November 14
Preconference Programs

7:00 AM-2:30 PM (Grand Hall AB Foyer (Lobby Level))
On-Site Check-In and Help Desk Open
Breakfast on your own.

8:30 AM-4:30 PM Full-Day Preconference Programs

Harbor Ballroom A (Second Level)
Biobanking in an Era of Research Towards Precision Medicine: Approaches to the Ethical, Regulatory, and Practical Challenges
Mark Barnes, Marianna J. Bledsoe, Sarah Dry, William E. Grizzle, Michele Russell-Einhorn

Harbor Ballroom B (Second Level)
Critical Topics in SBER
Dean R. Gallant and Linda E. Petree

Grand Hall B (Lobby Level)
Implementing the Revised Common Rule
Ivor A. Pritchard and Ada Sue Selwitz

Hillcrest (Third Level)
IRB 101sm
Daniel K. Nelson and David H. Strauss

Cortez Hill (Third Level)
IRB Chairs Boot Camp: Tools for Successful IRB Leadership
Francis J. DiMario, Jr. and R. Peter Iafrate

Harbor Ballroom C (Second Level)
Single IRBs: From Idea to Implementation
Nichelle Cobb, David G. Forster, Martha Jones, Susan Z. Kornetsky, P. Pearl O'Rourke

8:30 AM-12:30 PM Half-Day Preconference Programs: Morning

Old Town (Second Level)
Ethical and Practical Issues in Global Research
Okyere Boateng, Byung-in (B.I.) Choe, Sharon C. Freitag, Karen M. Hansen, Susan Miller, Delia Y. Wolf

La Jolla (Second Level)
Tips and Tools for Effective Education and Training
Elizabeth Kipp Campbell and Sharon Shriver

1:00 PM-4:30 PM Half-Day Preconference Programs: Afternoon

Old Town (Second Level)
Ethical and Regulatory Review of Research Case Studies
Bruce G. Gordon and Ernest D. Prentice

La Jolla (Second Level)
Ethical Study Design Is Good Science
Susan S. Fish and Lindsay McNair

4:30-5:30 PM (Grand Hall A (Lobby Level))
Preconference Programs Networking Reception
All those registered to attend a preconference program are welcome to attend this networking reception. Drinks and light refreshments will be served.

For session descriptions, view the full agenda online or in the AER18 app

Icon Key

Double Session · Common Rule · New in 2018 · Preregistration Required
Recorded Session · CIP Eligible · CME Accredited · Call for Session Proposals

Breakout Session Tracks

	Track	Descriptor	Sessions
1	A Dialogue With the Feds	This track will provide attendees with an opportunity to hear from and ask questions of federal agency representatives.	A1, B1, C1, C2, D1, E1
2	Boundaries and Balances	This track will explore potential models for streamlining IRB processes through an examination of existing regulatory flexibility and best practices, and will explore health-related activities that are often said to occur along the imprecisely drawn borders of human subjects research.	A3, B3, C3, D3, E3
3	Educating and Training	This track will help attendees develop effective educational programs for the assorted stakeholders involved in human subjects protections. In addition, the speakers in each session will describe, and then discuss with attendees, the various resources available for education and training.	A4, B4, C4, D4, E4
4	Empirical Research Ethics	Using current examples in empirical research ethics, this track will help attendees learn how to read and interpret empirical research ethics literature and make assessments on what counts as good research.	A5, B5, D5
5	FDA Regulations	This track will provide attendees with an opportunity to interact with and hear from representatives from the FDA, and other experts in the field, about important FDA initiatives and pertinent topics in the world of FDA-regulated clinical investigations.	A6, B2, B6, C6, D6, E6
6	Global Research	This track is designed for non-US-based research professionals and US-based professionals working outside North America. Sessions will examine issues related to the conduct of ethical research across geographic and cultural borders.	A7, B7, C7, D7, E7
7	Hot Topics	This track includes sessions on topics that are current, complex, and/or late breaking.	A2, A8, B8, B15, C8, D8
8	Institutional Officials and HRPP Leadership	This track will provide institutional officials, IRB chairs, HRPP directors, and others with oversight responsibilities with an opportunity to discuss shared concerns, problems, strategies, best practices, and other useful innovations.	A9, B9, C9, D9, E2, E9
9	IRB 101	This track is designed for those new to the field of human subjects protections and will provide rigorous training in the elements of IRB operations that are key to successful HRPPs/ IRBs and subject protections.	A10, B10, C10, D10, E10
10	IRB Chairs	This track will provide IRB chairs an opportunity to gain new insight, exchange ideas, share best practices, and discuss strategies for becoming a successful IRB chair. The track will review the skills, additional education, and resources that can help IRB chairs excel in their role as chair while managing an efficient and effective IRB.	A11, B11, C11, D11, E11
11	IRB Operations Advanced	This track is designed to provide experienced IRB administrators, coordinators, and other professionals involved with HRPP/IRB operations with an opportunity to discuss challenging issues, and will provide tools and strategies to address some of the complex issues and regulatory changes IRBs face.	A12, B12, C12, D12, E12
12	Pharma/Biotech Perspectives	This track will provide representatives from drug, device, and biotechnology industries and other HRPP professionals an opportunity to discuss topics of mutual interest, including ClinicalTrials.gov, the EU/EEA General Data Protection Regulation, expanded access, and more.	A13, B13, C13, D2, D13, E13

