

9:30-10:00 AM ET
Attendee Orientation



View this pre-recorded session to learn more about the AER20 Virtual Conference and PRIM&R. *This session is pre-recorded.*

10:00 AM-5:00 PM ET
Visit the Supporters/Exhibitors

Visit the AER20 Supporters and Exhibitors during the event, and learn about their important services. Participating companies will have virtual booth pages with information and resources, and some companies will participate in real-time video chat (accessible via the virtual booth pages).

10:00 AM-5:00 PM ET
Visit the Virtual Poster Gallery



View the virtual poster gallery and learn more about the important programmatic and scientific work being done by your peers in the field. Posters include the actual poster abstract and a 10-minute pre-recorded talk from the abstract authors. Attendees can also submit questions directly to poster authors.

10:00-10:15 AM ET
Welcome and Remarks from PRIM&R's Executive Director, Elisa A. Hurley, PhD



10:15-11:15 AM ET
Panel: Clarifying the Myths and Challenging Bias About Race in Research Review



The research enterprise has a distinct obligation to grapple with systemic racism, given its historical abuses of communities of color. The ethics framework governing research with human subjects was created in direct response to the exploitation of Black men in the US Public Health Service Syphilis Study at Tuskegee. This history, alongside inequities in employment, wealth, education, and housing, and the chronic devaluing of lives of people of color, has persistently undermined the health of these populations. Despite efforts to earn the trust of these communities, address racial biases in research, and increase the representation of people of color among research participants and beneficiaries, there is much more work to be done. How can HRPP/IRB professionals and researchers work to dismantle racism as it manifests in research? This panel will explore several levers for effecting change, including identifying and addressing bias within institutions conducting research, challenging myths and assumptions about communities of color, engaging in community participatory research, and ensuring equitable access to research results. Working groups will be held in the afternoon of each conference week to continue the discussion, allowing attendees to discuss how to implement the changes proposed and to document proposed efforts that can be disseminated with the wider community.

11:15-11:30 AM ET
Break

11:30 AM-12:45 PM ET
Panel: Coloring Outside the Lines: Ethical Conduct of Unregulated Research



FDA and DHHS regulations do not apply to all research involving human subjects, but much research that falls outside the regulatory purview raises ethical issues a little different from those arising in regulated research. In academic settings, institutions may be accustomed to imposing a modified version of regulatory requirements on research that is not federally funded, ranging from student projects to surgical research. In the biopharmaceutical industry, privately funded research on biospecimens and real-world data is often not subject to human research regulations, but raises similar ethical issues nonetheless. In the technology industry, privately funded research involving big data, including medical record data, has given rise to similar questions. This panel will discuss the types of research where bioethics questions are arising, possible opportunities for collaborative learning and standard-setting, and how addressing ethical issues in unregulated human subjects research should affect IRBs.

12:45-1:15 PM ET
Mid-Day Break

During this time, recharge, visit the supporters and exhibitors and/or poster gallery, or review pre-recorded content (see sessions designated with the pre-recorded icon).

ICON KEY

 Livestreamed session	 Pre-Recorded session	 Pre-registration required
 Breakout sessions new for 2020	 Call for Session Proposal	 CIP eligible
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.		Basic - for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.

12:45-1:15 PM ET

Supporter/Exhibitor Presentation from Axiom Mentor: Increase IRB Efficiency to Save Money



As the saying goes, "time is money" and this is as true for your IRB as any other organization. The hidden costs of high staff workload and associated inefficiency are magnified by the sometimes less obvious inefficiencies imposed on Investigators, Reviewers, and Board Members. In this session, speakers will review how a properly configured and supported IRB platform can save your organization tens of thousands of dollars.

Learning Objectives:

- Discuss the true costs of IRB inefficiencies (e.g., increased staffing; idle investigators as they wait for approvals; decreased cash flow from delayed grants payments)
- Learn how to make ERA Configuration work for you (e.g., integrations, workflow, Smartforms)
- Review how a Dynamic ERA Partnership can work for you (e.g., continuous improvement, transparent pricing, customer service)

Breakout Sessions Series A, 1:15-2:15 PM ET

W1A1: Defining Roles and Expectations for the Non-Scientist and Unaffiliated IRB Members



(Education and Training Track)

This session will describe the background, role, and expectations of non-scientist and unaffiliated IRB members, and define the research and regulatory terminology that commonly occurs during protocol review. A non-scientist IRB member will share their perspective about the "who, what, where, why, and how" of IRB membership. Speakers will also facilitate discussion, and provide tips for reviewing research and suggestions for success. During this session, speakers and attendees will:

- Review the role of non-scientist and unaffiliated IRB members on the IRB and the importance of these roles in the review process
- Identify problematic areas of protocols
- Outline specific issues for methodological consideration in IRB review
- Provide suggestions for reviewing challenging protocols
- Discuss first-hand knowledge and perspective of how non-scientist and unaffiliated IRB members can best contribute to the IRB

W1A2: Distinguishing Public Health Surveillance from Public Health Research



(Flexibility and Innovation in IRB Processes Track)

As noted in the 2018 Common Rule, some public health activities involve research and others do not; this presents many grey areas. Statutory authority of state and local health departments to conduct public health activities using methods similar to those used by researchers may add to the complexity (although the revised Common Rule now defines public health authority). Appropriate protections applicable for activities occurring at the boundary between public health surveillance and public health research are not readily interpretable from the regulations. Before attending this session, attendees should be knowledgeable about public health practice activities and the revised Common Rule's definition for "research," as well as have familiarity with the revised Common Rule definitions for "human subject," "public health authority," and "research."

Learning Objectives:

- Describe a framework for determining whether an activity is research, according to the revised Common Rule, borrowing from the CDC's approach
- Discuss key considerations and decision points unique to public health practice activities
- Review real-world examples to demonstrate the decision-making process to assist the audience in determining when something is public health surveillance versus public health research



W1A3: Bioresearch Monitoring (BIMO) Inspections—Regulatory Violations Observed in IRB, Clinical Investigator, and Sponsor-Investigator Inspections



(FDA Regulated Research Track)

FDA's BIMO program is designed to protect the rights, safety, and welfare of subjects. It also verifies the accuracy and reliability of clinical study data submitted to the agency in support of new product approvals and assesses compliance with FDA regulations. This session will provide an overview of the FDA Center for Drug Evaluation and Research (CDER) BIMO inspection process from initial notification through to post-inspection site visit and how to respond to an FDA Form 483. In addition, this session will review past and present inspection metrics highlighting common inspectional findings identified during IRB, clinical investigator, and sponsor-investigator inspections. Speakers will also discuss the relevant FDA compliance program and guidance documents an IRB, clinical investigator, sponsor-investigator, and institution should be aware of for an FDA inspection.

Learning Objectives:

- Describe the role of the Centers and Office of Regulatory Affairs in an inspection and how to respond to an FDA Form 483
- Review FY 2019 CDER BIMO inspection metrics and where to find them on FDA's website
- Identify common inspectional findings for IRBs, clinical investigators, and sponsor-investigators
- Review FDA materials (e.g., guidance, compliance program manuals, etc.) for inspections

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W1A4: Are Hospital Based IRBs Ready for the Endangered Species List

(Institutional Officials and HRPP Leadership Track)



Pursuant to the paradigm shift toward single IRB review coupled with the required harmonization of FDA and Common Rule regulations, hospital-based IRBs have encountered decreased volumes of work. Administrators are finding it increasingly difficult to justify allocating resources to support a local IRB in the hospital/healthcare system. This session will examine the pros and cons of maintaining an IRB in the healthcare setting.

Learning Objectives:

- Discuss the advantages and disadvantages of maintaining a local IRB in the hospital and health system setting
- Explore essential resources required to set forth an HRPP that does not include a local IRB or that includes an IRB that does not review greater than minimal risk research
- Share examples of various organizational structures and workflows that support an HRPP that does not include an IRB or that includes an IRB that does not review greater than minimal risk research

W1A5: The Etiquette and Necessity of Communication in the Single IRB World

(IRB Operations Advanced Track)



George Bernard Shaw stated, “the biggest problem in communication is the illusion that it has taken place,” which presaged one of the key challenges for single IRB review: how reviewing IRBs can effectively work with relying institutions and study teams to obtain and share the information necessary to ensure adequate oversight of a multi-site research study. When communication does not occur or go well, frustration, potential increase in research risks, and failure to provide new information to subjects can occur. Before attending this session, attendees should have some experience working with IRB reliance arrangements, either as a reviewing IRB or a relying institution. This session will use case studies to explore how institutions can work together proactively and collegially under the single IRB model by addressing critical components of communication.

Learning Objectives:

- Discuss unique needs and challenges to communicating with multiple parties in situations of reliance
- Explore the current landscape of local context, compare and contrast collection methods and discuss what information needs to be collected and who is responsible for it
- Discuss having difficult conversations with other IRB, internal and external PIs, and IRB members
- Learn tips to improve the style of your communication to improve efficiency and make work single IRB work more enjoyable

W1A6: Human Challenge Trials (HCTs) for COVID-19: What IRBs Should Know *(Pharma/Biotech Perspectives Track)*



HCTs, or a Controlled Human Infection Model, involve intentionally exposing participants to an infectious agent for the purpose of evaluating the ability of an investigational agent to prevent or treat infection. In the current COVID-19 pandemic, some have promoted human challenge trials as the best development path for a COVID -19 vaccine, primarily on the grounds that challenge trials may deliver results more quickly than traditional vaccine studies. HCTs have been used successfully in vaccine research and can be ethical when certain conditions are met. At the same time, the lack of a cure and/or broadly effective therapy for COVID-19 makes discerning their regulatory and ethical standing particularly complex. IRBs are charged with ensuring that participants are given the opportunity to provide voluntary and informed consent, that the potential benefits of research justify the risks, and that risks to participants are minimized. How should IRBs approach these decisions for COVID-19 human challenge studies? How should the risks and potential benefits of these studies be measured? What assumptions—both scientific and ethical—would be needed for COVID-19 HCTs to satisfy the regulatory criteria for approval? This session will provide tools for assisting IRBs in evaluating these questions and making well-informed decisions about whether or when COVID-19 HCTs merit approval.

Learning objectives:

- Review the defining features and history of HCTs
- Consider the scientific questions bearing on whether COVID-19 HCTs can be ethical
- Discuss different approaches to evaluating ethical issues for COVID-19 HCTs, including participant risk and social benefit, informed consent, and trust

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W1A7: Navigating Uncertainty: Research With Undocumented Immigrants and Refugees

(Populations Requiring Additional Protections Track)



With the increasing trend of forced migration due to political conflicts and climate change, refugees are becoming an increasingly popular population of study interest. International scientific societies and ethics organizations collectively recognize the vulnerability of refugees as study participants, but they are rarely addressed in international regulations and policies governing the conduct of research with specificity and action. In the United States, institutions in states that have a high number of undocumented/unauthorized immigrants, there are often IRB submissions requesting to enroll this vulnerable population, which lies outside the scope of vulnerable populations named in the code for federal regulations. Researchers are eager to understand the potential unique risks to these groups of vulnerable participants, especially from a trauma informed viewpoint. This session will delve into review strategies and best practices (including privacy and confidentiality protections, as well as flexibility in providing protections) for trauma informed care combined with cultural humility. Using case studies (e.g., longitudinal studies, studies with unaccompanied minors, undocumented students, etc.), speakers will discuss how IRBs can negotiate protecting these research participants while supporting the advancement of research in the midst of the current, and uncertain, political climate.

Learning Objectives

- Apply ethical standards to research involving undocumented students and refugees
- Consider the challenges facing researchers when conducting research involving refugees and review at how this compares/contrasts to domestic research involving undocumented persons
- Explore strategies/suggest solutions for review at all levels, with emphasis on full committee review
- Share ideas, experiences, and best practices for approving protocols involving undocumented and unauthorized immigrants

W1A8: Assessing and Addressing the Ethical, Regulatory, and Governance Challenges of Networking Biorepositories

(Research Involving Data and Biospecimens Track)



This session will explore the unique ethical, governance, and regulatory questions raised by networked biorepositories. We will present data from a mixed-methods study of the perspectives and experiences of stakeholders actively engaged in designing, operating, and governing networked biorepositories. Participants will have the opportunity to engage with our data through polling technology to agree or disagree with our findings and discuss their perspectives with the larger group.

Learning Objectives:

- Identify the unique ethical and regulatory challenges of creating and sustaining a networked biorepository
- Explore current practices and policies to address the ethical and regulatory challenges of networked science among existing biorepository networks
- Discuss possible regulatory and institutional approaches to inform best practices for future networked biorepositories
- Share recent examples of international blockages of research data and specimens, and cite specific laws that are impeding international transfers of data and specimens

W1A9: Beyond the Regulations: How to Effectively and Efficiently Manage Research Misconduct Cases *(Responsible Conduct of Research Track)*



Advanced

During this interactive session, speakers will go beyond the regulations to strategize and create organizational techniques to maximize efficiency with allegations, preliminary assessments, and sequestration. Speakers and attendees will discuss and compare processes used to collect evidence, document, and track research misconduct cases.

Learning objectives:

- Review how to maximize resources for sequestration activities
- Explore tools of the trade to enhance organization and documentation of research misconduct cases
- Share pros and cons of paper versus electronic systems for tracking and documentation

W1A10: Exempt or Not? Don't Get Psyched Out by the Benign Behavioral Intervention Research Exemption *(SBER Track)*



Using case studies, this session will review the draft guidance issued by OHRP on the exemption at 104(d)(3) concerning benign behavioral intervention research. The session 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.

