PRIMER R PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

PRIMR25/SBER25 Call for Session Proposals Information on Tracks, Target Audiences, and Session Formats

<u>Tracks</u>: Proposal authors can **select up to two of the following tracks** when submitting a proposal:

Track/Content Area	Descriptor
ACU/IACUC Program Management and Administration [Content Area: Animal Care and Use]	This track is designed for ACU/IACUC professionals grappling with challenges that extend beyond basic day-to-day operations. Sessions in this track will tackle tough issues, provide access to seasoned ACU/IACUC professionals who will discuss varied approaches and solutions for these issues, and offer tangible tools that may be implemented by attendees at their own organizations. This track will also cover issues related to program management, including program review and facility inspections, occupational health and safety, oversight of other animals on campus, and more.
Advancing Equity and Justice [Content Areas: Human Subjects Research, Animal Care and Use, Crossover, Institutional Leadership]	Let's find a way to DO BETTER as ethics Professionals. This track looks to explore race, inclusivity, and the advancement of justice in research and research oversight programs. Sessions will provide an opportunity for all audiences to explore and safely learn about systemic racism, privilege, and oppression and how we can address these in order to embody the Justice principle highlighted in the Belmont Report.
Animal Well-Being and the 3Rs [Content Area: Animal Care and Use]	This track reviews issues and challenges related to animal well-being and the 3Rs.
Communication With the Public [Content Areas: Human Subjects Research, Animal Care and Use, Crossover, Institutional Leadership]	The events of the last two years demonstrate that trust of science is alarmingly low. The promulgation of misinformation, a general lack of science literacy, and a history of exploiting and marginalizing some populations in medicine and research are contributing in complex ways to this mistrust. How can research ethics professionals contribute to educating the public around science and research? How are research programs structured to support community engagement and otherwise bolster the trustworthiness of the research enterprise? This track will address strategies and approaches for communicating with the public, challenges, and more.
Education, Qualifications, and Training [Content Areas: Human Subjects Research, Animal Care and Use, Crossover]	This track will help attendees develop effective educational programs to ensure individuals can protect participants and animal models by being knowledgeable about ethical principles, professional standards, organizational policies, and laws, regulations, and guidance. Speakers will describe different educational approaches and will include examples and educational resources.
Emerging Research Challenges and Breaking Issues [Content Areas: Human Subjects Research, Animal Care and Use, Crossover, Institutional Leadership]	This track will address emerging issues that impact research, ethics, and oversight, including challenges associated with new technologies, novel study designs, and domains of research that do not fall neatly into existing human or animal research oversight structures.
FDA Regulated Research [Content Areas: Human Subjects Research, Animal Care and Use, Crossover, Institutional Leadership]	This track will provide attendees with an opportunity to interact with and hear from representatives from the FDA about relevant topics in the world of FDA-regulated clinical investigations.
HRPP/IRB Management and Administration [Content Area: Human Subjects Research]	This track is designed for HRPP/IRB professionals grappling with challenges that extend beyond basic day-to-day operations. Sessions in this track will tackle tough issues, provide access to seasoned HRPP/IRB professionals who will discuss varied approaches and solutions for these issues, and offer tangible tools that may be implemented by attendees at their own organizations.
IACUC Fundamentals [Content Area: Animal Care and Use]	This track is a great opportunity for those newest to the field to learn the foundations of animal care and use, and it is a space for those more seasoned attendees to revisit the fundamentals, brush up on rusty skills, and re-discover the passion for the work we do. The focus is twofold: (1) foundational concepts and principles of research ethics, and (2) the basics of the IACUC/regulatory framework.
IACUC Review [Content Area: Animal Care and Use]	This track will provide best practices for both new and seasoned IACUC reviewers. Sessions will provide guidance on IACUC chair and member roles and responsibilities, discuss common review issues and provide new and creative insights to ways to address those issues.

