



Sunday, November 17: AER19 Preconference Programs

7:00 AM-5:00 PM
On-Site Check-In Open
Breakfast on your own.

Pre-Function Hall C

8:30 AM-12:00 PM
Tips and Tools for Effective IRB Education
Elizabeth Kipp Campbell, MaineHealth System; Sharon Shriver, PRIM&R

Room 201

8:30 AM-4:30 PM
Data-Driven Research: Ethical and Practical Considerations for IRBs
Elizabeth A. Buchanan, University of Wisconsin-Stout; Mary L. Gray, Microsoft Research/Indiana University

Room 210

IRB 101sm
Ada Sue Selwitz, University of Kentucky; David H. Strauss, Columbia University/The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard Medical School

Room 206

QA/QI in Human Subjects Research
Leslie Moser Howes, Harvard T.H. Chan School of Public Health; Sana Khoury-Shakour, University of Michigan; Eunice Yim Newbert, Boston Children's Hospital; Jessica Randall, Yale University; Alyssa A.K. Speier, Harvard T.H. Chan School of Public Health; Delia Y. Wolf, Harvard T.H. Chan School of Public Health

Room 203

Reimagining Your HRPP in the Single IRB Era
Jeremy J. Corsmo, Cincinnati Children's Hospital/University of Cincinnati College of Medicine; Martha Jones, Partners HealthCare System, Inc.; Susan Z. Kornetsky, Boston Children's Hospital; P. Pearl O'Rourke, Harvard Medical School; Megan Kasimatis Singleton, Johns Hopkins University School of Medicine

Room 202

1:00-4:30 PM
Ethical and Regulatory Review of Research Case Studies
Bruce G. Gordon, University of Nebraska Medical Center; Ernest D. Prentice, University of Nebraska Medical Center

Room 201

4:30-5:30 PM
Preconference Programs Networking Reception

Boylston Street Hallway,
 Level 2

ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
Breakout sessions new for 2019	
Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.	Basic – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.



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Pre-Function Hall C

7:00-8:00 AM
A Capella Musical Performance

Join us before the conference starts for a musical performance by a local a capella group. PRIM&R would like to thank Tech Software for supporting this performance.

Pre-Function Hall C/
 Veterans Memorial Auditorium

7:00-8:00 AM
Continental Breakfast to Welcome First-Time Attendees

Attending the AER Conference for the first time can be exciting and overwhelming, which is why PRIM&R invites all first-time attendees to participate in this special breakfast. This event is a great opportunity for first-time attendees to ask questions of the PRIM&R staff and seasoned attendees about the conference and PRIM&R in general, and to learn about strategies and resources that can help them make the most of their conference experience. Pre-registration required.

Ballroom A



8:00-8:15 AM
Welcome from the Conference Co-Chairs

Veterans Memorial Auditorium



8:15-8:40 AM
Remarks from PRIM&R's Executive Director, Elisa A. Hurley, PhD

Veterans Memorial Auditorium



8:40-9:45 AM
Keynote Address by Janine Austin Clayton MD, Associate Director for Research on Women's Health; Director Office of Research on Women's Health, NIH: It's About Quality Construction—Advancing a Foundational Framework for Rigorous Research Relevant to the Health of Women

Veterans Memorial Auditorium



9:45-10:15 AM
Beverage Break With Supporters and Exhibitors
 Join us for coffee in the exhibit hall. PRIM&R would like to thank iMedRIS for helping support this break.

Exhibit Hall C

10:15-11:30 AM: Concurrent Plenary Sessions

Panel I: Diverse Representation in Clinical Trials—Why Does it Matter and How Do We Move Forward?
Moderator: Barbara E. Bierer, The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard Medical School
Panelists: Denise Anne Dillard, Southcentral Foundation; Tesheia Johnson, Yale University School of Medicine; Paul Underwood, Boston Scientific Corporation

Ballroom B

The prescribing and marketing of drug products to subpopulations for whom response and tolerability have not been studied represents a shortcoming in medical science and raises justice-related concerns about access to appropriate treatment. Despite healthcare and ethical mandates, little progress has been made towards ensuring the composition of clinical trials reflects the diversity of the population at large. When historically under-represented groups remain understudied, variability in treatment response and tolerability go undetected. Although scholars caution against inappropriate use of population descriptors, such as race as a variable in clinical research, considerable data support the scientific and social value of inclusiveness in clinical trial enrollment across sex, gender, race, ethnicity, age, and socio-demographic factors to ensure study findings are relevant to all populations who stand to benefit from new interventions. What is the scientific value of diversity and inclusiveness in drug development? How do we understand the mandate for diversity on a global scale? What conceptual, cultural, organizational, and scientific factors impede progress? This session brings together leaders from industry and academia to discuss the importance of diversifying trials, with reference to success stories within indigenous communities and the international context. The panel will propose and discuss actionable and scalable solutions to address impediments at the level of trial development and implementation to promote the goal of diversity in enrollment and to facilitate necessary subgroup analyses in clinical trials.



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Monday, November 18: AER19

10:15-11:30 AM: Concurrent Plenary Sessions

Panel II: Using Social Behavioral Data to Provide Insight into Health-Related Experiences

Moderator: Kimberly M. Nelson, Boston University School of Public Health

Panelists: Teresa Doksum, Abt Associates, Inc.; Luke Gelinis, Advarra/The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard Medical School; Julie Slayton, University of Southern California

This panel will address questions and concerns that arise for IRBs as they review studies that may appear biomedical, but in actuality represent SBER. Studies may be related to health outcomes, yet focus primarily on participants' experiences and behaviors (e.g., collecting social media posts from pregnant women with cancer to focus on their experience with pregnancy, not the progression of their disease; collecting Twitter data of smoking study participants to see their level of smoking-related advertising exposure; collecting Facebook data documenting interactions between a LGBTQ support group leader and LGBTQ participants on risky behavior in an effort to decrease risky behavior, etc.). The panel will also address how IRBs can help educate biomedical and social science researchers on the "rules" or ethical considerations of working in the social media space while conducting SBER.

Veterans Memorial Auditorium



Panel III: What to Expect When We Sequence Expecting Moms

Moderator: Jeremy Sugarman, Johns Hopkins University

Panelists: Ingrid A. Holm, Boston Children's Hospital/Harvard Medical School; Josephine M. Johnston, The Hastings Center; Haley K. Sullivan, Duke University

Noninvasive prenatal testing can be used to perform prenatal whole genome sequencing (PWGS) by collecting fetal DNA from a simple maternal blood draw. Although prenatal genome sequencing isn't yet part of routine clinical care during pregnancy, many believe it will be shortly, as the price of sequencing continues to plummet and commercial entities in the health and ancestry space push the public to obtain more personal genetic information. Public interest in PWGS may also be on the rise as concerns increase about conducting research on germline CRISPR therapies, and the recognized need for international engagement on that technology makes any policy consensus on germline CRISPR unlikely in the near future. This panel will explore the ethical issues surrounding clinical research into PWGS, both in terms of population justice and in terms of protecting the autonomy and beneficence interests of future persons. Recent research indicates that expecting parents and treating clinicians may have different priorities and concerns. This panel will also explore what types of genetic information should be returned to prospective parents who undergo clinical trials of PWGS and how directive healthcare providers should be when communicating the information.

Ballroom C



11:30 AM-12:45 PM

Networking Luncheon

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

Exhibit Hall D

11:30 AM-12:45 PM

Meet the Author Luncheon and Book Signing: *The Perils of Partnership: Industry Influence, Institutional Integrity, and Public Health*

Moderator: Suzanne M. Rivera, Case Western Reserve University

Author: Jonathan H. Marks, Pennsylvania State University

Participate in a vibrant discussion of *The Perils of Partnership: Industry Influence, Institutional Integrity, and Public Health* by Jonathan H. Marks, director of the Bioethics Program at Penn State, and affiliate faculty in Law, Public Policy and International Affairs. In the book, Professor Marks shows how public-private partnerships and multi-stakeholder initiatives can create "webs of influence" that undermine the integrity of public health agencies; distort public health research and policy; and reinforce the framing of public health problems and their solutions in ways that are least threatening to the commercial interests of corporate "partners." He also offers a novel framework to help public bodies identify the systemic ethical implications of their current or proposed relationships with industry actors. Attendees will have the opportunity to hear from and participate in a discussion with Professor Marks about his book, and he will be available to sign books after the lunch. Professor Marks' book is available wherever books are sold online, and copies will be sold at the conference.

Note: Lunch will be served in this session and pre-registration is required. The formal presentation will start at 11:45 AM.

Ballroom A



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11:30 AM-12:45 PM

SBER Network Luncheon

Cecilia Brooke Chalka, University of Nevada, Reno; Linda E. Petree, The University of New Mexico

Join the [SBER Network](#) over lunch for an interesting and very relevant discussion! Identifying and addressing noncompliance in human research is one of an IRB's most important responsibilities. However, serious and continuing noncompliance are not specifically defined by regulations and there is a lack of guidance from OHRP. This lunch session will explore the meaning of noncompliance including variance among institutional definitions and reporting requirements, with a specific focus on noncompliance in SBER. There will be a short presentation, small group discussions of case studies, as well as interactive audience polling activities. All SBER Network members are welcome to attend (note: the SBER Network is a member benefit; contact sber@primr.org to join the Network). **Note:** Lunch will be served in this session and pre-registration is required.

Room 200



12:15-12:35 PM

Industry Expert Theater: Overview of the CIP® Exam

Join us in the AER19 Industry Expert Theatre to learn the ins and outs of the CIP® examination. During this time, CIP® Council members will provide an overview on how the examination is constructed, and will review sample examination questions and answer options. Please join us for this unique insight into the CIP® exam! If you are unable to join us, but would like to learn more about the CIP exam while on-site at the conference, stop by the PRIM&R Booth or email certification@primr.org, for more information.

Exhibit Hall C

12:15-12:45 PM

Meet and Greet With Supporters and Exhibitors

Network with the AER19 Supporters and Exhibitors, and learn about their important services.

Exhibit Hall C

12:15-12:45 PM

Federal Agency Office Hours

During this time, representatives from select federal agencies will be available to answer attendee questions, engage in dialogue, provide clarification, and/or direct attendees to additional resources. Attendees are encouraged to come prepared with questions, which will be taken on a first come basis. AAHRPP, Inc., DOD, DOE, DOJ, FDA, OHRP, SACHRP, and VA will be present at this time.

Exhibit Hall C



Breakout Sessions Series A, 1:00-2:15 PM

A1: The Seven Habits of Highly Effective and Flexible IRBs (*Flexibility and Innovation in IRB Processes Track*)

Jeff A. Cooper, WIRB-Copernicus Group; Jonathan M. Green, Office of Human Subjects Research Protections, NIH

During this session, attendees will learn how to identify ways the IRB can more effectively protect subjects, while also becoming more efficient. Expert presenters will explore ways to reduce time-consuming activities that can be eliminated, as well activities better served by other components of the HRPP in order to focus more effectively on the critical requirements of the IRB. During this session, speakers and attendees will:

Room 312



- Differentiate between IRB and institutional obligations and identify what activities may be best addressed by non-IRB components of an HRPP
- Discuss ways to streamline the IRB submission and review procedures, including how technology can be leveraged to improve processes
- Identify mechanisms to recognize and resolve issues before they go to the IRB for review

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Monday, November 18: AER19

Breakout Sessions Series A, 1:00-2:15 PM

A2: Defining Roles and Expectations for the Non-Scientist and Unaffiliated IRB Member—De-Constructing Regulatory and Research Terminology (*Educating and Training Track*)

Room 101

Glenn Ellis, *Strategies for Well-Being, LLC/Harvard University Medical School*; Michelle M. Feige, *AAHRPP, Inc.*; Nancy A. Olson, *Consultant*

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



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

A3: Ethics and Governance in Learning Healthcare Systems (*Empirical Research Ethics Track*)

Room 102

Steven Joffe, *University of Pennsylvania Perelman School of Medicine*; Nancy E. Kass, *Johns Hopkins University Bloomberg School of Public Health*; Paul Christopher McLean, *Patient/Family Advocate/Harvard Medical School*

The National Academy of Medicine defines learning healthcare systems as those in which “knowledge generation is so embedded into the core of the practice of medicine that it is a natural outgrowth and product of the healthcare delivery process and leads to continual improvement in care.” Learning healthcare systems bridge traditional boundaries between quality improvement and research, and so pose challenges for conventional regulatory frameworks. Based on the presenters' empirical work, this session will address the ethical challenges that such systems face, the governance mechanisms they have put in place, and the ways in which they might engage patients and families in governance and oversight. Before attending this session, attendees should be familiar with the regulations governing biomedical research in the United States in order to understand the challenges that learning healthcare systems pose. During this session, speakers and attendees will:



Advanced

- Identify the ethical challenges that learning healthcare systems face
- Describe the governance mechanisms that learning healthcare systems can use to ensure safe, high-quality, respectful learning
- Share how patients and families can contribute to governance of learning healthcare systems

A4: FDA Clinical Holds and 21 CFR 50 Subpart D (*FDA-Regulated Research Track*)

Room 206

David G. Forster, *WIRB-Copernicus Group*; Kevin A. Prohaska, *Office of Good Clinical Practice, FDA*; Donna L. Snyder, *Office of Pediatric Therapeutics, FDA*

A clinical hold is an order issued by the FDA to the sponsor of an Investigational New Drug (IND) application to delay a proposed clinical investigation or to suspend an ongoing investigation. All or some of the investigations conducted under an IND application may be placed on clinical hold. When a proposed study is placed on clinical hold, subjects may not be given the investigational drug. When an ongoing study is placed on clinical hold, no new subjects may be recruited to the study and given the investigational drug (patients already in the study are expected to be taken off therapy involving the investigational drug unless treatment continuation is specifically permitted by FDA in the interest of patient safety). The requirements of Subpart D (Additional Safeguards for Children in Clinical Investigations) can be the basis for a clinical hold. During this session, speakers and attendees will:



- Review the FDA’s grounds for imposing a clinical hold and the procedures for issuing a clinical hold
- Discuss situations where deficiencies in 21 CFR 50 Subpart D (Additional Safeguards for Children in Clinical Investigations) may result in a clinical hold
- Share best practices for IRBs to stay informed about the FDA status of a proposed or ongoing study

A5: Going Global for the First Time—Considerations for Reviewing International Research (*Global Research Track*)

Room 103

Delia Y. Wolf, *Harvard T.H. Chan School of Public Health*; Rachel Zand, *University of Toronto*

This session is intended for IRB members and staff of US IRBs that oversee human subjects research outside the US; however, the concepts could be applied more broadly. This session will describe the international research landscape and



Basic

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highlight associated IRB review challenges. It will also provide an overview of applicable US regulations and international guidelines, and share available resources to identify applicable local laws and regulations. Speakers will share best practices for reviewing transnational research. Attendees are encouraged to bring their questions/challenges for discussion with the group. During this session, speakers and attendees will:

- Discuss the common challenges facing US IRBs when reviewing international research
- Review various approaches to eliminating or mitigating challenges, emphasizing possible US regulatory flexibility
- Examine institutional policies/best practices for US IRB review of transnational research
- Describe ways that US IRBs may engage and partner with local ethics committees

Monday, November 18: AER19

Breakout Sessions Series A, 1:00-2:15 PM

A6: How to Investigate, Mitigate, Report, and Learn from Noncompliance—Avoiding Pitfalls and Seizing Opportunities for Improvement (Institutional Officials and HRPP Leadership Track) Room 310

Robert Hood, AAHRPP, Inc.; Julie Kaneshiro, OHRP (resource person); Scott J. Lipkin, Ankura Consulting

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



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

A7: Back to Basics—What Is the Common Rule, When Does it Apply, and What Does it Mean? (IRB Basics Track) Room 309

George Gasparis, PEER Consulting Group; Jaime O. Hernandez, OHRP; Judy Matuk, HRP Consulting Group

While most people in the research world have heard of the Common Rule, some are uncertain as to its scope. This session will provide basic training on what it means when the Common Rule applies and when it does not. Speakers will provide a brief overview of the scope of the Common Rule, and explain the implications to institutions for research that falls inside or outside the rule. During this session, speakers and attendees will:

Basic

- Provide a brief review of the scope of the Common Rule
- Highlight examples of activities that are and are not covered by the Common Rule Discuss what it means for research that falls within the scope of the Common Rule
- Outline institutional considerations and best practices for research that falls outside the scope of the Common Rule, including organizational considerations for research oversight more broadly
- Describe what a Federalwide Assurance is and when it is needed

A8: Tag, You're it! You've Been Appointed an IRB Chair, Now What? (IRB Chairs Track) Room 300

Francis J. DiMario, Connecticut Children's Medical Center/University of Connecticut School of Medicine; R. Peter Iafrate, University of Florida

This session is a primer for new or inexperienced IRB chairs, and will provide insight on how to become an effective IRB chair. During this session, speakers and attendees will:

Basic

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- Review a step by step guide on how to become an effective IRB chair
- Discuss the role of the IRB chair before, during, and after the board meetings
- Present case studies that demonstrate various situational learning examples

Monday, November 18: AER19

Breakout Sessions Series A, 1:00-2:15 PM

A9: The Etiquette and Necessity of Communication in the Single IRB World (IRB Operations Advanced Track)

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

- Review what local context information a reviewing IRB should collect, both about relying institutions and study implementation, how to tailor it for the study type, and mechanisms for retaining that information to reduce burdens on the relying institution
- Explore how to engage relying institutions so they address noncompliance and unanticipated problems (e.g., in the development of corrective action plans and reports to federal agencies and authorities)
- Determine when to reach out to relying institutions to obtain input on amendments
- Identify what information to include in approval notices or other documents to assist the relying institution with their oversight responsibilities
- Share writing policies that are accessible to and take into account the perspectives of relying institutions and relying site study teams

Note: this session will be repeated on November 20, 10:00-11:15 AM.

Room 304



A10: Management of Incidental Findings (IFs) in Pragmatic Clinical Trials (PCTs) (Pharma/Biotech Perspectives Track)

Juli Bollinger, Johns Hopkins University; Debra J.H. Mathews, Johns Hopkins University; Stephanie Morain, Baylor College of Medicine; Jeremy Sugarman, Johns Hopkins University (moderator)

Incidental and secondary findings pose numerous practical, ethical, and legal challenges for researchers, clinicians, institutions, and patients/research participants. While considerable attention has focused on IFs in genetics and imaging research studies, these issues have not been broadly considered in the context of PCTs. However, managing IFs in the context of PCTs poses challenges due to both the large scale of many PCTs, and the fact that many PCTs are done without patient consent or even their awareness of being involved in the research activity. In this session, speakers will present a conceptual overview of the issue, as well as results from new empirical research to inform deliberations about the ethical management of IFs in PCTs. During this session, speakers and attendees will:

- Discuss the ethical challenges for management of IFs in the context of PCTs
- Review original qualitative interview data with key PCT stakeholders on the ethical management of IFs in PCTs
- Go over original focus group data regarding patients' views on the ethical management of IFs in PCTs

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A11: Legal and Regulatory Changes: A Year in Review (*Legal Considerations for HRPPs Track*)

Holly Fernandez Lynch, *University of Pennsylvania Perelman School of Medicine*; Laura Odwazny, *DHHS*; Michele Russel-Einhorn, *Advarra*

A lot has happened this year! Get up to speed with this session designed to bring you the highlights and breaking news since last year's AER Conference. How are recent legal and regulatory changes fundamentally affecting research? What should institutions be ready for in the coming months and years? Get answers to these questions and more through this session's issue-spotting exploration and analysis of changes in laws, regulations, and guidance issued by FDA, HHS, and NIH.