Learning Objectives:

- Describe the key terms that define the scope of the exemption
- Consider what is meant by "prospective agreement" in the exemption
- Identify areas of discord between HRPP professionals and SBER researchers as to what constitutes a benign behavioral intervention
- Share conceptual framework/tools for better developing and implementing guidance on what constitutes benign behavioral interventions

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W1A11: Covering All of Your Bases: Considerations and Tips for How to Identify and Apply the Appropriate Federal Regulations for IRB Review (*IRB Basics Track*)



This session will assist IRB staff, chairs, and members with the initial review of non-exempt human subjects research. This session will provide the basic training necessary to determine whether a study qualifies for expedited or full board review; identify which regulations apply (e.g., Common Rule, FDA, the Family Educational Rights and Privacy Act, Health Insurance Portability and Accountability Act of, and other agency requirements), and what/how/where determinations should be documented (e.g., IRB minutes vs. reviewer checklist). *This session is pre-recorded.*

Learning Objectives:

- Identify and discuss regulations that impact IRB review
- Review the scope and applicability of those regulations
- Practice identifying applicable regulations using case studies

W1A12: Nuts and Bolts of Assessing IRB Compliance (*QA/QI and Post-Approval Monitoring Track*)



This session will introduce attendees to the various activities QA/QI programs can implement to assess IRB compliance with federal, state, and local requirements for research, including any changes programs may have made to address the revised Common Rule. *This session is pre-recorded*

Learning Objectives:

- Share considerations and mechanics for QA/QI review of IRB files, meeting minutes, and membership composition
- Identify triggers that may prompt QA/QI of the IRB
- Discuss approaches to self-auditing HRPP offices, including techniques and timing
- Review training approaches for QA/QI staff conducting quality assurance of the IRB
- Outline corrective and preventive actions that can be used to address IRB noncompliance

W1A13: How Might Ethics Review be Reimagined in the Age of DIY and Open Science? (*Research Conducted in the Digital World Track*)



Biohackers (aka DIY biologists, citizen scientists) are non-traditional researchers who operate outside of establishment research settings. They actively create knowledge and believe in open source sharing of scientific information and the democratization of science. Biohackers conduct their research in unconventional places, such as kitchens, garages, community labs, sheds and even a castle in the Netherlands. The biohacking movement has been gaining momentum over the course of the last decade, and members have begun loosely organizing themselves by holding annual conferences and by creating mission statements, biosafety manuals and codes of ethics. Many members of the biohacking community are not formally trained in biology, and while many have professional degrees and training, few have formal research training that comes with a doctorate degree. Without advanced, formal research training and without association with a corporate or academic institution, research designed by biohackers may not be compatible with what a traditional IRB would expect. Biohackers trying to solve their own health problems are frustrated with the traditional biomedical establishment and are working on therapies for their own diseases. Desperate patients have no choice but to assume huge risks because traditional IRBs do not allow for reasonable assumptions of patient risk. Are we preventing the development of open source biotechnology solutions by not broadening our definitions of researchers, research and blending establishment with non-establishment institutions? This session will educate attendees about the biohacker research community and present plans to create an ethics review process for non-traditional researchers who operate in non-establishment settings.

Learning Objectives:

- Educate attendees about the ways that citizen scientists (biohackers, DIY) are involved in health research
- Identify barriers to applying the current ethics review framework (IRBs, REBs, etc.) to research designed by citizen scientists
- Discuss possible routes toward a more effective, egalitarian system of ethics review

2:15-2:30 PM

Break

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Workshop: Introduction to the IRB: Ethics and Regulation

This workshop will offer an introduction to the ethical and regulatory fundamentals of IRB review for new IRB members, early career IRB administrators, and investigators. The program will include an overview of practical applications of the core ethical principles to IRB work and an orientation to the regulations and available resources. This workshop will allow those new to the field to start to build a foundation in effective review of human subjects research.



Workshop: Adaptable QA/QI Audit Approaches: How to Adjust Without Compromising Quality

In recent years, there have been both expected and unexpected changes that have impacted how research is being reviewed and conducted: the revised Common Rule, an increasing number of single IRBs and, most recently, the COVID-19 pandemic. During these times of transition and change, QA/QI professionals ask “How do we respond without compromising quality?” This interactive workshop will focus on developing and customizing an adaptable audit tool in response to the evolving research landscape.



Learning Objectives:

- Explore the importance of evaluating the values and goals of your institutional HRPP
- Share challenges, limitations, and solutions of conducting not-for-cause audits (on-site, remote, and principal investigator-self assessment)
- Discuss adaptable audit approaches that accommodate different kinds of audits: single IRB of both reviewing and relying sites, single-site versus multi-site, on-site versus remote, etc.

Afternoon Networking Sessions (*see agenda for times*)

2:30-3:30 PM ET

The Certified IRB Professional (CIP®) Credential Presentation



During this session, a member of the CIP Council and a CIP who recently earned their credential will discuss the CIP exam, eligibility guidelines, and exam preparation techniques. This session is geared toward individuals who are responsible for HRPP/IRB administrative functions and who will be eligible to take the certification exam in the next one to two years.

Learning Objectives:

- Discuss the CIP program and its value
- Review exam eligibility guidelines
- Walk through the exam content outline
- Discuss exam delivery options
- Go over exam preparation techniques and what to expect on exam day

2:30-3:30 PM ET

Virtual Roundtable: Racial Justice Working Group—IRB’s Role in Racial Bias



AER20’s Virtual Roundtables will enable participants to network and share knowledge and experience through a moderated group dialogue around a specific topic. The Racial Justice Working Group will meet each conference week (December 1, 8, and 15); participants will have an opportunity to discuss and address topics from Week 1’s panel, “Panel: Clarifying the Myths and Challenging Bias About Race in Research Review.” The group’s work will be documented and shared with the wider community. Week 1’s discussion will focus on the IRB’s role in racial bias and strategies for change. The group will discuss how to call out racial bias in IRB review (e.g., what types of bias exist in protocols with regard to study design, recruitment, participation, consent, etc.; how are populations excluded; how is local context considered; what assumptions are made/myths perpetuated about racial groups participating in research, etc.), how to work with researchers to resolve racial bias, and how IRB members interpret the principle of justice in IRB review. ***These sessions will be hosted in Zoom and attendees are encouraged use the video and audio features to actively participate in the dialogue.***

Virtual Roundtable: Ask the IRB Chairs!



AER20’s Virtual Roundtables will enable participants to network, learn, and benefit from the shared knowledge and experience of the group through a moderated dialogue around a specific topic. AER20 will feature two discussion groups for IRB chairs (December 1 and 8). IRB chairs are encouraged to attend these virtual roundtables to ask questions of and share strategies with one another on timely and challenging issues. The session(s) will start with a poll to gauge the most pressing issues, with subsequent discussion focusing on the most popular topics. ***These sessions will be hosted in Zoom and attendees are encouraged use the video and audio features to actively participate in the dialogue.***

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2:30-3:30 PM ET

Meet the Author Book Discussion: *Everybody Wants to Go to Heaven but Nobody Wants to Die: Bioethics and the Transformation of Health Care* 

Participate in a vibrant discussion of *Everybody Wants to Go to Heaven but Nobody Wants to Die: Bioethics and the Transformation of Health Care in America* by Drs. Amy Gutmann and Jonathan D. Moreno. In the book, the authors examine bioethics and American Healthcare, and the effects on American culture over the last 60 years. The book grapples with topics around healthcare reform and death-with-dignity to child vaccinations and gene editing, the authors explain how bioethics came to dominate the national spotlight, leading and responding to a revolution in doctor-patient relations, a burgeoning world of organ transplants, and new reproductive technologies that benefit millions, but create a host of legal and ethical challenges. Attendees will have the opportunity to hear from and participate in a discussion with Dr. Moreno during this session.

2:30-5:00 PM ET

Federal Agency/Accrediting Body Office hours 

During this time, representatives from select federal agencies will be available to answer attendee questions, engage in dialogue, provide clarification, and/or direct attendees to additional resources in real time via video chat. Attendees are encouraged to come prepared with questions, which will be taken on a first come basis. To participate in this offering, go to the Virtual Exhibit Hall, find the agency page you're interested in, and click on Video Chat. You'll be able to see when, during this timeframe, representatives are available to speak. **Agencies participating during this time include: AAHRPP, Inc., FDA, SACHRP, DOE and VA** (please keep checking the agenda for information on which agencies will be participating during this time).

2:30-5:00 PM

Visit the PRIM&R Booth 

Learn more about PRIM&R's programs and services, ask questions, and talk one-on-one with PRIM&R staff! A member of the Membership team will also be available to answer in-depth questions about PRIM&R membership. To visit the PRIM&R Booth, go to the Virtual Exhibit Hall, find the PRIM&R page you're interested in, and click on Video Chat.

2:30-5:00 PM

CIP Office Hours 

Whether you are considering certification, or are a current CIP who has questions about recertification, use video chat to speak one-on-one with a CIP Council member. To talk with our Council members using video chat, visit the CIP Booth in the Virtual Exhibit Hall during this time, navigate to the video chat tab, and click "join video chat" with the Council members available. We look forward to speaking with you during this time!

2:30-3:00 PM ET

PRIM&R's Ethical Research Oversight Course (EROC) Demonstration 

PRIM&R's EROC is the most comprehensive and convenient way for new HRPP/IRB members and staff to learn the fundamental ethical principles and key regulatory frameworks that govern their day-to-day work. This self-paced, interactive course was revised in 2019 - with a new platform and a more engaging audio-visual format, and it includes the most up-to-date information about best practices for HRPPs and applying the regulations. Unique features of EROC include observing an IRB in action as they review both biomedical and SBER research, interactive exercises and knowledge checks throughout the course, and best practice for fostering effective meeting dynamics. Visit primr.org to see a demo of EROC in action and learn about our options for individual and institutional subscriptions. ***This session is pre-recorded.***

2:30-3:00 PM ET

PRIM&R Membership Presentation 

This pre-recorded presentation will provide an overview of PRIM&R's membership community and the benefits and opportunities membership provides.

4:00-5:00 PM ET

Scientific Poster Panel: Outstanding Work 

Join this year's outstanding poster award winners for a discussion on their scientific-based work. During this session, poster authors will present on their work and take questions from the audience. Posters to be included are:

Poster Presenters:

- *Variation in Interpretation of Subpart B Conditions by Stakeholders in the IRB Review Process of Abortion Research, United States, 2019, Jessica Blackburn, Emory University*
- *Research Recruitment Through the Patient Portal: Acceptability and Preferences of Healthcare Users, Kathryn M. Porter, Seattle Children's Research Institute*
- *Comparing Payments between Sociobehavioral and Biomedical Studies in a Large Research University in Southern California, Brandon Brown, University of California, Riverside*

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10:00-11:15 AM ET

Panel: Scientific and Ethical Challenges of COVID-19 Prevention Trials in a Complex Sociopolitical Context



Recent months have brought unique challenges regarding design and conduct of clinical trials related to preventive therapies for coronavirus. A historic pandemic has created an unprecedented rush to develop, test, review, and implement vaccines and other therapeutic interventions. This urgency complicates already difficult issues related to research design, participant selection, and oversight, and the complex sociopolitical context of the current pandemic makes these issues far more difficult. These challenges touch every aspect of clinical research. This panel will address a wide range of critical issues, ranging from trial design, choice of comparator groups, and thresholds for equipoise to inclusion of traditionally underrepresented populations and intersections between trial design and downstream public health implementation. Importantly, this panel will bring academic, industry, and public health perspectives to this critical set of issues.

11:15-11:30 AM ET

Break

11:30-12:45 PM ET

Panel: Ethical, Legal, and Regulatory Challenges of Conducting Research on Involuntarily Admitted Patients



Patients are involuntarily admitted to psychiatric hospitals for a variety of conditions, including acute suicidality, severe psychosis, and inability to care for themselves, among others. Such patients are unable to leave the hospital on their own accord and are a particularly vulnerable population on the basis of their legal status. In some jurisdictions, even patients admitted voluntarily to psychiatric hospitals have restrictions placed on their ability to leave the unit immediately and experience some degree of this same vulnerability. Research on particular psychiatric conditions benefits from the inclusion of these subjects (e.g., looking to prevent suicidality or to understand the neurobiology of fulminant psychosis). Federal research regulations do not provide specific protections required for research in this population. Institutions have handled research in this population differently, with some outright banning it altogether, and others permitting it with additional safeguards for subjects in place (e.g., limited to minimal risk research or with special considerations for assurance of the consent process). This panel will include experts in psychiatric research, regulatory and legal complexities, and psychiatric ethics and IRB work to discuss the ethical, legal, and regulatory challenges of conducting research on involuntarily admitted patients. The panel will aim to provide a framework and pragmatic advice for IRBs to review studies of this nature, including specific safeguards that can be put in place to conduct this research most effectively and safely.

12:45-1:15 PM ET

Supporter/Exhibitor Presentation

Join one of PRIM&R's supporters/exhibitors for a topical and timely presentation. Information forthcoming.



Breakout Sessions Series B, 1:15-2:15 PM ET

W1B1: A Dialogue With FDA (*A Dialogue With the Feds Track*)



This session will be an open forum led by a panel of FDA representatives, and who will provide brief updates on FDA activities within their Center/Office. The session will then be open for audience questions. Attendees are encouraged to come with questions of interest to all.

Learning Objectives:

- Hear from FDA representatives about new and evolving issues, initiatives, regulations, and guidance
- Participate in an open discussion about topics relevant to FDA stakeholders
- Ask questions about evolving issues and initiatives at the FDA

ICON KEY

Livestreamed session	Pre-Recorded session	Pre-registration required
Breakout sessions new for 2020	Call for Session Proposal	CIP eligible
<p>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.</p>		<p>Basic - for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.</p>

W1B2: How Do Ancillary Review Committees Strengthen Our HRPPs? (*Institutional Officials and HRPP Leadership Track*)



Memo sent

What do Biohazard Use Authorizations, Radiation Use Authorizations, lasers, conflicts of interest, and Stem Cell Research Oversight have in common? These important ancillary review committees complement IRB review by providing approval for the accessory activities included in protocols. However, if you don't know what those committees review and how to coordinate their review with your office, then IRB reviews may be incomplete. In this session, speakers will explore and define ancillary committees so attendees understand what they review and how to ensure best practices at their HRPPs.

Learning Objectives:

- Describe what ancillary committees review, and the variations in titles of these committees at different institutions
- Share examples of human subjects protocols that involve materials or procedures for which ancillary review would be required, what office(s) should then be contacted, and discuss/deliberate how institutions might respond
- Outline best practices for creating solid, practical, and achievable plans for HRPPs

W1B3: Meeting Management for IRB Chairs (*IRB Chairs Track*)



This session will cover key topics in the management of an IRB from the IRB chair's perspective.

Learning Objectives:

- Discuss the fundamentals of meeting management and member interactions from a leadership perspective
- Explore how to increase engagement of members and interaction with staff/consultants
- Focus on tips, strategies, and approaches to build on attendees' skills and training as IRB chairs

W1B4: Shaping Your Clinical Research Culture (*Leadership Track*)



This session aims to assist attendees in understanding the full landscape of their research culture, beyond just the hard skills required for ideal outcomes. The goal is to empower favorable engagement by stakeholders and increase not only productivity, but also quality, by ensuring employee retention and a better working environment where research can take place.

Learning Objectives:

- Identify how to become indispensable to your organization by learning how to identify the symptoms of poor research culture (e.g. poor conflict resolution, lacking self-awareness, etc.)
- Review how to address the root cause of a lack of research culture and how to implement appropriate and effective corrective action
- Discuss how to master the most effective behaviors for a quality research culture environment, including championing organizational transformation and change management

W1B5: Navigating State Law Differences in the Era of Single IRB (sIRB) Review



(*Legal Considerations in HRPPs Track*)

Variations in state laws present complex challenges in the era of sIRB review. Relying organizations have the responsibility to identify and communicate their state law requirements, and institutional interpretation of these requirements, to an external entity. Reviewing IRBs now have a unique responsibility to understand and apply these differences in the context of their review. This session will highlight select areas where state laws have great variability, identify how these differences affect the IRB review process, and propose potential practical solutions for reviewing IRBs and relying organizations in navigating these variances.

