

A **PRIM^{ER}** Virtual Event

2021 Social, Behavioral, and Educational Research Conference

November 16

2021 Advancing Ethical Research Conference

November 16-19

AER21 Preconference Workshops: Tuesday, November 16

Morning Workshops, 10:00 AM-1:00 PM ET

Introduction to the IRB: Ethics and Regulation

Ada Sue Selwitz, University of Kentucky; David Strauss, Columbia University

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 build a foundation in the effective review of human subjects research. ***This workshop will take place in Zoom meeting. The use of attendee video is encouraged for participation and interaction with your peers.***

Learning Objectives:

- Outline the federal regulatory framework governing IRBs
- Describe basic requirements for IRB review of human subjects research
- Illustrate the ethical framework that undergirds human subjects protections

Target Audience: IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member



IRB Chairs Boot Camp

R. Peter Iafrate, University of Florida; Barbara Engel, Children's Hospital of Philadelphia

This workshop will provide current and future IRB chairs an opportunity to gain new insight, exchange ideas, share best practices, and discuss strategies for becoming a successful IRB chair. The course will include an assessment of one's leadership and management styles, as well as a case-based review of lessons learned beyond knowledge of the regulations. Attendees will learn about the skills, additional education, and resources that can help IRB chairs excel in their role as chair while managing an efficient and effective IRB. This will be a highly interactive workshop that will seek to integrate speaker and participant experiences and concerns. ***This workshop will take place in Zoom meeting. The use of attendee video is encouraged for participation and interaction with your peers.***

Learning Objectives:

- Discuss the fundamentals of meeting management and member interactions from a leadership perspective to be successful
- Explore how to increase engagement of members and interaction with staff/consultants
- Provide tips, strategies, and approaches when becoming an IRB chair and/or building on current skills and training to ensure you are prepared for each meeting or issue that occurs

Target Audience: IRB Members, Chairs, and Vice Chairs



Never Let a Crisis Go to Waste: Lessons Learned from the COVID-19 Pandemic for Clinical Research

Walter Straus, Moderna; Ann Johnson, University of Utah; Kevin Bugin, FDA

The COVID-19 pandemic has had wide-ranging effects on the research community, both in the rapid vaccine development and clinical trials, and the challenges of conducting non-COVID research under pandemic conditions. This session will bring together speakers from the pharmaceutical industry, academia, and the FDA to reflect on how the changes from this unprecedented year can lead to better clinical research even when the pandemic is behind us.

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Educators; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member



ICON LEGEND

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| Livestreamed Session | On-Demand Session | Pre-Registration Required | Additional Fee |
| New Breakout Sessions in 2021 | 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 to actively contribute to discussion and solutions. 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. | |



Crossing Borders: HRPPs and Protection of Subjects in Transnational Research

John Baumann, Indiana University; Nichelle Cobb, AAHRPP; Mariette Marsh, University of Arizona

While there are challenges to human subjects oversight of intranational research collaborations, they pale in comparison to those faced when participating in international research collaborations including, but not limited to, those arising from different cultural, regulatory, and institutional contexts. This session will consider the principles of international collaborations regardless of where researchers are based, as well as explore the various challenges HRPPs face when conducting collaborative international research, such as: What regulations to consider and how to approach unregulated international research; what expertise is needed for the review and conduct of the research; types of approvals that may be required related to the collaboration; factors that may affect risks assessment; ongoing oversight of research, including communication plans researchers should use if change their study. Using case studies, speakers will discuss how they would address a variety of issues that may arise regarding protections of human subjects in international research. **This workshop will take place in Zoom meeting. The use of attendee video is encouraged for participation and interaction with your peers.**

Learning Objectives:

- Identify the various challenges in human subjects protections in international research collaborations
- Discuss various approaches for the elimination or mitigation of challenges to human subjects oversight of international research collaborations
- Examine policy and process best practices for IRB/ethics committees in the review of international human subjects research

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member



Institutional Official Discussion: Emerging Oversight Challenges and Necessary Process Enhancements

Robert Nobles, Emory University; Jane Strasser, University of Cincinnati

The role of the Institutional Official is complex and has broad responsibility for compliance with the federal regulations for the protection of human subjects, through ensuring the institution has a robust integrated infrastructure with sufficient resources. In this dynamic session, speakers will put a broad set of issues on the table for discussion, including: cultivating an integrated HRPP with your other compliance programs (e.g., COI, COC, Export Control, Sponsored Programs, etc.); single IRB facilitation; supporting virtual IRB and workforce; promoting external evaluations (peer review) of your program; supporting internal quality assurance; assessing the value and risk of investigator initiated studies; leadership cultivation within the office and on the IRB; promoting diversity, equity, and inclusion within the office and on the IRB; and exploring recent noncompliance/issues of HRPP programs. This session is intended to be dynamic and rapid paced, in order to cover topics that Institutional Officials are currently faced with or should be anticipating. **This workshop will take place in Zoom meeting. The use of attendee video is encouraged for participation and interaction with your peers.**

Learning Objectives:

- Explore how to cultivate and support the HRPP in a changing environment
- Assess the intersections of the various components of the HRPP, while gaining an appreciation for internal and external assessments
- Reflect on recent issues of noncompliance and challenges of new and established HRPP

Target Audience: HRPP Leadership and Institutional Officials



Intersectionality in Research Oversight: A Theoretical and Practical Framework Exploring Inequality

Cecilia Brooke Chalka, University of Nevada, Reno; Tonya Ferraro, Boston Children's Hospital; ORA Social Justice Working Group from University; Jessica Blackburn, Jumione Tiako, Maria Davila

While diversity, equity, and inclusion efforts are growing more common throughout research, ethics, and regulatory communities, these concerns are too often relegated to a "check-the-box" approach. In the last year, the Black Lives Matter movement and COVID-19's effects on communities have highlighted systemic inequalities and provided an opportunity to pursue meaningful social change. Inequalities are complex and multi-dimensional, requiring examination of the aspects and experiences that inform them. This workshop will explore "intersectionality," a key theoretical framework for understanding how overlapping social identities, such as class, race, ethnicity, indigeneity, sexual orientation, age, religion, and disability, can create disadvantages, exclusion, and marginalization. How can we best invest in intersectional approaches, bring awareness to experiences of marginality, and improve representation? A variety of speakers will present "modules" through a multi-layered approach. **This workshop will take place in Zoom meeting. The use of attendee video is encouraged for participation and interaction with your peers.**

Learning Objectives:

- Understand the meaning and significance of intersectionality
- Discuss ways to apply this concept both internally within the HRPP and externally through community outreach



Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Leadership and

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Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs;
Non-Scientist/Unaffiliated IRB Member; SBER Professionals; Diversity, Equity, and Inclusion

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AER21 Day 1: Wednesday, November 17

10:00-11:30 AM ET

AER21 Opening General Session: Welcome Remarks from PRIM&R's Board Chair and Executive Director, and Plenary Session: Advancing Justice and Equity in Research—How Can Research Stakeholders Be Agents of Change?

Board Chair: Suzanne Rivera, Macalster University

ED Remarks: Elisa Hurley, PRIM&R



Moderator: Leslie Wolf, JD, MPH, Georgia State University

Panelists:

- *Linda Coleman, Yale University*
- *Rodney Lyn, Georgia State University*
- *Julie Slayton, University of Southern California*
- *Luther Clark, Merck & Co*

Justice has been a foundational principle of research ethics since the publication of the Belmont Report in 1979. But, what does justice in research mean and look like today as we, as a society, confront structural injustice in all its manifestations? How do we reckon with the ways in which the research enterprise inherits and reproduces such injustice? What would a research enterprise oriented toward eliminating systemic injustice and promoting equity look like? More specifically, how can stakeholders that are part of the biomedical and social behavioral research process be part of the solution to the issues we face regarding structural injustice? This Panel will briefly examine the history and evolution of the concept of justice in research, how we should think about justice in research now, and the relationship of justice to concepts such as diversity, inclusion, and equity in health and research, before turning to the question of where we go from here. Drawing on perspectives from researchers, funders, institutions, and HRPPs/IRBs, the session will identify the levers available to each of these groups to address injustice in research. Sessions in the Advancing Justice and Equity Track will provide additional opportunities to explore concrete ways that these various stakeholders can be agents of change.

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Educators; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; SBEP Professionals; Diversity, Equity, and Inclusion

11:30-11:45 AM ET

Break

Concurrent Panels, 11:45 AM-1:00 PM ET

Panel I: Inclusion of Persons With Disabilities in Clinical Research

Moderator: Barbara Bierer, Harvard Medical School

Panelists:








- *Benjamin Silverman, Partners HealthCare*
- *Heather Miller, PhD, Northcentral University*
- *Tinamarie Duff, Bristol Myers Squibb*

As a whole, the research community has not been attuned to the importance of inclusion of historically under-represented populations, including those with disabilities. The exclusion of persons with disabilities may not be based on scientific considerations; rather, the perceived inability to understand and/or participate in the clinical study activities. This plenary session will explore the ethical and legal foundations to include persons with disabilities and discuss similarities and differences related to inclusion of people with physical and/or cognitive disabilities. Panelists will describe measures to take an affirmative stance to the inclusion of people with disabilities and provide practical considerations to improve engagement and access of persons with disabilities in clinical research. A discussion around how IRBs can develop inclusive policies and processes for participants with disabilities will be presented.

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Educators; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; Diversity, Equity, and Inclusion



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Panel II: Weeding Out Useless Research: What's an IRB to Do?

Moderator: Alex John London, Carnegie Mellon University

Panelists:

- Luke Gelinas, Advarra
- Deborah Zarin, The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard
- Danielle Wenner, Carnegie Mellon University

There is ample evidence that many clinical research studies fail to yield scientific value. Such "uninformative" research is a source of waste and it raises important participant protections issues, given the risks of research are typically justified by an assumption that studies will yield scientific value. Despite the broader recognition that uninformative research studies can cause potential harms to participants and to the research enterprise, this issue remains largely unaddressed in practice by research stakeholders, including IRBs. As a result, uninformative trials continue to be initiated in large numbers. This panel will review the underlying ethical concerns, as well as provide data regarding the main causes of uninformative studies in both biomedical and social science research. Speakers will discuss potential practical approaches IRBs or other oversight bodies can take to ensure that any proposed trial is not unnecessarily redundant with, and is informed by, existing/past trials. A proposal of operational standards for assessing scientific value will be presented.

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Breakout Sessions Series A, 11:45 AM-12:45 PM ET
 (Note: These sessions run concurrently against the Panels.)
A1: Microaggressions, Unconscious Bias, and Systemic Racism: What Do These Terms Really Mean?**Track:** Advancing Justice and Equity

Dr. Kevin Harris, Virginia Commonwealth University

Often individuals new to advocacy and anti-racist work can become flustered by the terminology. This session will provide tools to begin the journey to understanding the terminology used in social and racial justice advocacy, and attendees will learn about integrating terminology that could also be added to IRB documents, submission forms, and templates.

Learning Objectives:

- Introduce advocacy language and provide resources
- Share examples of adding advocacy language to your reviews and documents
- Share examples of what to avoid and what might be a microaggression in reviews or IRB documentation

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Educators; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; SBER Professionals; Diversity, Equity, and Inclusion

**A2: Knock, Knock, FDA Is Here: What You Need to Know for Bioresearch Monitoring (BIMO) Inspections of IRBs, Clinical Investigators, and Sponsor Investigators****Track:** FDA Regulated Research

L'Oreal Walker, FDA; Jan Hewett, FDA

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 Office of Regulatory Affairs (ORA) and Center for Drug Evaluation and Research BIMO inspection process from initial notification through to post site visit, and how to respond to an FDA Form 483. In addition, speakers will review past and present inspection metrics highlighting common deficiencies identified during IRB and clinical investigator inspections and the inspection classification outcomes. Speakers will also discuss the relevant FDA compliance program and guidance documents stakeholders should be aware of for an FDA inspection.

Learning Objectives:

- Describe the role of the FDA ORA and Centers in an inspection
- Review FDA's FY20 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 (guidance, compliance program manuals, etc.) for inspections

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs

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AER21 Day 1: Wednesday, November 17

Breakout Sessions Series A, 11:45 AM-12:45 PM ET

(Note: These sessions run concurrently against the Panels.)