During this session, speakers and attendees will:

- Identify recently proposed and adopted legislative and regulatory initiatives affecting research
- Illustrate the likely impact on current practices and evaluate the importance of change
- Evaluate whether further change is necessary and/or likely forthcoming

Note: *this is an overview session; speakers will not review each change in detail, but will endeavor to point attendees to other conference offerings relevant to each topic covered.*

Room 302



Monday, November 18: AER19

Breakout Sessions Series A, 1:00-2:15 PM

A12: Operationalizing Data Sharing Policies—Challenges and Solutions

(*Research Involving Data and Biospecimens Track*)

Shannon Sowards, *Harvard University*; Carrie D. Wolinetz, *Office of Science Policy, NIH*

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

- Review the NIH's Genomic Data Sharing Policy
- Discuss the ethical and regulatory implications of data sharing
- Identify potential challenges for organizations and IRBs in complying with the policy
- Share examples to discuss operational solutions and review processes to facilitate compliance

Room 311



A13: Research With the Vulnerable—The Basics and Beyond (*Populations Requiring Additional Protections Track*)

Bruce G. Gordon, *University of Nebraska Medical Center*; Corinne Rogers, *New York State Psychiatric Institute*

During this session, speakers will discuss an expanded view of vulnerability beyond what is outlined in the regulations, including: diminished capacity, cultural sensitivities, and power differentials (e.g., students as subjects). Attendees should be prepared with a basic understanding of the regulations that cover vulnerable populations. During this session, speakers and attendees will:

- Share examples of different types of vulnerabilities and explore how to consider and deal with them in the context of clinical research
- Discuss the threshold questions an IRB should address before permitting research with these subjects
- Review examples of risks particular to these subjects that may differ from those usually considered
- Show how to incorporate appropriate additional protections into informed consent

Room 203



A14: Staying on Top of It All—Practical Strategies for Implementing Postapproval Monitoring (PAM) (*SBER Track*)

Cecilia Brooke Cholka, *University of Nevada, Reno*; Andrea R. McDowell, *Seattle University*

PAM is an important strategy for ensuring compliance of human subjects research, but can also be used as a creative way to educate researchers about IRB expectations and the ethical conduct of research. While PAM programs can be useful, they can also be difficult to implement, especially for offices with smaller staffs or large, diverse research portfolios. This session will discuss practical ways to implement a PAM program by sharing tools that cover common office practices, selection of projects to monitor, PAM activity options, messages, and reports. During this session, speakers and attendees will:

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- Discuss practical implementation and tools for PAM in a SBER IRB
- Explore a variety of PAM models that fit different institutional needs

A15: Privacy and Security Risks in Research With Wearable Technology

Room 210

(Research Conducted in the Digital World Track)

Megan Doerr, Sage Bionetworks; Adarsh K. Gupta, Rowan University; Sara Meeder, Maimonides Medical Center

Wearable technology has great potential to expand healthcare quality, ease data collection, and improve personal wellness. However, wearable technology also raises significant privacy and security challenges. Mobile-sensor data provides researchers unprecedented opportunities to collect objective data without patients' awareness. For instance, GPS data provides geo-exposure risk, movement patterns, and activity levels, among other data, which may disclose privacy information about the user. This session will cover the risks associated with wearable technology and strategies to lower those risks. During this session, speakers and attendees will:



Basic

- Explain what data types are collected via wearable technology
- Assess the research data risk with wearable technology
- Discuss strategies for lowering risk in research with wearable technology

Monday, November 18: AER19

Breakout Sessions Series A, 1:00-2:15 PM

A16: The Regulatory Intersection of Research Misconduct and Human Subjects Protections

Room 204

(Responsible Conduct of Research Track)

Lisa R. Buchanan, OHRP; Kate Gallin Heffernan, Verrill Dana LLP; Jim Kroll, National Science Foundation

Two separate, yet overlapping, regulatory structures govern research with human subjects: the Common Rule (45 CFR 46) and research misconduct (42 CFR 93). These regulations have different requirements and enforcement mechanisms, yet suspected violations of both sets of regulations often occur simultaneously. How should IRBs handle this? What do they need to know? During this session, speakers and attendees will:



- Discuss of the scope and focus of various regulations governing research with human subjects and research misconduct, and the mechanisms prescribed for oversight and investigation
- Identify the overlapping and independent responsibilities of committees tasked with investigating possible violations of human subjects research regulations and research misconduct
- Explore various scenarios and case studies highlighting appropriate mechanisms and best practices for handling situations in which violations of human subjects and research misconduct regulations may have occurred simultaneously

A17: Challenges and Opportunities for Institutions With Small Research Programs *(Small Research Programs Track)*

Room 107

Eric Allen, HRP Consulting Group; Fredeswinda Rivera-Ocasio, Interamerican University of Puerto Rico

Small research programs are identified as having fewer than 200 open protocols and three or fewer IRB staff. This interactive session will review the challenges faced by small to mid-sized academic IRBs and possible solutions. During this session, speakers and attendees will:



- Identify specific challenges and opportunities encountered by small research programs
- Provide possible solutions to overcome these challenges and how to harness opportunities
- Offer guidance on how best to use the resources available and comply with the regulations

A18: Certificates of Confidentiality (CoCs) *(SBER Track)*

Room 111

Adam C. Berger, Office of Science Policy, NIH; Lyndi Lahl, Office of Extramural Research, NIH; Mary Ramirez, University of Michigan

HHS now automatically issues CoCs for all NIH-funded studies involving the collection of identifiable, sensitive data. The NIH specifies that "identifiable, sensitive information" includes data where an individual is identified, or where there is a "very small risk" of an individual being identified through scientific practices or statistical methods. CoCs often cause confusion for SBER investigators and IRBs, particularly around the protections they afford and mandatory reporting. During this session, speakers and attendees will:

Basic

- Outline the changes to the CoC system under the 21st Century Cures Act
- Review the scope of legal protection and privilege afforded to researchers under a CoC, including a review of the

ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	Breakout sessions new for 2019
CIP eligible	
Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.	Basic – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.



- applicable regulations and federal guidance
- Discuss the implications for informed consent, and how CoCs interface with other protective laws and possible disclosures

A19: Fundamental Issues in Qualitative Research (SBER Track)

Patricia B. Condon, University of New Hampshire; Julie F. Simpson, University of New Hampshire

In qualitative inquiry, researchers study phenomena in their natural settings where the purpose is contextualization, interpretation, and/or understanding the perspectives of others. The role of qualitative researchers in a study is characterized by their personal involvement and empathetic understanding. This session will help IRB members facilitate the review of qualitative research applications by providing a better understanding of this type of research and the challenges faced by researchers using this paradigm, and will educate qualitative researchers on issues this research paradigm can present during review. Before attending this session, attendees should have a basic knowledge of SBER methodologies and of 45 CFR 46. During this session, speakers and attendees will:

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

Room 306



Monday, November 18: AER19

Breakout Sessions Series A, 1:00-2:15 PM

A20: Two Hats, One Head—When IRB Members Are Also Investigators (Educating and Training Track)

Stephanie Collins-Reed, New York State Psychiatric Institute/Columbia University Vagelos College of Physicians & Surgeons; Ilene F. Wilets, Icahn School of Medicine at Mount Sinai

Researchers who are also IRB members are tasked with writing protocols and, separately, reviewing protocols, which require skill sets and perspectives not entirely independent from one another. While these "dual-role" individuals often hold concordant perspectives in addressing these tasks, there are times when IRB and investigator perspectives conflict. This session will present a framework elucidating the tension between the two roles (two hats, one head) and provide attendees with practical guidance to manage this intrapersonal conflict when it arises. During this session, speakers and attendees will:

- Identify the challenges for IRB members who also conduct human subjects research
- Provide case-based scenarios illustrating the types of dual-role conflicts that sometimes occur during an IRB meeting
- Share practical strategies for managing this conflict, enabling the dual-role IRB member to leverage their unique position for instructive and incisive protocol review

Room 109



A21: An Introduction to the FDA and Their Regulations for the Non-Scientist IRB Member

(FDA-Regulated Research Track)

Janet Donnelly, Office of Good Clinical Practice, FDA; Patrick J. McNeilly, Office of Good Clinical Practice, FDA

FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices, and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. This session introduces the non-scientist IRB member to FDA's mission and organizational structure, and will provide a general overview of the FDA regulations for drugs, biologics, and medical devices. During this session, speakers will:

- Describe FDA's mission and present a high-level overview of FDA's organizational components
- Discuss FDA's regulatory framework and responsibilities
- Introduce the FDA regulations for drug, biologic, and medical devices studies

Room 108



A22: From Non-Exempt to Exempt and Back Again—Navigating Exemption 2iii (IRB Operations Advanced Track)

Laura R. Brasch, Uniformed Services University of the Health Sciences; Petrice B. Longenecker, Uniformed Services University of the Health Sciences

This session will help attendees navigate the changes to exemption category 2, which allows data collection to include sensitive data or data that could put subjects at risk. Speakers will focus on how to determine when a study qualifies for exemption 2 with a limited IRB review, when it should be reviewed by the IRB, and whether IRB review triggers a greater

Room 104



ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
Breakout sessions new for 2019	
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than minimal risk determination. Before attending this session, attendees should have experience with social behavioral studies that employ data collection methods using surveys, interviews, questionnaires and focus groups, an understanding of the exemption categories, particularly determining historically which studies can be considered exemption 2 versus requiring IRB review (under the pre-2018 Common Rule), and be familiar with applying the minimal risk definition and making determinations of what types of studies are greater than minimal risk. During this session, speakers and attendees will:

- Review the changes to exemption category 2
- Describe when to use a limited IRB review versus the full 7 at 111
- Determine whether surveys, interviews, and questionnaires can be considered "greater than minimal risk"

A23: Making Limited Review Work Without Reinventing the Wheel (IRB Operations Advanced Track)

David A. Borasky, Jr., WIRB-Copernicus Group; Teresa Doksum, Abt Associates, Inc.

Limited review is a new regulatory concept that was incorporated into the revised Common Rule as part of the review process for exempt research under categories §46.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (8)). However, the revised Common Rule does not describe how the limited IRB review mechanism should be implemented, and there has been no guidance from OHRP or SACHRP recommendations. In this session, speakers will describe the limited IRB review requirement and describe a process for managing the review without adding significant burdens to IRB programs. During this session, speakers and attendees will:

- Review the regulatory requirements related to limited IRB review
- Describe a process for conducting limited IRB review
- Go over documentation requirements

Room 313



Monday, November 18: AER19

2:15-2:45 PM

Beverage Break With the Supporters and Exhibitors

Join us for coffee in the exhibit hall. PRIM&R would like to thank HRP Consulting Group for helping support this break.

Exhibit Hall C

Breakout Sessions Series B:, 2:45-4:00 PM

B1: Standard of Care, Medical Innovation, or Research—How Should We Decide?

(Flexibility and Innovation in IRB Processes Track)

Alexander M. Capron, University of Southern California; Robert W. Frenck, Jr., Cincinnati Children's Medical Center/University of Cincinnati; Michele Russel-Einhorn, Advarra, Inc.

A frequent regulatory issue is whether a practice conducted by a physician or an institution, when consistently practiced in that institution, but novel and not yet adopted by the community, counts as medical innovation or research. For example: when a physician or group of physicians want to collect data on their consistently provided, but unique/novel practice (i.e., this practice "would be provided anyway" to their patients), is this standard of care, medical innovation, or research? If it is research, how should it be reviewed? This issue is important as it comes up frequently in IRB review, although it may be addressed differently by IRBs. This session will present the issue, discuss potential ways of addressing it, and attempt to problem solve the best treatment of these common situations. This session will make heavy use of active learning techniques, such as small group work, case studies, hands-on activities, and interactive discussion, and presumes sufficient experience and understanding to actively contribute to the discussion of and solution to these problems. This session will not review basic concepts. During this session, speakers and attendees will:

- Recognize how standard of care, medical innovation, and research are highly intertwined in medical contexts
- Analyze a case(s) where an IRB is faced with the decision of how to regulate a particular study, and the strengths and weaknesses of different approaches
- Suggest best practices when faced with this type of situation

Room 302



B2: Dear IRB, Please Tell Me What to Do and How to Avoid Mistakes (Educating and Training Track)

Ximena L. Levy, Florida Atlantic University; Muhammad Waseem, Lincoln Medical Center/Weill Cornell Medical College New York

This session is intended for researchers, and provides the investigator perspective on HRPP/IRB processes. Novice researchers are likely to welcome guidance on how to avoid common mistakes and may benefit from a liaison between researchers and HRPP staff. Speakers will include practical examples to better demonstrate the review process and improve HRPP efficiency via communication with research teams. During this session, speakers and attendees will:

- Explain the IRB's focus in reviewing a protocol and the review process
- Understand the importance of effective communication between investigators and IRBs

Room 200



ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
Breakout sessions new for 2019	
Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.	Basic – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.



- Describe common errors in IRB applications and how these can be avoided

B3: Why Informed Consent Doesn't Work and Why the Revised Common Rule Won't Fix It

(Empirical Research Ethics Track)

Stephanie S. Cargill, Saint Louis University

The revised Common Rule includes revisions to the "content, organization, and presentation of information included in the consent form and process." While revisions to the Common Rule have yet to be tested, previous interventions on the means of transmitting information to achieve informed consent have seen limited success, despite the amount of time and energy devoted to developing and implementing them. A central reason these interventions fail may be they fundamentally misunderstand how potential participants communicate and come to decisions regarding research. This session will review the barriers to participants understanding the informed consent information may not be based solely in the way information is transmitted to participants, which is the current focus of these interventions. Rather, following the health communications field in thinking about communication as a more complex phenomenon that is bidirectional, impacted by physical, psychological, social, and relational contexts, as well as the social norms that govern the broader context of which consent for research, is important. Until those working on informed consent recognize how these factors can serve as barriers and facilitators to communication, even the most radical improvements to the "content, organization, and presentation of information" will have minimal impact. During this session, speakers and attendees will:

- Learn about empirical interventions and their (limited) results around improving informed consent
- Explore the health communication literature relevant to how the human subjects research field approaches informed consent
- Engage new avenues of intervention based on the insights of health communication

Room 210



Monday, November 18: AER19
Breakout Sessions Series B, 2:45-4:00 PM

B4: Investigational Device Exemptions (IDE), Mobile Medical Applications, and IRB Review

(FDA-Regulated Research Track)

Soma Kalb, Center for Devices and Radiological Health, FDA; Bakul Patel, Center for Devices and Radiological Health, FDA; James Riddle, Advarra

In general, the IDE regulations apply to clinical investigations of medical devices designed to determine safety and effectiveness. When do you need an IDE for a clinical investigation of a medical device? What about mobile applications? When does a mobile application meet the definition of a medical device under the Food, Drug, and Cosmetic Act, and how does FDA intend to apply its regulatory authorities to mobile medical applications? IRBs may struggle with these questions and what their review responsibilities are when a protocol involves a mobile medical application. During this session, speakers and attendees will:

- Share a basic overview of the applicability of the IDE regulations that address when an IDE is required
- Distinguish when mobile applications meet the definition of a medical device
- Discuss FDA's current approach to applying its regulatory authorities to oversight of mobile medical applications
- Provide IRBs with a review framework for studies involving mobile medical applications and suggest policies and procedures to develop to ensure HRPPs remain relevant in a tech savvy world

Room 311



B5: Foreign Influence in Research—Foreign Research Support, "Foreign Components," and Personal Income from Foreign Entities

(Global Research Track)

Susan Stayn, Stanford University; Nicholas A. Wallace, Ropes & Gray LLP

PHS regulations require the reporting of investigators' foreign financial interests that create a conflict of interest (including when the financial interest arises from a foreign government or nonprofit institution). The PHS regulations also require reporting of "other support" and "foreign components" of a PHS-supported project. "Foreign components" are defined as any significant scientific element or segment of a project outside the US, either by the recipient or by a researcher employed by a foreign organization. Recent investigation by the NIH and FBI reveal that some research institutions have failed adequately to collect and report this information. What are the consequences of failure to report and how can your institution prevent this? This session will focus on the issues with using NIH grant funds abroad, and use specific recent cases to highlight specific steps organizations can take to protect themselves and their researchers. During this session, speakers and attendees will:

- Review recent investigations of US academic institutions that have failed to adequately report "foreign components" of federally-funded project
- Examine how PHS regulations and funding agency guidance apply to research conducted abroad
- Consider preventive steps academic institutions can take to ensure foreign research support is conducted in

Room 204

ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
Breakout sessions new for 2019	
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compliance with US law

B6: Use It or Lose It—Re-Calibrating and Re-Engineering the HRPP/IRB Office in Response to the Changing Regulatory Climate (*Institutional Officials and HRPP Leadership Track*)

Linda M. Coleman, Yale University; Michele Kennett, University of Missouri

Changes to NIH policies, the 21st Century Cures Act, and the revisions to the Common Rule are driving many changes to operational procedures in the HRPP/IRB office. As a result, institutions are busy redefining workflows, job descriptions, and staffing levels. For example, the paradigm shift to single IRB (sIRB) review of multi-site research has resulted in institutions creating reliance departments whose sole responsibility is to oversee studies whose IRB oversight has been ceded to a sIRB and/or have had a re-characterization of existing staff roles, an addition of staff, and redistribution of traditional IRB activities to other components of the HRPP. This session will review the logistical details of work-load reallocation and departmental staffing and budget requirements at academic medical centers, universities, and hospitals. Before attending this session, attendees should have an understanding of the revised Common Rule, familiarity of the revised Common Rule's impact on IRB operations, and an understanding of operational and compliance considerations related to sIRB.