IRB Fundamentals [Content Area: Human Subjects Research]	This track is a great opportunity for those newest to the field to learn the foundations of human subjects protections, and it is a space for those more seasoned attendees to revisit the fundamentals, brush up on rusty skills, and re-discover the passion for the work we do. The focus is twofold: (1) foundational concepts and principles of research ethics, and (2) the basics of the IRB/regulatory framework.	
IRB Review [Content Area: Human Subjects Research]	This track will provide best practices for both new and seasoned IRB reviewers. Sessions will provide guidance on IRB chair and member roles and responsibilities, discuss common review issues and provide new and creative insights to ways to address those issues.	
Oversight of Non-Typical Animals and Situations [Content Area: Animal Care and Use]	This track reviews the issues that can arise with protocols dealing with wildlife and aquatics, the role of the attending veterinarian in wildlife research, challenges in agricultural research, and more.	
Pharma/Biotech Perspectives [Content Areas: Human Subjects Research, Animal Care and Use, Crossover]	This track will provide research oversight professionals and representatives from the drug, device, and biotechnology industries an opportunity to discuss topics of mutual interest in the context of global research and development programs, including complex trial design, gene therapy programs, and more.	
Populations Requiring Additional Protections [Content Area: Human Subjects Research]	The human research protections regulations provide guideposts to IRBs as they seek to protect human subjects, but interpretive space as IRBs apply the Belmont principles to specific studies is broad. Different subject populations, communities, and circumstances often have different susceptibilities to research risk that require IRBs' careful consideration. This track explores that broad interpretive space, including the ethical/review considerations that can help IRBs and researchers craft appropriate additional protections to mitigate risk.	
QA/QI and Postapproval Monitoring [Content Areas: Human Subjects Research, Animal Care and Use, Crossover]	A characteristic of strong research oversight programs are that they conduct quality assurance (QA) and quality improvement (QI) activities to evaluate how well their operations are working to promote the protection of research participants and high-quality research that advances science. This track explores why a QA/QI program is important and what it should include, such as postapproval monitoring of research team performance and assessment of research review committee function, as well as tools and strategies to implement and maintain a robust program.	
Research Involving Data and New Technologies [Content Areas: Human Subjects Research, Crossover]	This track will provide new and creative insights into the regulatory and ethical considerations related to the use of data, biospecimens, and new technologies in research. The track will highlight issues related to consent, sharing, responsible data/biospecimen management, and participant engagement in the use of data/biospecimens for research. This track will also help us learn the basics of complex technology concepts, get an inside look at creative solutions to new challenges, and think about how to apply principles of respect for persons, beneficence, and justice to a rapidly changing landscape.	
Research Oversight Leaders and Institutional Officials [Content Area: Institutional Leadership]	This track is designed to address practical and ethical issues that research oversight leaders and Institutional Officials face in research oversight and management. The track will provide guidance on defining and supporting a research program, tackling management challenges, budget creation and management, legal issues, creating a vision as an institutional leader, and evaluating opportunities for program improvements.	
Shared Research Oversight Challenges [Content Areas: Human Subjects Research, Animal Care and Use, Crossover]	While research oversight programs are typically separated according to the type of research being reviewed, these programs increasingly overlap in terms of personnel, processes, and challenges to address, including training of personnel, succession planning, addressing regulatory and administrative burden, working with scarce resources, navigating regulatory change, and more. This track aims to bring together oversight professionals from across the research enterprise to learn from each other, share strategies, and develop shared solutions to shared challenges that will help advance high-quality, ethical research.	
Social, Behavioral, and Educational Research [Content Area: Human Subjects Research]	This track will cover basic and advanced issues related to the conduct and review of SBER. Proposals will be considered for both the 2023 SBER Conference and the 2023 PRIM&R Annual Conference.	
Single IRB [Content Areas: Human Subjects Research]	The single IRB requirement can be tricky to navigate. This track will discuss how to consider local context, key responsibilities, communication strategies, and issues for reviewing IRBs and relying institutions.	

Session Formats: Indicate what format the content should be presented in:

Session Type	Descriptor	Examples
Thought Leader Series	The Thought Leader Series will present high-level concepts on research, oversight, and ethical issues, and are meant to stimulate thinking beyond process and procedural matters. These sessions bring professionals from across the research program together to think about topics collectively. Sessions will include one or more speakers who are thought leaders in the field.	Category includes: Keynotes, panels, living room conversations, debates [75 minutes]

Learning Lab Series	Sessions in the Learning Lab series are focused on brainstorming new solutions/approaches, problem solving challenging issues, and/or knowledge-sharing on a particular topic. Sessions will include a mix of speaker presentations and interaction among attendees.	Category includes: Breakout sessions [75 minutes]
Networking Series	The Networking Series is intended to facilitate connection and dialogue among attendees on the challenges and opportunities associated with a particular topic or professional role. Networking Sessions that are breakout sessions will be structured and moderated by a facilitator but will emphasize interaction and participation among attendees.	Category includes: Networking sessions, Office Hours, Poster Presentations [60 minutes]