A3: Beyond Reliance Agreements: Local Considerations, Risk Mitigation, and Compliance

Tracks: Flexibility and Innovation in HRPP Processes; HRPP Leadership and Institutional Officials; IRB Operations
Advanced

Ivana Simic, University of Florida; Nichelle Cobb, AAHRPP

Collaborative research among different legal entities, such as when faculty from one legal entity hold a dual appointment and cross over to another legal entity to engage in research there brings some challenges when it comes to streamlining IRB review and ensuring regulatory compliance. Issues stretch from permission to engage in research in another legal entity to data flows/HIPAA issues, sovereign immunity, local ancillary reviews and sign offs, consent forms, ceding review to an entity beyond affiliated institutions, and more. The session will explore the following concepts through the use of lecture and case studies.

Learning Objectives:

- Identify regulatory requirements for research involving personnel from one institution who perform research activities at another legal entity where they are also credentialed
- Discuss the content and format of agreements used to cover research activities and streamline regulatory oversight
- Use case studies to explore issues that arise in collaborative research across affiliated institutions, such as when an affiliate does not have a local IRB office, chart review studies, ceding IRB review to an entity beyond the affiliated institutions, etc.

Target Audience: Compliance, Regulatory, and QA/QI Professionals, HRPP Educators, HRPP Leadership and Institutional Officials, IRB Administrators, Manager and Staff, IRB Members, Chairs, and Vice Chairs



A4: Finding the Right Balance: Appropriate Secondary Use of Clinical Trial Data

Track: Pharma/Biotech Perspectives

Karla Childers, Johnson & Johnson; Matt Rotelli, Eli Lilly & Co

Society has been hearing about the power and potential of health data for years. With improvements in computing power, cloud-based sharing, and increasing demands for large volumes of data to feed artificial intelligence and machine learning models, sponsors of clinical trials are seeing increased requests for broad, unlimited use of data from those trials. Using case studies, this session will describe examples of some of the proposed uses that can blur the line between what might be considered appropriate secondary use and what might run afoul of a participant's expectation based on their understanding of language in informed consent documents. These examples will highlight points to consider as HRP professionals reviewing protocols and participant-facing materials.

Learning Objectives:

- Understand the tension between maximizing the benefit from clinical trial data and an individual's right to direct how their health data are used in the future
- Identify important features of secondary or future uses of data that may help delineate appropriate vs. inappropriate uses
- Develop an understanding of how provisions included in protocols and informed consent forms influence future use of data collected in the course of research

Target Audience: Clinical Research Staff; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member



A5: QA/QI Solutions for a Changing Research Landscape

Track: QA/QI and Postapproval Monitoring

Sana Khoury-Shakour, University of Michigan (SF); Piper Hawkins-Green, Northwestern University

QA/QI programs can play an important role in the changing face of human subjects protections by identifying gaps and areas for improvement. However, QA/QI programs are often asked to do more with their limited resources and adapt their review methods and approaches to a changing research landscape and institutional priorities. This session will explore various QA/QI activities and review methods that could maximize the impact of your program, including utilization of self-assessment tools, examples of focused review areas, remote audit methods, and strategies to ensure that your workplan aligns with institutional priorities.

Learning Objectives:

- Review processes for utilizing self-assessment tools
- Describe innovative postapproval review approaches
- Identify strategies to maximize your resources, and discuss communication strategies to get input from and communicate outcome of QA/QI activities to leadership

Target Audience: Compliance, Regulatory, and QA/QI Professionals, HRPP Leadership and Institutional Officials, IRB Administrators, Manager and Staff

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1:00-1:45 PM ET

Mid-Day Break

1:00 PM – 1:45 PM ET

AER21 Mid-day Break Sponsored Presentation by WCG IRB: Critical Considerations for Informed Consent in Cell and Gene Therapy Trials

Daniel Kavanagh, WCG

Compared to other types of clinical research, the informed consent process in cell and gene therapy poses special challenges when it comes to ensuring that participants are fully informed about issues relating to investigational products and associated risks.

Learning Objectives:

- Learn about the history of NIH guidance for review of informed consent forms in human gene transfer research
- Review current best practices for IRBs and IBCs to work together on informed consent form review
- Outline major categories of risk associated with cell and gene therapy clinical research
- Share tips for clear communication regarding complex and novel gene transfer technologies



Breakout Sessions Series B, 1:45 PM-2:45 PM ET

B1: A Dialogue With OHRP

Track: A Dialogue with the Feds

Yvonne Lau, OHRP; Lisa Buchanan, OHRP; Natalie Klein, OHRP; Julie Kaneshiro, OHRP

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

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Educators; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; SBER Professionals

**B2: Justice in Human Research: Accessibility, Inclusivity, and Intersectionality**

Track: Advancing Justice and Equity

Ivy Tillman, Augusta University; Teal Benevides, Augusta University

This session will examine the Belmont Principle of Justice through the theoretical framework of intersectionality. Before attending this session, attendees should have an understanding of the Belmont Report principle of Justice and its application in research design and IRB review.

Learning Objectives:

- Identify areas of intersectionality of marginalized groups participating in human subjects research, including: disability, gender, race, and social class
- Discuss how the social location of privilege and oppression affect research design and IRB review
- Identify strategies for research design and IRB review to ensure the principle of justice is adequately addressed for marginalized populations

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Educators; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; SBER Professionals; Diversity, Equity, and Inclusion

**B3: How to Conduct Education About Emergency Preparedness**

Track: Education and Training

Megan Kasimatis Singleton, Johns Hopkins University; Martha Jones, Mass General Brigham;

Lauren Sauer, University of Nebraska Medical Center

Emergencies involve uncertainty, so it is challenging to teach emergency preparedness in advance, and education needs to quickly adapt to the emergency as it evolves. This session will focus on tools for people in HRPPs who conduct education, including increasing researcher awareness of the need for resilient protocol design and awareness of organizational leadership, IRB members, and staff on strategies for proportionate response to emergencies that maintain research where possible while preserving the safety and welfare of human research participants. The session will provide links to checklists and examples.

Learning Objectives:

- Review the impacts of different types of emergencies on research programs (e.g., extreme weather events, natural or human-caused disasters, or infectious disease outbreaks)
- Understand key features of an HRPP's plan for emergency preparedness and response for HRPPs

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- Share how to develop an educational strategy that addresses the needs of different audiences

Target Audience: HRPP Educators; IRB Administrators, Managers, and Staff; HRPP Leadership and Institutional Officials; IRB Members, Chairs, and Vice Chairs

AER21 Day 1: Wednesday, November 17

Breakout Sessions Series B, 1:45 PM-2:45 PM ET

B4: When Is an Investigational Device Exemption (IDE) Needed for Medical Device Clinical Investigations?



Track: FDA Regulated Research

Guided Rouabhi, FDA; Brittany Schuck, FDA

In general, the IDE regulations apply to clinical investigations of medical devices designed to determine safety and effectiveness. The IDE regulations at 21 CFR 812 describe three types of device studies: significant risk, nonsignificant risk, and exempt studies. So, which studies require the submission of an IDE application, and who determines which studies require an IDE? What is the applicability of the IDE regulations when the product is a companion diagnostic or when the clinical evidence is being generated in the real world?

Learning Objectives:

- Provide an overview of the applicability of the IDE regulations that address when an IDE is required for Medical devices
- Discuss how to apply the IDE regulations to studies involving investigational and marketed medical device products, particularly when data may be gathered in the real world
- Review considerations to assist sponsors and IRBs in understanding when an IDE might be needed for a clinical investigation of a companion diagnostic and considerations for real world clinical evidence generation

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member

B5: Research Silos—The Growing Problem of Restricting International Transfer of Data and Specimens



Tracks: Global Research; Research Involving Data and Biospecimens

David Peloquin, Multiregional Clinical Trials Center at Brigham and Women's Hospital and Harvard;

Rita Lawlor, ARC-NET: Centre for Applied Research on Cancer

Human subjects research is becoming increasingly international in scope. Studies often seek to recruit volunteers from multiple countries to meet recruitment targets. Biobanks may contain millions of specimens from multiple countries. Big data research is expanding, but in a growing number of countries, policies are restricting or even thwarting cross-national transfers of specimens and data.

Learning Objectives:

- Describe recent examples of international blockages of research data and specimens
- Cite specific laws that are impeding international transfers of data and specimens
- Explain strategies to resolve these barriers

Target Audience: Clinical Research Staff; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs

B6: Essential Documentation: IRB Record Keeping, Written Procedures, Minutes, and More



Track: IRB Basics

Ada Sue Selwitz, University of Kentucky; Janet Donnelly, FDA; Amanda Sly, OHRP

The federal regulations define the requirements for IRB recordkeeping, documenting IRB discussions and findings, and communicating IRB decisions. This session will provide a basic overview of regulatory requirements for documenting these essential IRB functions.

Learning Objectives:

- Outline the federal requirements for IRB records and documentation
- Provide an overview of the federal policies and requirements for the preparation and maintenance of IRB written procedures, and accurate, complete, and timely IRB meeting minutes
- Apply the knowledge gained through an interactive quiz with fellow attendees

Target Audience: IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member

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AER21 Day 1: Wednesday, November 17

Breakout Sessions Series B, 1:45 PM-2:45 PM ET

B7: How to Manage Your Non-IRB Gatekeeping Functions as an IRB

Track: IRB Operations Advanced

Susan Robb, Virginia Commonwealth University; Iris Jenkins, UMASS Amherst; Amanda C. Jointer, Wayne State University

Ever wonder why investigators complain about IRB over-reach? It could be due to the fact that the IRB is also the gatekeeper for other institutional compliance concerns. IRBs are often asked to put stop-gap procedures in place to catch and address other compliance, including Conflict of Interest, biosafety, data management and security, and marketing and branding, to name a few. On top of these add-ons, the IRB is already responsible for numerous Federal and state regulations. So, how do we keep up with it all?

Learning Objectives:

- Learn how to effectively manage the IRB review process to address other compliance areas related to IRB and the conduct of research
- Share tips and tools IRB offices can use to train staff and IRB members on these "added" responsibilities
- Provide strategies for when and how to push back when the expectations for IRB review become unreasonable and how to redirect the responsibility and ownership to more appropriate entities

Target Audience: HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff



B8: The Workplace Shift—New Realities, Future Uncertainty, and Meeting Staff Needs in a Post-Pandemic World

Tracks: Leadership; HRPP Leadership and Institutional Officials

Brenda Ruotolo, Columbia University; Nathalia Henry Whitely, Northwestern University

The COVID-19 pandemic created a whole new world of IRB professionals working remotely. For some, it is idyllic; for others, they yearn to be back in a traditional office environment. The shift occurred suddenly and there is no telling when it will reach a final state. Staff and management must be transparent and flexible if evolving staff needs are to be met and valuable staff will be retained.

Learning Objectives:

- Explore the changes that have occurred since the start of the pandemic and consider possible end states, as the first step in identifying new staff needs
- Share ways to keep staff engaged and positive while some or all may be working remotely for the short- or long-term, and how to elicit and address staff concerns about uncertain long-term work environments
- Consider best practices for managing the workplace changes and potential complications (e.g., staff who do not want to return to on-site work)

Target Audience: HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff



B9: Explaining Explainable Machine Learning (XML)—What Research Review Boards Need to Know

Track: Research Conducted in the Digital World

Sara Jordan, The Future of Privacy Forum; Rob van Eijk, The Future of Privacy Forum;

Rachele Hendricks-Sturup, Duke-Margolis Center for Health Policy

Sophisticated uses of machine learning can be a challenge for research review boards to evaluate. Savvy researchers know to use XML or explainable artificial intelligence (XAI) tools and terminology, but how do research reviewers know whether an XML or XAI tool accomplished the regulatory and ethical objectives of explanation, such as for risk-benefit assessment or informed consent forms?