During this session, speakers and attendees will:

- Review the various operational changes that are required to comply with the evolving research regulatory environment, and discuss the budgetary and structural impact
- Share examples of revised job descriptions, and approaches to staffing levels in response to changing operational systems
- Discuss resource allocation related to reliance oversight, limited IRB review, broad consent, and other newly created procedural requirements
- Provide practical strategies to assist organizations in re-evaluating their own staffing structures

Room 312



Monday, November 18: AER19
Breakout Sessions Series B:, 2:45-4:00 PM

B7: You'll Know it When You See it, or Will You? Exploring the Regulatory Definitions for "Human Subjects Research" (*IRB Basics Track*)

Warren Capell, University of Colorado Denver; Yvonne Lau, OHRP; Linda E. Petree, The University of New Mexico

Interpretation of key terms in the regulatory definitions, including "about whom," "systemic," and "generalizable" can be difficult. This basic session will tease apart the regulatory definitions of "human subjects research," highlighting key terms designed to facilitate interpretation and application for both the routine and grey fact-scenarios. During this session, speakers and attendees will:

- Review the regulatory definitions for "research" and "human subjects"
- Define a process, including criteria, for determining when an activity is research, and whether a study involves human subjects
- Examine tricky issues related to the definition of human subjects research, including when quality improvement activities constitute "research" under the regulatory definition and therefore might fall under the revised Common Rule

Room 309

Basic

B8: The Revised Common Rule—Operational Considerations for IRB Chairs (*IRB Chairs Track*)

Jeremy J. Corsmo, Cincinnati Children's Hospital/University of Cincinnati College of Medicine; Barbara C. Engel, Children's Hospital of Philadelphia; Julia G. Gorey, OHRP (resource person)

Speakers will discuss key operational challenges that directly affect the IRB chair and IRB review as a result of the revised Common Rule. During this session, speakers and attendees will:

- Identify key operational challenges with implementation of the revised Common Rule
- Discuss how to reconcile differences between the revised Common Rule, FDA, and Department of Justice regulations
- Provide case examples and discuss various operational solutions

Room 310

B9: Taking the Plunge—Transitioning Studies to the Revised Common Rule (*IRB Operations Advanced Track*)

Lauren Hartsmith, OHRP; John Heldens, University of Colorado Denver, Anschutz Medical Campus; Nathalia Henry, Northwestern University

Many organizations working to adapt to the revised Common Rule are facing the decision of whether or not to transition existing research to the new requirements and, more importantly, how to operationalize this change. With the help of representatives from OHRP, this session will review the transition provisions outlined in the revised Common Rule, and discuss varied approaches to practical implementation of this transition. Speakers will review which studies to transition, the best timing for transition, what documentation is needed to reflect the change, and how the change and its implications

Room 306



ICON KEY

Double session	Call for Session Proposal	
Pre-registration required	Recorded session	Breakout sessions new for 2019
Reviews changes to the Common Rule	CIP eligible	
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should be communicated to researchers. Lessons learned to date from organizations that have begun to transition studies will be shared and tools to help manage the change will be reviewed. Before attending this session, attendees should have basic knowledge of the regulatory requirements related to informed consent and be familiar with the new key information requirement of the Revised Common Rule. During this session, speakers and attendees will:

- Review the transition provisions for the revised Common Rule
- Discuss different approaches for transitioning research and managing the change, and share lessons learned from making the change
- Explore tools to assist with the transition process

B10: Right to Try—Legal, Ethical, and Implementation Issues (*Pharma/Biotech Perspectives Track*)

Richard Klein, GE2P2 Global; Holly Fernandez Lynch, University of Pennsylvania Perelman School of Medicine; Christine MacCracken, Janssen, Pharmaceutical Companies of Johnson & Johnson

On May 30, 2018, President Trump signed into law the Trickett Wendler, Frank Mongiello, Jordan McLinn and Matthew Bellina Right to Try Act, offering a new pathway—distinct from FDA’s longstanding Expanded Access pathway—for patients to access investigational products outside of clinical trials. This session will explore the key attributes of both Expanded Access and Right to Try, including legal and ethical considerations. Participants will learn how industry is responding to Right to Try, as well as how to guide their own institution’s policy and practice regarding pre-approval access to investigational products. The session will also include a group discussion about whether and how both pathways have arisen and been addressed at their institutions, as well as the factors contributing to pathway selection. During this session, speakers and attendees will:

- Describe and differentiate key tenets of Expanded Access and Right to Try
- Identify ethical considerations for investigational use outside of the clinical trial setting
- Understand key industry perspectives on pre-approval access
- Review the patient protections afforded by each pathway and the role of the institution in determining how they will be applied
- Develop key considerations for institutional policy for Right to Try and Expanded Access

Room 203



Monday, November 18: AER19

Breakout Sessions Series B; 2:45-4:00 PM

B11: Navigating State Law Differences in the Era of Single IRB (sIRB) Review (*Legal Considerations for HRPPs Track*)

David G. Forster, WIRB-Copernicus Group; Michael J. Linke, University of Cincinnati College of Medicine

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

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

Room 202



B12: Data and Biospecimens Across International Borders (*Research Involving Data and Biospecimens Track*)

Edward E. Bartlett, OHRP (resource person); Marianna J. Bledsoe, Marianna J. Bledsoe Consulting, LLC/International Society for Biological and Environmental Repositories; Marianne K. Henderson, National Cancer Institute; A. Roxana Lescano, United States Naval Medical Research Unit No. 6

Big data knows no borders; however, a growing number of countries have developed restrictive policies prohibiting data/biospecimen transfer, while others have imposed additional requirements. These requirements introduce challenges that could alter how the research is carried out. This session will describe the landscape of international data transfer requirements highlighting challenges and success stories for international data sharing, as well provide approaches/strategies for overcoming obstacles. During this session, speakers and attendees will:

- Discuss the complexities inherent in international data/biospecimen sharing
- Examine challenges and effective strategies for supporting data/biospecimen sharing across borders
- Review the Nagoya Protocol on Access and Benefit Sharing, including its three objectives

Room 102



B13: Engaging the Principal Investigators of Tomorrow With Research Ethics Today: Is It Possible?

(*Responsible Conduct of Research Track*)

Charlotte H. Coley, University of North Carolina at Chapel Hill; Leah R. Eisenberg, University of Arkansas for Medical Sciences

This presentation will look at how to encourage research trainees to be curious about ethics, so it is something they wish to continually think about, even after their IRB application is approved. Institutional research ethics classes that focus on

Room 101



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Pre-registration required	Recorded session
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learning a list of regulations are often perfunctory and fail to teach trainees how to identify and respond to complex ethical issues. This session will describe a year-long pilot of a research ethics seminar, which appears to offer a better way to dynamically mentor future independent researchers. During this session, speakers and attendees will:

- Identify shortcomings with the way research ethics is taught in many classrooms
- Recognize the wide-ranging personal and institutional problems that can result when researchers do not fully understand ethics
- Assess whether a year-long ethics seminar series is a more effective teaching methodology than a didactic ethics course

B14: Nuts and Bolts of Assessing IRB Compliance (QA/QI and Postapproval Monitoring Track)

Room 103

Lisa Denney, Stanford University; Keren R. Dunn, Cedars-Sinai Medical Center

This session will introduce attendees to the various activities QA/QI programs can implement to assess IRB compliance with federal, state, and local requirements for research. During this session, speakers and attendees will:

Basic

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

Monday, November 18: AER19

Breakout Sessions Series B; 2:45-4:00 PM

B15: The Secrets of Big Data—Public, Private, or Something Else? (Research Conducted in the Digital World Track)

Room 304

Ivor A. Pritchard, OHRP

Information is commonly thought to be either "public" or "private," with no third alternative. However, a considerable portion of big data could be considered to be neither public nor private, but rather information with access that is controlled or limited by such things as "privacy agreements," which actually serve to identify the extent to which information may be used and restricted. How should the norms of sharing information be constructed, and by whom?



During this session, speakers and attendees will:

- Examine when there could be a difference between "private information" and "confidential non-public information," and how this would alter the application of the regulations
- Share important legal cases regarding the evolving idea of privacy in US law
- Discuss current perspectives on how access to confidential information in various forms should be circumscribed in research

Note: this session will be repeated on November 20, 10:00-11:15 AM.

B16: Agents and Rogues—The Limits of Agency, Institutional Engagement, and Institutional Responsibility (Responsible Conduct of Research Track)

Room 107

Robert S. Bienkowski, Central Michigan University; Joseph Crossno, Central Michigan University

This session will explore the limits of agency, institutional engagement, and institutional responsibility when a faculty member "goes rogue" and conducts unapproved human subjects research. Two scenarios will be discussed: (1) when research is conducted at the university and uses institutional resources; and (2) when research based on intellectual property developed by a faculty member is licensed to an offsite company founded by the faculty member. Attendees will participate in developing recommendations for strengthening compliance oversight activities to detect unapproved research conducted on campus, and analyzing the limits of compliance oversight when research is conducted by an entity with which the university has an arms length relationship. During this session, speakers and attendees will:



- Review the concepts of agency and engagement as treated in the revised Common Rule, OHRP guidance, institutional standard operating procedures, and IRB and institutional procedures for responding to allegations of conducting unapproved research
- Analyze compliance monitoring processes to detect unapproved research involving human subjects conducted using institutional resources, and develop recommendations for improvement

ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
Breakout sessions new for 2019	
Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.	Basic – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.



- Discuss the limits of compliance oversight authority when evaluating how a licensee conducts human subjects research

B17: How to Identify, Navigate, and Manage Conflicts of Interest (COI) at a Small Research Organization

(Small Research Programs Track)

Melissa McGee, University of New Hampshire; Heather H. Pierce, AAMC

It is typical for members of small research organizations to wear many hats: researcher, academic administrator, IRB member, peer reviewer, thesis committee member, etc. These multiple roles, as well as the various personal and professional relationships between members of the organization, may lead to potential, actual, and perceived conflicts of interest (COIs). In this highly interactive, case-based session, speakers and attendees will:

- Identify different types of COIs (e.g., financial, institutional, professional, personal)
- Discuss how multiple COI policies can apply to different research projects depending on funding source and researcher affiliation
- Learn about how conflicts in SBER can be just as vexing as biomedical COI
- Consider strategies for encouraging innovation while managing institutional COI
- Participate in a “What would you do?” discussion with colleagues and peers

Room 201



Monday, November 18: AER19

Breakout Sessions Series B, 2:45-4:00 PM

B18: A Comparison of Human Subjects Protections Auditing Between Biomedical and Social-Behavioral Human Subjects Research (SBER Track)

Narayan A. Escolin, Rutgers University; Kate Sasamoto, University of Michigan

While there are some similarities in the conduct of biomedical and SBE human subjects research, there are many differences: applicable regulations and guidelines, institutional policies, standard research practices, background/makeup of research teams, etc. As such, the approach to auditing these protocols must be distinct and depends on the type of research being conducted. Auditors must take into account subject populations, types of interventions, levels of research experience, and common research tools, among other things. A nuanced approach tailored by the appropriate considerations can affect factors such as principal investigator cooperation, comprehensiveness of the audit review, and duration of the audit process. During this session, speakers and attendees will:

- Compare and contrast the obstacles in each step of the auditing process for the two types of human subjects research
- Provide the reasons for these differences
- Share examples that highlight current practices and considerations

Room 313



B19: Research With Native American and Indigenous Populations: Ethical and Regulatory Perspectives

(Populations Requiring Additional Protections Track)

Jyoti Angal, Avera Research Institute; Anita B. Frederick, Tribal Nations Research Group; Heather L. Larsen, Tribal Research Office, Sisseton-Wahpeton Oyate

This session will provide attendees with an overview of tribal IRB processes. The speakers will address common challenges in navigating the regulatory landscape of research with Native American populations and on tribal lands and provide examples of successful collaborations. During this session, speakers and attendees will:

- Provide an overview of the research and collaborative initiatives of the Collaborative Research Center for American Indian Health
- Discuss specific and unique ethical and regulatory aspects to conducting research with Native American and Indigenous populations and on tribal lands
- Outline the specific ethical considerations of conducting research on an Indigenous population from a Western perspective versus using indigenous methodologies to understand their experiences

Room 300



Advanced

ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
Breakout sessions new for 2019	
Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.	Basic – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.



- Reflect on the revised Common Rule changes affecting tribal sovereignty and IRBs
- Review the Tribal IRB Toolkit

B20: Distinguishing Public Health Surveillance from Public Health Research at the Centers for Disease Control and Prevention (CDC) (*Flexibility and Innovation in IRB Processes Track*)

Irene E. Stith-Coleman, OHRP; Laura Youngblood, CDC

As the nation's health protection agency, the CDC conducts critical science, provides health information that protects the nation against health threats, and responds when health threats arise. The CDC has a vital role in ensuring the highest quality of scientific products originating from the agency are used as a foundation for putting public health research into much needed practice. As noted in the revised Common Rule, some public health activities involve research and others do not; this presents many grey areas. Statutory authority of state and local health departments to conduct public health activities using methods similar to those used by researchers may add to the complexity (although the revised Common Rule now defines public health authority). Appropriate protections applicable for activities occurring at the boundary between public health surveillance and public health research are not readily interpretable from the regulations. Before attending this session, attendees should be knowledgeable about public health practice activities and the revised Common Rule's definition for "research," as well as have familiarity with the revised Common Rule definitions for "human subject," "public health authority," and "research." During this session, speakers and attendees will:

- Describe the CDC's process and criteria for determining whether an activity is research, according to the revised Common Rule
- Discuss key considerations and decision points unique to public health practice activities (e.g., surveillance, public health response investigations, program evaluation)
- Review real-world examples to demonstrate the decision-making process to assist the audience in determining when something is public health surveillance vs. public health research

Room 104



Advanced

Monday, November 18: AER19

Breakout Sessions Series B, 2:45-4:00 PM

B21: ClinicalTrials.gov—How Academic Institutions Can Meet Clinical Trial Disclosure Requirements

(*Pharma/Biotech Perspectives Track*)

Sarah A. White, The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard Medical School; Rebecca J. Williams, ClinicalTrials.gov, National Library of Medicine, NIH

The federal regulations (42 CFR Part 11) and NIH Policy on Dissemination of NIH-Funded Clinical Trial Information have been in effect since January 2017. The regulations and policy expand the expectations for sponsors and investigators to register clinical trials and submit summary results information to ClinicalTrials.gov. Other publication policies and federal requirements also leverage ClinicalTrials.gov to fulfill their policy objectives, including the new International Committee of Medical Journal Editors policy on registration of an individual participant data sharing statement and the revised Common Rule requiring posting of informed consent documents. This session will explain these requirements, provide an update on recent and future activities at ClinicalTrials.gov, and describe specific examples of how research institutions are implementing processes to support investigators in ensuring prospective compliance with these requirements. This session will also give insight into how to succeed in posting summary results information on ClinicalTrials.gov, including effective planning and preparing of results information and insights into the quality control review process at ClinicalTrials.gov. Speakers will examine the tools specific institutions are using to support compliance efforts based on the experience of the National Clinical Trials Registration and Results Reporting Taskforce (comprised of over 100 academic institutions). During this session, speakers and attendees will:

- Discuss legal, funder, and journal requirements for the submission of registration and results information by trial sponsors to ClinicalTrials.gov, including which information must be submitted and when
- Review resources and specific examples of how academic institutions are implementing processes to support ClinicalTrials.gov reporting and identify ways in which institutions can help ensure compliance with registration and results submission requirements
- Share recent updates at ClinicalTrials.gov, including information on the quality control process, posting of study protocols, and new tools available to support institutions in their compliance activities

Room 206



New

B22: Ethical Considerations in Vaccine Development and Use (*Pharma/Biotech Perspectives Track*)

Jennifer E. Gerber, Johns Hopkins University Bloomberg School of Public Health; Jason L. Schwartz, Yale University School of

Room 108

ICON KEY

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Public Health; Walter L. Straus, Merck Co., Inc.

Using examples drawn from early and late stage vaccine development, as well as public health vaccine use, this session will provide attendees with insight into ongoing and emerging issues in human subjects protections and public responsibility in the development and use of vaccines. During this session, speakers and attendees will:



- Discuss the challenges of conducting a compassionate use program for investigational vaccines in a war zone
- Consider the balance between individual rights and societal interests as they pertain to vaccine exemptions
- Provide a foundation in vaccinomics, including issues bearing upon human research subjects protections

B23: Flexible Strategies to Manage Unregulated Research in the Era of the Revised Common Rule

(Flexibility and Innovation in IRB Processes Track)

Jeffrey A. Cooper, WIRB-Copernicus Group

In the era of the revised Common Rule, research may be subject to FDA regulations, the pre-revised Common Rule, the revised Common Rule, or be unregulated. This session will describe the opportunities for flexible review of unregulated research in ways that are consistent with the revised Common Rule and other regulations. Before attending this session, attendees should have experience in managing or overseeing IRBs or HRPPs, and in writing and maintaining standard operating procedures. During this session, speakers and attendees will:

Room 111



- Review the ethical requirements for the oversight of unregulated research
- Go over strategies for flexibly handling unregulated research in a manner that is consistent with current regulatory requirements
- Discuss how to apply flexibility in the review of unregulated research in a manner consistent with local institutional requirements

4:00-5:00 PM

AER19 Welcome Reception Supported by CITI Program

Join us to celebrate the opening of the conference. Drinks and light refreshments will be served. *PRIM&R would like to thank CITI Program for helping support this reception.*

Exhibit Hall C

Monday, November 18: AER19
Breakout Sessions Series B, 2:45-4:00 PM

4:10-4:30 PM

Industry Expert Theater: Overview and Demonstration of PRIM&R's Ethical Research Oversight Course (EROC)

PRIM&R's online EROC is back and better than ever! Recently updated to reflect the revised Common Rule, this self-paced interactive course, with a new platform and engaging audio-visual format, is the most comprehensive and convenient way for new HRPP/IRB members and staff to learn the fundamental ethical principles and key regulatory frameworks that govern their day-to-day work. Join PRIM&R in the Industry Expert Theater to see EROC in action and learn about our convenient individual and institutional subscriptions. If you are unable to join us, visit primr.org/eroc for more information, or [email](mailto:nora@primr.org) Nora Murphy, online learning manager.

Exhibit Hall C

5:00-6:00 PM

Young Professionals Networking Reception

Connect with other young professionals interested in research ethics and relax after a busy day at AER19. This year's event will take place at Trident Booksellers and Café on 338 Newbury Street in Boston (approximately a five minute walk from the convention center). Don't forget to bring the drink ticket you received when you checked in on-site. While all attendees are welcome, complimentary drink tickets were only provided for young professional registrants.

Trident Booksellers and Café
(off-site)

ICON KEY

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Tuesday, November 19: AER19

7:00 AM-5:00 PM
On-Site Check-in Open

Pre-Function Hall C

7:00-8:00 AM
Networking Breakfast

Time to connect...over breakfast! Meet the AER19 Supporters and Exhibitors, as well as your peers, for conversation and networking. All are welcome!

Exhibit Halls C and D

7:00-8:00 AM
A Capella Musical Performance

Join us before the conference starts for a musical performance by a local capella group. PRIM&R would like to thank Tech Software for supporting this performance.