Learning Objectives:

- Review key areas where state laws vary, and identify how these variances impact the IRB review process
- Provide guidance on identifying/communicating state law requirements to reviewing IRBs
- Share practical tips for reviewing IRBs in considering/applying these variances as part of their review

ICON KEY

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W1B6: Research with Children: Ethical Considerations, Parental Permission, and Assent

(Populations Requiring Additional Protections Track)



This session will start with a brief review of the Subpart D requirements, and their historical and ethical basis. Presenters will discuss the complexities of categorizing risk and assessing the consent process. They will present strategies for thinking through the parental permission requirement and both the challenge and protection offered by the option for waiver. Attendees will be presented with difficult waiver scenarios and guided through the necessary determinations and their thoughtful justification. Presenters will then discuss common IRB pitfalls related to youth assent and creating a meaningful assent process. Attendees will receive practical suggestions for implementing effective assent in research with children and tools for creating effective assent forms, and then simulate the process of assent with a child and family.

Learning Objectives:

- Review the additional requirements for inclusion of children in research
- Examine the unique issues presented by research with children
- Identify complex and unique issues related to parental permission in research settings and as it relates to vulnerable children
- Share how to thoughtfully waive (or deny waiver of) the requirement for parental permission in complex and varied research scenarios
- Explore strategies for making the assent process useful for research participants
- Assess the quality and quantity of information required in the assent form and introduce tools to effectively present information to young participants in clinical studies
- Discuss additional requirements for research with children, and explore nuances of those requirements

W1B7: Protocol Deviations, Protocol Violations, Protocol Variances, Protocol Exceptions, and Noncompliance: What Really Needs to be Reported to an IRB

(QA/QI and Post-Approval Monitoring Track)



The Common Rule and sections 21 CFR 50 and 56 of the FDA regulations only refer to serious and continuing noncompliance but do not define any of the terms while the phrase protocol deviations only occurs in FDA device regulations. Even though protocol deviations, exceptions, and violations are common parlance amongst research teams, auditors and monitors, IRBs and HRPPs, the regulations are unclear regarding what events should be reported to an IRB, which has led to significant variation in IRB reporting requirements.

Learning Objectives:

- Define the regulatory basis of event reporting, variation in IRB requirements for event reporting, the consequences of this variation, and opportunities for harmonization
- Review SACHRP's recommendations regarding protocol deviations
- Consider what events should be reported to IRBs to promote the protection of human subjects

W1B8: Online Research: Design and Review in a World of Bots, Hackers, and Evolving Technology

(Research Conducted in the Digital World Track)



Recent decades have seen a proliferation of research surveys administered online and through social media. With this surge in online research methodology comes an increased possibility for inaccurate data and fake results due to bots and hackers (i.e., fake participants). Speakers will present real-life case studies of survey compromise and discuss design and review best practices that will minimize these issues. This session is for research investigators, IRB administrators, and committee members who provide guidance to survey researchers about how to protect against attacks and handle the aftermath of survey compromise. Learn how to protect your online survey research to be resistant to bots and fake participants while protecting your actual participants and obtaining usable data.

Learning Objectives:

- Identify signs of online survey compromise, differentiate fake from real research participants, and modify procedures to protect from further compromise through real-life case study examples
- Discuss how the IRB members and administrators can advise principal investigators to handle survey compromise in terms of reporting requirements, compensation provision, and maintaining data confidentiality
- Share best practices for design of online research and for cybersecurity monitoring of survey data
- Describe best practices for data interpretation post-compromise

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W1B9: Challenges and Opportunities for Institutions With Small Research Programs (*Small Research Programs Track*)



Small research programs are identified as having fewer than 200 open protocols and three or fewer IRB staff. This session will explore the organizational, professional, and procedural challenges and opportunities experienced by small research programs and single staff HRPP/IRB offices. Attendees will discuss current and future needs to professional development and support, and will discuss how and with whom to develop these networks, both within their organizations and outside, through mentorship and other relevant professional groups.

Learning Objectives:

- Identify specific challenges and opportunities encountered by small research programs
- Provide possible solutions to overcome these challenges and how to harness opportunities
- Offer guidance on how best to use the resources available and comply with the regulations
- Develop strategies for connecting, networking, and mentorship with others in the HRPP and greater research ethics and compliance community

W1B10: College Students and Research: Challenges and Issues for IRBs (*SBER Track*)



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.

Learning Objectives:

- 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 investigator
- 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

W1B11: A Dialogue With the VA



This session will be led by representatives from the VA. *This session is pre-recorded.*

Learning Objectives:

- Hear from representatives of the VA's Office of Research and Development and Office of Research Oversight about issues and activities related to the conduct of VA research
- Learn about the VA's current policies related to human subjects protections and the direction of the VA's future policies

2:15-2:30 PM ET

Break

Workshops, 2:30-5:30 PM ET (workshops are an additional fee)

2:30-5:30 PM ET

Workshop: Achieving Excellence in Research: Moving from Diversity and Inclusion to Equity and Justice



The concept of equal human rights has been an ongoing concern since the founding of America. However, these concerns have been recently magnified by the recent murders which have been caught on video and broadcasted in multiple media outlets. The murders have caused our society to examine the notion of justice and how it may, or may not be, playing out particularly in populations which have been historically vulnerable to injustice and mistreatment. As the human subjects research industry reflects the global state and well-being of public health, the protection of human subjects must carefully consider how societal ills could potentially affect our approach to this very important work. In this talk, the presenters will provide material which will assist attendees in having crucial and sometimes difficult conversations around defining current diversity and inclusion efforts while reflecting on historical events which have shaped our expectations for human research protections. Additionally, the presenters will discuss strategies on transitioning diversity and inclusion efforts to equity and justice efforts and the deliverables which should be associated with this transition.

ICON KEY

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2:30-3:30 PM ET

SBER Network Discussion



Join the [SBER Network](#) in discussing researcher training ideas for consent forms and consent processes. In this train-the-trainer style session, the presenters will share their experiences with developing and delivering informed consent trainings and then we will break into small groups where we will participate in a training session, and we will end with a discussion of ways to adapt the training ideas to various institutions. Participants will leave this session with resources they can use to develop a consent training for their research community.

2:30-3:30 PM ET

Virtual Roundtable: COVID-19’s Impact on the Field—Challenges for IRBs in Reviewing COVID-Related Research

AER20’s Virtual Roundtables will enable participants to network, learn, and benefit from the shared knowledge and experience of the group through a moderated dialogue around a specific topic. AER20 will feature two discussion groups on COVID-19 related issues (December 1 and 16). During Week 1’s group, moderators will review the results from surveys completed by COVID-19 researchers and IRB directors/chairs who reviewed COVID-19 research, as well as stories the moderators have curated for an issue of *Narrative Inquiry in Bioethics* on the ethical, regulatory and practical challenges of doing research in a pandemic. Attendees will then discuss the results, share their own stories/challenges, and share/brainstorm potential solutions. **These sessions will be hosted in Zoom and attendees are encouraged use the video and audio features to actively participate in the dialogue.**

2:30-3:30 PM ET

Virtual Roundtable: IRB Administrators Group—Tools, Tips, and Tricks for Managing Single IRB (sIRB) Review



AER20’s Virtual Roundtables will enable participants to network, learn, and benefit from the shared knowledge and experience of the group through a moderated dialogue around a specific topic. The IRB Administrators Group will meet each conference week (December 2, 9, and 15); participants will have an opportunity to discuss timely topics of importance to IRB Administrators. Week 1’s group will focus on sharing tools, tips, and tricks for managing sIRB review. Attendees are encouraged to come with their solutions, as well as questions on challenging issues that the group can respond to/brainstorm. **These sessions will be hosted in Zoom and attendees are encouraged use the video and audio features to actively participate in the dialogue.**

2:30-5:00 PM

CIP Office Hours



Whether you are considering certification, or are a current CIP who has questions about recertification, use video chat to speak one-on-one with a CIP Council member. To talk with our Council members using video chat, visit the CIP Booth in the Virtual Exhibit Hall during this time, navigate to the video chat tab, and click “join video chat” with the Council members available. We look forward to speaking with you during this time!

2:30-5:00 PM ET

Federal Agency/Accrediting Body Office hours



During this time, representatives from select federal agencies will be available to answer attendee questions, engage in dialogue, provide clarification, and/or direct attendees to additional resources in real time. **Agencies participating during this time include: AAHRPP, Inc., OHRP, VA** (please keep checking the agenda for information on which agencies will be participating during this time).

2:30-5:00 PM

Visit the PRIM&R Booth



Learn more about PRIM&R’s programs and services, ask questions, and talk one-on-one with PRIM&R staff! A member of the Membership team will also be available to answer in-depth questions about PRIM&R membership. To visit the PRIM&R Booth, go to the Virtual Exhibit Hall, find the PRIM&R page you’re interested in, and click on Video Chat.

4:00-5:00 PM ET

Programmatic Poster Panel: Outstanding Work



Join this year’s outstanding poster award winners for a discussion on their programmatic-based work. During this session, poster authors will present on their work and take questions from the audience.

Poster Presenters:

- *Harnessing the Power of the Participant Perspective Through Research Participant Advisory Groups*, Julie Wijesooriya, Cincinnati Children’s Hospital/University of Cincinnati - CCTST
- *Successes and Pitfalls Centralizing an Electronic Consent Platform in an NIH Funded Multi-Site Clinical Trials Network*, Deneil Harney, University of Michigan
- *Key Findings and Utilization of Results from a Systematic Participant Experience Survey*, Courtney Jarboe, University of Minnesota

ICON KEY

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9:30-10:00 AM ET

Attendee Orientation

View this pre-recorded session to learn more about the AER20 Virtual Conference and PRIM&R. *This session is pre-recorded.*



10:00 AM-5:00 PM ET

Visit the Supporters/Exhibitors

Visit the AER20 Supporters and Exhibitors during the event, and learn about their important services. Participating companies will have virtual booth pages with information and resources, and some companies will participate in real-time video chat (accessible via the virtual booth pages).



10:00 AM-5:00 PM ET

Visit the Virtual Poster Gallery

View the virtual poster gallery and learn more about the important programmatic and scientific work being done by your peers in the field. Posters include the actual poster abstract and a 10-minute pre-recorded talk from the abstract authors. Attendees can also submit questions directly to poster authors.



10:00-10:15 AM ET

Welcome and Remarks from PRIM&R Board Chair, Natalie Mays, BA, LATG, CPIA, New York University Grossman School of Medicine

Presentation of PRIM&R's Applied Research Ethics National Association (ARENA) Legacy Award to Linda E. Mayo, Director of the HRPP, The University of New Mexico



10:15-11:15 AM ET

Keynote Address: Improving Openness and Reproducibility of Research



11:15-11:30 PM ET

Break

11:30-12:45 PM ET

Panel Presentation: In IRBs We Trust? Building Trust Between IRBs and Researchers and Between IRBs Under Single IRB (sIRB)

At its core, the relationship between IRBs and researchers and between IRBs under sIRB must be built upon a foundation of mutual trust to be successful. IRBs must trust researchers and researchers must trust their IRB; relying IRBs must trust reviewing IRBs and vice versa as well as mutual trust between researcher(s) and reviewing IRB. But, this doesn't just exist. Trust must be proactively sought, developed, and nurtured, and possibly within an environment of approval, confidentiality, and control that may inhibit trust between parties. Speakers will discuss how to build and sustain a relationship of trust from a variety of perspectives: IRB senior leadership, researcher/IRB member, and "cross-institutional" insights.



12:45-1:15 PM ET

Mid-Day Break

During this time, recharge, visit the supporters and exhibitors and/or poster gallery, or review pre-recorded content (see sessions designated with the pre-recorded icon).

12:45-1:15 PM ET

Supporter/Exhibitor Presentation from Advarra: Operational Data as a Communication Mechanism Between Research Administration and Research Teams

Efficient clinical research is a partnership between multiple stakeholders, and like any productive relationship, effective communication is key to performing and ensuring high-quality research. Join Wendy Tate, Director, Research Operations at Advarra in discussing the process in which clinical research teams collect protocol- and portfolio-level data regarding performance, compliance, and trial demographics, bringing shared understanding to workflows and processes and how this information is helpful to research compliance personnel.



Learning Objectives:

- Describe how operational data can facilitate conversations between research teams and research compliance/administration personnel
- Identify ways to use data to form a common ground regarding benchmarks between stakeholders
- Discuss the importance of metrics in both protocol-related and portfolio-wide conversations

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W2A1: Vaccine Research During a Global Pandemic: A Case Study of COVID-19 (*Pharma/Biotech Perspectives Track*)



The session is intended to provide the audience with insight into ongoing and emerging issues in human research subjects protections and in public responsibility in the development and use of vaccines to prevent COVID-19. It will do so through examples drawn from the experiences of two vaccine manufacturers currently involved in the development of a vaccine.

Learning Objectives:

- Discuss what traditional vaccine development looks like as well as the challenges of conducting vaccine research during a global pandemic
- Consider the balance between individual rights and societal interests as they pertain to vaccine research
- Share examples that describe different approaches to managing these challenges

W2A2: Single IRB (sIRB) Strategies to Streamline IRB and HRPP Review (*Flexibility and Innovation in IRB Processes Track*)



The requirements for sIRB review of multi-site research have introduced new challenges for reviewing IRBs and relying organizations and have changed how HRPPs and IRBs operationalize review, particularly when involving multiple institutions in differing roles. Reviewing IRBs have adopted a variety of strategies for what types of submissions should be considered at an IRB-level, and what types may be the responsibility of the HRPP. For IRBs, these strategies include reviewing and approving short forms, recruitment material, and other study documents at a study-wide level to reduce the need for multiple site-specific amendments from the relying sites. For HRPPs, these strategies may include maintaining Health Insurance Portability and Accountability Act Privacy responsibilities locally, efforts to determine which institutions are engaged, and implementation of non-IRB institutional policies. This session will highlight some of the key challenges in HRPP/IRB review for multi-site studies reviewed by a sIRB and offer practical tools and strategies for participating sites to consider.

Learning Objectives:

- Identify the challenges faced by reviewing IRBs related to volume of submissions from multiple sites and the IRB's responsibilities
- Describe the differing responsibilities of the reviewing IRB and the HRPPs of reviewing and relying organizations
- Identify best practices for addressing the distinct role different institutions might play in a multi-site project, including engagement in human subjects research
- Share tools and strategies to enhance review for multi-site research for HRPPs/IRBs
- Explore opportunities for potential harmonization and best practice for what constitutes HRPP/IRB responsibilities

W2A3: Implementing a Streamlined Process to Facilitate Physicians' Requests for Individual Patient Expanded Access Applications at an Academic Medical Center (*FDA Regulated Research Track*)



The University of Colorado Denver, Anschutz Medical Campus has developed a unique and efficient strategy for processing Individual Patient Expanded Access Applications (i.e., Single Patient Investigational New Drugs (S-INDs)) that leverages the strengths and capabilities of the various stakeholders involved by streamlining data collection to eliminate redundancies, address bottlenecks and responsibility gaps, and decrease each stakeholder's regulatory and administrative burdens. In this advanced session, speakers will describe the steps and requirements for treating patients under a S-IND, identify practical strategies for harmonizing stakeholder goals and institutional procedures to efficiently and effectively process the S-IND, and address the maintenance of S-INDs. Attendees should be familiar with the FDA drug and device regulations regarding expanded access before attending this session.