Learning Objectives:

- Provide an overview of XML and XAI, and how these differ from Machine Intelligence and Artificial Intelligence
- Identify when XML tools should be included in research proposals
- Pair proposed machine learning methods with appropriate XML metrics and tools
- Respond to gaps in machine learning-based research proposals and request appropriate amendments

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; SBER Professionals



ICON LEGEND

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| Livestreamed Session | On-Demand Session | Pre-Registration Required | Additional Fee |
| New New Breakout Sessions in 2021 | 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 to actively contribute to discussion and solutions. 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. | |

**B10: Data Risks—Strategies for Maintaining Research Integrity via Conflict of Interest (COI) Review****Tracks:** Responsible Conduct of Research; Research Involving Data and Biospecimens*Christina Gasdia, Yale University; Eric Allen, University of South Florida*

Often research activities that involve data-only will be perceived as less "risky" or free from conflict of interest. However, when the COI or conflict of commitment is not obvious, it becomes even more challenging to manage the potential or perceived conflicts via committee review. The need for alternative approaches to promoting trust and integrity in the data is critical. Attendees will be provided with examples on managing COI in these types of scenarios and actions from promoting trust and integrity.

Learning Objectives:

- Identify the framework for reviewing COI within the context of data-only research
- Provide examples for alternative approaches to promoting trust and integrity in data-only research
- Review COI management plans in relevant scenarios

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Educators; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; SBER Professionals

**B11: How Do Ancillary Review Committees Strengthen Our HRPPs?****Tracks:** HRPP Leadership and Institutional Officials; IRB Operations Advanced*Linnea Anderson, University of Minnesota; Kim Summers, University of Texas Health San Antonio; Suzanne Stone, UC Berkeley*

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. This session 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 be contacted, and discuss/deliberate how institutions might respond
- Outline best practices for creating solid, practical, and achievable plans for HRPPs

Target Audience: HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff

**B12: How Do I Consent Thee? Let Me Count the Ways****Tracks:** IRB Chairs; Research Conducted in the Digital World*Kindra Cooper, Advarra; Joshua Fedewa, MS, CIP, UT Southwestern; Ivor Pritchard, OHRP*

The challenges of obtaining and documenting informed consent during a pandemic have forced researchers and regulators to embrace remote consent. While options for obtaining remote consent abound, there is no one-size-fits-all method guaranteed to comply with various research regulations. This session will review the options available to researchers for remote consent, including electronic consent (eConsent), telephone, fax/email, postal mail, etc., and the regulations IRBs must consider in review of these methods. In addition, attendees will have the opportunity to deepen their understanding by working through hypothetical remote consent scenarios highlighting assorted practical and regulatory challenges.

Learning Objectives:

- Identify and discuss options for obtaining informed consent remotely, as well as the differences between implementing a remote consent process and waiving documentation of consent
- Analyze the regulations applicable to informed consent and define the responsibilities of the IRB in review and approval of remote consent processes (including eConsent)
- Consider and discuss a set of hypothetical scenarios designed to help clarify which methods of remote consent would be most and least appropriate from an IRB/regulatory compliance perspective with minimal operational burden

Target Audience: IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member

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| New New Breakout Sessions in 2021 | Call for Session Proposal | CIP Eligible | |
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B13: Complex Conflict of Interest (COI)—Understanding the COI Landscape**Tracks:** Legal Considerations in HRPPs; Responsible Conduct of Research*Laura Evans, Johns Hopkins University; Stacy Pritt, UT Southwestern*

The research community's understanding of COI 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. This session will help the research community understand conflicts and methods of conflict management so we can be better stewards of the public trust in research. Before attending this session, attendees should have broad experience working in or advising on COI, technology transfer, partnerships and licensing, and novel arrangements to promote research and commercialization, and working knowledge of the regulatory, legal, policy, and ethical conditions for addressing COI.

Learning Objectives:

- Discuss the shifting understanding, oversight, and enforcement efforts for complex COI
- Identify how complex COI, including cases of foreign influence, academic/industry partnerships, and institutional conflicts might affect human subjects research protections
- Review best practices for identifying and managing COI and foreign influence in research
- Explore different management plans for different types of COI

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs

**B14: Research With Children—Parental Permission and Assent and Child-Centric Trial Education****Track:** Populations Requiring Additional Protections*Elisa Koppelman, The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard;**Meghan Wike, International Children's Advisory Network; Casey Mumaw, Indiana University;**Ran Goldman, MD, University of British Columbia*

This session will review the Subpart D requirements, and their historical and ethical basis. Presenters will discuss the particular complexities of assessing the consent process in research with youth and present strategies for thinking through the parental permission requirement and the challenge and protection offered by the option for waiver. Speakers will also discuss common IRB pitfalls related to youth assent and creating a meaningful assent process, and offer practical suggestions for implementing effective assent in research with children. This session is intended to provide a foundation for developing materials by and for youth that explain various aspects of clinical trial participation. Through sharing the processes involved in developing these materials, attendees will become familiar with an inclusive approach to material development. Before attending this session, attendees should be familiar with the criteria for the inclusion of children in research.

Learning Objectives:

- Describe the importance of creating and disseminating age/content/medium appropriate materials by and for children to support inclusive pediatric participation in clinical trials
- Identify better practices in the development and vetting of pediatric educational materials with established child and youth groups
- Learn to create educational materials that are widely available, accessible, acceptable, and useful for the intended pediatric audiences
- Explore complex and unique issues related to parental permission in research settings
- 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
- Become comfortable applying the criteria for waivers of parental consent scenarios for consideration and discussion

Target Audience: Clinical Research Staff; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs

**ICON LEGEND**

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AER21 Day 1: Wednesday, November 17

Breakout Sessions Series B, 1:45 PM-2:45 PM ET

B15: Operationalizing Research Databases and Biobanks at Your Institution



Track: Research Involving Data and Biospecimens

Peter Iafrate, University of Florida; Lauren Sauer, University of Nebraska Medical Center; Jaime Hernandez, OHRP

This session will explore the legal and practical challenges 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

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs

B16: A Dialogue With AAHRPP, Inc.



Track: A Dialogue with the Feds

Elyse I. Summers, AAHRPP; Michelle Feige, AAHRPP; Robert Hood, AAHRPP; Nichelle Cobb, AAHRPP; Kate Vulakovich, AAHRPP

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 session is designed to answer questions about accreditation for organizations considering AAHRPP accreditation and those that are already AAHRPP accredited. This session is pre-recorded.

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

2:45-3:00 PM ET

Break

3:00 PM – 3:30 PM ET

Sponsored Session by Cayuse: Best Practice Applications and Emerging Research Designs



Alicia Asgari, Cayuse; Michael Leary, Lindenwood University

Join this session to discuss how to design your Human Ethics smart forms to ensure researchers are guided towards easy to understand risk assessments, informed consent, and vulnerable population justifications. Speakers will also discuss emerging research designs and how to support obtaining IRB approval while still allowing research design and methods to expand and evolve as data collection begins. Will these new research designs be supported by IRB committees and how can we look at policy to guide us?

Afternoon Networking Opportunities, 3:00 PM-4:00 PM ET

3:00-3:30 PM ET: Membership Overview and Online Community Demo



Shana Sonbolian, PRIM&R

This pre-recorded presentation will provide an overview of PRIM&R's membership community and benefits, as well as a demonstration of the [PRIM&R Online Community](#), which hosts the IRB Forum and members-only IACUC Channel and SBER Network.

ICON LEGEND

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3:00-4:00 PM ET: Challenges and Opportunities for Institutions With Small Research Programs

Tracks: Networking; Small Research Programs

Delilah Ofosu-Barko, Trillium Health Partners; Elaine Radmer, PhD, Gonzaga University

Small research programs and single staff HRPP/IRB offices experience particular organizational, professional, and procedural challenges. This session will explore how to identify and capitalize on professional development opportunities and community. Attendees will discuss how to develop effective professional networks, both within and outside their organizations.

Target Audience: HRPP Educators; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff



AER21 Day 1: Wednesday, November 17

Afternoon Networking Opportunities, 3:00 PM-4:00 PM ET

3:00-4:00 PM ET: SBER Network Discussion: Postapproval Monitoring for SBER—Alternatives to Continuing Review for Minimal Risk Research

Tracks: Networking; SBER; QA/QI and Postapproval Monitoring

John Baumann, Indiana University; Erin Odor, Ohio State University; Sharon Zack, Westat;

Cecilia Brooke Chalka, University of Nevada, Reno (moderator), Linda Mayo, University of New Mexico

Join the [SBER Network](#) in discussing postapproval monitoring for SBER. The 2018 Common Rule sought to strengthen participant protections while reducing administrative burdens. One of the burden reducing provisions includes removal of the requirement of continuing review for minimal risk research (unless FDA-regulated). IRBs are responsible for oversight of active human research and historically, continuing reviews were a mechanism for monitoring research. This SBER Network session will offer diverse perspectives on these issues. What are institutions doing now to monitor active studies after initial IRB approval? Has the continuing review process changed (and how)? How are monitoring efforts working and what are the challenges? Has administrative burden been reduced and have monitoring efforts been more effective? ***This session will take place in Zoom meeting. The use of attendee video is encouraged for participation and interaction with your peers.***

Learning objectives:

- Review different forms of PAM and how they are working
- Discuss procedures for determining when studies undergoing continuing review or a PAM alternative
- Share experiences with educating PIs and research personnel about the changes to the new system

Note: The SBER Network is a member benefit; [learn more](#) about joining the Network!

Target Audience: Compliance, Regulatory, and QA/QI Professionals; IRB Administrators, Managers, and Staff; SBER Professionals



CIP

3:00-4:00 PM ET: Return of the IRB Jedi: Exploring Regulations, Guidance, and Institutional Policies

Tracks: Networking; IRB Basics

Tonya Ferraro, Boston Children's Hospital; Kim Serpico, Harvard T.H. Chan School of Public Health; Andrew Hedrick, Ohio State University; Paul Lees, OHRP Resource Person

The Revised Common Rule reigns. There is unrest in the research galaxy. Implemented in January 2019, the research community must navigate between pre-2018 and 2018 regulatory requirements. Previously approved studies are in flux. The exempt category realm has expanded. Single IRB controls collaborative studies and informed consent requires key information. With new frontiers, IRBs are challenged to examine their practices and extend their expertise across two sets of regulations. This session will examine the importance of understanding where regulations end, where guidance begins (i.e., OHRP, SACHP, etc.), the acknowledgement of institutional policies, and the challenges of this intersection. It will demonstrate application of the regulations and practical strategies for "it depends" scenarios. These strategies can serve as a foundation to adopt approaches taking in your institution's size, staff resources, and/or research community's portfolio. ***This session will take place in Zoom meeting. The use of attendee video is encouraged for participation and interaction with your peers.***

Learning Objectives:

- Differentiate regulations, guidance, and institutional policies
- Discuss opportunities and challenges of exploring guidance
- Share creative solutions while staying compliant and being consistent

Target Audience: IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member



New

Basic

3:00-4:00 PM ET: Scientific Poster Panel: Outstanding Work

Kathleen A. Seabolt, Children's National Hospital; Khadijah A. Holley, Northwell Health; Hannah Claire Sibold, Emory University Winship Cancer Institute








Moderator: Lindsay McNair, WIRB-Copernicus Group

Join this year's outstanding poster award winners for a discussion on their scientific-based work. Posters will be available to attendees via the Virtual Poster Gallery (starting on November 2). During this session, the following abstracts will be presented:

- Assessing HRPP Determination of Non-Compliance by Khadijah Holley, MBA, CIM, Northwell Health
- Obtaining Assent from Children for Research Participation: Perspectives from Pediatric Physicians in a University Setting by Kathy Seabolt, CIM, CIC, CIP, Children's National Hospital
- Improving First in Human and Window of Opportunity Informed Consent Forms Through Participant Feedback by Hannah Claire Sibold, BS, Emory University



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AER21 Day 1: Wednesday, November 17

Afternoon Networking Opportunities, 3:00 PM-4:00 PM ET

3:00-4:00 PM ET: Federal Agency Affiliate Session: Everything You Wanted to Know About the DoD-Wide HRPP, Including Classified Research

Stephanie Bruce, DoD

A discussion of how DoD conducts its HRPP, both internally, and externally, collaborating and supporting partners.



Note: This is an affiliate session being run outside of the PRIM&R AER Conference, but is accessible to all AER21 Attendees via the online platform (streaming link will take you to a third-party streaming service (e.g., Zoom, GTM, etc.). This session will only be run live; no on-demand recording will be made available by PRIM&R.