Pre-Function Hall C/
 Veterans Memorial Auditorium

7:15-7:35 AM

Industry Expert Theater: AER19 Poster Presentation—Accelerating Clinical Coordinator Excellence (ACCE): Building for Excellence, Success, and Empowerment

Join us in the Industry Expert Theater to hear from one of this year's outstanding poster abstract authors about their important and timely work. During this timeslot, Abby Keeley, Washington University in St. Louis, will present their poster, and attendees will have the ability to comment and ask questions.

Exhibit Hall C

7:40-8:00 AM

Industry Expert Theater: SkyiRIS Research Network for the NIH Single IRB of Use

Envision a network where institutions can ubiquitously submit their research to other institutions and maintain a level of local review. This vision is now a reality: introducing the SkyiRIS Research Network. This module allows institutions to link their research databases to a collaborative network. What makes SkyiRIS stand out is that it promotes collaboration between institutions involved in multi-site research and allows internal/external communication between research teams and the review board without limiting the system functionality to a document review process. It behaves and works with the complete functionality of a robust eIRB system, specifically SMART forms and workflows. One of the primary benefits of the SkyiRIS Research Network's system to system feature is that it enables institutions to perform local review on other regulatory processes that are not handled by the remote affiliate such as Conflict of Interest, Radiation Safety, Bio Safety, Environmental Safety, Feasibility, etc.

Exhibit Hall C

8:00-8:05 AM

Welcome from the Conference Co-Chairs

Veterans Memorial Auditorium



8:05-8:10 AM

Presentation of PRIM&R's Distinguished Service Award to Robert S. Bienkowski, PhD, Central Michigan University

Veterans Memorial Auditorium



8:10-8:15 AM

Presentation of PRIM&R's Applied Research Ethics National Association Legacy Award to Susan Z. Kornetsky, MPH, Boston Children's Hospital

Veterans Memorial Auditorium



8:15-8:40 AM

Remarks from PRIM&R's Board of Directors Chair, Heather H. Pierce, JD, MPH

Veterans Memorial Auditorium



8:40-9:45 AM

Keynote Address by Scott D. Halpern, MD, PhD, Professor of Medicine, Epidemiology, and Medical Ethics and Health Policy, University of Pennsylvania Perelman School of Medicine: Financial Incentives and Nudges for Research Participation—Undue, Unjust, or Uncertain?

Veterans Memorial Auditorium



9:45-10:15 AM

Beverage Break With Supporters and Exhibitors

Join us for coffee in the exhibit hall. PRIM&R would like to thank Huron Consulting Group for helping support this break.

Exhibit Hall C

ICON KEY

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Tuesday, November 19: AER19

Breakout Sessions Series C, 10:15-11:30 AM

C1: HRPP Innovation Showcase—Creative Approaches to IRB Challenges

(Flexibility and Innovation in IRB Processes Track)

Madelon V. Baranoski, Yale University School of Medicine; Jeri Burr, University of Utah; Martha Jones, Partners HealthCare System, Inc. (moderator); Christine Suver, Sage Bionetworks

Get inspired! Hear about innovations your colleagues are putting in place to make life easier for participants, researchers, IRBs, and HRPPs, which you could adopt or adapt for your institution. This moderated session highlights initiatives in three areas: managing the single IRB process, handling noncompliance, and informed consent. A panel of expert speakers will describe their projects, the challenges the initiatives intended to solve, resources needed to implement the effort, and lessons learned. The moderator will lead an interactive discussion between panelists and audience members on the specific projects, including universal themes, when innovation is warranted, the pros and cons of innovation, and what is required for successful implementation of process changes. During this double session, speakers and attendees will:

- Discuss cases of innovation and the problems they posed to solve
- Explore different approaches to addressing challenges IRBs face
- Identify what is needed for successful implementation of innovation

Note: This is a double session and will end at 12:45 PM.

Room 203



C2: I Love My Job!? Perspectives Throughout a Career in Human Research Protections *(Educating and Training Track)*

Tonya Ferraro, Boston Children's Hospital; Danielle A. Griffin, University of Houston; Ada Sue Selwitz, University of Kentucky; Laura Youngblood, CDC

This session will share perspectives from HRPP professionals at different points in their careers about the joy (and challenges) of working in this field. What can a career in human research protections look like? Speakers will discuss the range of jobs and opportunities available in the field, and the types of institutions where HRPP professionals work. During this double session, speakers and attendees will:

- Discuss how to advance in this profession, including the opportunities to seek (or create!)
- Share how engagement with the HRPP community can enhance experience in this field (e.g., networking, mentorship, PRIM&R membership, etc.)

Note: This is a double session and will end at 12:45 PM.

Room 312



C3: Tissue Repositories and Data Banks in the Era of the Revised Common Rule

(Research Involving Data and Biospecimens Track)

Julie Ozier, Vanderbilt University and Medical Center; Nicholas A. Wallace, Ropes & Gray LLP; Carol Juliet Weil, National Cancer Institute

The revised Common Rule introduced the option of broad consent for secondary research, as well as two new exemptions (exemptions seven and eight) for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens when broad consent is used and limited IRB review occurs. These options, and the revised definitions of "human subject," offer new opportunities and challenges for the research enterprise and IRB professionals, but also raise questions about how and whether they can be effectively utilized to facilitate research. With almost a year of implementation underway, this session will review whether institutions have implemented these options and, if so, what the benefits and challenges have been. Have any institutions adopted broad consent and, if so, in what circumstances? What has limited IRB review looked like in practice? Attendee participation and sharing of best practices developed since the revised Common Rule went into effect will be encouraged. During this session, speakers and attendees will:

- Describe the new options of broad consent and exemptions seven and eight in the revised Common Rule, and review requirements for their use, restrictions to waiver and alteration of broad consent, and other problems that may be caused by these requirements
- Use case studies to explore potential challenges in operationalizing the use of these options, including issues with tracking, IRB reviews, etc.
- Review how operational problems might or might not be overcome, and share practical suggestions for institutions as they continue to operate research repositories under the new regulatory framework

Note: this session will be repeated on November 20, 10:00-11:15 AM.

Ballroom A



ICON KEY

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Tuesday, November 19: AER19

Breakout Sessions Series C, 10:15-11:30 AM

C4: Bioresearch Monitoring (BIMO) Inspections—Regulatory Violations Observed in IRB and Clinical Investigator Inspections (FDA-Regulated Research Track)

Kavita C. Dada, Office of Scientific Investigations, FDA; Jan L. Hewett, Office of Scientific Investigations, 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 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, this session 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 an IRB and institution should be aware of for an FDA inspection. During this session, speakers and attendees will:

Room 101

Basic

- Review the IRB and clinical investigator site selection and inspection process
- Describe the role of the Centers and Office of Regulatory Affairs in an inspection
- Review recent FDA BIMO inspection metrics and where to find them on FDA's website
- Share FDA materials (e.g., guidance, compliance program manuals, etc.) for inspections

C5: European Union (EU) General Data Protection Regulation (GDPR) (Global Research Track)

Kristin J. Craun, University of California, Los Angeles; Michael A. DiMaio, Ropes & Gray LLP

The EU's GDPR took effect on May 25, 2018, and applies to researchers in the European Economic Area (EEA), as well as those located outside the EEA, that process data of individuals located in the EEA. It is therefore essential researchers who use any personal data originating in the EEA have an understanding of the regulation. This session will begin with a brief overview of the critical elements that impact international research, identify areas where research has been restricted, and provide practical steps that American medical college and universities can use to ensure compliance with GDPR. During this session, speakers and attendees will:

Room 302

- Explore the impact of the EU GDPR on human subjects research
- Highlight the challenges posed by the GDPR to clinical research, biobanking and data banking, and big data research
- Discuss how the GDPR interacts with the Health Insurance Portability and Accountability Act of and the revised Common Rule
- Identify operational practices that academic medical centers and universities can put in place to ensure compliance with GDPR

C6: Not Less Work, but Different—Re-Engineering for Single IRB (sIRB) Review

(Institutional Officials and HRPP Leadership Track)

Megan Kasimatis Singleton, Johns Hopkins University School of Medicine; Kimberly K. Summers, University of Texas Health Science Center at San Antonio

As institutions adapt to the brave new world of sIRB review, HRPPs/IRBs face new challenges. The shift to sIRB review required by NIH policy and the revised Common Rule offers the opportunity to rethink and reconfigure approaches to research oversight. This session will tease apart institutional and IRB roles when using a sIRB, as well as highlight potential approaches to fulfilling the role of a relying organization. The potential pros/cons of various models will be discussed. Attendees are expected to have sufficient experience and understanding to actively contribute to the discussion. This session will not review basic concepts. Institutional officials and HRPP leaders responsible for establishing HRPP approaches to sIRB review requirements are encouraged to attend. During this session, speakers and attendees will:

Room 210

Advanced

- Delineate the distinct roles for reviewing IRBs and relying institutions by identifying and separating appropriate (non-IRB) responsibilities of institutions from functions that are, by regulation, within the purview of the IRB
- Identify different models that may be adopted by institutions to effectively support single IRB review processes as a relying organization
- Use case examples to explore the pros/cons of various approaches to upholding the organizational responsibilities under a sIRB review model

ICON KEY

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Tuesday, November 19: AER19

Breakout Sessions Series C, 10:15-11:30 AM

C7: Covering All Your Bases: Considerations and Tips for How to Identify and Apply the Appropriate Federal Regulations for IRB Review (IRB Basics Track)

Warren Capell, University of Colorado Denver; Danielle Giltner, Indiana University; Leslie M. Howes, Harvard T.H. Chan School of Public Health

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

- Revisit the ethical principles underlying regulatory protections for research involving human subjects
- Identify and discuss regulations that impact IRB review and how to identify when they should be considered
- Discuss the criteria for expedited review and models for documenting reviews and when referral to a convened IRB may be warranted
- Practice applying the 111 criteria to various case examples

Note: This is a double session and will end at 12:45 PM.

Room 304



Basic

C8: IRB Chairs Forum—A Structured Discussion for IRB Chairs (IRB Chairs Track)

Luke Gelinis, Advarra, Inc.; R. Peter Iafrate, University of Florida; Brenda J. Klement, Morehouse School of Medicine

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. During this double session, speakers and attendees will:

- 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
- Share best practices, policies and procedures, forms, and methods that aid in resolving difficult issues presented by investigators and research study staff
- Discuss real-world situations and problems attendees face with a focus on coming up with a few possible and concrete solutions

Note: This is a double session and will end at 12:45 PM.

Room 200



C9: Creative Solutions for Serving as a Reviewing IRB (IRB Operations Advanced Track)

Holly Bante, University of Cincinnati; Ann Johnson, University of Utah; Hallie Kassin, Northwell Health; Janelle A. Maddox-Regis, Johns Hopkins University School of Medicine

Is your organization contemplating whether to act as a single IRB (sIRB) for multi-site research? This lively, discussion-oriented session will candidly discuss the challenges in assuming this new role and offer practical solutions from organizations serving in this capacity. Topics to be covered include consent form development, handling conflicts of interest, methods of communicating with relying institutions and study teams (including obtaining local context information) during initial reliance arrangements and review, and addressing post-initial review requirements (e.g., amendments and continuing review). This session is designed to share experiences and offer practical tools for organizations embracing this new challenge. Before attending this session, attendees should be knowledgeable about sIRB requirements. Attendees will have the opportunity to ask specific questions relevant to serving as a sIRB. During this double session, speakers and attendees will:

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

Note: This is a double session and will end at 12:45 PM.

Room 306



Advanced

ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
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Tuesday, November 19: AER19

Breakout Sessions Series C, 10:15-11:30 AM

C10: A Case-Based Assessment of Post-Trial Access to Investigational Medicines

(Pharma/Biotech Perspectives Track)

Karla Childers, Johnson & Johnson; Ariella Kelman, Genentech, member of the Roche Group

This session will focus on real world cases that demonstrate the complexity of decision making in providing continued access to investigational medicines after a clinical trial. During this session, speakers and attendees will:

- Share challenges of defining a broadly applicable policy for post-trial access
- Discuss key considerations in making decisions about granting post-trial access
- Provide an understanding of how to apply bioethical principles through real world examples

Room 107



C11: Risky Business—Defining Research Risks and Who Faces Them in the Age of Comparative Effectiveness Research and Alternative Trial Design *(Legal Considerations for HRPPs Track)*

Kate Gallin Heffernan, Verrill Dana LLP; Jerry A. Menikoff, OHRP (resource person); Todd W. Rice, Vanderbilt University School of Medicine

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

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

Room 103



Note: This is a double session and will end at 12:45 PM.

C12: Considerations for Return of Results and Incidental Findings *(Research Involving Data and Biospecimens Track)*

Marianna J. Bledsoe, Marianna J. Bledsoe Consulting, LLC/International Society for Biological and Environmental Repositories;

P. Pearl O'Rourke, Harvard Medical School

The return of individual research results seems like a simple enough expectation that respects a subject's rights to information about themselves. In practice, though, highly complex considerations, finding the right balance for protecting autonomy, and promoting beneficence are not easy. Before attending this session, attendees should have a basic understanding of the ethical and regulatory challenges related to the return of individual research results and incidental findings. During this session, speakers and attendees will:

- Understand how IRBs and researchers balance the ethical considerations of sharing results or incidental findings with the logistics and practical limitations of doing so (e.g., What does ethical return of results look like? What are the challenges of sharing results or incidental findings? What resources are needed? What should investigators think about when developing a protocol?)
- Discuss whether new questions should be added to IRB applications regarding whether results or incidental findings will be shared
- Share case studies and real-world scenarios for return of results or incidental findings from participant and researcher perspectives

Room 102



ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
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Tuesday, November 19: AER19

Breakout Sessions Series C, 10:15-11:30 AM

C13: IRB Review of Research With Children (*Populations Requiring Additional Protections Track*)

Ran Goldman, University of British Columbia; Bethany Johnson, Indiana University; Andrew Neel, Indiana University

IRB review of research with children requires special consideration of commonly-accepted safeguards; however, the nuances of those safeguards often aren't well understood by IRB staff and members. This session will use case studies to explore specific complexities in the IRB's review of research involving children, those beyond the basics of categorizing risk and planning for assent. Specific attention will be paid to greater than minimal risk research, including discussion of how and when to apply the FDA's preferred component analysis method, and conducting research via social media platforms and including children. In addition, the session will cover parental permission and the IRB's role in determining when consent from one parent is sufficient, especially when a parent can be considered not reasonably available. Speakers will do a deeper dive into ethical and regulatory complexities of conducting research with children and teens. Before attending this session, attendees should have a foundation in the regulations that govern research with children, as well as knowledge of Subpart D requirements, including considerations in making determinations regarding category of risk to children. During this double session, speakers and attendees will:

- Review additional requirements for research with children, and explore nuances of that review
- Discuss complex issues related to conducting research with minors, including research conducted in school settings
- Review ethical and practical issues related to assent and parental permission requirements and best practices
- Discuss unique issues that may impact research with minors, including: internet research; emancipated minors; returning research results, etc.
- Understand what limitations the Children's Online Privacy Protection Rule may have on research

Note: This is a double session and will end at 12:45 PM.

Room 309



Advanced

C14: Nuts and Bolts of Investigator Site Audits (*QA/QI and Postapproval Monitoring Track*)

Stephanie deRijke, Emory University; Kelly Dornin-Koss, University of Pittsburgh

Investigator site audits are the hallmark of postapproval monitoring and are integrated into many IRB QA/QI programs. This session will introduce attendees to the key concepts and practical strategies for developing investigator on-site audit activities while being mindful of the institution's research portfolio, whether primarily biomedical or SBER. During this session, speakers and attendees will:

- Provide an overview of the investigator site review/audit process
- Address specific considerations of the investigator audit activity, including but not limited to: research portfolio (biomedical research vs. SBER), triggers for audits, sampling plans, grading/scaling on-site reviews, and who receives the report (the considerations will be compared/contrasted between multiple QA/QI programs)
- Discuss how audits can be an opportunity for investigator education
- Review practical and useful tools that sites can modify for their own use

Room 202



Basic

C15: Social Media in Research—Recruitment, Subject Communication, and Data Source

(*Research Conducted in the Digital World Track*)

Emily Largent, University of Pennsylvania Perelman School of Medicine; Holly Fernandez Lynch, University of Pennsylvania Perelman School of Medicine; Stephanie Morain, Baylor University of Medicine

Social media have become integrated into the fabric of modern life, making it no surprise these platforms are being used for, and are having an impact on, human subjects research. Through a series of brief lectures, this session will address three important facets of social media in research. First, speakers will introduce a methodology for assessing the ethics of participant recruitment to research studies via social media based on the norms of respect for privacy and investigator transparency. Next, speakers will identify some of the ways in which social media communication by study participants can jeopardize study integrity and participant safety, and describe strategies for mitigating these challenges. Finally, speakers will discuss ethical issues that arise when social media platforms are used as the source of research data, including considerations related to public awareness and trust, when data can be viewed as "publicly available," and how IRBs can best review such research. Case studies will be used to demonstrate key concepts. During this session, speakers and attendees will:

- Clarify similarities and differences between recruitment via social media and recruitment via traditional means, to evaluate ethically acceptable approaches

Ballroom C



ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
Breakout sessions new for 2019	
Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.	Basic – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.



- Identify the risks that social media communication amongst study participants can pose for a trial, and strategies for mitigation
- Provide tools for ethical oversight of research using social media platforms as a data source

Tuesday, November 19: AER19

Breakout Sessions Series C, 10:15-11:30 AM

C16: Conducting Research Misconduct Investigations When Human Subjects Research Is Involved—Case Studies and Best Practices (*Responsible Conduct of Research Track*)

Lisa R. Buchanan, OHRP (resource person); Yvette M. Carter, ORI; David J. Hudson, University of Virginia

This session will explore the intersection of two prominent and regulatory bound committees when cases of research misconduct involve human research participants and/or their data. This session will systematically take participants through the boundaries and requirements of research misconduct assessments, inquiries, and investigations, while incorporating best practices for partnering, including, or excluding the IRB members or team from the process. Case study examples will be provided and explored with the audience as examples of what to do and not to do when these situations arise. During this session, speakers and attendees will:

Room 300



- Review the concepts of research misconduct policies and associated processes
- Compare and contrast research misconduct committee and IRB processes for investigations for allegations of noncompliance, including how committee related actions can be combined
- Discuss the pros and cons of various strategies, including best practices to maximize outcomes
- Provide case examples as learning tools for the audience

C17: How to Maintain Institutional Memory at a Small Research Program (*Small Research Programs Track*)

Sharon C. Freitag, Unity Health Toronto Providence St. Joseph's and St. Michael's Healthcare; Jennifer L. Pacheco, Baystate Health/Elms College

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

Room 201



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

C18: Reaching the Masses—Ideas for Researcher Education (*SBER Track*)

Emily E. Anderson, Stritch School of Medicine, Loyola University of Chicago; Cecilia Brooke Cholka, University of Nevada, Reno

Some institutions are struggling to find resources to provide human research protections training to their research community. Resources are limited and commercial sources for training can be cost prohibitive for small programs. This session will discuss different approaches to training principal investigators and research teams with a focus on university (non-medical) settings and social science and humanities faculty, student, and community researchers. During this session, speakers and attendees will:

Room 204



- Share different strategies for implementing and tracking researcher trainings
- Discuss the needs of different types of researchers (e.g., faculty, student, community)
- Identify existing resources to help develop a researcher training offerings

C19: Risk Mitigation in Mixed SBER and Biomedical Research (*SBER Track*)

Lara N. Sloboda, Dana Farber Cancer Institute; Matt D. Stafford, Boston Children's Hospital/Harvard Catalyst

Room 104

ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
Breakout sessions new for 2019	
Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.	Basic – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.



