discuss continuing obligations regarding active ClinicalTrials.gov records
- Describe the process for reporting study results on ClinicalTrials.gov

***Note**: Part I of this session will take place from 9:15-10:30 AM (Session A2).*

C5: Benign Behavioral Interventions (BBI) in Practice *(Hot Topics Track)*

★ New CIP Advanced

This session will focus on how IRBs are defining BBI in Exempt Category 3 and how IRBs are making the determination of whether an intervention meets the Exempt category 3 criteria or not. Sample cases of BBIs in SBER and mixed SBER/biomedical research will be explored. Additionally, IRB decision-making processes for each case will be discussed with the goal of promoting IRB best-practices. Attendees should have working knowledge of the revised Common Rule, its exemption categories, and familiarity with SBER disciplines before attending this session. During this session, speakers and attendees will:

- Review the definition of BBIs per federal regulations, OHRP, and the Secretary's Advisory Committee on Human Research Protections guidance
- Explore real-life examples of SBER involving BBIs that IRBs reviewed, as well as the resulting determination of whether the intervention did or did not meet the BBI definition in Exempt category 3(?)
- Discuss IRB best practices when determining whether research involving BBI in SBER and mixed SBER/biomedical research meets the federal regulatory definition in Exempt category 3

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Breakout Series C, 3:15-4:30 PM

C6: College Students and Research: Challenges and Issues for IRBs *(Basic Track)*

CIP Basic

A considerable amount of research takes place on college/university campuses involving college 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 the specific ethical issues that arise when reviewing research in which college students on campus are subjects, and when they may serve as investigators or study staff. During this session, speakers and attendees will:

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

C7: Incentives and Compensation for Subjects in SBER *(IRB Policy/Operations Track)*

Colleen Kohashi, Melissa McGee

★ New CIP

The federal regulations state that the compensation of subjects must be free from coercion and undue influence. However, it can often be difficult for IRBs to unpack what "appropriate compensation" entails, especially within the realms of traditional vulnerable populations (e.g., minors), non-traditional vulnerable populations (e.g., homeless, undocumented, and college students), and internet-based subjects (e.g., mTurk participants). During this session, speakers and attendees will:

- Outline the considerations and best practices for compensation with various vulnerable subjects groups
- Discuss compensation for Amazon mTurk subjects (i.e., what is reasonable and what are the implications for subject anonymity when disbursing compensation?)
- Share best practices for the use of drawings (lotteries) in research and the intersection of research with state law

C8: Reserved for Late-Breaking Session

Boylston Street Hallway, Level 3

4:30-5:30 PM
SBER19 Networking Reception
Join us to celebrate SBER19 and network with your colleagues. Light refreshments will be served.

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