4:00-5:00 PM ET Sponsored Happy Hour by Advarra: Trivia and Networking



Tracks: Networking

This is not your typical networking event! Bring your preferred happy hour beverage and enjoy your favorite tunes with other industry professionals across the country for a "Through the Decades"-themed trivia game.

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AER21 Day 2: Thursday, November 18

10:00-11:15 AM ET

Conference Welcome; In Memoriam: Tribute to Robert J. Levine, MD, and Jeffrey Cohen, PhD; and

Keynote Address: Ethics of AI Research: Implementation and Implications

Tribute: David Borasky, WCG (Bob Levine); Elizabeth Buchanan, Marshfield Clinic (Jeff Cohen)

Keynote: Cansu Canca, PhD, Founder and Director, AI Ethics Lab

AER21 day two will begin with a tribute to Robert J. Levine, MD, and Jeffrey Cohen, PhD, who both passed in 2021, and then we'll present our keynote address, Ethics of AI Research: Implementation and Implications, by Cansu Canca, PhD



11:15-11:30 AM ET

Break

Concurrent Panels, 11:30 AM-12:45 PM ET

Panel III: Exception from Informed Consent (EFIC) for Research at 25

Moderator: Neal Dickert, Emory University School of Medicine

Panelists:

- *Adrianne Haggins, University of Michigan*
- *Michelle Biros, University of Minnesota*
- *Michael Linke, University of Cincinnati, College of Medicine*
- *Robert Silbergleit, University of Michigan*

The EFIC for Research in emergency settings was passed 25 years ago. In this time, significant experience has been accumulated, and important studies have been conducted. However, there remain challenges related to the ethical and regulatory aspects of this significant category of research. These challenges can be significant for investigators and for IRBs. There is lingering uncertainty about the most effective approaches to community consultation and public disclosure as heterogeneous practices and expectations have emerged. Important questions have arisen about the scope of EFIC regulations, specifically, about when consent is truly impracticable, what to do in situations where capacity is marginal or variable, and about how to approach studies evaluating standard of care interventions. Finally, questions have been raised regarding minority inclusion in and perspectives on EFIC research. This panel brings together experts to address these important issues, reflecting on the past 25 years of EFIC.

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Educators; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; SBIR Professionals; Diversity, Equity, and Inclusion



Panel IV: Data Advocacy, Governance, and Ethics in an Age of Big Data

Moderator: Brenda Curtis, NIH

Panelists:








- *Renée Cummings, University of Virginia*
- *Chhavi Chauhan, The American Society for Investigative Pathology*
- *Linda Coleman, Yale University*

This session will explore the ethical issues regarding Big Data and the use of algorithms in biomedical and social and behavioral research. Speakers will review the evolution of Big Data and the use of algorithms in research and provide examples regarding the benefits and risks posed by this type of research. Speakers will consider how IRBs assess the potential risks and how these risk have changed over time and become more complex. Areas of discussion also will include data privacy, algorithmic bias, algorithmic auditing, risk of harm, and transparency and how the research community – beyond the IRB – can respond appropriately. We hope to explore how the research community can evaluate these types of studies to ensure we are promoting good research including generalizability, data sharing, and research that serves the public good and not perpetuating bias or ignoring other important ethical issues.

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; SBIR Professionals



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|  Livestreamed Session |  On-Demand Session |  Pre-Registration Required |  Additional Fee |
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AER21 Day 2: Thursday, November 18

Breakout Sessions Series C, 11:30 AM-12:30 PM ET

(Note: These sessions run concurrently against the Panels.)

C1: Teaching Social Justice and Advocacy for Social Change—Ideas for Researchers, Leadership, IRB Members, Staff, and Communities

Tracks: Education and Training; Advancing Equity and Justice

Ivy Tillman, Augusta University; Angela Braggs-Brown, University of Cincinnati

Structural issues impact participation in research and, to address this, organizations need to teach on how research studies can advance social justice and equity, and the challenges organizations and researchers need to overcome (such as lack of awareness of social justice, structural racism, and lack of community engagement and engagement with groups underrepresented in research studies).

Learning Objectives:

- Describe key concepts in social justice and structural racism
- Develop strategies for community engagement
- Recognize structural racism in research and how HRPPs, IRBs, and researchers can improve research studies

Target Audience: HRPP Educators; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Members; Diversity, Equity, and Inclusion; HRPP Leadership and Institutional Officials



C2: Is Your Institution Ready to Conduct Human Gene Therapy Research?

Tracks: Pharma/Biotech Perspectives; Research Involving Data and Biospecimens

James Riddle, Advarra ; Rhonda Oilepo, University of Texas Southwestern

This session is designed for those who are new to IBC/gene therapy or whose hospital/health system was thrust into this space by COVID-19. The world has been introduced to mRNA and was surprisingly comfortable with genetically engineered treatments. Gene therapy-based products are entering human trials at an exponential growth rate. During this session, speakers will review the basics of conducting human gene therapy research and the requirements for IBC review as outlined in NIH Office of Science Policy guidelines.

Learning Objectives:

- Review the basic regulations and guidelines governing IBCs and gene therapy research
- Explain the role of the IBC and where their oversight is different from the IRB
- Share key takeaways to prepare your research organization to participate in this growing field of research

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Members



C3: Situational Vulnerability/Research With Risk Susceptible Populations Not Referenced in the Regulations

Track: Populations Requiring Additional Protections; Advancing Equity and Justice

Marianna Azar, OHRP; Colleen Kohashi, MA, CIP, University of California Berkeley; Meg Quint, Fenway Health

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 circumstances of the proposed research participants in addition the Common Rule categories and focus on coercion and undue influence. Before attending this session, attendees should have an understanding of the appropriate regulations and ethical principles as these will not be covered in detail.

Learning Objectives:

- Understand the notion of vulnerability in the revised Common Rule, how to apply it, and how it interacts with 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,



Advanced

CSP 234

ICON LEGEND

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| Livestreamed Session | On-Demand Session | Pre-Registration Required | Additional Fee |
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stigmatization of research subjects)

Target Audience: Clinical Research Staff; HRPP Educators; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; SBEP Professionals; Diversity, Equity, and Inclusion

AER21 Day 2: Thursday, November 18

Breakout Sessions Series C, 11:30 AM-12:30 PM ET

(Note: These sessions run concurrently against the Panels.)

C4: Beyond eConsent—Virtual Research in the Digital Age

Track: Research Conducted in the Digital World

Challace Pahlevan-Ibrekic, Northwell Health; Hallie Kassan, Northwell Health; Naline Patin, Clemson University

The session will bring awareness and attention to the conduct of virtual research—not just use of e-consent, but of conducting entirely remote protocols. After an introduction of how a virtual research service line operates, speakers will discuss how IRBs can and should review such virtual research, identifying areas for concern and flexibility, and providing practical solutions for implementation.

Learning Objectives:

- Outline the operational process of virtual research and its intersection with IRB review
- Discuss the IRB review process (e.g., review of interventional vs. non-interventional research) and IRB member training
- Provide practical recommendations for reviewing studies

Target Audience: Clinical Research Staff; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member



C5: When The @#&% Hits the Fan—When HRPP Noncompliance and Research Misconduct Occur

Together

Tracks: Responsible Conduct of Research; HRPP Leadership and Institutional Officials

John Baumann, Indiana University; Crystal Kelly, OHRP Resource Person; Scott Lipkin, Baptist Health South Florida

Research misconduct (e.g., fabrication, falsification, and plagiarism) is never good, but it becomes exponentially bad when it takes place within the context of or overlaps with noncompliance in human subjects research. This session will explore the processes for and unique challenges of HRPP's collaboration with Research Integrity/Misconduct Offices to identify, manage, and resolve research misconduct allegations.

Learning Objectives:

- Identify and discuss challenges of identification and processing of research misconduct allegations in human subjects research
- Discuss best practices—policy and process—for HRPP's collaboration with research misconduct offices to address research misconduct allegations
- Share a case study in research misconduct that involves human subject research

Target Audience: Compliance, Regulatory, and QA/QI Professionals; HRPP Educators; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs



12:45 -1:30 PM ET

Mid-Day Break

12:45 – 1:30 PM ET

AER21 Mid-day Break: Sponsored Presentation by Advarra--The Post-Pandemic Pivot: How to Leverage Strategic Partners So Your Teams Can Focus on What Matters

Robann Cunningham, Advarra

Tracks: HRPP Leadership and Institutional Officials Track; IRB Operations Advanced

Many institutional administrators are continuing to work through the effects of 2020: reduced and/or remote workforces, office closures, increased pressure for speed, and more. With limited budgets and the extreme shortage in research staffing, many sites are at a crossroads: Do they continue to support research activities in house at the risk of overwhelming limited local resources? Or leverage third-party partners to absorb some of the workload and help mitigate risk?

Learning Objectives:

- Describe different organizational models for an institutional IRB office
- Understand sponsor's expectations of institutional activation processes and timelines
- Develop a plan that articulates risks and benefits of leveraging external providers



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| Livestreamed Session | On-Demand Session | Pre-Registration Required | Additional Fee |
| New New Breakout Sessions in 2021 | 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 to actively contribute to discussion and solutions. 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. | |

AER21 Day 2: Thursday, November 18

Breakout Sessions Series D, 1:30 PM-2:30 PM ET

D1: A Dialogue With FDA



Tracks: A Dialogue with the Feds; FDA Regulated Research

Ann Meeker O'Connell, FDA; Kevin Prohaska, FDA; Bridget Foltz, FDA; Laurie Muldowney, FDA; Diane Maloney, FDA; Minerva Hughes, FDA

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
- Ask questions about evolving issues and initiatives at the FDA

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Educators; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member

D2: Embedding a Racial Justice Lens into Research and IRB Review With Human Subjects—How to Be an Anti-Racist at Work Every Day



Track: Advancing Justice and Equity

Doretha Walker, Institution; Hila Berger, Montclair State University

This session will highlight racism in research design, both in medical and non-medical research, while providing attendees with methods to address these issues in the ethics review process. Approaches and guidance documents generated from [a working group on Black Lives Matter in Research](#) will be used with specific case studies. "It is time for researchers to take a knee, because black lives matter, even in research" (Mnguni, L. (2020). #BlackLivesMatter, even in research: A call to researchers to take a knee *South African Journal of Science*, 116(spe), 1-5.)

Learning Objectives:

- Bring attention and awareness to implicit bias and racism in research design and in ethics review processes
- Share approaches and documents to assist IRB professionals in addressing Black Lives in research review
- Explore approaches for IRB professional that will assist researchers radically change research design

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Educators; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; SBIR Professionals; Diversity, Equity, and Inclusion

D3: Developing a Rapid Response Central IRB Model—Use of an Emergency Preparedness Model to Develop and Streamline Procedures



Advanced

Tracks: Flexibility and Innovation in HRPP Processes; Global Research; IRB Operations Advanced; HRPP Leadership and Institutional Officials

Bruce Gordon, University of Nebraska Medical Center; Stephen Rosenfeld, Freeport Research Systems;

Abigail Lowe, University of Nebraska Medical Center

The COVID-19 pandemic has highlighted the need for emergency preparedness of HRPPs and rapid IRB review. But, this is not the first time this need has been obvious. In 2019, one institution visualized the use of the rapid response paradigm in a central IRB setting focused on public health emergency research and has built and refined a Rapid Response Central IRB model. Join this session to learn more about different approaches to HRPP emergency preparedness. Before attending this session, attendees should have an understanding of IRB functions and the concept of central IRBs.

Learning Objectives:

- Describe the impact of timely, substantive IRB review of research in a public health emergency
- Review how to develop a plan or policy for a Central IRB
- Discuss three key features of rapid response central IRB review in a public health emergency

Target Audience: Clinical Research Staff, Compliance, Regulatory, and QA/QI Professionals, HRPP Leadership and Institutional Officials, IRB Administrators, Manager and Staff, IRB Members, Chairs, and Vice Chairs

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AER21 Day 2: Thursday, November 18

Breakout Sessions Series D, 1:30 PM-2:30 PM ET

D4: Electronic Consent and Other Emerging Approaches to Consent in Global Research



Track: Global Research

David Borasky, WCG; Ian Chen, National Taiwan University Hospital; Samia Hassan Rizk, Cairo University School of Medicine (Egypt)

While the challenges of consent in global research have received much attention, this session will review new challenges such as the emergence of electronic consent processes and best practices for organizations in the US and other countries conducting global research. The session will include perspectives from HRPPs in other countries who are also conducting global research and who can address different country-specific requirements and differences in cultural norms.