Using case studies, this session will focus on risk mitigation in research involving both biomedical and social science methods. Case studies will include piloting initiatives to overcome reluctance to utilize support/recovery services for persons affected by opioid abuse, and an evaluation of an early intervention program to ameliorate psychosocial effects of Chronic Traumatic Encephalopathy in youth who play contact sports. Before attending this session, attendees should have a basic foundation in human research protections ethics and principles, including the criteria for approval and definitions from HHS and FDA regulations. During this session, speakers and attendees will:



- Review the nature of the risks, harms, and impacts associated with mixed SBER/biomedical research
- Explore factors likely to contribute to increased risk in research spanning both medical and social/behavioral arenas
- Discuss how to design research with sufficient protections and minimize risk through study design

Tuesday, November 19: AER19

Breakout Sessions Series C, 10:15-11:30 AM

C20: Implementing the Key Information Requirements of the Revised Common Rule—Perspectives on Early Approaches
(IRB Operations Advanced Track)

Susan Z. Kornetsky, Boston Children's Hospital; Sariah Fuller, University of Utah; Holly A. Taylor, Department of Bioethics, Clinical Center, NIH; Yvonne Lau, OHRP (resource person)

The revised Common Rule includes a requirement that the consent form begin with a concise and focused presentation of the key information that is most likely to assist a subject in understanding why s/he may or may not want to participate in the research. With little guidance available about what key information is and how to address it, most organizations have developed their own guidance and approach to complying with this new regulatory requirement. With variations in approach, it is important to explore possible advantages and disadvantages of these varied approaches. This session will review existing approaches to addressing key information for clinical and non-clinical studies, incorporating IRB and participant perspectives on the requirements for the new provisions regarding key information in informed consent. Through case examples, attendees will have the opportunity to consider various approaches to implementation of the key information requirement and the potential pros/cons of each approach. Before attending this session, attendees should have a basic understanding of the revised Common Rule and be familiar with the transition provisions of the revised Common Rule. During this double session, speakers and attendees will:

Room 311



- Review the new regulatory requirement for inclusion of key information in the consent form
- Identify varied approaches organizations have adopted to comply with this requirement
- Through case examples, practically identify the potential pros/cons of each approach

Note: This is a double session and will end at 12:45 PM.

C21: A Look into the Crystal Ball—The HRPP of the Future (Institutional Officials and HRPP Leadership Track)

John R. Baumann, Indiana University; Nichelle Cobb, University of Wisconsin-Madison; Rachel A. Wenzl, University of Nebraska-Lincoln

"The times, they are a changin'." Expansion of exemptions? Lack of continuing review? Single IRB review? Clinicaltrials.gov requirements? The revised Common Rule and changes in NIH policies will have a significant impact on nearly every dimension of the HRPP. Will there be a decrease in staff at institutions? Will staff need to be added? Will staff change what they do? Will new functions or responsibilities be removed? In this session, speakers will lead a discussion on what the future holds for HRPPs, and identify the opportunities, risks, and potholes regulatory and policy changes can present from the perspective of the institution, the IRB office/staff, and IRB members. Using case studies, these concepts will be explored to promote dialogue about the HRPP of the future. During this double session, speakers and attendees will:

Room 310



- Identify potential effects of regulatory and policy changes on institutional processes and infrastructure for both large and small research enterprises
- Examine the potential opportunities regulatory and policy changes can present for institutions
- Discuss strategies for adapting institutional infrastructure and processes to the revised Common Rule and new NIH policies

Note: This is a double session and will end at 12:45 PM.

C22: Scientific Aspects of Study Design—A Primer for Non-Scientists (Educating and Training Track)

Susan S. Fish, Boston University School of Public Health; Lindsay McNair, WIRB-Copernicus Group

This session will serve as a primer on the scientific process, clinical study designs, and the structure of research programs for the nonscientist IRB member. During this session, speakers and attendees will:

Room 108



ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
Breakout sessions new for 2019	
Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.	Basic – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.



- Discuss the essential components of a study question and how the question can be addressed in a clinical study
- Review the basics of both observational and interventional clinical study designs, and the strengths, weaknesses, and application of each design
- Explain the essential considerations that can impact the validity of a clinical study and the analysis of study data

Note: This is a double session and will end at 12:45 PM.

Tuesday, November 19: AER19

Breakout Sessions Series C, 10:15-11:30 AM

C23: Exempt Human Subjects Research Case Studies—Implementing Changes to the Exemption Categories Under the Revised Common Rule (IRB Operations Advanced Track)

Room 206

Caitlin Alcorn, University of Oregon; Christine DeLussey, Children's Hospital of Philadelphia; Julie M. Eiserman, Office of Human Subjects Research Protections, NIH

The revised Common Rule includes many changes to the categories of exemption including the introduction of new categories. The main implication of these changes is that some human subjects research that previously required expedited IRB review may now be considered exempt. The research oversight community is awaiting detailed guidance about how to interpret and apply these regulatory changes. This session will evaluate determinations of exemption under the revised Common Rule at different institutions. Using real case examples, this session will delineate how organizational requirements, along with the special considerations of exempt reviewers, may factor into exempt determinations. Before attending this session, attendees should be familiar with the revised Common Rule exempt categories. During this session, speakers and attendees will:



- Identify important changes to the exemption categories under the revised Common Rule, including requirements for limited IRB review
- Review examples of studies that qualify for exemption under the revised Common Rule and features that allow or prohibit exemption within certain categories
- Discuss areas of confusion and identify resources to navigate questions in absence of federally issued guidance
- Explore operational considerations for the changes to exemption and become familiar with review strategies that address limited IRB review
- Understand how different organizations are approaching the review of applications that may qualify for exemption under the revised Common Rule and share resources that can aid in navigating the revised exempt criteria

Note: This is a double session and will end at 12:45 PM.

11:30-11:45 AM

Break

Sessions, 11:45 AM-12:45 PM

A Dialogue With AAHRPP, Inc.

Room 202

Mary L. Fields; Robert Hood; Lori Kravchick; Elyse I. Summers; Kate Vulakovich, Jemelle Williams

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

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

ICON KEY

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A Dialogue With DOD

Laura R. Brosch; Stephanie Bruce; John Lee Melton

Room 313



This session will be led by senior leaders and subject matter experts from DOD's HRPPs. During this session, speakers and attendees will:

- Discuss DOD Component policies and guidance for implementing the revised Common Rule in DOD-conducted and DOD-supported human subject research (HSR)
- Explore DOD guidance pertaining to the oversight of DOD-conducted and DOD-supported HSR involving DOD personnel, particularly DOD-unique requirements
- Participate in an open discussion about DOD-related topics relevant to the research protections community, internally to the DOD as well as the extramurally-supported partner

Tuesday, November 19: AER19

Sessions, 11:45 AM-12:45 PM

A Dialogue With DOE

Cheri Hautala-Bateman; James E. Morris; Elizabeth P. White

Room 204



This session will be led by representatives from DOE. During this session, speakers and attendees will:

- Provide a brief overview of the DOE human subjects portfolio and program for the protection of human subjects.
- Engage in open discussions for questions and answers regarding the DOE Human Subjects Protection Program

A Dialogue With FDA

Kavita C. Dada; Soma Kalb; Joanne R. Less; Diane M. Maloney; Patrick J. McNeilly; Kevin A. Prohaska

Ballroom C



This interactive 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 open up for audience questions. Attendees are encouraged to come with questions of interest to all. During this session, speakers and attendees will:

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

A Dialogue With NIH

Carrie D. Wolinetz

Room 101



This session will be led by a representative from the NIH, and will include discussion of NIH's work toward developing a new policy on the management and sharing of scientific data, the agency's efforts to work with the community on registration and results reporting for basic experimental studies involving humans, and return of individual results from clinical studies. Attendees are encouraged to come with questions of interest to all. During this session, speakers and attendees will:

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

A Dialogue With DHHS Office for Civil Rights (OCR)

Marissa Gordon-Nguyen; Linda Sanchez; Nick Heesters

Room 107

This interactive session will be an open forum led by two senior advisors in OCR's health information privacy division, who will provide brief updates on OCR's HIPAA policy and enforcement activities. Attendees are encouraged to come with questions of interest to all. During this session, speakers and attendees will:

- Address questions about how the HIPAA rules apply in the research context
- Discuss the individual's right to access their health information
- Review OCR's enforcement actions involving breaches of protected health information

A Dialogue With OHRP

Lisa R. Buchanan; Julie Kaneshiro; Yvonne Lau; Ivor A. Pritchard; Irene Stith-Coleman;

Ballroom B



This session will be led by representatives from OHRP. Attendees are encouraged to come with questions of interest to all. During this session, speakers and attendees will:

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- Hear from OHRP representatives about evolving initiatives, issues, and guidance
- Ask questions of OHRP representatives
- Participate in an open discussion on topics raised at the session
- Note: Submit written questions in advance of the session to the staff at OHRP's booth (#210) in Exhibit Hall C

A Dialogue With ORI

Yvette M. Carter

This session will be led by a representative from ORI. Attendees are encouraged to come with questions of interest to all. During this session, speakers and attendees will:

- Participate in an open discussion of issues relevant to ORI stakeholders
- Ask questions about new and ongoing initiatives at ORI from ORI's Director

Room 109



Tuesday, November 19: AER19

Sessions, 11:45 AM-12:45 PM

A Dialogue With Patient Centered Outcomes Research Institute (PCORI)

Jason Gerson

This interactive session will be led by a representative from PCORI, a funder of clinical comparative effectiveness research (CER). Critical human subjects protections challenges arise in the conduct of the "real-world" studies funded by PCORI, such as big data studies requiring data linkages between two or more data sets (e.g., claims data, electronic health record data, and registry data) that are held by different entities, which raises privacy and informed consent issues for the data owners, funders, researchers, and IRBs. For cluster randomized clinical trials where individual informed consent is not usually feasible, alternative ways of involving and informing patient communities that a study is underway would be extremely valuable. PCORI staff will discuss some of these challenges. Attendees are encouraged to come with questions of interest to all. During this session, speakers and attendees will:

- Hear from a representative of PCORI about their experience with human subjects protections issues (e.g., informed consent, privacy, and data and safety monitoring)
- Ask questions about key human subjects protections challenges in conducting CER

Room 111



A Dialogue With SACHRP

David G. Forster, WIRB-Copernicus Group; Julia G. Gorey, OHRP; Nancy M.P. King, Wake Forest School of Medicine; Stephen J. Rosenfeld, Freeport Research Systems, LLC

This session will be led by representatives from SACHRP. Attendees are encouraged to come with questions of interest to all. During this session, speakers and attendees will:

- Hear from SACHRP representatives about evolving initiatives, issues, and guidance
- Participate in an open discussion about topics relevant to SACHRP stakeholders
- Discuss best practices currently under consideration by SACHRP
- Ask questions of SACHRP representatives

Room 201



A Dialogue With the VA

Kristina C. Borrer; Cynthia L. Boudreaux; Charlotte K. Jeans; Mary M. Klote

This session will be led by representatives from the VA. Attendees are encouraged to come with questions about VA research. During this session, speakers and attendees will:

- 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
- Participate in an interactive dialogue about topics related to VA research
- Ask questions about the VA's current policies related to human subjects protections and the direction of the VA's future policies

Room 302



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

Michelle M. Feige, AAHRPP, Inc.; Megan Kasimatis Singleton, Johns Hopkins University School of Medicine; Kelly Unsworth, University of Rochester

Are you interested in speaking at PRIM&R's conferences? Have you spoken at PRIM&R's events before, but are interested in learning more about how to facilitate engaging sessions? Join us for this session where new and experienced PRIM&R presenters will provide tips and insight on how to become a speaker, submit potential conference content, and facilitate

Room 300

ICON KEY

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session content in a way that promotes understanding, retention, and interaction. During this session, speakers and attendees will:

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

Tuesday, November 19: AER19
Sessions, 11:45 AM-12:45 PM

The Certified IRB Professional (CIP®) Credential—How Do I Get Started?

Room 102

Lori Roesch, Children's Hospital of Wisconsin/Medical College of Wisconsin; Andrew Hedrick, The Ohio State University; David C. Matesanz, Kaiser Permanente

This session will be led by a CIP Council member, a newly certified individual, and an individual who recently recertified by exam. Participants are encouraged to come with questions about the CIP program and exam preparation. During this session, speakers and attendees will:

- Discuss the CIP credential and the eligibility guidelines
- Review the types of questions on the CIP exam
- Share study preparation strategies
- Provide insight into test question development/validation and exam administration

Note: this session will not review specific exam questions.

11:45 AM-12:45 PM

Exhibit Hall C

Meet and Greet With the Supporters and Exhibitors, View the AER19 Posters

During this time, the AER19 Supporters and Exhibitors will be available for networking so attendees can learn more about their important services. Attendees can also use this time to further explore PRIM&R's AER19 Poster gallery.

11:45 AM-12:05 PM

Exhibit Hall C

Industry Expert Theater: AER19 Poster Presentation—IRB Members' Assessment of Minimal Risk Procedures in Pregnancy

Join us in the Industry Expert Theater to hear from one of this year's outstanding poster abstract authors about their important and timely work. During this timeslot, Amina White, University of North Carolina at Chapel Hill, will present their poster, and attendees will have the ability to comment and ask questions.

12:10-12:30 PM

Exhibit Hall C

Industry Expert Theater: AER19 Poster Presentation: What Ethical Challenges Do Pragmatic Trials Pose for the Oversight of Human Subjects Research? An Interview Study With Key Stakeholders

Join us in the Industry Expert Theater to hear from one of this year's outstanding poster abstract authors about their important and timely work. During this timeslot, Stuart Nicholls, Ottawa Hospital Research Institute, will present their poster, and attendees will have the ability to comment and ask questions.

12:45-1:45 PM

Attendee Open Lunch Period

During this time, attendees will eat lunch on their own. Learn more about dining options in the hotel and area [here](#).

2:00-3:15 PM: Plenary Sessions

Panel IV: Identifying and Avoiding the Conduct of Low Value Clinical Trials

Ballroom B

Moderators: *Laura Odwazny, DHHS*

Panelists: *Eileen M. O'Reilly, Memorial Sloan Kettering Cancer Center; Stephen J. Rosenfeld, Freeport Research Systems, LLC;*

ICON KEY

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Pre-registration required	Recorded session
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Deborah A Zarin, Harvard Medical School, Brigham and Women's Hospital

Clinical trials are conducted and subjects are recruited in the name of advancing science. However, a growing body of research suggests that many initiated trials have little or no chance of providing valuable information (e.g., trials that address a question that has already been answered; trials that address a trivial question that is of no scientific or clinical import; trials that have design flaws that predictably would block them from producing a valid answer; trials that are very unlikely to complete as planned because of lack of subject recruitment). More broadly, human experimentation that has little to no prospect of generating valuable knowledge violates basic ethical principles and can cause considerable harm. First, participants may be burdened by the demands of study enrolment, while mistakenly believing that they are contributing to medical progress. Second, trials lacking social value divert participants, researchers, and other resources from other endeavors, including more valuable trials. Third, valueless trials degrade the evidence used in research, care and policy. Academic medical centers and IRBs frequently serve as the main gatekeeper to the initiation of new studies, and thus must do what they can to ensure that the promise of scientific advancement is reasonably likely to be achieved. This panel will address the role academic institutions and IRBs can play in identifying and reducing the initiation and continuation of low value trials by (a) understanding key principles underlying potential value of a trial; (b) ensuring a landscape analysis has been conducted to enable consideration of the scientific context in which the research will occur; and (c) ensuring the trial will be registered and reported in accordance with current legal and other policies.



Tuesday, November 19: AER19

2:00-3:15 PM: Plenary Sessions

Panel V: Bioethics Turns 50—Reflections from The Hastings Center

Moderator: Mildred Z. Solomon, The Hastings Center

Panelists: Steven Joffe, University of Pennsylvania Perelman School of Medicine; Nancy M. P. King, Wake Forest School of Medicine; Alex John London, Carnegie Mellon University; Karen J. Maschke, The Hastings Center

In honor of The Hastings Center's 50th anniversary, this panel will compare and contrast 21st century biomedical technologies with those of the mid-20th century, when the field of bioethics was just forming. This panel will explore historical continuities and discontinuities, and consider challenges to oversight across the contemporary research enterprise, from discovery to post-trial monitoring, including comparative effectiveness research and other modes of continuous learning. Panelists will consider the roles bioethicists, scientists, healthcare leaders, patients, and the public should play in ensuring today's powerful, transformative technologies—including artificial intelligence, gene editing, human-animal chimeras, emerging neuro-technologies, and more—enhance our collective human flourishing.

Ballroom C



Panel VI: Studying Suicide and Subjects at Risk for Suicide—Identifying and Minimizing Risk to Promote Necessary Research

Moderator and panelist: David H. Strauss, Columbia University/ The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard Medical School

Panelists: Celia B. Fisher, Fordham University; Samantha Marquez McKetchnie, Massachusetts General Hospital

Suicide is a major public health concern and is among the leading causes of death in the US. While the National Institute of Mental Health, the National Action Alliance for Suicide Prevention, and suicide researchers all agree the lack of suicide and related research limits developing novel suicide prevention and treatment approaches, research with patients at risk for suicide presents a range of safety and ethical questions. This panel will discuss what IRB members need to know about suicide starting with a brief overview of the epidemiology of suicide and suicide risks. Panelists will then discuss the types of research that raise concerns about increased risks for suicide (i.e., safety plans aren't just for "suicide studies"), which begs the question of how to best identify risks and how researchers should respond to risks. Finally, speakers will review how to assess proposed safety plans and how to help investigators create these plans.

Veterans Memorial Auditorium



3:15-3:45 PM

Beverage Break With the Supporters and Exhibitors

Join us for coffee in the exhibit hall.