	Track	Descriptor	Sessions
13	Legal	This track explores hot button issues in research compliance from a legal perspective, but also how to best leverage legal expertise to ensure a robust HRPP. Although this track covers issues of interest to a legal audience, the sessions should also be relevant to anyone who encounters legal questions raised in connection with human subjects research and its associated operations.	A14, B14, C5, C14, D14, E14
14	Non-Scientist IRB Members	This track will focus on IRB members that have a unique or specialized role and perspective, in particular, the non-scientist and the unaffiliated members. This track will explore the roles, expectations, relationships, challenges, and strategies of these important IRB members. Sessions will be of interest to the IRB community in general, as well as to non-scientist and unaffiliated IRB members.	A15, C15, D15, E15
15	Research Involving Data and Biospecimens	This track explores issues that arise in the context of research on data and human specimens. Many sessions include topics relevant to an SBER audience and are not limited to biomedical research.	A16, B16, C16, D16, E16
16	Populations Requiring Additional Protections	This track will explore issues related to vulnerable populations, including regulations, guidance, best practices, ethical principles, and community engagement. In addition, this track will redefine vulnerability by looking beyond populations recognized in the federal regulations.	A17, B17, C17, D17, E17
17	QA/QI and Post-Approval Monitoring	This track is intended for those who are responsible for post-approval monitoring/auditing of investigator sites and/or IRBs for their institution/organization. Sessions are intended to span the spectrum of research, and will provide examples and approaches appropriate for those concerned with either biomedical or SBER human subjects research.	A18, B18, C18, D18, E5, E18
18	Research Conducted in the Digital World	This track will explore the risks, benefits, and challenges of using the internet, social media, and mobile health applications in research.	A19, B19, C19, D19, E8, E19
19	Responsible Conduct of Research (RCR)	This track will cover the area of RCR and how it intersects with the research enterprise and HRPP/IRB responsibilities. Participants will gain greater understanding of the scope of RCR, as it often includes the general areas of research with human and animal subjects, research misconduct (plagiarism, falsification, and fabrication), data management, publication practices, and much more. HRPP/IRB professionals will gain a better appreciation of the complexities and interest of RCR and issues related to IRB noncompliance (and vice versa).	A20, B20, C20, D20, E20
20	Small Research Program	Running small research programs, regardless of institution size, may pose both challenges and opportunities. This track provides guidance, advice, and opportunities for brainstorming on how to be efficient and effective in a small IRB office.	A21, B21, C21, D21, E21
21	SBER	These tracks will cover basic and advanced issues related to the conduct and review of SBER, including assessing the risks and benefits of SBER, mandatory reporting, building an HRPP in a primarily SBER institution, scientific merit in qualitative research, student research, FDA oversight in SBER, research investigating illegal behaviors, using social media in SBER, and more.	A22, A23, B22, B23, C22, C23, D22, D23, E22, E23

Thursday, November 15

7:00 AM-5:30 PM
Exhibit Hall FG Foyer

On-Site Check-In
Breakfast on your own.

7:00-8:00 AM
Ballroom 20A

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 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.
Preregistration was required for this event.

7:15-8:00 AM
Exhibit Hall FG and Exhibit Hall H

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.