Learning Objectives:

- Describe the use of emerging technologies such as the use of electronic devices to document consent, and the use of social media to engage communities in different countries, and how to integrate electronic consent processes and ensure compliance with drug and device regulatory agency requirements in the US and other countries
- Describe best practices for US organizations conducting research in other countries
- Address considerations for interventional social science and public health research in other countries

Target Audience: Clinical Research Staff, HRPP Leadership and Institutional Officials, IRB Administrators, Manager and Staff, IRB Members, Chairs, and Vice Chairs

D5: Defining and Implementing Your HRPP Vision—The Importance of HRPP Leadership



Tracks: HRPP Leadership and Institutional Officials; Leadership

Robert Hood, AAHRPP; Robert Nobles, Emory University; Ann Johnson, University of Utah

Join experienced Institutional Officials (IOs) and HRPP leaders for a session focused on defining and implementing a vision for human research protections at your organization. Often, the importance of the role of the IO in setting the tone for compliance, research ethics, and a commitment to protections is underestimated. This session will review the roles and responsibilities of IOs and strategies for effective implementation of an HRPP vision. Speakers will review models for HRPP leadership that can complement and support the role of the IO, strategies for determining which IO responsibilities to delegate and lessons learned from individuals who have served in the IO role.

Learning Objectives:

- Understand the importance of the IO in setting and implementing an HRPP vision
- Identify strategies for operating as an IO, including varied HRPP leadership models that may help support the role
- Apply lessons learned from direct IO experiences to make organizational improvements

Target Audience: HRPP Leadership and Institutional Officials

D6: Unique Challenges Being an IRB Chairperson at Medium to Small Institution



Tracks: IRB Chairs; Small Research Programs

Brenda J. Klement, Morehouse School of Medicine (SF); Liza Dawson, Walter Reed Army Institute of Research

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

Learning Objectives:

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

Target Audience: IRB Members, Chairs, and Vice Chairs

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AER21 Day 2: Thursday, November 18

Breakout Sessions Series D, 1:30 PM-2:30 PM ET

D7: Championing Cohesion and Collaboration Through Change

Tracks: Leadership; HRPP Leadership and Institutional Officials

Kenia Viamonte, University of Miami; Margaret Rankovic, CITI Program

Cohesion and collaboration are key markers when seeking out a team's success. Individuals that feel connected to an outcome rather than being instructed are more likely to arrive at the desired result and be happier as they work towards that common goal. This session will discuss the differences between engagement and execution and how one can ensure the other. There is great value in engaging employees in the strategic planning process, as well as long- and short-term goals. This allows for the opportunity to feel empowered and committed not just towards a specific action item, but more importantly, to the team, the unit and the larger organization.

Learning Objectives:

- Discuss the benefits of creating a team driven culture while maximizing on individual strengths
- Explore the value in proactively creating opportunities for engagement
- Provide practical strategies to couple engagement exercises with execution/deliverables/project management

Target Audience: HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff



D8: Navigating the Regulatory Maze When Proposing Study Visits in Participant Homes

Track: Legal Considerations in HRPPs

Brenda Ruotolo, Columbia University; Mitchell Parrish, H Clinical; Natalie Klein, OHRP resource person

Proposals by sponsors and investigators to offer an option for study visits in participant homes have exploded due to the COVID-19 pandemic and Decentralized Clinical Trials. Research personnel may conduct such visits or a home healthcare agency may be contracted by the research institution or an industry sponsor. This session will explore the ethical, practical, and regulatory factors that must be considered. Before attending this session, attendees should have an understanding of human research protections regulations at the federal, state, and local level, understanding of the basic ethical principles for human subjects research, and familiarity with best consent process.

Learning Objectives:

- Identify the reasons for which a home study visit may facilitate recruitment and retention of study participants, and accout participants with mobility challenges
- Create an awareness of the factors that must be addressed before approving home study visits, including, but not limited to, liability coverage, communication between the research team and home healthcare agency, determining engagement and the need for IRB review, and training and documentation of procedures conducted in the home
- Discuss the language that is required for consent documents when home study visits are an option or when they are optional
- Outline home visit team safety issues and mandatory reporting requirements

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; SBIR Professionals



D9: New Guidelines for Human Stem Cell-Related Research—Implications for IRBs and Institutions

Track: Research Involving Data and Biospecimens

Jeremy Sugarman, Johns Hopkins University; Insoo Hyun, Harvard Medical School; Rosario Isasi, University of Miami;

There have been stunning scientific advances in human stem cell-related research that about an array of ethical and regulatory issues. To help address these issues at a practical level, the International Society for Stem Cell Research (ISSCR) updated its guidelines, which were released in May 2021. This session, which includes bioethics members of the global task force that updated the guidelines, will guide attendees through important IRB-specific aspects of the revised ISSCR guidelines. Speakers will provide an overview of the guidelines and discuss areas of human stem cell-related research that merit IRB review, including the



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procurement of biospecimens used to derive new stem cell lines, unique considerations for clinical translational research, and the differences between IRB review and the ISSCR's specialized oversight system for stem cell research.

Learning Objectives:

- Discuss the implications of the Guidelines to IRB review
- Review aspects of this research (such as the biospecimens used in it)
- Learn about unique considerations for clinical translational research, and when and how specialized oversight of research that falls outside the remit of IRBs should occur

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs

AER21 Day 2: Thursday, November 18

Breakout Sessions Series D, 1:30 PM-2:30 PM ET

D10: Clinical Trials in SBER

Track: SBER

Wendy J. Weber, NCCIH, NIH; Kate Sasamoto, University of Michigan

NIH has implemented policies designed to improve stewardship, accountability, and transparency of clinical trials, including some research characterized as basic science. SBER IRBs (and their research communities) need to understand the special NIH requirements for clinical trials. The revised Common Rule also imposes additional requirements for projects identified as clinical trials. Before attending this session, attendees should have a basic knowledge of NIH clinical trial policies and 45 CFR 46. NIH-funded research projects meeting the NIH definition of clinical trials must be registered and results reported on ClinicalTrials.gov. For investigators and institutions that do not typically work with clinical trials, meeting these requirements can be challenging. This session is designed to provide an overview and tips for assisting SBE researchers and institutions with ClinicalTrials.gov responsibilities. Before attending this session, attendees should have basic knowledge of ClinicalTrials.gov.

Learning Objectives:

- Consider the similarities and differences between NIH and OHRP requirements related to SBER clinical trials, including the requirements associated with "basic research"
- Provide examples of SBER studies that fall under these requirements
- Review requirements for registering a study on ClinicalTrials.gov
- Discuss continuing obligations regarding active ClinicalTrials.gov records
- Describe the process for reporting study results on ClinicalTrials.gov

Target Audience: Compliance, Regulatory, and QA/QI Professionals; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; SBER Professionals



D11: Educating While Engaging—Strategies for IRB Member and Staff Continuing Education

Track: Education and Training

Edith Paal, University of Arkansas for Medical Sciences; Tracy Wilson-Holden, Case Western Reserve

The session will describe educational program models intended to engage research teams while keeping them current on human subjects protections issues, including those that allow for interaction between various HRPP staffers and participants in the research community, and that allow the sharing of best practices.

Learning Objectives:

- Review different research education models
- Discuss how to encourage ongoing education throughout the HRPP
- Explore how to minimize education-related costs

Target Audience: HRPP Educators; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs



D12: "Ain't No Mountain High Enough"—Ensuring a Successful Informed Consent Process Throughout the Life of the Study

Track: IRB Basics

Cynthia Gates, University of Miami; John Horigan, NIH; Yvonne Lau, OHRP

This session will discuss the critical need to carry out a robust consent process from cradle to grave. For study participants, reading consent forms can seem daunting and overwhelming like scaling a mountain. But, for a successful research encounter to effectively reach its summit, one that truly has respect for persons at the forefront, the process needs to be meaningful, pulling out all the stops. Audience, amount of information, circumstances, setting, and a wide range of other factors can contribute (or not) to a successful consent process.

Learning Objectives:

- Define the principle of respect as related to the informed consent and the value it affords the participant,



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as well as the success of a study

- Discuss the elements of informed consent and which ones matter to who (subject, institution, and sponsor)
- Explore best practices and practical tips for standard consents, waivers and nuances of different regulations

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member

AER21 Day 2: Thursday, November 18

Breakout Sessions Series D, 1:30 PM-2:30 PM ET

D13: Best Practices for Ancillary Review in a Single IRB World

Track: IRB Operations Advanced

Nichelle Cobb, PhD, AAHRPP; Ivana Simic, PhD, University of Florida; Suzanne Stone, MA, CIP, University of California Berkeley

The NIH and Common Rule require single IRB review for most multi-site research. The primary motivation behind the single IRB requirement was to streamline time to study start up and completion. However, IRB review is only one component of the study activation. If ancillary review, as required by the institution, is not streamlined, any gains from single IRB review are limited. This session will explore the relationship between ancillary reviews and IRB review, especially in a single IRB arrangement, and best practice recommendations for ancillary review proposed by a SMART IRB Harmonization Working Group.

Learning Objectives:

- Discuss the challenges ancillary reviews present for IRB approval of participating sites and for study activation at different participating sites
- Define ancillary reviews, identify when ancillary reviews should be completed in relation to the single IRB's review and approval of a participating site, and distinguish which ancillary reviews are relevant to study activation at a participating site
- Review the roles and responsibilities related to ancillary review in a single IRB arrangement

Target Audience: HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff



D14: Ideas and Practices for Auditing of Single IRB Studies

Track: QA/QI and Postapproval Monitoring

Neala Lane, Indiana University; Julie Chamberlin, Harvard T.H. Chan School of Public Health; Lisa Buchanan, OHRP

Single IRB is becoming commonplace in the human subjects' clinical trial enterprise. As institutions transition to roles as reviewing IRBs or relying institutions, they face new challenges with respect to ensuring appropriate oversight of the research and study team(s). QA/QI and postapproval monitoring programs will play a critical role in ensuring study teams are aware of their responsibilities, remain in compliance, and investigate areas of concern on behalf of the Reviewing IRB. This session will highlight strategies to effectively conduct audits of single IRB studies and demonstrate best practices through a mock audit of a multi-site ceded study.

Learning Objectives:

- Gain familiarity of the applicable regulations and policies governing multi-site research and key challenges for oversight of studies using a single IRB
- Using case studies, learn how to identify compliance concerns, including both regulatory and institutional, for a ceded study
- Discuss practical considerations and best practices for conducting audits of single IRB studies and communicating with the single IRB

Target Audience: Compliance, Regulatory, and QA/QI Professionals, HRPP Leadership and Institutional Officials, IRB Administrators, Manager and Staff, IRB Members, Chairs, and Vice Chairs



D15: How to Maintain Institutional Memory at a Small Research Program

Track: Small Research Programs

Kristen Connal, The Fenway Institute; AnneMarie Winkler, Syneos Health

HRPP decisions and policies are made within a larger institutional and community framework. In a small research program, with something as routine as the departure of a single staff or IRB member, that history, rationale, and context can be lost—to catastrophic effect. To prevent this, institutional memory must be preserved in an accessible, shareable fashion. Before attending



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this session, attendees should have some knowledge of drafting policies, guidelines, or standard operating procedures (SOPs).

Learning Objectives:

- Consider how to effectively capture context within institutional documents (SOPs, policies, guidance, meeting minutes, etc.)
- Review a sampling of document archiving and sharing strategies
- Explore the role of succession planning, on-boarding, and off-boarding strategies

Target Audience: HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff

AER21 Day 2: Thursday, November 18

Breakout Sessions Series D, 1:30 PM-2:30 PM ET

D16: A Dialogue With ORI



Track: A Dialogue with the Feds

Yvette Carter, Department of Health and Human Services; Ning Du, Department of Health and Human Services

Join representatives from ORI for a session that will provide insight into an institutional response to allegations of clinical research misconduct and protocol violations, ORI's oversight review of the institutional process, and identification of research misconduct in translational and clinical research, as part of the research continuum. This session will include case examples and the implementation of the federal regulations at 42 C.F.R. Part 93, to address allegations of research misconduct.