Exhibit Hall C

Breakout Sessions Series D, 3:45-5:00 PM

D1: Lost in Transition? Flexible and Innovative Approaches to the Revised Common Rule

(Flexibility and Innovation in IRB Processes Track)

Charles Brightbill, Geisinger Health System; Jaime O. Hernandez, OHRP (resource person); Cindy S. Shindlecker, University of Michigan

The revised Common Rule now aligns with the many flexibility initiatives already implemented at institutions for research that is not federally supported. This session showcases flexible approaches to applying the revised Common Rule: (1) a decision-making tool to identify which studies approved before the revised Common Rule could (or should) be transitioned; and (2) an effort to allow researchers more autonomy in making exemption determinations. During this session, speakers and attendees will:

Room 210



ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
Breakout sessions new for 2019	
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- Explore how and why to implement flexibility and innovation into HRPP processes and policies
- Discuss practical approaches HRPPs use to approach the requirements of the new rule through the presentation of examples of innovative and flexible initiatives
- Share how to create an institutional culture of innovation and flexibility

Note: this session will be repeated on November 20, 10:00-11:15 AM.

Tuesday, November 19: AER19

Breakout Sessions Series D, 3:45-5:00 PM

D2: Paving the Road to Success—Meeting the Challenges of Investigator and Study Team Education

(Educating and Training Track)

Mina P. Busch, Cincinnati Children's Hospital Medical Center; Kelly Unsworth, University of Rochester Medical Center

Once a clinical researcher meets the basic education requirements, professional development is often left to the discretion of the individual or their institution. In an effort to create a coordinated solution to close this educational gap, interactive training focused on enabling investigators to enhance knowledge of research ethics, quality standards, and regulations, and apply best practice principles throughout the complex life-cycle of research studies, has been utilized. This session will explore challenges in meeting the educational needs of a diverse team of clinical research team members. During this session, speakers and attendees will:

Room 200



- Identify and describe how to utilize research-related competencies in the design of research team education
- Share best practices related to adoption of new knowledge among research team members
- Discuss strategies of engaging study team members in training design and implementation
- Describe how to assess, implement, and evaluate training for research investigators and teams

D3: Looking Through the Bars—Responsible Research With Prisoners (Populations Requiring Additional Protections)

Wayne Carriker, Hopequest Ministry Group, Inc.; Julia G. Gorey, OHRP

Speakers will discuss the regulatory fundamentals of using prisoners in research, as well as what it means to truly see things from the eyes of a prisoner. Speakers will use the seven additional approval criteria from Subpart C of 45 CFR 46 as a framework to present important insights, as well as discuss the experience of recruiting a former prisoner to serve on the IRB. Case studies and personal experience will illustrate how including a former prisoner on the IRB can provide a perspective not available from someone who has only worked with prisoners, and how that person can improve the ability of the IRB to protect prisoners as research subjects. During this session, speakers and attendees will:

Room 203



- Review the regulatory requirements and certification process when working with prisoners
- Interpret the federal requirements for membership in IRBs that review research on prisoners
- Analyze the criteria for approval for prisoner research, incorporating the perspective of an IRB member who was a prisoner
- Discuss how an academic IRB was able to incorporate a former prisoner as a valued member of their board

D4: FDA's Oversight of ClinicalTrials.gov Requirements (FDA-Regulated Research Track)

Anthony Keyes, Johns Hopkins University School of Medicine; Patrick J. McNeilly, Office of Good Clinical Practice, FDA

Investigators and institutions conducting certain clinical trials of FDA-regulated drug, biologic, and medical device products must submit registration and results information to ClinicalTrials.gov, as required by Title VIII of the FDA Amendments Act of 2007 (FDAAA) and its implementing regulations at 42 CFR part 11 (Final Rule). FDA has been given certain implementation and compliance/enforcement responsibilities related to ClinicalTrials.gov. This session will outline the requirements, consequences of noncompliance, and current and future enforcement activities. Speakers will also address the revised Common Rule requirement to post informed consent forms to either ClinicalTrials.gov or Regulations.gov. Attendees will learn how academic medical centers build programs and educate investigators and research teams, including the specific steps investigators and institutions can take to ensure 100% compliance with the relevant regulations. During this session, speakers and attendees will:

Room 309



ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
Breakout sessions new for 2019	
Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.	Basic – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.



- Review the basic requirements for registration and results information submission to ClinicalTrials.gov
- Discuss FDA's current and potential future approaches to monitoring compliance and potential consequences of noncompliance under FDAAA and 42 CFR part 11
- Share tools and resources available to help investigators and institutions ensure compliance with FDAAA, 42 CFR part 11, and the revised Common Rule

D5: Export Controls (Global Research Track)

Robert S. Bienkowski, Central Michigan University; Lisa A. Griffin, Brigham and Women's Healthcare, Inc.;

Export controls are federal laws that govern how physical items, technology, information, and data may be exported from the USs or shared with foreign persons within the US. This session will review the relevant regulations, use case studies to identify the impact of export controls on international research, and provide practical tips to managing export controls.

During this session, speakers and attendees will:

- Review the relevant export controls regulations administered by the US Departments of State, Commerce, and Treasury
- Describe when the IRB or investigator should consider export controls
- Use case examples to highlight different situations that triggered export control regulation

Room 300



Tuesday, November 19: AER19

Breakout Sessions Series D, 3:45-5:00 PM

D6: Complex Institutional Relationships—Going Beyond the Multi-Site Model

(Institutional Officials and HRPP Leadership Track)

Kristin J. Craun, University of California, Los Angeles; Sara Chandros Hull, National Human Genome Research Institute, NIH; Mary M. Klote, Veterans Health Administration/Uniformed Services University of the Health Sciences; Theresa M. Straut, Army Research Laboratory's Human Research Protection Program

Research collaborations with other institutions are widely seen as beneficial and necessary in order to advance science. These collaborations can involve various combinations of academic institutions, government agencies, and industry partners, which can mean new requirements and complex relationships and responsibilities for the IRB and HRPP staff to navigate. This session will provide real world examples and strategies for successfully managing these collaborations and single IRB review. During this session, speakers and attendees will:

- Share strategies that aid in navigating the complex regulatory landscape that exists when collaborators have different institutional requirements
- Share approaches for selecting the IRB of record in a collaborative environment, and how to strategize for addressing a variety of local context issues on the same project
- Discuss the importance of a well-constructed reliance agreement and how this agreement can be a useful tool for facilitating research collaborations

Room 202



D7: Writing and Updating Standard Operating Procedures (SOPs) for the Revised Common Rule (IRB Basics Track)

Elizabeth A. Bankert, Dartmouth College; Lauren Hartsmith, OHRP; Cheryl A. Savini, HRP Consulting Group

This session will provide attendees with the basic foundation necessary to successfully develop and maintain essential HRPP/IRB SOPs. Speakers will provide guidance, tools, and share best practices designed to craft regulatory compliant SOPs and ensure available guidance is incorporated, as necessary. During this session, speakers and attendees will:

- Discuss the components of comprehensive and effective HRPP/IRB SOPs
- Identify key areas in which OHRP/FDA guidance has become available and may warrant revision or review of existing SOPs
- Share how to effectively evaluate SOPs and make revisions as necessary

Room 306



D8: The Role of IRBs Chairs in Protocol Exceptions, Violations, Noncompliance, and Unanticipated Problems

(IRB Chairs Track)

Lisa R. Buchanan, OHRP (resource person); Francis J. DiMario, Connecticut Children's Medical Center/University of Connecticut School of Medicine; Michael J. Linke, University of Cincinnati College of Medicine

This session will discuss "best practice" operational procedures when reviewing protocol exceptions, violations, noncompliance, and unanticipated problems. Before attending this session, attendees should have an understanding of violations and deviations, experience managing noncompliance, and familiarity with reviewing protocol exception requests.

During this session, speakers and attendees will:

- Describe institutional procedures when reviewing protocol exceptions, violations, noncompliance, and unanticipated problems

Room 311



ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
Breakout sessions new for 2019	
Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.	Basic – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.



- Evaluate challenges and present solutions to difficult scenarios

D9: Ensuring IRB Compliance in a Hybrid World—Strategies for Operating in a World Where Multiple Regulatory Frameworks Apply (*IRB Operations Advanced Track*)

Martha Jones, Partners HealthCare System, Inc.; Megan Kasimatis Singleton, Johns Hopkins University School of Medicine

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

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

Room 310



Tuesday, November 19: AER19

Breakout Sessions Series D, 3:45-5:00 PM

D10: Returning Research Results to Participants—Whose Job Is It? (*Pharma/Biotech Perspectives Track*)

Karla Childers, Johnson & Johnson; Gianna McMillian, Loyola Marymount University; Carol Juliet Weil, National Cancer Institute

Returning both the summary results of a clinical trial and individual research results to participants honors the essential contributions and voluntarism of study participants in clinical trials, while improving the transparency of those trials. Return of results also involves communicating in plain language understandable to the trial participants. HRPPs often struggle with what results "should" or could be returned, whose responsibility it is to return results, and whether IRB oversight is needed. The complexity of whether and how to return results differ by the type and nature of the research, the study population, and the medical significance, analytical validity, and personal utility (value) of the result. Strategies to support sponsors, investigators and their study teams, and IRBs to communicate results will be discussed, a framework for decision-making will be presented, and resources to assist in the process will be offered. During this session, speakers and attendees will:

- Discuss the ethical imperative behind the return of research results
- Identify strategies to integrate the return of results into the research workflow
- Provide resources and tools that support investigators and study teams in returning research results to study participants

Room 201



D11: Is Your HRPP Due for a Policy Refresh? Re-Thinking Policies and Processes Related to Conflicts of Interest and Research Integrity (*Legal Considerations for HRPPs Track*)

Heather H. Pierce, Association of American Medical Colleges; Emily M. Q. Schriver, The Ohio State University; Michael J. Vernick, Hogan Lovells LLP

Several prominent organizations have recently received public scrutiny as cases of research misconduct and conflicts of interest have been exposed. These cases have resulted in higher level officials resigning their positions and financial penalties. This session will review the regulatory requirements pertaining to research misconduct and conflicts of interest, and outline institutional obligations and potential liabilities under these requirements. Additionally, this session will use recent case examples to identify areas where HRPPs may wish to consider policy and procedural enhancements to mitigate organizational vulnerabilities. During this session, speakers and attendees will:

- Review the relevant regulatory frameworks governing research misconduct and research conflicts of interest
- Explore recent cases where institutions faced scrutiny and/or liability related to concerns surrounding research misconduct or conflicts of interest in research
- Share practical suggestions for institutional policies responsive to these recent developments and ways institutions can mitigate liability

Room 206



D12: Assessing Plans to Maintain Confidentiality—How IRBs Determine Whether Data Security and Management Plans Are Sufficient (*Research Involving Data and Biospecimens Track*)

Gretchen L.J. Anding, University of Wisconsin-Madison; Elizabeth A. Buchanan, University of Wisconsin-Stout

The criteria for IRB approval have always included a requirement that IRBs consider, when appropriate, that there are sufficient protections in place to maintain the confidentiality of data. The revised Common Rule, specifically the new

Room 304



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Breakout sessions new for 2019	
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requirements for limited IRB review, place emphasis on this review criterion. Minimal guidance exists to assist IRBs in determining whether proposed safeguards for research data are sufficient. This session will review the challenges IRBs face in reviewing protocols to determine if the plans for maintaining confidentiality are sufficient, and it will highlight solutions for how data management and security review may be incorporated into the IRB review process. This session is appropriate for biomedical and SBE research audiences. During this session, speakers and attendees will:

- Review the requirements IRBs should consider in creating plans to maintain confidentiality as part of the IRB review process
- Highlight the ways in which the revised Common Rule may impact the IRB's review of confidentiality plans
- Discuss practical solutions for incorporating the review of data security and management plans in the IRB review process
- Provide case examples to help evaluate when data needs to be protected, how to know that, and what IRBs can do, particularly when there isn't a robust IT security department, or one that is not engaged

Tuesday, November 19: AER19

Breakout Sessions Series D, 3:45-5:00 PM

D13: Inclusion of Pregnant Women in Clinical Trials (Populations Requiring Additional Protections Track)

Leyla Sahin, Office of New Drugs, FDA; Kristine Shields, Shields Medical Writing and Consulting

The FDA Draft Guidance for Scientific and Ethical Considerations for the Inclusion of Pregnant Women in Clinical Trials was released in April 2018. IRB members, clinical trial investigators, industry personnel, regulators, etc., must be knowledgeable about the ethical and regulatory implications and expectations for such studies. During this session, speakers and attendees will:

- Discuss the contents and implications of the Draft FDA guidance on the inclusion of pregnant women in clinical trials
- Identify and discuss the ethical issues involved in including pregnant women in clinical trials
- Apply knowledge of regulatory, ethical, and business implications of the Draft FDA guidance to IRB decision-making

Room 101



D14: Ideas and Practices for Compliance and Auditing of Single IRB (sIRB) Studies

(QA/QI and Postapproval Monitoring Track)

Nichelle Cobb, University of Wisconsin-Madison; Neala Lane, Indiana University; Sarah A. White, The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard Medical School

sIRB is becoming commonplace in the human subjects clinical trial enterprise. As institutions transition to reviewing or relying IRBs, they face new challenges with respect to ensuring appropriate oversight of the clinical trial and study team, communication between the reviewing and relaying IRBs, and compliance with requirements. QA/QI and postapproval monitoring programs can play a critical role in ensuring study teams are aware of their responsibilities, remain in compliance, and identify communication gaps if they occur. During this session, speakers and attendees will:

- Identify key changes in the regulatory landscape that affect oversight responsibilities and processes for research under the sIRB model
- Review key challenges to QA/QI audits of sIRB studies
- Explore effective QA/QI audit processes
- Use case studies to discuss effective QA/QI audit opportunities and successes

Room 302



D15: Mobile Health Research: Regulatory and Ethical Challenges (Research Conducted in the Digital World Track)

Barbara E. Bierer, The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard Medical School; Luke Gelinas, Advarra, Inc.; Laura Odwazny, DHHS

The widespread use of mobile smart devices and wearables (e.g., smart phones and watches) holds the potential to drastically change how clinical research is conceptualized and conducted. While these developments can make research participation less burdensome and potentially improve participation rates, they raise challenges that IRBs and other stakeholders struggle to navigate. This session will address key ethical and regulatory issues associated with mobile health research. First, the session will describe some common forms of mobile health research, examine its key features and how

Ballroom A



ICON KEY

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Pre-registration required	Recorded session
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it differs from more traditional research, and give attendees a sense of its breadth. Second, the session will address regulatory challenges that stem from determining the correct regulatory framework and pathway for mobile applications and wearables, stemming from the IRB's practical need to determine whether a device requires submission to appropriate regulatory authorities before research commences and/or qualifies for a non-significant risk determination. Finally, the session will address the ethical issues that bear on the IRB's device risk determination and overall review of the study. During this session, speakers and attendees will:

- Describe some of the common types and key features of research being done with wearable devices and mobile applications
- Discuss the regulatory challenges associated with the use of wearable devices and mobile applications in research and strategies for navigating them
- Identify additional ethical challenges associated with the use of wearable devices and mobile applications in research—in particular, privacy concerns and the responsive obligations of researchers—and strategies for navigating them

Tuesday, November 19: AER19
Breakout Sessions Series D, 3:45-5:00 PM

D16: Responsible Conduct of Research (RCR) for Research Leaders—Integrating Research Administration for a Successful Collaborative Framework (*Responsible Conduct of Research Track*)

John R. Baumann, Indiana University; James Riddle, Advarra; Jane Strasser, University of Cincinnati

As funding for research continues to constrict, successful organizations must continuously improve, innovate, and advance. Integration of research administration functions from grants and contracts, clinical operations, to regulatory oversight through IRB/Institutional Animal Care and Use Committee/Institutional Biosafety Committee is crucial to ensure programs are organized and working together to support research. Integration doesn't always mean new technology; most improvements can be implemented with people and programs. This session will focus on program building and collaboration from the institutional level. Presenters will provide insights into the intersection of RCR with scholarly excellence (and its practical application). The speakers will explore mechanisms of incorporating a collaborative approach of awareness and oversight that includes partnerships with academic administrators (e.g., deans, department heads, etc.), research administrators, clinical staff, and investigators and faculty at all levels. Attendees should be administrators who have responsibilities that encompass, but are not limited to, HRPP/IRB operations, including cross institutional collaborations with academic program administrators. During this session, speakers and attendees will:

Room 107



- Discuss internal and external perspectives related to RCR, research excellence and scholarly responsibilities
- Understand how integration can establish or refine an infrastructure that supports scholarly excellence through RCR
- Highlight practical strategies for promoting research excellence, including case examples of successful integration and challenges in implementation

D17: Flying Solo—A Moderated Discussion on Opportunities Available for Single Staff IRB Offices

(*Small Research Programs Track*)

April V. Baker, National Opinion Research Center, University of Chicago; Andrea R. McDowell, Seattle University; Rachel Zand, University of Toronto

This interactive session will explore the organizational, professional, and procedural challenges and opportunities experienced by single staff HRPP/IRB offices. Attendees will discuss current and future needs to professional development and support, and will discuss how and with whom to develop these networks, both within their organizations and outside, through mentorship and other relevant professional groups. During this session, speakers and attendees will:

Room 204



- Review the organizational, professional, and procedural circumstances that provide challenges and opportunities for HRPPs with only one staff person
- Discuss how to optimize opportunities and implement solutions for challenges unique to single staff offices
- Develop strategies for connecting, networking, and mentorship with others in the HRPP and greater research ethics and compliance community

D18: Reviewing SBER—A Guide for the Non-Scientist, Unaffiliated IRB Member (*SBER Track*)

Room 108

ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
Breakout sessions new for 2019	
Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.	Basic – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.