Learning Objectives:

- Discuss Individual Patient Expanded Access Applications and FORM FDA 3926, including the regulatory requirements and responsibilities associated with these kinds of treatment protocols, and the difference from intermediate access and treatment INDs
- Share practical tools for implementing an S-IND facilitation program, including strategies for collaborating with key stakeholders (e.g., IRB, pharmacy, etc.) and managing limited resources
- Disclose implications and limitations of requesting an alternative IRB review procedure for individual patient expanded access and provide strategies for managing amendments and continuing review

ICON KEY

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Breakout sessions new for 2020	Call for Session Proposal	CIP eligible
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.		Basic – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.

W2A4: Evaluating the Quality and Effectiveness of HRPPs: Problems and New Approaches

(Institutional Officials and HRPP Leadership Track)



In this session, speakers will articulate barriers to evaluating the quality and effectiveness of research ethics oversight and explore why such evaluation is important, introducing the Consortium to Advance Effective Research Ethics Oversight, launched to make progress in this area (www.aereo.org). They will describe perspectives of U.S. leaders in research ethics oversight regarding how they currently assess IRB and HRPP quality and how they think it should be defined and measured, leading to discussion of the relative value of assessments based on process and structure versus deliberation and outcomes. Finally, speakers will address the role of patients and research participants in determining what it means for research ethics oversight to be done "well," perspectives that have been largely neglected to date.

Learning Objectives:

- Describe the importance and challenges of evaluating IRB and HRPP quality and effectiveness
- Consider the role of assessments based on process, structure, and outcomes, with ideas for how to evaluate quality from all angles
- Recognize the importance of including patient and research participant perspectives when evaluating IRB and HRPP quality and effectiveness

W2A5: Protecting Privacy in an Era of Shifting Requirements for Privacy and Concepts of Identifiability

(Legal Considerations in HRPPs Track)



This session will explore various regulatory and policy requirements for researchers and research institutions related to the protection of the privacy of research participants' information, including the Health Insurance Portability and Accountability Act, the European Union General Data Protection Regulation, Certificates of Confidentiality (as updated by the 21st Century Cures Act and the NIH Policy), and the revised Common Rule. Speakers will explore how changing definitions of identifiability may impact organizational approaches to privacy and confidentiality, and review the challenges presented by competing standards of protection across various regulatory frameworks. Finally, this session will provide practical guidance for how organizations may navigate this complex and changing environment.

Learning Objectives:

- Identify various regulatory and policy requirements related to the protection of the privacy of research participants' information and the challenges presented by these competing standards
- Explore how changing definitions of identifiability may impact organizational approaches to privacy and confidentiality
- Provide practical guidance for how organizations may navigate this complex and changing environment

W2A6: California Consumer Privacy Act (CCPA) and Emerging State Privacy Laws *(Pharma/Biotech Perspectives Track)*



The CCPA is a sweeping privacy law that took effect on January 1, 2020, and applies to the processing of personal information of California residents. While the CCPA contains certain exemptions for protected health information protected by Health Insurance Portability and Accountability Act (HIPAA) and personal information collected in "clinical trials" subject to the Common Rule or FDA regulations, the law has important implications for big data research and other studies that are not clinical trials. Other state legislatures are considering legislation that would enact similar privacy protections. This session will provide an update on these state laws and their impact on research to individuals who already have a basic understanding of HIPAA and the Common Rule.

Learning Objectives:

- Provide an overview of the basic requirements of the CCPA
- Explain how the CCPA applies to research activities
- Describe other state laws under consideration

W2A7: Situational Vulnerability: Considerations and Safeguards When Exploring Gender Identity, Social/Economic Challenges, and At-Risk Behavior *(Populations Requiring Additional Protections Track)*



Vulnerability relates to the ability to understand, protect, and advocate for one's own interest. This ability can vary based upon social, economic, or cultural context, subjecting many people to risk related to their marginalized status. In order to accurately assess risk and benefit, IRB's therefore need to specifically consider the situational vulnerabilities of the proposed research participants and ensure it has sufficient expertise and cultural competence to review.

Learning Objectives:

- Define and apply the concept of situational vulnerability.
- Identify characteristics that can impact situational vulnerability in the research context (e.g., homelessness, substance use, sexual orientation and gender identify, undocumented status)
- Review additional risks that may affect these marginalized populations (e.g., violence, discrimination, depression, suicide)
- Consider appropriate additional protections related to situational vulnerabilities of the research population (e.g., payment and undue influence, recruitment, maintaining contact with subjects, confidentiality, stigmatization of research subjects)

ICON KEY

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W2A8: Remote Study Auditing and Monitoring Best Practices (QA/QI and Post-Approval Monitoring Track)



A shift was already beginning as the result of budgets to increase remote QA/QI activities when the COVID-19 pandemic crystallized the need for organizations to be able to ensure compliance with human subjects regulations and IRB determinations without conducting on-site visits. Implementation of single IRB for investigator-initiated research also highlights the need for more explicit QA/QI monitoring plans to be put in place and that involve a prominent role for coordinating centers (or lead study teams) in ensuring compliance. Attendees should be familiar with the basics of study auditing and monitoring before attending this session.

Learning Objectives:

- Review the differences between remote and on-site compliance reviews that need to be considered and addressed
- Discuss how study teams play a key role in ensuring compliance, such as through self-audits or compliance reviews conducted by coordinating centers/lead study teams in the case of multi-site research
- Share strategies and tools to facilitate effective remote compliance auditing

W2A9: How to Maintain Institutional Memory at a Small Research Program (Small Research Programs Track)



It is important for HRPPs/IRBs to understand decisions and policies as being part of a larger institutional context. To do so, it is essential that institutional memory is preserved and can be easily accessed and shared with IRB staff, chairs, and members. Attendees should have experience as an IRB administrator or chair, including responsibility for recruitment and retention of IRB members and/or staff, and knowledge and experience drafting policies, guidelines and/or standard operating procedures.

Learning Objectives:

- Review how to create policies and procedures to assist in preserving institutional memory
- Discuss how documents related to the HRPP and IRB can be archived and stored
- Share strategies for succession planning
- Explore on-boarding and off-boarding of staff and members to retain institutional memory

W2A10: Fundamental Issues in Qualitative Research (SBER Track)



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 issues this research paradigm can present during review. Attendees should have a basic knowledge of SBER methodologies and of 45 CFR 46 before attending this session.

Learning Objectives:

- 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

W2A11: A Dialogue With the DOD (A Dialogue with the Feds Track)



This session will be led by senior leaders and subject matter experts from DOD's HRPPs. *This session is pre-recorded.*

Learning Objectives:

- Discuss the newly revised DOD Regulation 3216.02 and its implications for DOD-conducted and DOD-supported human subject research (HSR)
- Explore DOD guidance pertaining to the oversight of DOD-conducted and DOD-supported HSR involving DOD personnel, particularly DOD-unique requirements
- Hear from DOD staff about new flexibilities impacting the research protections communities, internally to the DOD as well as the extramurally-supported partners

W2A12: Dialogue With AAHRPP (A Dialogue With the Feds Track)



Memo sent

Join us to discuss and learn about AAHRPP accreditation. AAHRPP, founded by PRIM&R and six other research-focused organizations in 2001, is an international nonprofit organization that accredits high quality HRPPs. AAHRPP provides peer-based, collaborative, collegial and educationally based evaluations of HRPPs based on applicable standards and elements. This interactive session is designed to answer questions about accreditation for organizations considering AAHRPP accreditation and those that are already AAHRPP accredited.

Learning Objectives:

- Review the process of achieving or maintaining AAHRPP accreditation
- Discuss AAHRPP's approach to cutting edge issues in the human research enterprise
- Become familiar with AAHRPP staff and web resources available to all wishing to maintain or achieve a robust system of human research protections

ICON KEY

Livestreamed session	Pre-Recorded session	Pre-registration required
Breakout sessions new for 2020	Call for Session Proposal	CIP eligible
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.		Basic - for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.

W2A13: Getting IRB Review Right: Who Should Review a Study? (IRB Basics Track)



Common Rule and FDA regulations require IRBs to be "sufficiently qualified through the experience and expertise of its members (professional competence)." which prompts several questions: How do organizations ensure their IRBs are appropriately constituted to review the research they oversee? Can an IRB with five members, the minimal number required under regulations, include sufficient expertise? When should expertise from outside an IRB be obtained to assess a study? If a study involves a vulnerable population, who needs to be involved in the review? Are there different expectations for expertise for research reviewed by the convened board vs. expedited review? This session will use case studies to explore answers to these questions (and others) to identify strategies organizations may adopt to determine appropriate IRB composition, IRB reviewer assignments, and consultant selection.

Learning Objectives:

- Describe expertise requirements in the context of the review of human subjects research
- Identify considerations for IRB composition relevant to the research portfolio a committee may oversee
- Develop strategies to assess the expertise that may be necessary for appropriate assessment of a study's risk/benefit ratio and potential safeguards to minimize risks to subjects

2:15-2:30 PM ET
Break

Workshops, 2:30-5:30 PM ET (workshops are an additional fee)

Workshop: Research With American Indian and Alaska Native (AI/AN) Tribes and Communities



This interactive workshop will focus on considerations for HRPPs in oversight of research with AI/AN communities, both Tribal and non-Tribal. After describing the complex nature of "AI/AN communities" in the US, speakers will present a historical synopsis of research and varied ethical research practices with AI/AN communities. Speakers will outline basic information on Tribal sovereignty and its application in research, known as data sovereignty, discuss how 45 CFR 46 does and does not recognize Tribal sovereignty and data sovereignty, and examine differences and similarities in research with AI/AN who are associated with off-Reservation communities (also known as "Urban Indians") versus Tribe. Opportunities will be provided for attendees and speakers to share how AI/AN communities, IRBs, researchers, and HRPPs can best work together to achieve common goals.

Learning Objectives:

- Identify characteristics of ethical research with AI/AN Tribes and communities, and characteristics of questionably ethical versus ethical research.
- Outline two key core elements of Tribal sovereignty and data sovereignty.
- Describe actions your HRPP, researchers, or IRB have done, now do, or can realistically do, to better engage with AI/AN Tribes and communities in research.
- Apply this session's "lessons learned" to community-engaged research with underserved communities.

Afternoon Networking Sessions (see agenda for times)

2:30-3:30 PM ET

The Certified IRB Professional (CIP®) Credential Presentation



During this session, a member of the CIP Council and a CIP who recently earned their credential will discuss the CIP exam, eligibility guidelines, and exam preparation techniques. This session is geared toward individuals who are responsible for HRPP/IRB administrative functions and who will be eligible to take the certification exam in the next one to two years.

Learning Objectives:

- Discuss the CIP program and its value
- Review exam eligibility guidelines
- Walk through the exam content outline
- Discuss exam delivery options
- Go over exam preparation techniques and what to expect on exam day

2:30-3:30 PM ET

I Love My Job!? Perspectives Throughout a Career in Human Research Protections



*This session will share perspectives from HRPP professionals at different points in their careers about the joy (and challenges) of working in this field. What can a career in human research protections look like? **These sessions will be hosted in Zoom and attendees are encouraged use the video and audio features to actively participate in the dialogue.***

Learning Objectives:

- Engage with others in the HRPP community
- Discuss career development goals and career paths

ICON KEY

Livestreamed session	Pre-Recorded session	Pre-registration required
Breakout sessions new for 2020	Call for Session Proposal	CIP eligible
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.		Basic - for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.

2:30-3:30 PM ET

Virtual Roundtable: Racial Justice Working Group—Community-Based Participatory Research



AER20’s Virtual Roundtables will enable participants to network, learn, and benefit from the shared knowledge and experience of the group through a moderated dialogue around a specific topic. The Racial Justice Working Group will meet each conference week (December 1, 8, and 15); participants will have an opportunity to discuss and address topics from Week 1’s panel, “Panel: Clarifying the Myths and Challenging Bias About Race in Research Review.” The group’s work will be documented and shared with the wider community. Week 2’s discussion will focus on community-based participatory research. ***These sessions will be hosted in Zoom and attendees are encouraged use the video and audio features to actively participate in the dialogue.***

Virtual Roundtable: Ask the IRB Chairs!

AER20’s Virtual Roundtables will enable participants to network, learn, and benefit from the shared knowledge and experience of the group through a moderated dialogue around a specific topic. AER20 will feature two discussion groups for IRB chairs (December 1 and 8). IRB chairs are encouraged to attend these virtual roundtables to ask questions of and share strategies with one another on timely and challenging issues. The session(s) will start with a poll to gauge the most pressing issues, with subsequent discussion focusing on the most popular topics. ***These sessions will be hosted in Zoom and attendees are encouraged use the video and audio features to actively participate in the dialogue.***

2:30-5:00 PM ET

Federal Agency/Accrediting Body Office hours



During this time, representatives from select federal agencies will be available to answer attendee questions, engage in dialogue, provide clarification, and/or direct attendees to additional resources in real time via video chat. Attendees are encouraged to come prepared with questions, which will be taken on a first come basis. To participate in this offering, go to the Virtual Exhibit Hall, find the agency page you’re interested in, and click on Video Chat. You’ll be able to see when, during this timeframe, representatives are available to speak. **Agencies participating during this time include: AAHRPP, Inc., OHRP, DOE, and the VA** *(please keep checking the agenda for information on which agencies will be participating during this time).*

2:30-5:00 PM

Visit the PRIM&R Booth

Learn more about PRIM&R’s programs and services, ask questions, and talk one-on-one with PRIM&R staff! A member of the Membership team will also be available to answer in-depth questions about PRIM&R membership. To visit the PRIM&R Booth, go to the Virtual Exhibit Hall, find the PRIM&R page you’re interested in, and click on Video Chat.



2:30-5:00 PM

CIP Office Hours

Whether you are considering certification, or are a current CIP who has questions about recertification, use video chat to speak one-on-one with a CIP Council member. To talk with our Council members using video chat, visit the CIP Booth in the Virtual Exhibit Hall during this time, navigate to the video chat tab, and click “join video chat” with the Council members available. We look forward to speaking with you during this time!