Learning Objectives:

- Discuss ORI's mission and jurisdiction
- Consider each ORI's, DEI's, and DIO's responses to research misconduct
- Explore the distinction between clinical research misconduct and a protocol violation
- Discuss NIH's working definition of translational research
- Use case studies to show how to address allegations of research misconduct in translational research, as well as institutions' versus ORI's response to clinical research misconduct allegations

D17: A Dialogue With SACHRP



Track: A Dialogue with the Feds

Douglas Diekema, University of Washington School of Medicine; Michele Russell-Einhorn, Advarra; Mark Barnes, Ropes & Gray LLP; David Forster, WCG Clinical; David Strauss, Columbia University

This session will be led by representatives from SACHRP and its subcommittees.

Learning Objectives:

- Hear from SACHRP representatives about evolving recommendations on artificial intelligence, "engagement", HHS support, and third parties in research
- Learn about the scope and impact of SACHRP recommendations
- Learn how to access SACHRP meetings and materials, and make public comment

2:30-3:00 PM ET

Break

Afternoon Networking Opportunities, 3:00 PM-4:00 PM ET

3:00-3:30 PM ET: PRIM&R's Online Courses—EROC and AROC



Scott Rule, PRIM&R

PRIM&R offers engaging, interactive online courses that equip IRB and IACUC members for their roles through the demonstration of the ethical principles and regulatory frameworks that govern their day-to-day work. Features include:

- Interactive content. Come and see how learners can explore selected topics in depth and move through course content at their own pace. Interactivity includes drag-and-drop and matching activities, progress checks, mini-case studies, and more.
- Simulated IRB and IACUC Discussions. Observe principles in practice by watching the simulated IRB and IACUC in action. See how each member's expertise, background, and perspective contributes to the ethical review of research as they apply principles and regulations during their meetings.
- Case Studies. See how learners can apply their new knowledge to realistic scenarios, learn best practices for reviewing

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research protocols, and check their understanding of each unit's learning objectives with in-depth case studies paired with questions.

- Assessment, Certificate of Completion, and Credit. Learners who successfully complete either course's final assessment will receive a certificate of completion for that course as well as earn continuing education (CE) credit.

This session is pre-recorded and there is no option for real-time questions. Please address questions to Scott Rule, Digital Learning Designer, srule@primr.org.

AER21 Day 2: Thursday, November 18

Afternoon Networking Opportunities, 3:00 PM-4:00 PM ET

3:00-4:00 PM ET: HRPP/IRB Management 101—Real-World Discussions Regarding How to Effectively Run a HRPP/IRB Office



Track: Networking

Linda Coleman, Yale University; Nathalia Henry Whitely, Northwestern University;

Megan Kasimatis Singleton, Johns Hopkins University School of Medicine

Join HRPP and IRB directors for a candid discussion regarding how to tackle the most difficult management challenges! While most individuals assuming a leadership role overseeing a HRPP/IRB have sufficient regulatory expertise, many HRPP and IRB Directors are new to operational and strategic management. This session will discuss core HRPP/IRB leadership responsibilities such as staffing, performance management, organizational structure, budgeting, forecasting, establishing IRB review fees, overseeing the assessment of HRPP/IRB compliance, quality, efficiency and effectiveness, and advocating for resources. Specific strategies for tackling these management responsibilities, including the use of publicly available peer metrics and local organizational data will be discussed. Speakers will share their real-world experiences and the solutions they developed to address various management challenges. ***This session will take place in Zoom meeting. The use of attendee video is encouraged for participation and interaction with your peers.***

Learning Objectives:

- Understand critical management responsibilities for running a HRPP/IRB office
- Identify strategies HRPP/IRB Directors can adopt to effectively fulfill these responsibilities
- Through case examples, highlight real-world experiences of HRPP/IRB Directors and identify solutions for specific management challenges

Target Audience: HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff

3:00-4:00 PM ET: Meet the Author Book Discussion: *Adverse Events: Race, Inequality, and the Testing of New Pharmaceuticals*



Track: Networking

Moderator: Nancy King, Wake Forest University

Author: Jill A. Fisher, University of North Carolina at Chapel Hill

Participate in a vibrant discussion of *Adverse Events: Race, Inequality, and the Testing of New Pharmaceuticals* by Jill A. Fisher. During this interactive session, attendees will have the opportunity to hear from and participate in a discussion with the book's author on why they wrote the book and implications for the field. ***This session will take place in Zoom meeting. The use of attendee video is encouraged for participation and interaction with your peers.***

3:00-4:00 PM ET: Programmatic Poster Panel: Outstanding Work



Track: Networking

Speaker: Ivy Tillman, Augusta University

Speaker: Lana Gevorkyan, University of Michigan Medical School

Moderator: Warren H. Capell, University of Colorado Anschutz Medical Campus

Join this year's outstanding poster award winners for a discussion on their programmatic-based work. Posters will be available to attendees via the Virtual Poster Gallery (starting on November 2). During this session, the following abstracts will be presented:

- Bridging the Gap: HRPPs, Researchers, and Marginalized Communities by Ivy Tillman, MS, Augusta University
- Strengthening IRB and HRPP Partnerships: Initiatives to Improve Research Regulatory Review and Information Quality Toward Sustainable, Permanent Change by Corey Zolondek, PhD, CIP, University of Michigan

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| Advanced: Assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding to actively contribute to discussion and solutions. 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. | |

3:00-4:00 PM ET: The Certified IRB Professional (CIP®) Credential Presentation



Track: Networking

Lori Roesch, Children's Wisconsin; Ross Hickey, University of Southern Maine

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.

This session will take place in Zoom meeting. The use of attendee video is encouraged for participation and interaction with your peers.

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

Target Audience: IRB Administrators, Managers, and Staff

AER21 Day 2: Thursday, November 18

Afternoon Networking Opportunities, 3:00 PM-4:00 PM ET

4:00-5:00 PM ET: Federal Agency Affiliate Session: Department of Energy (DOE) Human Subjects Protection

Program (HSPP): Human Subjects Research or Not Human Subjects Research? (A Dialogue With the Feds Track)

Cheri Hautala-Bateman, NNSA HSP Program Manager; Steven Rupkey, IRB Coordinator, Argonne National Laboratory; Susan Varnum, Human Subjects Protection Program Manager, Pacific Northwest National Laboratory; Elizabeth White, DOE HSP Program Manager

Join DOE representatives for a session that will provide a brief overview of their HSPP, followed by a more in-depth presentation on and discussion of a collaborative effort between headquarters and their sites to streamline the human subjects research (HSR)/not HSR determination process for research using big data and/or biospecimens. DOE's goal is to balance the need for efficient IRB review/determination while ensuring continued compliance with the ethical principles in the Belmont Report, the Common Rule, and DOE/ National Nuclear Security Administration -specific requirements.








Note: This is an affiliate session being run outside of the PRIM&R AER Conference, but is accessible to all AER21 Attendees via the online platform (streaming link will take you to a third-party streaming service (e.g., Zoom, GTM, etc.). This session will only be run live; no on-demand recording will be made available by PRIM&R.

5:00 – 6:00 PM ET

Sponsored Happy Hour by WCG Clinical: An Evening With Second City Improv

Join WCG IRB for a virtual comedy happy hour with Second City Improv!

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AER21 Day 3: Friday, November 19

10:00-11:15 AM ET

Conference Welcome and Keynote Address: Chasing My Cure: Lessons and Ethical Implications of Being a Physician-Scientist-Subject-Patient-Advocate



David Fajgenbaum, MD, MBA, MSC, FCPP, Assistant Professor of Medicine in Translational Medicine and Human Genetics, University of Pennsylvania; Founding Director, Center for Cytokine Storm Treatment and Laboratory; Associate Director, Patient Impact of the Penn Orphan Disease Center; Co-Founder/President, Castleman Disease Collaborative Network; Author, Chasing My Cure: A Doctor's Race to Turn Hope Into Action

11:15-11:30 AM ET

Break

Concurrent Panels, 11:30 AM-12:45 PM ET

Panel V: Ongoing and Future Challenges of COVID-19: Preparing for the Next Pandemic



Moderator: Christine Grady, NIH Clinical Center

Panelists:

- *Christine Grady, NIH Clinical Center*
- *Michele Andrasik, Fred Hutchinson*
- *Michele Russell-Einhorn, Advarra*
- *A.J. Allen, Eli Lilly*

An armchair panel discussion about bioethics and human research protections topics that have arisen during the recent pandemic. This discussion will provide information on ongoing and future challenges of COVID-19, the COVID-19 vaccine, "the next pandemic" and related ethical challenges.

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Educators; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; Diversity, Equity, and Inclusion

Panel VI: The Conceit of Consent—What Does it Do and What Should We Ask it to Do?










Moderator: Carol Weil, National Cancer Institute, NIH

Panelists:

- *Laura Beskow, Vanderbilt University School of Medicine*
- *Aisha Langford, New York University Langone Medical Center*
- *Emily Largent, University of Pennsylvania*

Informed consent is deeply entrenched in human subjects research from both ethical and regulatory perspectives. There are also persistent issues related to length and complexity of consent forms. However, there are deeper questions about whether informed consent can bear the weight it is asked to bear from a human subjects protections perspective and how consent intersects with other important considerations related to justice and representation in research. It has long been recognized that understanding is suboptimal among many individuals who enroll in research studies, yet research has not been halted. What does this mean, and what should change? There are prominent efforts to increase diversity among research subjects, but increasing engagement with populations who have low health literacy will predictably raise challenges with regard to informed consent. How should this be navigated? Power differentials can complicate consent processes, and lack of trust may be significant.

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However, factors that help to facilitate trust and enhance respect may threaten some conceptions of autonomy. How should we balance what appear to be competing goals? This panel will address these questions.

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Educators; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; Diversity, Equity, and Inclusion

Breakout Sessions Series E, 11:30 AM-12:30 PM ET
(Note: These sessions run concurrently against the Panels.)

E1: A Philosopher's Look at the Belmont Principles (aka "Chicken Soup for the HRPP Professional's Soul")



Track: IRB Basics

Robert Hood, AAHRPP; Phoebe Friesen, McGill University; Toby Schonfeld, U.S. Department of Veterans Affairs; Ivor Pritchard, OHRP resource person

In this session, our philosophically minded colleagues will share their thoughts on the Belmont Principles, their deeper meaning, roots, and why these principles over so many others. Join this session to get back to the basics and recharge your HRPP professional battery!

Learning Objectives:

- Explore and discuss the philosophical background of the Belmont Principles
- Understand why these three principles made the cut and why so many others didn't
- Learn how to apply the principles where the regulations are silent

Target Audience: HRPP Educators; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; SBIR Professionals

AER21 Day 3: Friday, November 19

Breakout Sessions Series E, 11:30 AM-12:30 PM ET
(Note: These sessions run concurrently against the Panels.)

E2: Indigenous-Centered Approaches to the New Common Rule and the Single IRB Mandate



Tracks: Populations Requiring Additional Protections; Advancing Equity and Justice

Rachell Tenorio, PhD, Albuquerque Area Indian Health Board; Emily Haozous, Pacific Institute for Research and Evaluation; William Freeman, Northwest Indian College

This breakout session will address a descriptive question regarding the new Common Rule and single IRB mandate from NIH, as both introduce new concerns in American Indian and Alaska Native (AI/AN) communities. The elimination of continuing review for minimal risk research, modifications to broad consent, and an option for single IRB threaten tribal sovereignty.

Learning Objectives:

- Define and understand how Tribal Sovereignty can be applied to a cultural review
- Identify how the common rule both challenges and favors Tribal Sovereignty
- Discuss future solutions to address the limitations in the new common rule

Target Audience: HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; Diversity, Equity, and Inclusion

CSP 257

E3: How Might Ethics Review Be Reimagined in the Age of DIY and Open Science?