Emily E. Anderson, Stritch School of Medicine, Loyola University Chicago; Amy Corneli, Duke University

The current ethical and regulatory frameworks for prospective ethical review of research were developed for clinical medical research that poses more than minimal risk (i.e., physical risk). This mismatch can often lead to under- and over-estimation of risks in SBER by IRBs. The session will be delivered in a question and answer format, following the format of a recent user-friendly reference book published by the session presenters specific to SBER. During this session, speakers and attendees will:



- Review the unique design features of SBER that may raise ethical concerns
- Explain the unique risks and benefits of SBER
- Describe key protections for minimizing risks to participants in SBER, particularly that which poses greater than minimal risk

Tuesday, November 19: AER19

Breakout Sessions Series D, 3:45-5:00 PM

D19: IRBs and Ethnographers—Unpacking the Dimensions of a Challenging Relationship to Increase Mutual Understanding (SBER Track)

Shannon Sowards, Harvard University; Montana Miller, Bowling Green State University

Anthropologists' core method of ethnography can be argued to offer the greatest challenges for the IRB review process, for researcher and review alike. These challenges are also appearing more frequently for many IRBs, with increasing numbers of researchers across disciplines adopting ethnographic approaches. This session will present a dialogue across three perspectives: (1) the anthropological view informed by the field; (2) the practice of ethnographic review; and (3) the overarching regulations. The conversation aims to identify legacies, trends, patterns of process, ways that perspectives are articulated, and moments of struggle for mutual understanding that characterize the IRB-anthropologist relationship, aiming to contribute to an improved IRB-ethnographer dialogue within the review process. Before attending this session, attendees should have a working knowledge of 45 CFR 46, particularly regulatory flexibility for informed consent, and of ethnography as a research methodology. During this session, speakers and attendees will:

Room 313



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

D20: Staying Current and Keeping Pace—A Primer for IRB Chairs (IRB Chairs Track)

Kerry A. Agnitsch, Iowa State University; J. Andrew Bertolatus, University of Iowa; Robert W. Frenck, Jr., Cincinnati Children's Medical Center/University of Cincinnati

In this session, speakers will review the scope of information relevant to IRB chairs. Experienced biomedical and SBER chairs will discuss ways to identify and obtain the regulatory knowledge that is most relevant to the chairs' specific institutional research programs. Speakers will provide creative ways to keep pace with the changing regulations, and will provide examples of how to learn from mishaps at other institutions. During this session, speakers and attendees will:

Room 104



- Provide methodologies to evaluate an IRB
- Determine the regulatory knowledge to focus on
- Discuss likely issues that will require additional attention by the chair
- Suggest both local and national websites, listservs, and other resources to help stay current
- Share benchmarking standards that can be used to resolve issues

D21: Situational Vulnerability—Considerations and Safeguards When Exploring Gender Identity, Social/Economic Challenges, and At-Risk Behavior (Populations Requiring Additional Protections Track)

Matan Benyishay, AIDS Action Committee/Fenway Health; John A. Guidry, TRX Development Solutions/New York University; Dana J. Pardee, The Fenway Institute

Room 312

ICON KEY

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There are many populations that have vulnerabilities related to their marginalized status. Thus, it is important for IRBs to understand the expertise needed to review studies with these populations and some of the special or heightened concerns related to these groups. During this session, speakers and attendees will:



- Identify vulnerabilities beyond those addressed by federal regulations (e.g., homelessness, substance abuse, LGBT status, undocumented residency)
- Examine the special considerations investigators and IRBs should take into account in designing and reviewing studies involving these populations (e.g., payment and undue influence, recruitment, maintaining contact with subjects, confidentiality, stigmatization of research subjects)
- Review additional risks that may affect these marginalized populations (e.g., violence, discrimination, depression, suicide)

D22: The Keys to Key Information—An Interactive Workshop (*IRB Operations Advanced Track*)

Yvonne Lau, OHRP; Jerry A. Menikoff, OHRP

The requirements for a key information section and for providing information in a way that enhances potential subjects' understanding of why one might or might not want to participate in the research with the goal of making informed consent more meaningful to research participants constitutes a major revision to the Common Rule. This interactive workshop explores OHRP's thinking about the new requirements for informed consent at 45 CFR 46.116(a)(5), how they could be met, and what might be some examples of best practices. The workshop will focus on biomedical clinical trials, will use case examples for discussion, and provide concrete suggestions for making consensus document a meaningful decision tool for participants. During this session, speakers and attendees will:

Room 103



- Review the new requirements for informed consent at 45 CFR 46.116(a)(5)
- Explore what might be "key information" for potential clinical trial research participants
- Describe best practices and approaches for key information in the setting of clinical trials

Tuesday, November 19: AER19

Breakout Sessions Series D, 3:45-5:00 PM

D23: Challenges and Lessons for Implementing New Exemption 4(iii)—Secondary Research Involving Only Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule-Protected Identifiable Health Information

(*Research Involving Data and Biospecimens Track*)

Kim Fowler, University of Georgia; Megan McFarland, Army Human Research Protections Office

This didactic session centers on the unique challenges and lessons learned for operationalizing the new exemption category 104(d)(4)(iii) for secondary research involving the use of only identifiable health information, when such use is regulated by the HIPAA Privacy Rule. While such use may now be deemed no longer in need of both revised Common Rule as well as HIPAA Privacy Rule protection, research institutions, researchers and those who make exemption determinations may lack the tradition, processes and expertise necessary to ensure adequate compliance of these exempt activities without IRB oversight. Case studies for implementing appropriate procedures and reviews to satisfy the conditions for this exempt category will be used for discussion, and will include explanations of the relevant HIPAA Privacy Rule provisions, including valid authorizations, waivers of authorization with Privacy Board review and approval, uses preparatory to research, and uses and disclosures of limited data sets with data use agreements. During this session, speakers and attendees will:

Room 102



- Review the regulatory requirements for research involving HIPAA Privacy Rule-protected identifiable health information
- Discuss how research activities may be transitioned to or fall within new Common Rule exemption category 104(d)(4)(iii)
- Share insight on developing institutional policies, procedures, and practices for the review of exemption category 10(d)(4)(iii) activities that are compliant with the HIPAA Privacy Rule

5:00-6:00 PM

Networking Reception With the Supporters and Exhibitors

Join us in the exhibit hall to meet and greet the AER19 Supporters and Exhibitors. Light refreshments will be served, and a cash bar will be available.

Exhibit Hall C

5:00-6:00 PM

Meet the AER19 Poster Authors

Visit with the AER19 Poster Presentation Program authors and learn more about their innovative and important work on new program initiatives, empirical research, and conceptual analysis. The presentation of the posters promotes interdisciplinary sharing and collaboration, and facilitates the exchange of ideas, information, and practical strategies for managing the many challenges faced by research professionals.

Exhibit Hall C

5:00-6:00 PM

Exhibit Hall C

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Federal Agency Office Hours

During this time, representatives from select federal agencies will be available to answer attendee questions, engage in dialogue, provide clarification, and/or direct attendees to additional resources. Attendees are encouraged to come prepared with questions, which will be taken on a first come basis. AAHRPP, Inc., DOD, DOE, DOJ, FDA, OHRP, ORI, SACHRP, and VA will be present at this time.



5:10-5:30 PM

Industry Expert Theater: AER19 Poster Presentation—*Novice Researcher Confidence Before and After the Implementation of an Informed Consent Simulation Workshop Enlisting the Feedback of Former Research Volunteers*

Join us in the Industry Expert Theater to hear from two of this year's outstanding poster abstract authors about their important and timely work. During this timeslot authors Susan Garrow-Sloan and Judith Pride, Baystate Health, will present their poster and attendees will have the ability to comment and ask questions.

Exhibit Hall C

5:35-5:55 PM

Industry Expert Theater: AER19 Poster Presentation—*The Consent Language Explicit and Reasonable (CLEAR) Initiative*

Join us in the Industry Expert Theater to hear from one of this year's outstanding poster abstract authors about their important and timely work. During this timeslot, Marilyn Eshikena, Icahn School of Medicine at Mount Sinai, will present their poster, and attendees will have the ability to comment and ask questions.

Exhibit Hall C

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Wednesday, November 20: AER19

7:00 AM-12:30 PM
On-Site Check-in Open
Breakfast on your own.

Pre-Function Hall C

7:00-8:00 AM
A Capella Musical Performance
 Join us before the conference starts for a musical performance by a local a capella group. PRIM&R would like to thank Tech Software for supporting this performance.

Pre-Function Hall C/
 Veterans Memorial Auditorium

8:00-8:10 AM
Welcome from the Conference Co-Chairs

Veterans Memorial Auditorium



8:10-8:20 AM
PRIM&R Membership Update

Veterans Memorial Auditorium



8:20-8:30 AM
PRIM&R CIP® Update

Veterans Memorial Auditorium



8:30-9:30 AM
Keynote Address by Mary Elizabeth Williams, BA, Writer, Speaker, Consultant: Keeping the Humanity in Human Subjects Trials

Veterans Memorial Auditorium



9:30-10:00 AM
Beverage Break With Supporters and Exhibitors
 Join us for coffee in the exhibit hall.

Exhibit Hall C

9:30-10:00 AM
Book Signing With Keynote Speaker Mary Elizabeth Williams, BA, Writer, Speaker, Consultant
 Join us at the conference bookstore in the exhibit hall for a book signing with keynote speaker, Mary Elizabeth Williams. Copies of Ms. Williams' book, A Series of Catastrophes and Miracles: A True Story of Love, Science, and Cancer, will be available for sale at the bookstore.

Exhibit Hall C

10:00-11:15 AM: Plenary Sessions and Repeat Breakout Sessions

Panel VII: From Fortnite to Facebook—Data Security and Breaches, Downstream Harms, and the (Precarious) Role of IRBs
Moderator: Elizabeth A. Buchanan, University of Wisconsin-Stout
Panelists: James R. Foulds, University of Maryland, Baltimore County; Jacob Metcalf, Ethical Resolve, LLC/Data Society and Research Institute; Stephen J. Rosenfeld, Freeport Research Systems, LLC

Ballroom B



By mid-April, 2019, we had already experienced upwards of 50 major data breaches in the US (those are the ones we know of). We've heard Facebook's admission that it has not secured 600 million user passwords since 2012, and we've been alerted to the 540 million records, including account names, Facebook IDs, and user activity, that were left exposed. Even our favorite pastime, the amazingly popular game Fortnite, and its 200 million users' accounts, were compromised and personal account information left vulnerable. And, the list of medical institutions or hospital systems breaches continues to grow daily. All too often, the end result is the same: "The sensitive data included names, patient ID numbers, dates of birth, addresses, phone numbers, health insurance information, payment information, driver's licenses, and Social Security numbers...." As data sources, from our social media to our medical records, become more co-mingled and accessible, what is the role of the IRB in this contested space of industry, government records, and the research enterprise? This panel will provide an overview of the current state of data risks and security as they pertains to this unregulated space, while delving into topics including the continuing loss of privacy and its impact on minimal risk.



ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
Breakout sessions new for 2019	
Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.	Basic – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.



Wednesday, November 20: AER19

10:00-11:15 AM: Plenary Sessions and Repeat Breakout Sessions

Panel VIII: The Challenges of Studying Marijuana Use in the United States

Moderator: Albert J. Allen, Eli Lilly and Company

Panelists: Juliette Roddy, University of Michigan—Dearborn; Benjamin C. Silverman, Partners HealthCare System, Inc./Harvard University; Beth Watters, Partners HealthCare System, Inc.

This panel will discuss the need for and challenges of conducting scientific and behavioral research into the potential medical uses and risks of cannabis and its components. The importance of scientific scrutiny is growing as more states legalize recreational and medical marijuana. This plenary session will discuss the regulatory challenges of studying marijuana use in both the lab and community settings, the chasm between federal and state laws, and special considerations for IRB review of marijuana research.

Ballroom C



Repeat Breakout Session (A9): The Etiquette and Necessity of Communication in the Single IRB World

(IRB Operations Advanced Track)

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

Room 302



- Review what local context information a reviewing IRB should collect, both about relying institutions and study implementation, how to tailor it for the study type, and mechanisms for retaining that information to reduce burdens on the relying institution
- Explore how to engage relying institutions so they address noncompliance and unanticipated problems (e.g., in the development of corrective action plans and reports to federal agencies and authorities)
- Determine when to reach out to relying institutions to obtain input on amendments
- Identify what information to include in approval notices or other documents to assist the relying institution with their oversight responsibilities
- Share writing policies that are accessible to and take into account the perspectives of relying institutions and relying site study teams

Repeat Breakout Session (B15): The Secrets of Big Data—Public, Private, or Something Else? *(Research Conducted in the Digital World Track)*

Ivor A. Pritchard, OHRP

Information is commonly thought to be either "public" or "private," with no third alternative. However, a considerable portion of big data could be considered to be neither public nor private, but rather information with access that is controlled or limited by such things as "privacy agreements," which actually serve to identify the extent to which information may be used and restricted. How should the norms of sharing information be constructed, and by whom?

During this session, speakers and attendees will:

Room 306



- Examine when there could be a difference between "private information" and "confidential non-public information," and how this would alter the application of the regulations
- Share important legal cases regarding the evolving idea of privacy in US law
- Discuss current perspectives on how access to confidential information in various forms should be circumscribed in research

ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
Breakout sessions new for 2019	
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Wednesday, November 20: AER19

10:00-11:15 AM: Plenary Sessions and Repeat Breakout Sessions

Repeat Breakout Session (C3): Tissue Repositories and Data Banks in the Era of the Revised Common Rule

(Research Involving Data and Biospecimens Track)

Julie Ozier, Vanderbilt University and Medical Center; Nicholas A. Wallace, Ropes & Gray LLP; Carol Juliet Weil, National Cancer Institute

Room 312



The revised Common Rule introduced the option of broad consent for secondary research, as well as two new exemptions (exemptions seven and eight) for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens when broad consent is used and limited IRB review occurs. These options, and the revised definitions of "human subject," offer new opportunities and challenges for the research enterprise and IRB professionals, but also raise questions about how and whether they can be effectively utilized to facilitate research. With almost a year of implementation underway, this session will review whether institutions have implemented these options and, if so, what the benefits and challenges have been. Have any institutions adopted broad consent and, if so, in what circumstances? What has limited IRB review looked like in practice? Attendee participation and sharing of best practices developed since the revised Common Rule went into effect will be encouraged. During this session, speakers and attendees will:

- Describe the new options of broad consent and exemptions seven and eight in the revised Common Rule, and review requirements for their use, restrictions to waiver and alteration of broad consent, and other problems that may be caused by these requirements
- Use case studies to explore potential challenges in operationalizing the use of these options, including issues with tracking, IRB reviews, etc.
- Review how operational problems might or might not be overcome, and share practical suggestions for institutions as they continue to operate research repositories under the new regulatory framework

Repeat Breakout Session (D1): Lost in Transition? Flexible and Innovative Approaches to the Revised Common Rule

(Flexibility and Innovation in IRB Processes Track)

Charles Brightbill, Geisinger Health System; Jaime O. Hernandez, OHRP (resource person); Cindy S. Shindlecker, University of Michigan

Room 210



The revised Common Rule now aligns with the many flexibility initiatives already implemented at institutions for research that is not federally supported. This session showcases flexible approaches to applying the revised Common Rule: (1) a decision-making tool to identify which studies approved before the revised Common Rule could (or should) be transitioned; and (2) an effort to allow researchers more autonomy in making exemption determinations. During this session, speakers and attendees will:

- Explore how and why to implement flexibility and innovation into HRPP processes and policies
- Discuss practical approaches HRPPs use to approach the requirements of the new rule through the presentation of examples of innovative and flexible initiatives
- Share how to create an institutional culture of innovation and flexibility

Repeat Breakout Session (E2): Strategies for IRB Member Education (Educating and Training Track)

Emily E. Anderson, Stritch School of Medicine, Loyola University Chicago; Toby L. Schonfeld, Prime Review Board

This session will offer innovative strategies and resources for developing and delivering IRB member education. Speakers will highlight educational methods and materials that are interactive and adaptable, particularly case studies, and that cover a range of topics including clinical and SBER. During this session, speakers and attendees will:

Room 304



- Identify resources for IRB member education
- Develop strategies for increasing buy-in and engagement of IRB members in educational activities
- Assess the potential of different educational strategies for teaching about different topics

11:15-11:30 AM

Break

ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
Breakout sessions new for 2019	
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Wednesday, November 20: AER19

Breakout Sessions Series E 11:30 AM-12:45 PM

E1: Innovations in IRB Evaluation and Improvement (*Flexibility and Innovation in IRB Processes Track*)

Holly A. Taylor, Department of Bioethics, Clinical Center, NIH; Ilene F. Wilets, Icahn School of Medicine At Mount Sinai

Through a highly interactive and collaborative format, speakers will provide attendees with a concrete framework and practical suggestions for conducting research on their HRPPs to help address challenges that arise in everyday practice. In addition, this session will discuss how HRPPs are well positioned to conduct empirical research addressing various process and policy challenges. Before attending this session, attendees should have sufficient experience and understanding to actively contribute to the discussion of and solution to these problems. This session will not review basic concepts. During this session, speakers and attendees will:

- Review how HRPPs can conduct their own research to address challenges in everyday practice
- Outline different ways HRPPs can engage the various communities they serve (scientific, non-scientific, and unaffiliated) to improve their research protections policies and processes
- Share practical strategies for leveraging limited institutional resources to develop and accomplish a research agenda

Room 210



Advanced

E2: Strategies for IRB Member Education (*Educating and Training Track*)

Emily E. Anderson, Stritch School of Medicine, Loyola University Chicago; Toby L. Schonfeld, Prime Review Board

This session will offer innovative strategies and resources for developing and delivering IRB member education. Speakers will highlight educational methods and materials that are interactive and adaptable, particularly case studies, and that cover a range of topics including clinical and SBER. During this session, speakers and attendees will:

- Identify resources for IRB member education
- Develop strategies for increasing buy-in and engagement of IRB members in educational activities
- Assess the potential of different educational strategies for teaching about different topics

Room 304



Note: this session was previously held on November 20, 10:00-11:15 AM.