2:30-3:00 PM ET

PRIM&R’s Ethical Research Oversight Course (EROC) Demonstration



Scott Rule, PRIM&R

PRIM&R’s EROC is the most comprehensive and convenient way for new HRPP/IRB members and staff to learn the fundamental ethical principles and key regulatory frameworks that govern their day-to-day work. This self-paced, interactive course was revised in 2019 - with a new platform and a more engaging audio-visual format, and it includes the most up-to-date information about best practices for HRPPs and applying the regulations. Unique features of EROC include observing an IRB in action as they review both biomedical and SBER research, interactive exercises and knowledge checks throughout the course, and best practice for fostering effective meeting dynamics. Visit primr.org to see a demo of EROC in action and learn about our options for individual and institutional subscriptions. ***This session is pre-recorded.***

2:30-3:00 PM ET

PRIM&R Membership Presentation

This pre-recorded presentation will provide an overview of PRIM&R’s membership community and the benefits and opportunities membership provides.



ICON KEY

Livestreamed session	Pre-Recorded session	Pre-registration required
Breakout sessions new for 2020	Call for Session Proposal	CIP eligible
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2:30-3:00 PM ET

Supporter/Exhibitor Presentation from iMedRIS: Beyond Boundaries--Collaborative Work With National and International Studies in a Rapidly Changing Research Environment

Social distancing mandates, locally and globally, are no match to iMedRIS' scalable and adaptable software. Mitigate risks associated with protocol pauses or suspensions, documentation, and audit processes.



Learning Objectives:

- Post-Approval Monitoring, Not for Cause Audits, For Cause Audits, or subpoenas
- Preparatory for research: increase and diversify subject populations
- Multi-site capabilities and a multi-lingual Research Administration Platform

4:00-5:00 PM ET

Scientific Poster Panel: Outstanding Work

Join this year's outstanding poster award winners for a discussion on their scientific-based work. During this session, poster authors will present on their work and take questions from the audience.



Posters to be included are:

- *Variation in Interpretation of Subpart B Conditions by Stakeholders in the IRB Review Process of Abortion Research, United States, 2019, Jessica Blackburn, Emory University*
- *Research Recruitment Through the Patient Portal: Acceptability and Preferences of Healthcare Users, Kathryn M. Porter, Seattle Children's Research Institute*
- *Comparing Payments between Sociobehavioral and Biomedical Studies in a Large Research University in Southern California, Brandon Brown, University of California, Riverside*

ICON KEY

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Breakout sessions new for 2020	Call for Session Proposal	CIP eligible
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10:00 AM-5:00 PM ET

Visit the Supporters/Exhibitors

Visit the AER20 Supporters and Exhibitors during the event, and learn about their important services. Participating companies will have virtual booth pages with information and resources, and some companies will participate in real-time video chat (accessible via the virtual booth pages).



10:00 AM-5:00 PM ET

Visit the Virtual Poster Gallery

View the virtual poster gallery and learn more about the important programmatic and scientific work being done by your peers in the field. Posters include the actual poster abstract and a 10-minute pre-recorded talk from the abstract authors. Attendees can also submit questions directly to poster authors.



10:00-11:15 AM ET

Panel: Reworking Justice in Research: The Time Is Now

Justice has been a central principle to research ethics for at least the last 40 years, since the publication of the Belmont Report. While the concept of justice as outlined in Belmont has done much important work over the decades, it does not capture the range of issues related to justice in research. Guided by Belmont and the regulatory framework based on it, IRBs are in the troubling position of trying to solve all justice issues in research as problems of distributive justice. However, many of those issues do not fit neatly into a distributive justice framework. After all, social and structural injustices provide the backdrop for parts of the research enterprise. This panel aims to provide the IRB audience with conceptual, practical, and policy tools to recognize these broader justice issues in their work.



11:15-11:30 AM ET

Break

11:30-12:45 PM ET

Panel: Ethical and Regulatory Challenges in Adaptive and Platform Trials

Adaptive clinical trials modify key features of studies using pre-determined criteria and prospectively planned, periodic data analysis. The goal is to make a clinical trial that is flexible, efficient, and fast without compromising validity and integrity. Platform trials similarly alter designs in ways that allow for adaptation and testing of multiple therapies and potential for a shared control group. Ultimately, these designs are intended to reduce the number of patients assigned to ineffective therapies, to generate knowledge quickly, and to allow studies to evolve as knowledge accumulates. For many of these reasons, adaptive and platform trials have emerged as an effective trial design to test promising products in the COVID-19 crisis. However, adaptive designs and platform trials raise interesting ethical challenges related to informed consent, clinical equipoise, and justice. They are also very complex and raise important practical issues related to IRB oversight. This panel will explore these important ethical and practical advantages and challenges of adaptive and platform trials.



Breakout Sessions Series B, 1:15-2:15 PM ET

W2B1: A Dialogue With OHRP (*A Dialogue With the Feds Track*)

This session will be led by representatives from OHRP. Attendees are encouraged to come with questions of interest to all.

Learning Objectives:

- Hear from OHRP representatives about evolving initiatives, issues, and guidance
- Ask questions of OHRP representatives
- Participate in an open discussion on topics raised at the session



W2B2: Mobile Medical Applications and IRB Review (*FDA Regulated Research Track*)

When does a mobile application (mobile app) meet the definition of a medical device under the Food Drug, and Cosmetic(FD&C) Act, and how does FDA intend to apply its regulatory authorities to mobile medical apps? IRBs may struggle with these questions and what their review responsibilities are when a protocol involves a mobile medical app.

Learning Objectives:

- Distinguish when mobile apps meet the definition of a medical device
- Discuss FDA's current approach to applying its regulatory authorities to oversight of mobile medical apps
- Provide IRBs with a review framework for studies involving mobile medical apps and suggest policies and procedures to develop to ensure HRPPs remains relevant in a tech savvy world



ICON KEY

Livestreamed session	Pre-Recorded session	Pre-registration required
Breakout sessions new for 2020	Call for Session Proposal	CIP eligible
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.		Basic - for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.

W2B3: Going Global for the First Time—Considerations for Reviewing International Research (*Global Research Track*)



This session is intended for IRB members and staff of US IRBs that oversee human subjects research outside the US; however, the concepts could be applied more broadly. This session will describe the history of and current international research landscape and highlight associated IRB review challenges. It will also provide an overview of applicable US regulations and international guidelines, and share available resources to identify applicable local laws and regulations, and to ensure equivalent protections. Speakers will share best practices for reviewing transnational research.

Learning Objectives:

- Review the history of unethical research outside of the United States
- Discuss the common challenges facing US IRBs when reviewing international research, including cultural practices that may not be acceptable in the US
- Consider various approaches to eliminating or mitigating challenges, including possible US regulatory flexibility
- Examine institutional policies/best practices for US IRB review of transnational research
- Share ways that US IRBs may engage and partner with local ethics committees
- Explore the ways others are doing excellent research and protecting subjects outside the US

W2B4: Strategies that Promote Diversity and Inclusion in Clinical Research: What Role Does the IRB Play?



(*Hot Topics Track*)

The focus of the session is to orient attendees to the important role IRBs play in ensuring the diversity of enrolled study participants, and how well-defined expectations during IRB review, attention to patient and community perspective, and clear communications with patients, research staff, and clinicians can contribute to a more inclusive research environment that supports the enrollment of a more diverse study population. The presenters will cover areas such as: (1) the scientific and ethical imperative to include diverse populations in research; (2) IRB review of enrollment and recruitment plans (at time of initial approval and continuing review to ensure a representative and diverse population is being recruited into the study) and participant-facing study materials that address and support the diversity of the population most likely to benefit from the research and its findings; and (3) best practices and practical resources in diversity and inclusion, including patient engagement and health literacy techniques that are foundational to the conduct of ethical research. Instruction will involve a didactic presentation, with review of case studies, and before/after examples that demonstrate diversity activities in action.

Learning Objectives:

- Understand the scientific and ethical arguments that support the connection between human research participant protections and the inclusion of diverse study participants
- Identify the role IRBs can play in supporting the diversity of clinical trial participants and communication of research information that fosters the inclusion of a representative sample of participants
- Apply appropriate principles and practices to the IRB's role (i.e., to boilerplates and templates, study review criteria, and by providing staff trainings) that promote a culture of diverse representation and clear communication

W2B5: Unique Challenges of Being an IRB Chairperson at Medium to Small Institution (*IRB Chairs 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 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.

Learning Objectives:

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

ICON KEY

Livestreamed session	Pre-Recorded session	Pre-registration required
Breakout sessions new for 2020	Call for Session Proposal	CIP eligible
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.		Basic – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.

W2B6: Ensuring IRB Compliance in a Hybrid World—Strategies for Operating in a World Where Multiple Regulatory Frameworks Apply (*IRB Operations Advanced Track*)



While the revised Common Rule permits organizations to transition their entire research portfolio to the revised Rule, many organizations have found this type of transition impractical and burdensome to researchers. Organizations that do not make a complete transition are now required to implement strategies for operating their IRBs in a world where two sets of regulatory criteria apply. Moreover, for organizations that must also comply with FDA regulations, a third set of regulatory criterion may apply. Challenges include appropriate identification and application of the correct regulatory framework to existing and new studies, ensuring IRB members and staff are aware of and appropriately apply the applicable criteria, and effectively communicating applicable requirements to study teams. This session will explore these challenges, identify potential compliance risks and offer solutions developed by two IRBs to address this hybrid world. Attendees should have an understanding of the requirements of the revised Common Rule and of the requirements for IRB record keeping including meeting minutes before attending this session.

Learning Objectives:

- Identify the challenges faced by IRBs operating under varied regulatory frameworks
- Understand how these challenges can create potential compliance risks for IRBs in performing and documenting their key responsibilities
- Consider examples of potential operational solutions and how to adapt them for their own HRPP

W2B7: Toolkit for HRPP Leaders: Tips for Overseeing a Human Research Protection Program (*Leadership Track*)



Join current HRPP leaders for a dynamic discussion-based session designed to tackle the day to day challenges of managing a human research protections office or program. Many HRPP leaders are challenged by questions about how to effectively manage their HRPP. How does one create a budget for an HRPP office or decide on staffing structures and the number of positions needed? How does one effectively advocate for new resources or determine how their program is performing in comparison to other HRPPs? This session will afford HRPP leaders the opportunity to share experiences and strategies for effective management of their HRPP. Attendees are encouraged to bring questions and solutions!

Learning Objectives:

- Identify effective strategies for management of an HRPP program/office
- Explore tools/processes used by HRPP leaders and consider how they may be adopted for their own program
- Learn from peer experiences to develop customized solutions for their own organizations.

W2B8: Improvements in the FDA Expanded Access Program Compared to Growing Demand for Right to Try Laws (*Pharma/Biotech Perspectives Track*)



The FDA has provided improvements in their Expanded Access Program. How does this effort compare to right to try laws? Attendees with familiarity with Expanded Access regulations will be taken through a comparison of the strengths and weaknesses of each approach.

Learning Objectives:

- Review Project Facilitate and Improvements in the FDA Expanded Access Program
- Discuss the requirements of many of the new Right to Try Laws on state and federal level
- Identify the strengths and weaknesses in each program and what makes more sense for institutions

W2B9: Operationalizing Research Databases and Biobanks at Your Institution

(*Research Involving Data and Biospecimens Track*)



This session explores the legal and practical challenges that institutions face when implementing an institution-wide research database or specimen repository. From the approach to consent, the banking protocol submitted to the IRB, the use of steering or access committees with associated policies and procedures, as well as the agreements and processes necessary for sharing the resource for downstream research purposes, there are a number of important points institutions need to consider when developing institutional resources to ensure they are done in a compliant and ethical manner. This session will offer an overview of applicable regulatory requirements, as well as practical suggestions for how institutions can effectively operationalize these resources.

Learning Objectives:

- Review regulatory requirements and best practices for research databases and biobanks
- Discuss various approaches to informed consent for participation in databases and biobanks, including how the revised Common Rule has impacted those options and how honest brokers can be used to facilitate secondary research
- Outline practical steps institutions can take when initiating, operating and terminating/transferring institutional research databases and biobanks to maximize the value of the resource and minimize risk, including issues related to financial sustainability

ICON KEY

Livestreamed session	Pre-Recorded session	Pre-registration required
Breakout sessions new for 2020	Call for Session Proposal	CIP eligible
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.		Basic - for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.

W2B10: Assessing the Ethics of Using Wearable Technologies to Facilitate Public Health Initiatives

(Research Conducted in the Digital World Track)



Wearable technologies and wellness apps are playing an increasing part in a variety of contexts including clinical care, research, and in public health monitoring. While employing such technologies in these contexts has the possibility of contributing to the public good, it also provokes major ethical concerns. This session will explore the possible uses of wearable technologies and wellness apps in research and public health monitoring. It will examine the potential risks to individuals and marginalized groups, how these risks could be minimized, and whether they are worth the promised good to the public.

Learning Objectives:

- Describe the various ways wearable technologies and wellness apps are being used or considered for use to support public health initiatives and in clinical care and research
- Discuss how the human subjects research community can assess validity of claims of public good
- Review the ethical concerns and risks to individuals that these technologies may pose, as well as the ethical issues surrounding communication of privacy issues and incentivization for participation with potential subjects
- Consider if there may be reasonable solutions for minimizing risks to individuals and marginalized groups while also promoting the public good

W2B11: Planning for Respondent Distress (Populations Requiring Additional Protections Track)



In order to reduce risk when conducting research with sensitive topics or vulnerable populations, HRPPs should consider creating and implementing a distress protocol. In the event that a respondent becomes upset during a data collection activity (e.g., interviews, focus groups), distress protocols assist researchers in identifying various signs of distress. Regardless of the respondent's age, the distress protocol can be a very effective layer of protection for the researchers and their participants. These protocols also easily outline steps to identify each level of distress (e.g., low, moderate, high). This session will review the creation and implementation of distress protocols, conducting training for the researchers and provide examples of research where distress protocols were put into place. ***This session is pre-recorded.***

Learning Objectives:

- Explore when a distress protocol should be included
- Review components of a distress protocol in order to reduce risk and share examples of when a distress protocol was implemented
- Present researcher training protocols

W2B12: Ethics of Mandatory Research Biopsies in Clinical Trials (Research Involving Data and Biospecimens Track)



Discussion of the ethical considerations related to non-therapeutic research biopsies that are becoming a common mandatory component of some clinical trials. As the scientific value of tissue has expanded, it has become increasingly common for clinical trials to require research subjects to also agree to undergo research biopsies, with known risks, and no expectation of direct benefit. As this practice has increased, some have questioned whether this practice is ethical, and identified recommendations for how to improve the ethical conduct of such studies. ***This session is pre-recorded.***

Learning Objectives:

- Learn about the current practice of requiring mandatory, non-therapeutic research biopsies as a condition of participation in a clinical trial
- Discuss the ethical concerns raised by such mandatory research biopsies
- Identify the relevant regulatory provisions that IRBs should consider when reviewing such studies

2:15-2:30 PM ET

Break

Workshops, 2:30-5:30 PM ET (workshops are an additional fee)

Workshop: Operational Solutions for Conducting Research During a National Emergency: What's in Your Research Emergency Management Kit?