Track: Research Conducted in the Digital World

Megan Doerr, Sage Bionetworks (moderator); Sarah Blossom Ware, PhD, Blossom Bio Labs Inc; Camille Castelyn, Voices in Bioethics

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. Members of the biohacking community have begun loosely organizing themselves by holding annual conferences and by creating mission statements, biosafety manuals, and codes of ethics. 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 may assume huge risks on unregulated experimental treatments because the traditionally paternalistic stance IRBs take on risk does not allow for a dialogue about reasonable assumptions of patient risk. Are we preventing the development of open-source biotechnology solutions by not broadening our definitions of researchers and research, and by not blending establishment with non-establishment institutions? This session will explore some of the cooperative projects in the biohacking community, and facilitate discussion of how to move forward.

Learning Objectives:

- Review ethical requirements for the oversight of research and discuss what it means for research to be "unregulated"
- Discuss how to apply flexibility in the review of unregulated research in a manner consistent with ethical principles and identify the challenges of applying traditional institution-based ethics review framework (e.g., IRBs, REBs, etc.) to research designed by citizen scientists
- Educate attendees about the ways that citizen scientists (biohackers, DIY) are involved in health research
- Explore possible routes toward a more effective, egalitarian system of ethics review
- Provide practical recommendations for reviewing studies at your own institution

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Target Audience: HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member

E4: Advancing Justice Through Community Engagement in Governance for Research Biobanks



Tracks: Research Involving Data and Biospecimens; Advancing Justice and Equity

Andrea Cooper, Esq Senior Director, HR Compliance, CoreCivic Member, BioVU Community Advisory Board; Victoria Baptiste, member Henrietta Lacks family

The legacy of Henrietta Lacks has taught the human research protections community many important lessons regarding consent, community engagement, and the power of an individual's contribution to the health and welfare of many. Perhaps one of the most important outcomes of the Lacks family legacy has been the public recognition of the importance of incorporating the participant perspective and voice into the process for oversight and governance of the responsible use of biospecimens in research. The incorporation of members of the Lack's family into the HeLa Genome Data Access Working Group serves as an example of participant engagement in oversight of biospecimens and calls HRPPs to evaluate how they might adopt similar solutions for the oversight of biospecimen use at their own organizations. Drawing from the lessons learned from the Lacks family legacy, this session explore potential strategies for engaging the participant perspective in decisions regarding the responsible use of biospecimens. Various models for participant engagement and oversight will be discussed.

Learning Objectives:

- Understand various models for participant engagement in issues related to the use of biospecimens in research
- Identify strategies for incorporating the participant perspective into oversight for the responsible use of biospecimens
- Consider specific types of research that may warrant special procedures/protections to ensure the participant perspective is adequately represented in plans for biospecimen use

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; Diversity, Equity, and Inclusion

AER21 Day 3: Friday, November 19

Breakout Sessions Series E, 11:30 AM-12:30 PM ET

(Note: These sessions run concurrently against the Panels.)

E5: Extending Education Beyond the IRB



Track: SBER; Education and Training

Christine Wallace, University of Nevada, Reno; Emily Anderson, Loyola University

While research integrity is central to HRPPs, it can be advantageous to expand educational efforts across the institution and outwardly to community partners. This session will discuss two models of SBER education: community research partnership training and an institutional initiative involving stakeholders to foster a culture of integrity.

Learning Objectives:

- Review strategies for initiating HRPP partnerships
- Share insights about education for community-engaged SBER
- Identify challenges and considerations with both models

Target Audience: HRPP Educators; IRB Administrators, Managers, and Staff; SBER Professionals

12:45 -1:30 PM ET

Mid-Day Break

12:45 PM – 1:30 PM ET

AER21 Mid-day Break: Sponsored Presentation by Huron Consulting Group--Managing and Improving HRPP Efficiency and Effectiveness Post-Pandemic



Thomas M. Bechert, Huron Consulting Group

HRPPs are not immune to the various operational and staffing challenges experienced nationwide that have arisen throughout the pandemic. For many institutions, these challenges will not go away in the near future as staffing and hiring remain an ongoing challenge. As such, HRPP leaders need to use this time as an opportunity to reexamine current processes, tools, and approaches and find new opportunities to streamline and simplify current processes to reduce administrative workload and burden while remaining compliant. During this session, Huron will provide an overview of three important approaches aimed at helping HRPPs improve their overall efficiency and effectiveness.

Learning Objectives:

- Explore IRB Transformation assessments and support to improve office operations and make the most of your available resources and staff
- Review HRPP Toolkit implementations aimed at simplifying policies and procedures and reducing ongoing time and effort associated with policy and procedure upkeep
- Discuss Huron IRB Software System approaches to simplifying IRB submission processes and reducing administrative burdens for study team members and IRB administrators

Breakout Sessions Series F, 1:30 PM-2:30 PM ET

F1: A Dialogue With the NIH



Track: A Dialogue With the Feds

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Lyric Jorgenson, NIH

This session will be led by a representative from the NIH, and will include discussion of NIH's work.

Learning Objectives:

- Hear from a representative of the NIH Office of Science Policy about activities relevant to clinical research, including clinical trials, and protection and respect for human participants in research
- Ask questions about new and ongoing initiatives at the NIH

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member

AER21 Day 3: Friday, November 19

Breakout Sessions Series F, 1:30 PM-2:30 PM ET

F2: The Return of Data—Meeting Black Folx Where They Are While Explaining the Research and the Importance of Returning the Results to Them



Track: Advancing Justice and Equity

Jason Williams, Montclair State University; Doretha Walker, Independent Scholar

More and more research initiatives and funding agencies are asking researchers to focus on social justice and equity. Even more so, researchers are being asked to improve equity by considering inclusivity and enrolling or recruiting race or ethnic minorities/parti Researchers and ethics professionals have a moral obligation to learn and understand the medical experimentation history from colonial times to the present (Washington, H. A. (2006). *Medical apartheid: The dark history of medical experimentation on Black Americans from colonial times to the present*. New York: Doubleday.). What we do with this information during the consent process and during recruitment is critical to slowly building back trust with participants while focusing on equity and justice. This session will allow for conversation on the potential for exploitation.

Learning Objectives:

- Expand awareness of medical experimentation beyond Tuskegee and known historical injustices
- Learn and listen to representative presenters explain more about why medical research is not trusted in the US
- Establish ground rules for working with the Black community and explain the obligation for returning results in a manner that is useful to the community

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; Diversity, Equity, and Inclusion

F3: The IRB's Critical Role in Understanding Sponsor and Investigator Responsibilities for Investigational New Drug Application (IND) Safety Reporting in Order to Assure the Protection of Human Subjects



Track: FDA Regulated Research

Paul Gouge, FDA; Janet Donnelly, FDA

This session will provide an overview of FDA IND safety reporting responsibilities for the sponsor and clinical investigator in the safety reporting process of clinical trials. This overview will provide IRB staff and members with information to understand the obligations that both sponsors and investigators have in relation to IND safety reporting. Further, this session will emphasize the critical role that the IRB plays in identifying the type of safety information that requires submission to the IRB as an unanticipated problem and developing oversight procedures to ensure the protection of human subjects.

Learning Objectives:

- Review the responsibilities that sponsors, investigators, and the IRB have in relation to IND safety reporting
- Consider how the IRB's written procedures for unanticipated problems impacts successful identification and submission of safety information to the IRB
- Discuss what type of safety data must be reported to the IRB as an unanticipated problem and the strategies and procedures the IRB should employ to assure the protection of the rights and welfare of human subjects

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member

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F4: Bringing Continuous Improvement to Your HRPP—Proving Your HRPP Processes Are Hitting All the Right Milestones for Your Stakeholders



Tracks: HRPP Leadership and Institutional Officials; Education and Training; QA/QI and Postapproval Monitoring

Michael Leavitt, Intermountain HealthCare; Shelby Moench, Intermountain Healthcare;

David Matesanz, Kaiser Permanente, Northern California

HRPPs and IRBs must adapt to an evolving research world of changes and increased expectations of performance. Old processes need to be evaluated and improved to evolve with the changes. However, it seems like a daunting mission with the constant daily tasks, urgent requests, and other important items to address. There are tools and methods that are effective in improving team efficiency that take only a small percentage of the workday, and implementing these tools has shown to improve IRB approval turnaround time, balance workload, improve submission quality in and out of the IRB, elevate team innovation, and more. This session will review the common challenges HRPPs and IRBs may be facing and the continuous improvement tools that could help minimize the impact of these challenges and improve efficiency.

Learning Objectives:

- Review tools and methods that can improve outcomes, quality, and effectiveness
- Discuss strategies for implementing tools, challenges to avoid, and the importance of collecting data to drive improvement
- Share methods to improve collaboration within the HRPP, and between ancillary teams and research teams

Target Audience: HRPP Leadership and Institutional Officials; Compliance, Regulatory, and QA/QI Professionals; IRB Administrators, Managers, and Staff

AER21 Day 3: Friday, November 19

Breakout Sessions Series F, 1:30 PM-2:30 PM ET

F5: Advancing Justice and Equity Through IRB Review



Tracks: IRB Operations Advanced; Advancing Justice and Equity

Danielle Griffin, University of Houston; Megan Kasimatis Singleton, Johns Hopkins University; Eric Allen, University of Southern Florida

The principle of justice is considered a foundational component of human research protections and a core consideration to establish whether research is ethical. Despite this, few IRBs have implemented operational processes that support the advancement of this principle. This session will evaluate mechanisms IRBs may implement to take a proactive role in advancing equity and justice in research through the IRB review process. Strategies will be explored for revamping IRB applications, review checklists, committee composition and training of IRB staff and members to advance equity and justice in research.

Learning Objectives:

- Explore mechanisms IRBs may incorporate to advance justice and equity through the IRB review process
- Identify samples of operational tools IRBs may adopt/implement
- Understand how changes to IRB operations/review processes may be used as a mechanism for advancing investigator understanding of issues related to justice and equity in research

Target Audience: HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Diversity, Equity, and Inclusion

F6: Bystanders in Human Subject Research



Track: Legal Considerations in HRPPs

Jonathan Kimmelman, McGill University; Seema Shah, Ann & Robert H. Lurie Children's Hospital of Chicago;

Julia Gorey, OHRP resource person

The ethics and regulations guiding review of human subjects research are focused almost exclusively on participants in studies. The research and regulatory communities are still coming to terms with how to think about non-participants or bystanders who are inadvertently included in research, either through unintended capture, association with study participants, or data pooling. This session will explore legal precedent for broadening ethics review to non-participants.

Learning Objectives:

- Identify types of studies that may involve bystanders/non-participants
- Explore legal precedent regarding bystanders/non-participants
- Discuss risk mitigation for this inadvertent study population








Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member

F7: Ethical Issues in Complex Trial Design



Track: Pharma/Biotech Perspectives

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|  Livestreamed Session |  On-Demand Session |  Pre-Registration Required |  Additional Fee |
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Marianne Kearney Chase, MGH; Luke Gelinas, PhD, Advarra; Jerry Menikoff, OHRP resource person

Complex clinical trial designs (e.g., 'adaptive' designs that modify key features of studies mid-stream, 'platform' or 'umbrella' designs that test multiple therapies on multiple populations, human challenge studies, etc.) promise greater efficiency, but carry distinctive ethical and practical concerns, and can be challenging for IRBs to review. This session will 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 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

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member

AER21 Day 3: Friday, November 19

Breakout Sessions Series F, 1:30 PM-2:30 PM ET

F8: Trust, But Verify—Conducting Routine Audits of IRB to Help Ensure Compliance

Track: QA/QI and Postapproval Monitoring

Kenia Viamonte, University of Miami; Debbie Dykhuis, University of Minnesota; John Heldens, University of Colorado

The IRB is the hub of much of the regulatory activities that surround research compliance. The work this group carries out is mission critical to safeguard the participants, as well as the institution. But, the IRB is a very dynamic realm where human or system errors can create a very unfortunate confluence of circumstances. This session will discuss the value of periodic spot checks on standard practices involved in regulatory review. It will offer an opportunity to also think about building in efficiencies wherever possible to ensure the focus on quality is not overshadowed by clunky, duplicative, or altogether unnecessary processes.