E3: Integrating Empirical Research Ethics into IRB Decisions for Studies Involving Vulnerable Populations

(*Empirical Research Ethics Track*)

Celia B. Fisher, Fordham University; Nicole M. Overstreet, Clark University

Using current examples in empirical research ethics, this session will help attendees learn how to read and interpret empirical research ethics literature and apply these findings to work with investigators in evaluating and strengthening human subjects protections. Topics covered include risk and benefits of socially sensitive research, fair use of incentives, and waiver of guardian permission in research involving socially vulnerable populations. During this session, speakers and attendees will:

- Increase the ability of IRB members to apply results from quantitative studies to the evaluation of participants' risks and benefits for studies involving socially sensitive topics
- Discuss how IRB members should interpret the transferability of qualitative studies to decisions regarding the use of incentives for research involving persons who use drugs
- Explore how IRB members should apply data from both qualitative and quantitative studies to decisions regarding waiver of guardian permission for adolescent participation in health research

Room 104



E4: Assessing the Prospect of Direct Benefit in Early-Phase Pediatric Studies (*FDA-Regulated Research Track*)

Melanie Bhatnagar, Office of Pediatric Therapeutics, FDA; Donna L. Snyder, Office of Pediatric Therapeutics, FDA; Albert J. Allen, Eli Lilly and Company








FDA regulations permit IRBs to approve pediatric research that presents more than a low level of risk if participation in the research holds out the prospect of direct benefit for the individual subjects. Given that there is no regulatory definition for prospect of direct benefit, how should it be defined? How should IRBs consider the prospect of direct benefit in the context of early-phase clinical trials involving pediatric subjects? During this session, speakers and attendees will:

- Discuss IRB considerations for assessing prospect of direct benefit in pediatric studies
- Examine how to assess prospect of direct benefit in the setting of early-phase clinical trials
- Use case examples to explore concepts such as the appropriate use of non-human data and the applicability of biomarkers to reflect clinical benefit

Room 202



ICON KEY

 Double session	 Call for Session Proposal
 Pre-registration required	 Recorded session
 Reviews changes to the Common Rule	 CIP eligible
 Breakout sessions new for 2019	
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Wednesday, November 20: AER19

Breakout Sessions Series E 11:30 AM-12:45 PM

E5: Applying US Human Research Protections Regulations and Embedded Cultural Values to Research Conducted in Different Cultures (*Global Research Track*)

Derek Englis, *Armed Forces Services Corp./Magellan Federal*; A. Roxana Lescano, *United States Naval Medical Research Unit No. 6*; Bussara Sukpanichnant, *Institute of Medical Sciences (AFRIMS)*; Edward E. Bartlett, *OHRP*

The US human research protections regulations reflect the cultural values and worldviews of some groups in the US, and institutions that conduct research outside of the US may face challenges in applying the US regulations and departmental policies (e.g., Department of Defense) within the local cultures. In this session, speakers will discuss possible strategies for HRPP staff who are tasked with ensuring compliance with US-based human research protections requirements within diverse cultures. During this session, speakers and attendees will:

- Review how US human research protections regulations reflect cultural values of US groups
- Discuss the importance of being sensitive to local culture when conducting human subjects research
- Identify possible strategies to the challenges that arise when applying US-based regulations for research involving subjects from different cultures

Room 302



E6: Making Your HRPP Distinct and Organized in a Single IRB World (*Institutional Officials and HRPP Leadership Track*)

Ann Johnson, *University of Utah*; Julie Ozier, *Vanderbilt University and Medical Center*

The concept of a HRPP can often blur together with the roles and responsibilities of the IRB. This session will present strategies for setting up the HRPP with clear and distinct roles, responsibilities, and review processes to ensure efficient completion of review and effective oversight of research using an external single IRB. Presentation and discussion within the session will be facilitated and sample process documents will be shared. Before attending this session, attendees should be familiar with the regulatory responsibilities of IRBs and HRPPs. During this session, speakers and attendees will:

- Review and discuss strategies for making the HRPP a distinct and organized entity at the institution
- Understand the review efficiency problems that can occur if the site HRPP does not have an organized process for the review of projects using an external single IRB
- Share key components of a successful HRPP review process when using an external single IRB

Room 102



E7: Essential Documentation—IRB Record Keeping, Written Procedures, Minutes, and More (*IRB Basics Track*)

Janet C. Donnelly, *Office of Good Clinical Practice, FDA*; Ada Sue Selwitz, *University of Kentucky*; Irene E. Stith-Coleman, *OHRP*

The federal regulations define the requirements for IRB record keeping, for documenting IRB procedures, discussions, and findings, and communicating IRB decisions. This session will provide a basic overview of the regulatory requirements for documenting these essential IRB functions. During this session, speakers and attendees will:

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

Room 309

Basic

E8: Meeting Management for IRB Chairs (*IRB Chairs Track*)

Francis J. DiMario, *Connecticut Children's Medical Center/University of Connecticut School of Medicine*; Robert H. Romanchuk, *Advarra*

This session will cover key topics in the management of an IRB from the IRB chair's perspective. During this session, speakers and attendees will:

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

Room 300

Basic

ICON KEY

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Wednesday, November 20: AER19

Breakout Sessions Series E 11:30 AM-12:45 PM

E9: How IRBs Identify Research vs. Non-Research Risks—The Impact of the “Standard of Care” Concept

(IRB Operations Advanced Track)

Sharon Ellison, Duke University Health System/Duke University; Anthony E. Magit, University of California, San Diego; Jerry A. Menikoff, OHRP (resource person)

The FDA and revised Common Rule regulations require IRBs to ensure research risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In addition, in evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). For both single site or multi-site research, identifying what research risks are can be challenging because the therapies a subject could receive may vary based on the standard of care within that institution or across organizations. In other words, the risks, benefits, and alternatives of research participation could be different for each subject. This variability in standard of care, especially under the single IRB model or for the review of comparative effectiveness research, can have significant pragmatic consequences, such as consent form content and risk level determination. Before attending this session attendees should have an understanding of the criteria for approval related to risks in research and be familiar with the concept of standard of care as it relates to research. During this session, speakers and attendees will:

- Discuss the potential impact of the intersection between research and clinical care on the assessment of risks, benefits, and alternatives
- Debate whether “standard of care” is the appropriate standard to use for assessing research vs. non-research risks, or if other standards, such as usual practice or standard practice, are more appropriate
- Share strategies for addressing variability in standard of care under the single IRB model, such as at the protocol writing stage, and how to identify the variability for IRB assessment

Ballroom A



Advanced

E10: Reserved for Late-Breaking

E11: Protecting Privacy in an Era of Shifting Requirements for Privacy and Concepts of Identifiability

(Legal Considerations for HRPPs Track)

Valerie Bonham, Ropes & Gray LLP; Theresa J. Colecchia, Johns Hopkins University

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

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

Room 312



ICON KEY

Double session	Call for Session Proposal
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Wednesday, November 20: AER19

Breakout Sessions Series E 11:30 AM-12:45 PM

E12: Operationalizing Research Databases and Biobanks at Your Institution

(Research Involving Data and Biospecimens Track)

Marianna J. Bledsoe, Marianna J. Bledsoe Consulting, LLC/International Society for Biological and Environmental Repositories; Marylana Saadeh Helou, Verrill Dana LLP; R. Peter Iafrate, University of Florida

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

- 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

Room 200



E13: Under the Influence—Capacity and Consent *(Populations Requiring Additional Protections Track)*

Amy Ben-Arieh, The Fenway Institute at Fenway Health; Lara N. Sloboda, Dana Farber Cancer Institute

This session will focus on the challenges presented by the informed consent process when research participants competence or capacity to provide consent may be in question due to use of intoxicant substances. The session will provide an overview of recent literature on the topic, an introduction to relevant regulatory and ethical guidelines, and a few brief case discussions. Before attending this session, attendees should have one year or more IRB administration experience or research experience, and have a solid foundation of knowledge of the HHS and FDA regulations and applications thereof. During this session, speakers and attendees will:

- Explore how to define the threshold for intoxication under which truly effective consent can be obtained, and explore strategies for assessing comprehension and learn when HHS and FDA regulations might allow for waiving consent in certain circumstances
- Become familiar with legal and clinical precedents for determining research participants' capacity to consent when under the influence
- Review the recent literature on this topic, and how the issue is addressed by relevant professional groups
- Apply best practice and regulatory framework to cases adapted from actual studies

Room 203



E14: Impact of the Revised Common Rule on the Work of a QA/QI Program

(QA/QI and Postapproval Monitoring Track)

Leslie M. Howes, Harvard T.H. Chan School of Public Health; Mary-Tara Roth, Boston University Medical School/Boston Medical Center

Institutions and universities have changed policies and procedures to be in compliance with the revised Common Rule. Some of the new provisions decrease the oversight and administrative burden of the IRB while simultaneously increasing the investigator's responsibility. QA/QI programs have long been instrumental in educating and auditing investigator sites to ensure compliance, and this is another opportunity. During this session, speakers and attendees will:

- Identify key changes in the revised Common Rule where QA/QI programs can collaborate with IRBs, or other components of the HRPP, to ensure compliance
- Discuss options for flexing a QA/QI program's auditing efforts as a result of the revised Common Rule
- Use case studies to highlight different QA/QI program monitoring models.

Room 311



Note: Attendees are encouraged to bring their own case studies (including works in progress) for group discussion and further best practice brainstorming.

ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
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Wednesday, November 20: AER19

Breakout Sessions Series E 11:30 AM-12:45 PM

E15: The Regulatory and Ethical Implications of Melding Consumer "Big Data" With Medical "Big Data"

(Research Conducted in the Digital World Track)

Elizabeth A. Buchanan, University of Wisconsin-Stout; James Riddle, Advarra

The increasing availability of consumer "big data" has entered the health outcomes and research world. From the Obama administration cancer initiatives to NIH genomics sharing requirements, the utilization and re-use of data is an ever present and evolving field. What are the implications of melding all the research data, with its fortifications of protections from the Health Insurance Portability and Accountability Act and the revised Common Rule, with the relatively looser world of consumer data? How does the European Union General Data Protection Regulation fit in? If the data exists, why shouldn't consumer habits be matched with medical records to study health outcomes? This session will explore the regulatory and ethical considerations presented by use of "big data" in a research setting, along with what sponsors and investigators should know about their human subjects protections obligations in this area. During this session, speakers and attendees will:

- Explain the regulations surrounding research use of data
- Examine where the utilization of consumer data crosses into research
- Discuss the ethical and practical implications of utilization of big data in research

Room 310



E16: IRBs and Conflict of Interest (COI) Oversight—Mind the Gaps *(Responsible Conduct of Research Track)*

John R. Baumann, Indiana University; Scott J. Lipkin, Ankura Consulting; Shelby Moench, Intermountain Healthcare

This session will present three areas highlighting shared goals of IRB and COI oversight, including: (1) the point of intersection between COI and IRB review with a focus on where these processes overlap and where they diverge, and how this combination of overlap and divergence may introduce gaps in the review and management of said conflict; (2) the need for and set up of the foundations of a strong research COI program, with a case study discussion on how a national multi-centered research group convened a national COIs Advisory Council, as well as the goals for the Council; (3) while there are federal COI regulations, designed to promote objectivity in research and mandate disclosure, management, and reporting of COIs related to research, there are no controls related to COI disclosure requirements to scientific journals. Moreover, journals do not fact-check or enforce COI disclosure requirements and those who fail to disclose financial relationships to journals create circumstances that call into question the objectivity and validity of their research, leading to institutional vulnerability. During this session, speakers and attendees will:

- Review the regulatory requirements and ethical principles as related to research COI and the foundations of a strong research COI program
- Identify points of overlap and divergence in the COI and IRB processes
- Discuss best practices for COI and IRB review of outside financial interests related to human subjects research
- Share challenges that the IRB faces in assessing conflicts of interest, and approaches to minimize them
- Explore the pros and cons of monitoring faculty/staff journal disclosures and provide examples of sample monitoring programs

Room 206



E17: Building Models for Hospital and Practice-Based Research Programs—Agony and Ecstasy

(Small Research Programs Track)

Paul Papagni, Holy Cross Hospital/Trinity Health, Patricia Seymour, WCG Clinical

Would you accept the challenge to build a community hospital research program from the ground up? Do you understand all the elements that go into a successful program? Speakers will discuss the challenges and rewards of working closely with physicians, coordinators, IRBs, patients, and compliance officers in a "build it yourself" atmosphere. During this session, speakers and attendees will:

- Review the elements of a healthy, ethical, and compliant hospital and/or practice-based research program
- Discuss how to build a centralized operational model to maximize communication and oversight
- Share how, when, and why collaboration is necessary for growth
- Explore local oversight of human subjects protections when outsourcing studies to commercial IRBs

Room 107



ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
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Wednesday, November 20: AER19

Breakout Sessions Series E 11:30 AM-12:45 PM

E18: Beyond Auditing and Monitoring of the IRB Towards Quality Improvement

(QA/QI and Postapproval Monitoring Track)

Cheryl L. Byers, *Moffitt Cancer Center & Research Institute*; Kristen Connal, *The Fenway Institute at Fenway Health*; Mariette Marsh, *University of Arizona*

HRPPs engage in audits and not for cause monitoring activities, but are they making full use of the information, resources, and opportunities that auditing and monitoring offer? Are they integrating individual audit/monitoring findings into a broader analysis of institutional strengths, weaknesses, or gaps of quality improvement? In this session, speakers from various HRPPs will discuss how they integrate auditing and monitoring into a coherent program of quality improvement through their review and analysis of audit/monitoring findings as a collective whole. During this session, speakers and attendees will:

- Review how audit and monitoring findings can be integrated into a program of quality improvement
- Discuss how institutions are developing quality improvement programs based, in part, on the analysis of auditing and monitoring findings
- Explore how to develop quality improvement programs based on auditing and monitoring findings

Room 103



E19: Navigating Uncertainty—Developing Best Practices for Review of Research on the Edge *(SBER Track)*

Jeffrey M. Cohen, *Clarkson University*; Juliette Roddy, *University of Michigan-Dearborn*

Insofar as human subjects research involves the study of human behaviors, social values, and public policy, such research studies may involve the investigation of illegal/illicit behaviors. Collecting data about illegal/illicit behaviors exposes all stakeholders, individual human subjects, investigators, and institutions, to risks and harms to personal well-being, social standing, and legal culpability. This session will use a case study approach to identify practical, ethical, and legal complexities in order to discuss and develop best practices for reviewing such research. Topics to be discussed include: informed consent, risk and risk/benefit assessment, and issues related to mandatory reporting, confidentiality, and privacy, as well as flexibility in providing protections. Before attending this session, attendees should have a basic foundation in human subjects research protections ethics and principles, including the criteria for approval. During this session, speakers and attendees will:

- Discuss and provide case examples of protocol applications involving the investigation of illegal/illicit behaviors
- Apply ethical standards to research involving illegal/illicit behaviors
- Explore strategies for review at all levels, with emphasis on full committee review
- Engage audience members to share their own ideas, experiences, and best practices for approving protocols involving illegal/illicit behaviors

Room 306



E20: Who's Minding the Store? Local Oversight of Research Without an IRB

(Institutional Officials and HRPP Leadership Track)

Hallie Kassin, *Northwell Health*; Greg E. Manship, *OSF HealthCare*; Megan Kasimatis Singleton, *Johns Hopkins University School of Medicine*

The focus of this session is to address the regulatory, structural, and operational challenges facing organizations that have multiple facilities (e.g., a multi-hospital system, a multi-facility academic medical center, etc.) that are engaged in human subjects research. These challenges are exacerbated by simplification and centralization of organizational structures, such as a single, organization-wide Federalwide Assurance (FWA), no internal IRB, and a centralized HRPP. Such organizations have the added challenge of establishing and maintaining local research oversight programming in order to meet expectations of external IRBs and fulfill FWA responsibilities. This session will bring together experiences and resources from various institutions to provide information and materials that equip institutions to develop, implement, and assess local research oversight programming. Before attending this session, attendees should have proficiency with FWA responsibilities, requirements, and maintenance; working with external IRBs (e.g., reliance agreements, master service agreements, etc.); and at least two years working as HRPP staff/administration in a multi-facility organization. During this session, speakers and attendees will:

Room 201



ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
Breakout sessions new for 2019	
Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.	Basic – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.



- Identify the "pros" and "cons" of FWA and HRPP consolidation in multi-facility organizations
- Recognize policy, procedural, and structural challenges to providing local research oversight in facilities that do not have an IRB and/or HRPP presence
- Develop strategies for creating and implementing local research oversight programming

Wednesday, November 20: AER19

Breakout Sessions Series E 11:30 AM-12:45 PM

E21: Strategies for Conducting an Effective Local Context Review as a Relying Organization

(Institutional Officials and HRPP Leadership Track)

Sarah Mumford, University of Utah; Kimberly K. Summers, University of Texas Health San Antonio

The requirements for single IRB review have resulted in many organizations taking on a new role as a relying organization. An important component of this new role is performing an organizational review and communicating any local issues to the reviewing IRB. These local issues, often called "local context", may include identification of local state law or organizational policy requirements, communication of ancillary review outcomes or communication of local standards or expectations. A challenge of this new role has been the lack of guidance on how this job should be performed and who within an organization is best positioned to perform this review. This session will focus on the process through which relying organizations can perform a local context review and provide practical examples of how this review may be organized.

During this session, speakers and attendees will:

- Review the responsibilities of a relying organization under a sIRB model
- Define "local context review" and the various components of this review
- Discuss strategies for development of an effective local context review process

Room 101



E22: Implementation of a System to Promote Compliance With 45 CFR 46.116(h)—Posting Consent Forms

(HRPP Leadership and Institutional Officials Track)

Lauren Hartsmith, OHRP; Matthew Ogrodnik, Boston Medical Center/Boston University Medical Campus

This session will explore the use of a monitoring system designed to comply with 45 CFR 46.116(h) of the revised Common Rule, which requires an unsigned copy of one IRB-approved consent form (ICF) that has been used in enrolling participants in a clinical trial conducted or supported by a Common Rule department/agency be posted on a publicly available federal website. This posting must occur after recruitment closes, and no later than 60 days after the last study visit. Although this specific timeframe poses challenges, it's possible to leverage a number of extant policies and resources to develop and implement an ICF Posting System to promote compliance with this requirement. During this session, speakers and attendees will:

- Review the requirements of 45 CFR 46.116(h)
- Discuss how existing institutional HRPP policies can provide a framework for implementation of a system designed to comply with 45 CFR 46.116(h) of the revised Common Rule
- Describe a plan for ongoing monitoring of compliance

Room 313



E23: Implementing Key Information in Multi-Site Research (IRB Operations Advanced Track)

Joan Affleck, Merck & Co.; David G. Forster, WIRB-Copernicus Group; Jeanne Velders, Washington University in St. Louis

The revised Common Rule requires a concise and focused presentation of the key information at the beginning of the consent form. Many parties, including IRBs, institutions, and sponsors, have proposed templates for key information. This session will compare the various templates as well as any available agency guidance. During this session, speakers and attendees will:

- Review the requirement for key information
- Compare and contrast templates for key information
- Discuss best practices for key information, especially for multi-site research

Room 108



ICON KEY

Double session	Call for Session Proposal
Pre-registration required	Recorded session
Reviews changes to the Common Rule	CIP eligible
Breakout sessions new for 2019	
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Wednesday, November 20: AER19

Breakout Sessions Series E 11:30 AM-12:45 PM

12:45-2:30 PM: Closing General Session Luncheon—Designing Ethical Cars and Computing Clinicians: Research and the Ethics of Artificial Intelligence (AI) Programming

Moderator: Neal W. Dickert Jr., Emory University







Panelists: Marshall Chin, University of Chicago; David Magnus, Stanford University; Tamiko Eto, SRI International

Autonomous cars will need to be programmed to execute ethical decisions in life-threatening situations; if there's an accident, the car may go straight or swerve, with different results for the affected parties. Should cars be programmed to value all lives equally (e.g., should they sacrifice adults to save children?). Similarly, when AI programs are designed to make recommendations to clinicians about medical diagnosis and treatment, those programs may reflect different ethical perspectives about what the "right" course of action should be (e.g., should programs favor the most efficient use of medical resources or should they favor the patient's ability to choose their desired treatment?). Will these AI programs serve to increase the gap between those who get better or worse healthcare, or can and should they be designed to reduce those differences? Many of these decisions are made implicitly at present, but development of AI algorithms forces us to make these decisions explicitly. This session will consider the policy and research issues raised by these two developing technologies. Someone—government, producers, or consumers—will be making decisions about which ethical perspectives will be built into autonomous cars and clinical assistance programs, and everyone will feel the consequences. If research is to inform any of these decisions, IRBs may be reviewing research proposals designed to compare different ways to implement autonomous cars and computing clinicians, almost certainly without the informed consent affected by the interventions (and, who are the subjects?). Before you leave the conference in a car or make your next doctor's appointment, you might want to hear what these panelists say about what's coming down the road. **Note:** Lunch will be served during this session and pre-registration is encouraged. The formal presentation will begin at 1:15 PM.

Veterans Memorial Auditorium



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