This workshop will take an in-depth look at the challenges faced by research systems and the practical solutions and infrastructure necessary to manage through short and extended emergencies. The focus of the course will be tools you need in your "research emergency kit" to effectively lead and operate during the disruptions of a national emergency, and instruction will include discussion, didactic, and case study elements to provide strategies and share operational best practices. *Please note: Workshop registrants will also have an opportunity to review highlights from PRIM&R's 2020 Research Ethics and COVID-19 online meeting, with a new emphasis on operational considerations raised by those discussions.*

Learning Objectives:

- Identify key systems and workstreams that are disrupted during a national emergency
- Describe and understand operational changes that are necessary to manage research, including shutdown and ramp up of research, documentation of changes, and how to work with federal regulators
- Evaluate leadership strategies that create effective and flexible operations and support rapidly evolving emergency conditions

ICON KEY

Livestreamed session	Pre-Recorded session	Pre-registration required
Breakout sessions new for 2020	Call for Session Proposal	CIP eligible
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2:30-3:30 PM ET

Human Subjects Trivia Game



This session will be a review of regulatory requirements in the form of a game. Categories include 2018 Common Rule, vulnerable subjects, informed consent, investigational drugs, and investigational devices. Attendees will be divided into teams. After a team provides the question to the answer given, the host will provide an explanation for the answer. This session experience will help attendees understand the fundamentals, as well as serve as a refresher for people with advanced knowledge. In addition, attendees will build teamwork skills while developing an answer to questions about human subject research. *These sessions will be hosted in Zoom and attendees are encouraged use the video and audio features to actively participate in the dialogue.*

2:30-3:30 PM ET

Virtual Roundtable: IRB Administrators Group—Challenges and Opportunities for IRB Administrators at Small to Mid-Size Research Programs

AER20's Virtual Roundtables will enable participants to network, learn, and benefit from the shared knowledge and experience of the group through a moderated dialogue around a specific topic. The IRB Administrators Group will meet each conference week (December 2, 9, and 15), and provide an opportunity for attendees to discuss timely topics of importance to IRB Administrators. Week 2's group will focus on the organizational, professional, and procedural challenges experienced by IRB administrators working in small research programs and single staff HRPP/IRB offices. Attendees will have an opportunity to share on obstacles they face and potential solutions, thus creating a small research program information-sharing community. *These sessions will be hosted in Zoom and attendees are encouraged use the video and audio features to actively participate in the dialogue.*

2:30-3:30 PM ET

Virtual Roundtable: SBER Professionals

AER20's Virtual Roundtables will enable participants to network, learn, and benefit from the shared knowledge and experience of the group through a moderated dialogue around a specific topic. This group will allow SBER professionals to discuss issues of importance to their work. *These sessions will be hosted in Zoom and attendees are encouraged use the video and audio features to actively participate in the dialogue.*

2:30-5:00 PM ET

Federal Agency/Accrediting Body Office hours



During this time, representatives from select federal agencies will be available to answer attendee questions, engage in dialogue, provide clarification, and/or direct attendees to additional resources in real time. **Agencies participating during this time include: AAHRPP, Inc., and the VA** (please keep checking the agenda for information on which agencies will be participating during this time).

2:30-5:00 PM

Visit the PRIM&R Booth

Learn more about PRIM&R's programs and services, ask questions, and talk one-on-one with PRIM&R staff! A member of the Membership team will also be available to answer in-depth questions about PRIM&R membership. To visit the PRIM&R Booth, go to the Virtual Exhibit Hall, find the PRIM&R page you're interested in, and click on Video Chat.



2:30-5:00 PM

CIP Office Hours

Whether you are considering certification, or are a current CIP who has questions about recertification, use video chat to speak one-on-one with a CIP Council member. To talk with our Council members using video chat, visit the CIP Booth in the Virtual Exhibit Hall during this time, navigate to the video chat tab, and click "join video chat" with the Council members available. We look forward to speaking with you during this time!



4:00-5:00 PM ET

Programmatic Poster Panel: Outstanding Work



Join this year's outstanding poster award winners for a discussion on their programmatic-based work. During this session, poster authors will present on their work and take questions from the audience.

Posters to be included are:

- *Harnessing the Power of the Participant Perspective Through Research Participant Advisory Groups, Julie Wijesooriya, Cincinnati Children's Hospital/University of Cincinnati - CCTST*
- *Successes and Pitfalls Centralizing an Electronic Consent Platform in an NIH Funded Multi-Site Clinical Trials Network, Deneil Harney, University of Michigan*
- *Key Findings and Utilization of Results from a Systematic Participant Experience Survey, Courtney Jarboe, University of Minnesota*

ICON KEY

 Livestreamed session	 Pre-Recorded session	 Pre-registration required
 Breakout sessions new for 2020	 Call for Session Proposal	 CIP eligible
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A PRIM&R Virtual Event

2020 Advancing Ethical Research Conference

AER20 Week 3: Tuesday, December 15

9:30-10:00 AM ET
Attendee Orientation

View this pre-recorded session to learn more about the AER20 Virtual Conference and PRIM&R. *This session is pre-recorded.*



10:00 AM-5:00 PM ET
Visit the Supporters/Exhibitors

Visit the AER20 Supporters and Exhibitors during the event, and learn about their important services. Participating companies will have virtual booth pages with information and resources, and some companies will participate in real-time video chat (accessible via the virtual booth pages).



10:00 AM-5:00 PM ET
Visit the Virtual Poster Gallery

View the virtual poster gallery and learn more about the important programmatic and scientific work being done by your peers in the field. Posters include the actual poster abstract and a 10-minute pre-recorded talk from the abstract authors. Attendees can also submit questions directly to poster authors.



10:00-10:15 AM ET
Conference Welcome



10:15-11:15 AM ET
Keynote Address: Wylie Burke, MD, PhD, Professor Emeritus and former Chair, Department of Bioethics and Humanities, University of Washington: Learning from Communities about Diversity and Justice



11:15-11:30 AM ET
Break

11:30-12:45 PM ET

Panel: Subjects Consenting Versus Consenting Subjects: The Ethics of Nudging People Toward Research Participation

Behavioral economics research has demonstrated various ways in which the framing of information presented to decision makers influences the outcomes of those decisions. These “nudges” supposedly influence choices in a “good” way without taking away the decision maker’s options. Nudges could be employed in the process of seeking informed consent, and in constructing informed consent forms, in such a way as to “nudge” people in the direction of consenting to research. However, the popularity of the phrase “Consenting Subjects” suggests the possibility that nudges might serve to undermine the prospective subject’s autonomy. The “best interest” of the prospective subject, which is sometimes used in the clinical or policy context to justify nudging, may not be so useful in the context of research participation. And, might the ethics of nudging vary depending on whether some prospective subjects may be disadvantaged with respect to the options they have, or the power relationship between the investigator and prospective subject? Does nudging represent a threat to the informed decision-making of prospective subjects, or can it be used in legitimate ways? What if it is both, a threat and legitimate? Panelists will discuss these issues and more during the session.



12:45-1:15 PM ET
Mid-Day Break

During this time, recharge, visit the supporters and exhibitors and/or poster gallery, or review pre-recorded content (see sessions designated with the pre-recorded icon).

Breakout Sessions Series A, 1:15-2:15 PM ET

W3A1: A Dialogue With the NIH (A Dialogue With the Feds Track)

This session will be led by a representative from the NIH, and will include discussion of NIH’s work related to research participation and data sharing.



Learning Objectives:

- Hear from a representative of the NIH Office of Science Policy about activities that are pertinent to clinical research policy and the protection of human participants in research
- Participate in an open discussion about topics relevant to NIH stakeholders
- Ask questions about new and ongoing initiatives at the NIH

ICON KEY

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W3A2: Strategies for IRB Member & Staff Education (*Education and Training Track*)

This session will offer innovative strategies and resources for developing and delivering education for IRB members. Speakers will highlight educational methods and materials that are interactive, adaptable, and readily available videos, webinars & recordings, particularly case studies, and cover a range of topics including clinical and SBE research.

Learning Objectives:

- Discuss resources for IRB member & staff education, including what experienced IRB members still need to learn
- Develop strategies for increasing buy-in and engagement of IRB members in educational activities
- Assess the potential of different educational strategies for teaching about different topics
- Explore options for educating IRB members in a virtual setting



W3A3: Consent Through a Wider Lens: Broadening the Scope of Ethical Review to Reflect the Realities of Research

Decision-Making (*Empirical Research Ethics Track*)

Recent empirical ethics work has elucidated how little prospective research participants rely on consent forms when they decide whether to enroll in research, but other elements of the recruitment and enrollment process lack the same degree of ethical scrutiny. A better understanding of how and when individuals make decisions about participating in research is needed to develop guidance for IRBs and investigators to ensure they are achieving the goals of the consent process. This session will examine empirical data about the timing of research decision-making, describe our growing understanding of how people process information and what they value in research relationships, and propose specific approaches to better support decision-making by refocusing ethical review outside of the consent form.

Learning objectives:

- Describe empirical data demonstrating the relatively minimal role of consent forms in prospective participants' decisions about research enrollment
- Examine our evolving understanding of how people make decisions and the implications for the role and relevance of consent forms
- Identify potential approaches to demonstrating respect for persons and supporting decision-making throughout the research recruitment and enrollment process



W3A4: Assessing Benefit and Risk in Pediatric Clinical Trials (*FDA Regulated Research Track*)

FDA regulations permit IRBs to approve pediatric research that either offers a low level of risk or offers a prospect of direct benefit to the individual child. Differentiating interventions or procedures in a clinical trial that offer a prospect of direct benefit, are minimal risk or a minor increase over minimal risk, may raise challenges for IRBs.

Learning Objectives:

- Discuss IRB considerations for assessing prospect of direct benefit and risk in pediatric studies
- Define minimal risk and minor increase over minimal risk thresholds
- Review how to perform a component analysis of a protocol
- Explore the concepts of benefit and risk in the context of specific cases handled by an IRB



W3A5: How to Investigate, Mitigate, Report, and Learn from Noncompliance: Avoiding Pitfalls and Seizing Opportunities for Improvement (*Institutional Officials and HRPP Leadership Track*)

During this session, speakers will explore how institutions can use incidents of alleged noncompliance (both investigator and IRB) as learning opportunities, and will identify strategic and substantive pitfalls to avoid. Topics covered will include: preventative measures to prepare for managing noncompliance; how to undertake a thorough and effective noncompliance investigation; strategies to manage interactions with federal agencies when reporting and implementing corrective actions; and the unique challenges presented when IRB noncompliance is implicated.

Learning Objectives:

- Review what constitutes "noncompliance" within the applicable federal regulations, when institutions have an obligation to report to federal agencies, and to whom findings should be communicated when operating in a reliance relationship
- Explore how institutions structure their policies and approach investigations to effectively and consistently uncover the relevant facts, and best position the institution (vis-a-vis federal agencies), and the targets of such investigations
- Identify the challenges that can arise when potential IRB noncompliance is at issue
- Address ways institutions can use these experiences for programmatic improvement and opportunities for increased compliance moving forward
- Discuss specific approaches to corrective action plans, including how to follow-up on plans



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W3A6: Overturning Staff Turnover: Retaining Your Greatest Assets (*Leadership Track*)



Adequate staffing and the ability to retain highly specialized staff are critical resource components of an effective HRPP. This session will provide strategies for office leadership for evaluating staff climate and proactively identifying factors that can lead to dissatisfaction, and how to implement and then monitor strategies to retain the most valuable resource of these offices: the staff. The session will start with a brief overview of basic personnel concepts, followed by audience engagement through several brief group exercises to provide illustrative examples of staffing challenges, strategies for reducing turnover, and monitoring success.

Learning objectives:

- Discuss participatory methods to assess staff climate (e.g., satisfaction or lack thereof with office environment, performance expectations, communication, salaries, workload, flexibility, etc.) in order to avoid loss of personnel through burnout
- Review how office leadership can proactively monitor an acceptable workload overtime, and advocate for additional resources or altered use of available resources to assist staff with workloads
- Share strategies for addressing factors that staff or leadership perceive as less than optimal and for monitoring the effect of strategies that are implemented

W3A7: Risky Business—Defining Research Risks and Who Faces Them in the Age of Comparative Effectiveness Research and Alternative Trial Design (*Legal Considerations in HRPPs Track*)



As the nature of and approach to research has evolved, it has become increasingly challenging for IRBs, researchers, and regulators to identify which aspects of a project are appropriately characterized as “research risks” and “research benefits,” as opposed to the risks and benefits of standard clinical care. Similarly, identifying who qualifies as a research participant in a given project can be daunting in the context of certain innovative research. The proliferation of comparative effectiveness research, as well as alternative trial designs, such as cluster randomized trials, has engendered debate over which risks need to be communicated and to whom the communication must flow.

Learning Objectives:

- Review the regulatory basis for defining research risks, the connection to legally effective informed consent, and how recent trends in research substance and design have challenged those norms
- Explore recent cases where specific trials and areas of research have been scrutinized and criticized based on judgments about identifying who is participating in the research and which are research risks
- Discuss the draft OHRP guidance on identifying research risks and provide practical suggestions to IRBs, legal counsel, and others reviewing and advising on how to identify research risks

W3A8: Ideas and Practices for Compliance and Auditing of Single IRB (sIRB) Studies



(*QA/QI and Post-Approval Monitoring Track*)

Advanced

sIRB is becoming commonplace in the human subjects' clinical trial enterprise. As institutions transition to reviewing IRBs or relying institutions, they face new challenges with respect to ensuring appropriate oversight of the clinical trial and study team, communication between the reviewing IRB and relying institutions, and compliance with requirements. QA/QI and postapproval monitoring programs play a critical role in ensuring study teams are aware of their responsibilities, remain in compliance, and identify communication gaps between the local site and reviewing IRB. This session will discuss strategies to effectively conduct for-cause and not-for-cause audits of sIRB studies, including recommendations for preparing for and conducting audits, the reviewing organization conducting an audit itself versus in collaboration with the relying organization, reporting and communicating to the IRB of record, and managing corrective action plans. This session is helpful for QA/QI programs who are being asked to conduct QA/QI audits of sIRB studies, or any study reviewed by an external IRB. It will be equally helpful to reviewing IRBs, relying sites, and principal investigators who are involved in sIRB studies. Attendees should have a familiarity with single IRB and QA/QI monitoring before attending this session.