Learning Objectives:

- Discuss the various areas within the IRB review that would benefit from periodic spot checks
- Describe the value in proactively identifying opportunities for enhancement/ improvement in IRB processes
- Provide practical strategies to identify procedural gaps that may otherwise lead to undesirable trends and ultimately noncompliance

Target Audience: Compliance, Regulatory, and QA/QI Professionals, IRB Administrators, Manager and Staff, IRB Members, Chairs, and Vice Chairs



F9: NIH's New Data Management and Sharing Policy—How Academic Medical Centers Can Prepare for January 2023

Track: Research Involving Data and Biospecimens

Sara Samuel, University of Michigan Medical School; Taunton Paine, NIH Office of Science Policy; Cindy Danielson, NIH resource person

NIH has announced a new Data Management and Sharing Policy, which takes effect for grants submitted on or after January 25, 2023. This policy will impact NIH-funded researchers, with implications for IRBs, research compliance associates, and other stakeholders. NIH's "expectations for robust data management and sharing practices [and] a future in which data sharing is a community norm" will require focused outreach, education, and development of tools during the coming year to prepare successful 2023 grant applications. In this presentation, we will outline NIH's expectations, explore specific challenges and opportunities afforded by the new policy, and offer suggestions for how academic medical centers can develop resources and work to support researchers and comply with the new policy.

Learning Objectives:

- Understand the specific guidelines, NIH's general expectations, and to whom they apply
- Discuss essential elements of and best practices for Data Management and Sharing Plans, including examples
- Identify the resources and stakeholders within an institution who will need to be engaged for researchers to develop adequate plans, along with the challenges they will face and the opportunities that the policy's requirements present

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Leadership and



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F10: From Big to Small and Back Again—Moving from a Large Research Program to a Small Research Program

Track: Small Research Programs

Kanti Crain, MA, MBA, CIP, Indiana University; Jesse Ripton, Boston Children's Hospital

In a niche field, moving to a different role within the HRPP is common. When the opportunity comes up, IRB administrators and/or auditors jump from one research program to another to explore professional improvement. This session will discuss the professional challenges and opportunities faced by IRB administrators and/or auditors when they make the decision to jump from a big research program to a small one, and vice versa.

Learning Objectives:

- Identify the challenges of moving to a different size research program
- Explore the opportunities gained by moving to a different size research program
- Share insights and practical strategies for assisting other IRB administrators and/or auditors during the transitions

Target Audience: HRPP Educators; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff

AER21 Day 3: Friday, November 19

Breakout Sessions Series F, 1:30 PM-2:30 PM ET

F11: “Customer Support” Is Not a Bad Word—Building Resources for Relying Institutions and Investigators



Tracks: Flexibility and Innovation in HRPP Processes; Leadership; IRB Operations Advanced

Linda Parreco, NCI; Stacy West, Virginia Commonwealth University; Janelle Maddox-Regis, Johns Hopkins University

A few years into this “sIRB” experiment, it’s helpful to reflect on what we’ve learned about supporting researchers when they’re relying on an IRB they’re not familiar with. This session will begin by reviewing the most crucial HRPP functions necessary for good “customer” support, and will then discuss the challenge of supporting investigators in multi-site studies. The session will provide pro tips from speakers experienced in supporting and navigating the single IRB waters.

Learning Objectives:

- Identify and discuss the key components for providing support to investigators in an HRPP
- Discuss and identify the unique challenges of supporting researchers from other institutions relying on your HRPP/IRB
- Gain a better understanding of researchers’ needs when relying on an IRB that is not their “own”
- Share best practices to support for relying institutions/investigators

Target Audience: HRPP Educators, HRPP Leadership and Institutional Officials, IRB Administrators, Manager and Staff, IRB Members, Chairs, and Vice Chairs

F12: Access to Clinical Research for People With Limited English Proficiency (LEP)



Tracks: Populations Requiring Additional Protections; Advancing Justice and Equity

Barbara Bierer, Harvard Medical School; Susan Kornetsky, Boston Children's Hospital; Kristen Ballesteros, PPD, Inc.

Due to eligibility criteria requiring that participants be able to speak, read, and/or understand English, individuals with LEP in the United States are often barred from clinical trial participation. However, there are strong ethical and legal arguments against routine exclusion. In this session, speakers will review empirical data on the rate at which participants with LEP are excluded, the impact of exclusions, and approaches that foster more inclusive eligibility criteria.

Learning Objectives:

- Understand the ethical and legal arguments against the routine exclusion of non-English speaking participants
- Review empirical data on exclusion of individuals with LEP from research
- Learn about methods to mitigate the exclusion of individuals with LEP and promote inclusive eligibility criteria

Target Audience: Clinical Research Staff; Compliance, Regulatory, and QA/QI Professionals; HRPP Educators; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; SBER Professionals; Diversity, Equity, and Inclusion

F13: Online Research: Design and Review in a World of Bots, Hackers, and Evolving Technology



ICON LEGEND

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|--|---------------------------|--|----------------|
| Livestreamed Session | On-Demand Session | Pre-Registration Required | Additional Fee |
| New Breakout Sessions in 2021 | 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 to actively contribute to discussion and solutions. 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. | |

Track: Research Conducted in the Digital World

Danielle Griffin, University of Houston; Christina Wright, Virginia Commonwealth University;

Chiara Acquati, Ph.D., MSW, Assistant Professor, University of Houston

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

Target Audience: Clinical Research Staff; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff; IRB Members, Chairs, and Vice Chairs; ; Non-Scientist/Unaffiliated IRB Member

AER21 Day 3: Friday, November 19

Breakout Sessions Series F, 1:30 PM-2:30 PM ET

F14: Translating Responsible Conduct of Research (RCR) Training at Your Organization—Tips and Tricks for Reaching Your Audience and Providing Practical Instruction



Tracks: Responsible Conduct of Research; Education and Training

Leslie Howes, Harvard T.H. Chan School of Public Health; Delia Wolf Christiani, MD, JD, MSCI, Harvard T.H. Chan School of Public Health; Sheila R. Garrity, JD, MPH, MBA, The George Washington University

The NIH requirements for instruction in RCR provide an institution with a helpful training framework, including considerations on format, subject matter, faculty participation, duration, and frequency. Institutions may wish to enhance such instruction and provide greater opportunity for further in-depth discussion of the topics and practical application. This session will discuss creative and innovative ways for organizations to strengthen its current integrity program and facilitate RCR training and education. Learn the good, the bad, and the ugly on how to adapt successful elements of these innovations into your organization to the benefit of enhancing research integrity. If you have any questions, feel free to reach out to Leslie Howes at lhowes@hsph.harvard.edu. Questions received prior to the conference might be featured during the session itself!

Learning Objectives:

- Review NIH requirements for instruction in RCR and the ways in which an institution can satisfy them
- Learn how an institution can enhance RCR training and instruction and facilitate its broader research integrity program
- Hear institution-specific success stories, which can be brought back home and adapted to your organization

Target Audience: HRPP Educators; HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff



Advanced

F15: Risk Mitigation in Mixed SBER and Biomedical Research—A Case-Based Approach

Track: SBER

Matt Stafford, Boston Children's Hospital; Lara Sloboda, Dana-Farber Cancer Institute

Using case studies to highlight common challenge areas and spur discussion, this session will focus on risk mitigation in research involving both biomedical and social science methods. Case study topics forthcoming. Before attending this session, attendees should have a basic foundation in human research protections ethics and regulations, including the criteria for approval and definitions from DHHS and FDA regulations.

Learning Objectives:

- Review the nature of potential harms associated with mixed social behavioral and biomedical research
- Explore factors likely to contribute to increased risk in this context
- Discuss how to design research with sufficient protections to mitigate risks

Target Audience: IRB Members, Chairs, and Vice Chairs; Non-Scientist/Unaffiliated IRB Member; SBER Professionals

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| New Breakout Sessions in 2021 | Call for Session Proposal | CIP Eligible | |
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F16: A Dialogue With the VA

Track: A Dialogue with the Feds

Molly Klote, VA; Karen Jeans, VA; Kristina Borrer, VA; Lindsay Masterson, 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
- Discuss the status of current and upcoming research enterprise initiatives related to VA research

2:30-3:00 PM ET

Break



Afternoon Networking Opportunities, 3:00 PM-4:00 PM ET

IRB Chairs Forum: A Structured Discussion for IRB Chairs

Tracks: Networking; IRB Chairs

Peter Iafrate, University of Florida; Sharon Ellison, Duke University Medical Center; Stephanie Solomon Cargill, Castle IRB

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. **This networking session will take place in Zoom meeting. The use of attendee video is encouraged for participation and interaction with your peers.**

Learning Objectives:

- Review and discuss contemporary issues related to human subjects protections that are commonly faced by IRB chairs, and that may not have clear guidance in the federal regulations
- Explore 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
- Share how to keep current as an IRB chair

Target Audience: IRB Members, Chairs, and Vice Chairs



AER21 Day 3: Friday, November 19

Afternoon Networking Opportunities, 3:00 PM-4:00 PM ET

The Ethical Research Podcast: Live Audience Recording

Track: Networking

Moderator: Ran Goldman, University of British Columbia

Speakers: David Fajgenbaum, University of Pennsylvania

Join pediatrician and scientist Dr. Goldman and guest Dr. David Fajgenbaum, immunologist and author of "Chasing my Cure" in a special PRIM&R live session of the [Ethical Research Podcast](#). Hear firsthand the voices of ethical research as we continue to explore the exciting stories behind conducting clinical and animal research. Be part of the podcast and get a chance to ask questions yourself as a participant in the live podcast. **This networking session will take place in Zoom meeting. The use of attendee video is encouraged for participation and interaction with your peers.**



I Love My Job!? Confessions of a Career Human Research Protection Professional

Tracks: Networking; Leadership; IRB Operations Advanced

Laura Youngblood, CDC; Danielle Griffin, University of Houston; Margaret Rankovic, CITI Program

Few people set out for a career in human research protections; many of us found ourselves here by accident or on the way to something else. Whatever the route, many of us have found our careers in human research protections to be personally rewarding, with unexpected opportunities for learning, teaching, and creative problem-solving. This session will share perspectives from three HRP professionals, each representing different roles and organizational structures, about the joy (and challenges) of working in this field, and what can a career in human research protections can look like. **This networking session will take place in Zoom meeting. The use of attendee video is encouraged for participation and interaction with your peers.**

Learning Objectives:

- Share experiences on career progression and the opportunities we have sought (or created!) to advance in the field
- Explore how engagement with the HRP community can enhance your experience in the field
- Discuss opportunities to engage more fully with the HRP community, including networking, mentorship, and membership in professional associations
- Review and apply career-mapping tools

Target Audience: HRPP Leadership and Institutional Officials; IRB Administrators, Managers, and Staff



Leveraging Community and Participant Perspective to Strengthen Research



ICON LEGEND

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Julie Brinker Wijesooriya, Cincinnati Childrens Hospital; Ivy Tillman, Augusta University

Track: Networking; Advancing Justice and Equity

Increasingly HRPPs are recognizing the need to tap into the experience and expertise of the communities they may serve and listen to the perspectives of research participants, to build trust with groups that are underrepresented in research to address issues of health equity. Speakers and attendees will share the strategies their institutions use to include participant and community voices in their HRPPs, including their IRBs, and the impact of these efforts, and the tools that can be used to develop a comprehensive HRPP community engagement model focused on community stakeholder access to research, agency, and advocacy. ***This networking session will take place in Zoom meeting. The use of attendee video is encouraged for participation and interaction with your peers.***

Learning Objectives:








- Discuss the importance of obtaining community and research participant input and how the lack of such efforts can adversely affect health equity and social justice initiatives
- Understand how the involvement of community perspectives and obtaining and acting on feedback from those who take part in studies improves the protection of research participants
- Share methods of promoting the involvement of community members in the design and implementation of research and the dissemination of results (e.g., through community advisory boards, etc.)
- Develop strategies for initial engagement with community stakeholders for the HRPP to serve as resource for education and advocacy

Federal Agency Affiliate Session: Protecting Research Participants During Emergencies: An Introduction to AAHRPP's Element I.1.H

Nichelle Cobb, AAHRPP; Robert Hood, AAHRPP

Note: *This is an affiliate session being run outside of the PRIM&R AER Conference, but is accessible to all AER21 Attendees via the online platform (streaming link will take you to a third-party streaming service (e.g., Zoom, GTM, etc.). This session will only be run live; no on-demand recording will be made available by PRIM&R.*

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|  Livestreamed Session |  On-Demand Session |  Pre-Registration Required |  Additional Fee |
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