Learning Objectives:

- Review the key challenges to QA/QI audits of single IRB (sIRB) studies
- Explore effective QA/QI audit processes, including a discussion of the SMART IRB proposed best practices for post-approval auditing
- Describe action plan for preparedness in post-approval auditing of sIRB studies

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W3A9: Research With Mobile Health (mHealth) and Other Wearable Technologies: An Ethical Landmine and What to Do About It (*Research Conducted in the Digital World Track*)

mHealth and other wearable technologies facilitate the ease of data collection and present a great potential for expansion of healthcare quality and improvement of personal wellness. Mobile-sensor data provides researchers unprecedented opportunities to collect objective data without requiring intensive subject engagement. However, these technologies also raise many ethical issues including privacy and security challenges. It is vital that researchers have the knowledge, skills, and resources to manage these challenges in order to ensure the viability and public trust for research with mHealth and wearable technologies. Speakers will use case studies to explore the diverse risks and ethical problems posed by research with mHealth and other wearable technologies, and discuss strategies, particularly the role of research design and governance, for dealing with them. Speakers are interested in hearing from you! Please send case studies without identifiers to the [speakers](#). Origin of all case studies will be confidential.

Learning Objectives:

- Describe the diverse types of data collected via mHealth and other wearable technologies and the risks and ethical issues they may pose
- Explore broad stakeholders' perspectives on data privacy, risks, and benefits of data sharing
- Discuss practical strategies for lowering risk in doing research with mHealth and wearable technologies, particularly through the role of research design and governance

W3A10: Confidentiality, Privacy and Anonymity in SBER (*SBER Track*)



Confidentiality, privacy, and anonymity are three terms frequently used, and misunderstood, in SBER involving human subjects. Contributing to the confusion are changing laws and regulations affecting privacy and confidentiality, advances in technology, and shifting expectations by individuals about use of their personal information, including in research. In this session, participants will learn about these concepts and the legal and regulatory environment affecting them in SBER; identify how these concepts play out in the lifecycle of a research study; and discuss strategies for IRBs and researchers to minimize risk in SBER studies related to these concepts.

Learning Objectives:

- Describe the concepts of confidentiality, privacy and anonymity, and laws and regulations impacting them in SBER
- Identify how confidentiality, privacy and anonymity come into play in the lifecycle of a research study
- Evaluate best practices for minimizing risk to participants in SBER related to these concepts

W3A11: Research in K-12 Settings (*SBER Track*)



Research conducted with students in elementary and secondary school settings presents specific considerations for IRBs and researchers. Using case studies, speakers will examine various topics as they relate to research conducted in K-12 schools. ***This session is pre-recorded.***

Learning Objectives:

- 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 institution.
- Address other IRB considerations (e.g., privacy and protection of data)

W3A12: A Dialogue With the Department of Energy (DOE) (*A Dialogue With the Feds Track*)



During this pre-recorded session, representatives from DOE will:

Learning Objectives:

- Provide a brief overview of the DOE human subjects portfolio and program for the protection of human subjects.

W3A13: A Dialogue With the Office of Research Integrity (ORI) (*A Dialogue With the Feds Track*)



During this pre-recorded session, a representative from ORI will:

- Review ORI's mission and jurisdiction
- Go over the distinction between clinical research misconduct and a protocol violation
- Discuss Protocol violations vs. clinical research misconduct
- Share about ORI key concerns faced in making federal findings of research misconduct

2:15-2:30 PM ET

Break

ICON KEY

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Workshop: Keeping Data Private, Secure, and Confidential: New International Privacy Regulations and Their Impact on Research



The European Union has grabbed headlines and attention with the General Data Protection Regulation (GDPR); however, around the globe, numerous countries from China to Thailand to Nepal have quietly been updating their privacy laws with huge implications for multi-national research. In this session, speakers will take a global tour of new regulations and their impact on research. Although many are similar to GDPR, some go much further with in-country registration requirements, and research administrators who oversee international research need to be prepared.

Learning Objectives:

- Understand the changing global privacy regulatory framework and its impact on research
- Identify which privacy regulations may apply to your research
- Learn key takeaways to prepare for compliance

Afternoon Networking Sessions (*see agenda for times*)

2:30-3:30 PM ET

The Certified IRB Professional (CIP®) Credential Presentation



During this session, a member of the CIP Council and a CIP who recently earned their credential will discuss the CIP exam, eligibility guidelines, and exam preparation techniques. This session is geared toward individuals who are responsible for HRPP/IRB administrative functions and who will be eligible to take the certification exam in the next one to two years.

Learning Objectives:

- Discuss the CIP program and its value
- Review exam eligibility guidelines
- Walk through the exam content outline
- Discuss exam delivery options
- Go over exam preparation techniques and what to expect on exam day

2:30-3:30 PM ET

Team Consent Village



This interactive session will allow attendees to re-examine the ethical principles guiding consent and how those principles are addressed in current practice. Attendees will have the opportunity to showcase consent systems and resources in a collaborative environment with the aim of improving creative consent processes grounded in ethics and regulation. *These sessions will be hosted in Zoom and attendees are encouraged use the video and audio features to actively participate in the dialogue.*

2:30-3:30 PM ET

Virtual Roundtable: Racial Justice Working Group—Diversity, Equity, and Inclusion in your Research Compliance Program



AER20's Virtual Roundtables will enable participants to network, learn, and benefit from the shared knowledge and experience of the group through a moderated dialogue around a specific topic. The Racial Justice Working Group will meet each conference week (December 1, 8, and 15); participants will have an opportunity to discuss and address topics from Week 1's panel, "Panel: Clarifying the Myths and Challenging Bias About Race in Research Review." The group's work will be documented and shared with the wider community. Week 3's discussion will center around ensuring diversity, equity, and inclusion in your research compliance program. Research compliance programs comprise individuals committed to the common goal of ensuring and promoting the ethical conduct of research. Diversity of perspectives, backgrounds, experiences, and social identities can strengthen a committee's overall ability to carry out its mission. How can research compliance staff and members foster and promote diverse representation on their committees, and utilize that diversity to enhance the oversight of research? Moreover, how can diverse committees work together effectively? *These sessions will be hosted in Zoom and attendees are encouraged use the video and audio features to actively participate in the dialogue.*

2:30-3:30 PM ET

Virtual Roundtable: IRB Administrators Group—Remote Training and Networking

AER20's Virtual Roundtables will enable participants to network, learn, and benefit from the shared knowledge and experience of the group through a moderated dialogue around a specific topic. The IRB Administrators Group will meet each conference week (December 2, 9, and 15); participants will have an opportunity to discuss timely topics of importance to IRB Administrators. Week 3's group will focus on IRB administrator training in a remote environment, and how to create/sustain a professional network in a remote capacity that can continue to provide education/knowledge necessary for professional development and career growth. *These sessions will be hosted in Zoom and attendees are encouraged use the video and audio features to actively participate in the dialogue.*

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2:30-5:00 PM ET

Federal Agency/Accrediting Body Office hours

During this time, representatives from select federal agencies will be available to answer attendee questions, engage in dialogue, provide clarification, and/or direct attendees to additional resources in real time. Agencies participating during this time include: FDA, OHRP, AAHRPP, Inc., DOE, VA (please keep checking the agenda for information on which agencies will be participating during this time).



2:30-5:00 PM

Visit the PRIM&R Booth

Learn more about PRIM&R's programs and services, ask questions, and talk one-on-one with PRIM&R staff! A member of the Membership team will also be available to answer in-depth questions about PRIM&R membership. To visit the PRIM&R Booth, go to the Virtual Exhibit Hall, find the PRIM&R page you're interested in, and click on Video Chat.



2:30-5:00 PM

CIP Office Hours

Whether you are considering certification, or are a current CIP who has questions about recertification, use video chat to speak one-on-one with a CIP Council member. To talk with our Council members using video chat, visit the CIP Booth in the Virtual Exhibit Hall during this time, navigate to the video chat tab, and click "join video chat" with the Council members available. We look forward to speaking with you during this time!



2:30-3:00 PM ET

PRIM&R's Ethical Research Oversight Course (EROC) Demonstration

Scott Rule, PRIM&R

PRIM&R's EROC is the most comprehensive and convenient way for new HRPP/IRB members and staff to learn the fundamental ethical principles and key regulatory frameworks that govern their day-to-day work. This self-paced, interactive course was revised in 2019 - with a new platform and a more engaging audio-visual format, and it includes the most up-to-date information about best practices for HRPPs and applying the regulations. Unique features of EROC include observing an IRB in action as they review both biomedical and SBER research, interactive exercises and knowledge checks throughout the course, and best practice for fostering effective meeting dynamics. Visit primr.org to see a demo of EROC in action and learn about our options for individual and institutional subscriptions. ***This session is pre-recorded.***



2:30-3:00 PM ET

PRIM&R Membership Presentation

This presentation will provide an overview of PRIM&R's membership community and the benefits and opportunities membership provides. ***This session is pre-recorded.***



4:00-5:00 PM ET

Scientific Poster Panel: Outstanding Work

Join this year's outstanding poster award winners for a discussion on their scientific-based work. During this session, poster authors will present on their work and take questions from the audience.

Posters to be included are:

- *Key Findings and Utilization of Results from a Systematic Participant Experience Survey, Jessica Blackburn, Emory University*
- *Research Recruitment Through the Patient Portal: Acceptability and Preferences of Healthcare Users, Kathryn M. Porter, Seattle Children's Research Institute*
- *Comparing Payments between Sociobehavioral and Biomedical Studies in a Large Research University in Southern California, Brandon Brown, University of California, Riverside*



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10:00 AM-5:00 PM ET

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10:00 AM-5:00 PM ET

Visit the Virtual Poster Gallery

View the virtual poster gallery and learn more about the important programmatic and scientific work being done by your peers in the field. Posters include the actual poster abstract and a 10-minute pre-recorded talk from the abstract authors. Attendees can also submit questions directly to poster authors.



10:00-11:15 AM ET

Panel: The Ethics and Methods of Conducting Digital Phenotyping Research

This panel will provide a detailed overview of passive data collection and digital phenotyping, and how these methods can be used in settings ranging from clinic based-research to large scale, national research. Speakers will look at the ways in which researchers utilize data and data sets to track behavioral health and location surveillance to study patterns of social movement and disease state. Digital phenotyping raises serious concerns around individual and communal privacy versus the public good, and risk versus benefits. This panel will explore the balance between individual privacy and the need for surveillance for the public good.



11:15-11:30 AM ET

Break

11:30-12:45 PM ET

Panel: Challenges in Decision Making in Global Adolescent Clinical Research

In the United States, adolescent children's participation in clinical research typically requires both the permission of one or both parents and affirmative agreement of the teen. However, in multi-regional research involving adolescents, investigators and IRBs/research ethics committees must navigate the norms and laws of each country in designing recruitment strategies for research. When clinical research crosses borders, who are the decision-makers for the child? Does the child have a voice? Is the legal, regulatory, and cultural landscape different in this respect and if so, how does it impact multi-regional adolescent research? Although some countries have well-established regulatory frameworks for research involving adolescent populations, many do not. Even if there is a regulatory framework to address adolescent research, differences exist in who decides whether the child or adolescent is enrolled into the trial. This panel will explore the legal, regulatory, and ethical issues related to decision making in multi-regional clinical research. From a global perspective, the panel will discuss how geographic and cultural differences impact the relationship between parent and child and further, will explore the extent to which the country's policies or guidance may constrain decision-making. Using their experience doing research with adolescents in global settings as examples, panelists will address who is the decision maker in global clinical research with adolescent populations? Does the child have a role in decision making? Is child dissent respected? In addition, panelists will discuss how they worked with IRB on the consent process. Knowledge learned may also apply to the conduct of domestic trials that require working across cultural norms.



12:45-1:15 PM ET

Mid-Day Break

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W3B1: Not Your Grandfather's Electronic Informed Consent (eConsent): An Interactive Tool to Enhance Informed Consent *(Flexibility and Innovation in IRB Processes Track)*



Not all eConsent implementations are the same. Some eConsents simply render the informed consent form in electronic format. Although this approach has its benefits, it does not fundamentally change the participant experience. Some eConsents integrate participant-centered design, multimedia components, interactive elements, and decision aids to improve understanding of study objectives and facilitate participant engagement. Informed consent of participants with memory or cognitive deficits poses unique ethical and operational challenges. This session will present an eConsent developed to replace a traditional IRB-approved paper consent for two longitudinal Alzheimer's Disease (AD) studies at Emory University and the University of Wisconsin Alzheimer's Disease Research Centers. The presenters will discuss the steps to design a participants-centered eConsent, the regulatory issues this eConsent approach raised (and how they were resolved), and how study coordinators and participants viewed the eConsent approach compared to the paper consent document.

Learning Objectives:

- Review a participant-centered approach to presenting study information for AD research
- Share the relative advantages and disadvantages of eConsent from the perspective of study participants and study coordinators
- Identify regulatory challenges and solutions that an interactive eConsent approach can present

W3B2: A Conversation With All of Us: Considerations for a Diverse Cohort at a National Scale *(Hot Topics Track)*



This session will provide an in-depth exploration of goals, progress, and challenges faced by the All of Us Research Program (AoURP), a large federal longitudinal cohort program designed to be ethically robust and inclusive of the national population. The AoURP aims to include in particular, historically under-represented groups and communities, and to have the large and heterogeneous database be open and accessible to a wide array of researchers and data users. This session will examine, through the lenses of program/consortium partners, NIH staff, and IRB members, topics such as: All of Us strategies for facilitating trusting relationships with diverse participant populations; ensuring appropriate communication of population-specific risks/benefits, implications, and limitations in consent and other materials; and approaching bidirectional data sharing in responsible, culturally competent ways.

Learning Objectives:

- Review the considerations All of Us uses with regards to meaningful inclusion of diverse participant populations across multiple axes of diversity, including challenges encountered and solutions leveraged
- Explore the All of Us research oversight process, including challenges and opportunities of using a single IRB model and crucial considerations when approaching and respectfully including significant and population diverse
- Discuss the All of Us informed consent process and bidirectional data-sharing practices, including the development and deployment of electronic informed consent and modular consent to meet the challenges of obtaining quality informed consent

W3B3: IRB Chairs Forum: A structured Discussion for IRB Chairs *(IRB Chairs Track)*



Given it can be difficult to find venues where IRB chairs can convene to discuss and wrestle with tough questions, this session will provide IRB chairs a forum to share ideas and best practices. Attendees will be surveyed on topics of interest to them, and speakers will provide a summary of each issue during the session. Any off-topic issues that arise during the discussion will be placed in a "parking lot" for later discussion, if time permits.

Learning Objectives:

- Review and discuss contemporary issues related to human subject's protections that are commonly faced by IRB chairs, and that may not have clear guidance in the federal regulations
- Share best practices, policies and procedures, forms, and methods that aid in resolving difficult issues presented by investigators and research study staff
- Discuss real-world situations and problems attendees face with a focus on coming up with a few possible and concrete solutions

W3B4: Advanced Considerations for Serving as a Reviewing IRB *(IRB Operations Advanced Track)*



Is your organization contemplating whether to act as a single IRB (sIRB) for multi-site research? Do you work for a smaller organizations that has now been asked to serve in this role because of the Revised Common Rule? This session will candidly discuss the challenges in assuming this new role and offer practical solutions from organizations serving in this capacity. Topics to be covered include consent form development, handling conflicts of interest, methods of communicating with relying institutions and study teams (including obtaining local context information) during initial reliance arrangements and review, and addressing post-initial review requirements (e.g., amendments and continuing review). This session will also provide guidance as to how reviewing IRBs can effectively review and respond to reported unanticipated problems and incidents of noncompliance at relying sites. This session is designed to share experiences and offer practical tools for organizations embracing this new challenge. Before attending this session, attendees should be knowledgeable about sIRB requirements. Attendees will have the opportunity to ask specific questions relevant to serving as a sIRB.

Learning Objectives:

- Share lessons learned from early implementation of sIRB review
- Engage the audience in a discussion of the challenges and solutions for operationalizing sIRB review from the perspective of the reviewing IRB
- Provide practical tools to facilitate serving as the IRB of Record for multi-site research

Memo sent

ICON KEY

Livestreamed session	Pre-Recorded session	Pre-registration required
Breakout sessions new for 2020	Call for Session Proposal	CIP eligible
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.		Basic - for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.

W3B5: Making Metrics Meaningful: How HRPPs Can Efficiently and Effectively Use Their Data

(IRB Operations Advanced Track)



HRPPs generate an abundance of performance data that is essential for growth and improvement. However, these metrics must be grounded in insight to be actionable. In an environment where metrics and big data rule, how can HRPPs make sense of their data to meet both programmatic and institutional goals and objectives? How can HRPPs use both quantitative and qualitative data to demonstrate their needs and priorities? How can HRPPs create meaning from their data using human insight rather than just relying on numbers and figures? This session will focus on how HRPPs use operational metrics and identify the iterative phases used to develop such metrics. This session will also consider the breadth of data that could be used by a highly efficient HRPP, identify characteristics of the most useful metrics, demonstrate practical approaches to presenting and visualizing data, and how data can be used to enhance HRPPs.

Learning Objectives:

- Identify meaningful metrics to assess HRPP performance
- Discuss how to build a metrics framework for HRPPs based on priorities and goals
- Consider how to combine both quantitative and qualitative data into metrics programs to demonstrate real-world utility
- Review how to engage constituents when disseminating metrics and provide focus for future implementation
- Share how to create strategies for using data so it can be most effective for a program's own operational needs

W3B6: Effectively Managing Teams and Meetings in a Remote Environment *(Leadership Track)*



With COVID-19 rendering most offices remote, most HRPP/IRB office operations and meetings are taking place online. How can offices effectively utilize online tools to keep operations moving? How do you remotely manage a team and run effective meetings? How will online work impact future considerations around office set-up, operations, etc.?

Learning objectives:

- Share approaches for running effective online meetings, and tools used to keep people engaged, allow for collaboration online, etc.
- Discuss how to remotely manage a team, and what's critical to make effective decisions
- Review future considerations for office set-up/operations (i.e., for a long time, offices hired only locally, but remote allows for a greater reach)
- Consider how to maintain and build rapport (i.e., trust and free-flowing conversation are key; how do we build that remotely?)

W3B7: Ethical Issues in Complex Trial Design *(Pharma/Biotech Perspectives Track)*



Complex clinical trial designs (such as 'adaptive' designs that modify key features of studies mid-stream, and 'platform' or 'umbrella' designs that test multiple therapies on multiple populations) promise greater efficiency, but carry distinctive ethical and practical concerns, and can be challenging for IRBs to review. This session would aim to give IRB members and human research professionals the tools needed to identify and distinguish different types of complex study designs, identify the distinctive ethical and regulatory challenges they raise, and effectively navigate those challenges.

Learning Objectives:

- Provide a clear taxonomy of clinical trial designs so that IRB members can effectively identify and distinguish complex designs, based on their key features
- Review the most important distinctive ethical and practical challenges these study designs raise for IRB review
- Share actionable recommendations for how IRBs can navigate these challenges in ways that satisfy regulatory and ethical obligations and effectively protect participants

W3B8: Advancing Ethical Research in Pregnancy: Subpart B, FDA Guidance, and the Example of HIV Research

(Populations Requiring Additional Protections Track)



Basic

Numerous barriers to the inclusion of pregnant women in biomedical research have resulted in profound and consequential evidence gaps. There is critical need for responsible research with pregnant women, both in general and in the HIV-space specifically. Pregnant women deserve an evidence base that allows for protection against risk and timely access to new medicine, yet a complex set of barriers, including regulatory, oversight, and confusion about the ethical principles that should frame approaches, has made it difficult to make adequate progress. IRB members, clinical trial investigators, industry personnel, regulators, etc., must be knowledgeable about the ethical and regulatory implications and expectations for such studies. This session will review the FDA draft guidance, Subpart B requirements, and the recommendations from Pregnancy and HIV/AIDS Seeking Equitable Study (PHASES) Working Group has developed concrete, engagement-driven ethics guidance. This session will engage participants in the PHASES Ethics Guidance, highlighting lessons for IRBs navigating these ethically complex waters.

Learning Objectives:

- Provide an overview of the Subpart B requirements
- Summarize the FDA draft guidance for Inclusion of Pregnant Women in Clinical Trials
- Articulate the ethical foundations for advancing HIV-related biomedical research with pregnant women
- Summarize the engagement-driven process utilized to develop the PHASES guidance
- Describe and discuss actionable approaches IRBs can implement to advance ethical research with pregnant women

Sent memo

ICON KEY

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W3B9: Research Using Artificial Intelligence (AI): Regulatory and Privacy Implications and Protections

(Research Conducted in the Digital World Track)



This session will employ a case scenario teaching method to introduce the participants to the privacy concerns related to use of machine learning techniques in healthcare research. Session presenters will guide the audience through evaluation of case scenarios in which they must make decisions founded in concerns about privacy as an ethical objective. They will elicit feedback from the audience on their current problems and practices around privacy and machine learning in their settings.

Learning Objectives:

- Give a lay overview of Artificial Intelligence concepts and terms
- Describe privacy implications for use of machine learning in health research
- Evaluate privacy implications when machine learning is used in healthcare research
- Apply privacy concepts to evaluation of healthcare research using machine learning products or processes

W3B10: Operationalizing Data Sharing Policies: Challenges and Solutions

(Research Involving Data and Biospecimens Track)



The NIH Genomic Data Sharing Policy became effective in January 2015, and the policy applies to all NIH-funded research that generates large-scale human or non-human genomic data, as well as the use of these data for subsequent research. Since then, data sharing has expanded to the point where many journals will not accept manuscripts, even those not involving genomic data unless it can be shown that the data is being shared within some national data base. Compliance with these policies requires engagement of both the organization receiving federal funds and the IRB to complete the required institutional certification and provide assurances that the requirements of the policy have been met. This process is not without challenge and involves complex considerations (e.g., assessment of the adequacy of consent to permit sharing; potential limitations on data sharing that should be indicated by the organization; certifications when multiple institutions are contributing; protecting privacy and confidentiality; etc.).

Learning Objectives:

- Provide an overview of the various Data Sharing Policies
- Consider the ethical and regulatory implications of data sharing
- Discuss the various options and locations on which to share research data
- Review the requirements IRBs need to consider in creating plans to maintain confidentiality as part of the IRB review process
- Identify potential challenges for organizations and IRBs in complying with the policy
- Share examples to discuss operational solutions and review processes to facilitate compliance

W3B11: Complex Conflict of Interest (COI): Understanding the COI Landscape

(Legal Considerations in HRPPs Track)



Advanced

The research community's understanding of COIs and commitment has evolved over time, causing us to re-examine traditional institutional and researcher ties while scrutinizing a new wave of partnerships that bring added complexity to our understanding and mitigation of COI. At the same time, federal scrutiny of foreign influence and conflicts has left many of us unsure what to look for and, having found potential conflict, how to report and mitigate. The purpose of this session is to help the research community understand conflicts so we can be better stewards of the public trust in research. Attendees should have broad experience working in or advising on conflicts of interest, technology transfer, partnerships and licensing, and novel arrangements to promote research and commercialization. Additionally, attendees need working knowledge of the underlying regulatory, legal, policy and ethical conditions for addressing conflicts of interest. ***This session is pre-recorded.***

Learning Objectives:

- Discuss the shifting understanding, oversight, and enforcement efforts for complex COIs
- Identify how complex COI, including cases of foreign influence, academic/industry partnerships, and institutional conflicts might affect human subjects research protections
- Discuss best practices for identifying and managing COI and foreign influence in research
- Consider measures institutions can take to ensure compliance with COI management plans

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W3B12: Planned Emergency Research (*Hot Topics Track*)

Planned emergency research (subject to the 21 CFR 50.24 regulations) permits greater than minimal risk research to go forward without informed consent with the additional requirements of community consultation and public disclosure. This type of research is challenging for IRBs to review under any circumstance. Now, in the era of single IRB (sIRB), add in the complexity of serving as the designated sIRB reviewing 50.24 research for other institutions in dispersed geographic locations with uniquely different communities. Should there be special training requirements for IRBs that review planned emergency research? How does the IRB of record ensure plans for community consultation and public disclosure are adequate? After a plan is approved, how does the IRB ensure that the plan is properly executed, and the results are acceptable? And, how does the relying institution ensure that its local context is considered as part of the community consultation? In this session, speakers will explore the basics of conducting a 50.24 review from the perspectives of the reviewing IRB and the relying institution, presenting different views on how best to prepare for conducting planned emergency research in the era of sIRB.

This session is pre-recorded.

Learning Objectives:

- Identify the regulatory requirements for planned emergency research
- Learn about the challenges faced by the IRB in reviewing this unique type of research, including overseeing planned emergency research as the designated sIRB
- Outline practical tips for institutions to implement in preparation to conduct or review planned emergency research

2:15-2:30 PM ET

Break

Workshop, 2:30-5:30 PM ET

Workshops are an additional fee.



Workshop: Exploring Hot Topics in SBER

This workshop will examine issues of concern to IRBs that review SBER protocols. Intermediate and general level presentations will include case discussion, and will focus on the practical (and realistic) application of ethical and regulatory concepts and principles. Speakers will explore the topics of students as participants in research, including Family Educational Rights and Privacy Act; issues surrounding privacy, confidentiality, and anonymity; and data-sharing in SBER. There will be ample opportunity for discussion and sharing of best practices.

Learning Objectives:

- Understand and describe basic concepts of the topics presented and their regulatory or legal basis
- Identify how the concepts apply in research studies that IRBs review
- Evaluate best practices for minimizing risk to participants in SBER related to these concepts

Afternoon Networking Sessions (*see agenda for times*)

2:30-3:30 PM ET

PRIM&R's Guide to Speaking at the AER Conference



Are you interested in speaking at PRIM&R's conferences? Have you spoken at PRIM&R's events before, but are interested in learning more about how to facilitate engaging sessions? Join us for this session where new and experienced PRIM&R presenters will provide tips and insight on how to become a speaker, submit potential conference content, and facilitate session content in a way that promotes understanding, retention, and interaction. ***These sessions will be hosted in Zoom and attendees are encouraged use the video and audio features to actively participate in the dialogue.***

Learning Objectives:

- Review how PRIM&R's planning committees develop content, including how they review submissions from PRIM&R's Call for Session Proposals program and select speakers
- Provide insight on how to develop session proposals for the conference agenda
- Share strategies for presenting at PRIM&R's conferences (i.e., types of session facilitation; what attendees want out of sessions; how to use PPTs and interactive activities; etc.)
- Discuss what's involved in speaking at a PRIM&R conference (e.g., speaker responsibilities, working with presenters, on-site facilitation of sessions, etc.)

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2:30-3:30 PM ET

Virtual Roundtable: COVID-19's Impact on the Field—Prioritization of Research of Studies During the COVID-19 Pandemic



AER20's Virtual Roundtables will enable participants to network, learn, and benefit from the shared knowledge and experience of the group through a moderated dialogue around a specific topic. AER20 will feature two discussion groups on COVID-19 related issues (December 1 and 16). During Week 3's group, attendees will discuss prioritization of COVID-19-related versus non-COVID-19- related research, examining factors such as assessing risk/benefit ratio; recruitment/enrollment of participants (e.g., what precautions are put in place to keep people safe; use of testing; technology disparities if studies are online, etc.); and ensuring quality when research dynamics are changing. ***These sessions will be hosted in Zoom and attendees are encouraged use the video and audio features to actively participate in the dialogue.***

2:30-3:30 PM ET

Virtual Roundtable: What's New in QA/QI—Approaches to Novel Research Situations



AER20's Virtual Roundtables will enable participants to network, learn, and benefit from the shared knowledge and experience of the group through a moderated dialogue around a specific topic. Research during the time of COVID-19 and single IRB review require QA/QI programs to be flexible and creative. Also, QA/QI programs are often asked to do more with their limited resources. This group will provide QA/QI professionals an opportunity to share their experiences and solutions, learn new tools and tricks to face the changing research landscape, and ask questions of each other on challenging issues. ***These sessions will be hosted in Zoom and it's encouraged that attendees use the video and audio features to actively participate in the dialogue.***

2:30-5:00 PM ET

Federal Agency/Accrediting Body Office hours



During this time, representatives from select federal agencies will be available to answer attendee questions, engage in dialogue, provide clarification, and/or direct attendees to additional resources in real time. Agencies participating during this time include: AAHRPP, Inc., SACHRP, VA (please keep checking the agenda for information on which agencies will be participating during this time).

2:30-5:00 PM

Visit the PRIM&R Booth



Learn more about PRIM&R's programs and services, ask questions, and talk one-on-one with PRIM&R staff! A member of the Membership team will also be available to answer in-depth questions about PRIM&R membership. To visit the PRIM&R Booth, go to the Virtual Exhibit Hall, find the PRIM&R page you're interested in, and click on Video Chat.

2:30-5:00 PM

CIP Office Hours



Whether you are considering certification, or are a current CIP who has questions about recertification, use video chat to speak one-on-one with a CIP Council member. To talk with our Council members using video chat, visit the CIP Booth in the Virtual Exhibit Hall during this time, navigate to the video chat tab, and click "join video chat" with the Council members available. We look forward to speaking with you during this time!

4:00-5:00 PM ET

Programmatic Poster Panel: Outstanding Work



Join this year's outstanding poster award winners for a discussion on their programmatic-based work. During this session, poster authors will present on their work and take questions from the audience.

Posters to be included are:

- *Harnessing the Power of the Participant Perspective Through Research Participant Advisory Groups, Julie Wijesooriya, Cincinnati Children's Hospital/University of Cincinnati - CCTST*
- *Successes and Pitfalls Centralizing an Electronic Consent Platform in an NIH Funded Multi-Site Clinical Trials Network, Deneil Harney, University of Michigan*
- *Key Findings and Utilization of Results from a Systematic Participant Experience Survey, Courtney Jarboe, University of Minnesota*

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