8:00-8:15 AM
Exhibit Hall H

Conference Welcome Remarks from the Co-Chairs

8:15-8:40 AM
Exhibit Hall H

Remarks from PRIM&R's Executive Director, Elisa A. Hurley, PhD

8:40-9:00 AM
Exhibit Hall H

PRIM&R Board Chair's Address by Heather H. Pierce, JD, MPH

9:00-10:00 AM
Exhibit Hall H

Keynote Address by Timothy Caulfield, LLB, LLM, FRSC, FCAHS: Celebrities, Science-y, and Pseudoscience: Tackling Misinformation in the Era of Health Noise

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10:00-10:30 AM
Exhibit Hall FG

Beverage Break with the Supporters and Exhibitors
Join us for coffee in the exhibit hall. *PRIM&R would like to thank Kinetiq for helping support this break.*

10:30-11:45 AM Concurrent Plenary Sessions

Ballroom 20D

Panel I: Gun Violence and Public Health: Facts, Fiction, and the Future
Moderator: *Cynthia A. Gómez*
Panelists: *Patrick M. Carter, Harold D. Cox, Zoe Grover*

Ballroom 20BC

Panel II: At the Crossroads of Hope and Hype: Recruiting the Desperately Ill for Clinical Trials
Moderator: *Alexander M. Capron*
Panelists: *Andrea Denicoff, Betty R. Ferrell, Jodi Halpern, Carol Juliet Weil*

Exhibit Hall H

Panel III: The New Rule's Identity Crisis: Should Identifiability Be Changed?
Moderator: *Laura Odwazny*
Panelists: *William E. Grizzle, Suzanne M. Rivera*

11:45 AM-1:00 PM
Exhibit Hall FG

Networking Lunch Supported by CITI Program, a division of BRANY
Time to connect…over lunch! Meet peers for conversation and networking. All are welcome!
PRIM&R would like to thank CITI Program, a division of BRANY, for helping support this lunch.

11:45 AM-1:00 PM
Ballroom 20A

Research Ethics Discussion Luncheon: Fighting Health Myths With Stories, Art, and Fun
Moderator: *Melissa E. Abraham*
Author: *Timothy Caulfield*
Note: A buffet lunch will be served in the session room. The formal presentation will start at 12:00 PM.

For session descriptions, view the full agenda online or in the AER18 app

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11:45 AM-1:00 PM Room 24A
Lunch Session: A Dialogue With Patient-Centered Outcomes Research Institute
Jason Gerson
Note: Lunch will be served outside the session room. The formal presentation will start at 12:00 PM.

11:45 AM -1:00 PM Room 24B
Lunch Session: A Dialogue With the Department of Energy
Cheri Hautala-Bateman, Elizabeth P. White
Note: Lunch will be served outside the session room. The formal presentation will start at 12:00 PM.

11:45 AM-1:00 PM Room 24C
Lunch Session: A Dialogue With the Office of Research Integrity
Scott J. Moore
Note: Lunch will be served outside the session room. The formal presentation will start at 12:00 PM.

11:45 AM-1:00 PM Room 25AB
Lunch Session: A Dialogue With the VA
Kristina C. Borror, Richard D'Augusta, Charlotte K. Jeans, Molly M. Klote
Note: Lunch will be served outside the session room. The formal presentation will start at 12:00 PM.

12:15-12:35 PM Exhibit Hall FG Demo Theater
Overview of the CIP® Exam

12:30-1:00 PM Exhibit Hall FG
Meet and Greet With the AER18 Supporters and Exhibitors

12:30-1:00 PM Exhibit Hall FG
Federal Agency/Accrediting Body Office Hours
For the list of agencies participating in this office hours session, see the online agenda or the conference app.

12:40-1:00 PM Exhibit Hall FG Demo Theater
eConsent: Modernize Your Consent Process—Don't Change It
Join Mitchell E. Parrish, Executive Vice President for Quorum Review IRB, to find out the true impact of eConsent on the informed consent process. You'll gain insightful perspectives on trial participants, primary investigators (and staff), and institutions. Go beyond the claims. Understand the realities. See eConsent in action.

1:15-2:30 PM Breakout Session Series A

A1 Room 28ABC
A Dialogue With OHRP
A Dialogue With the Feds Track
Misti Ault Anderson, Lisa R. Buchanan, Ivor A. Pritchard, Irene E. Stith-Coleman

A2 Room 23C
Does Diversity Matter in the Conduct of a Clinical Trial?
Hot Topics Track
Barbara E. Bierer, Owen Garrick

A3 Room 29B
Distinguishing Public Health Surveillance From Public Health Research at the Centers for Disease Control and Prevention
Boundaries and Balance Track
Micah H. Bass, Julia G. Gorey, Laura Youngblood
Advanced

A4 Room 25C
Stories Matter: The Use of Narrative in IRB Member Education
Educating and Training Track
Michael Leary, Gianna McMillan

A5 Room 22
Empirical Research on Ethical Issues in Patient Centered Outcomes Research: New Data to Inform Deliberations
Empirical Research Ethics Track
Emily Largent, Stephanie Morain, Jeremy Sugarman

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A6 Room 31C
Demystifying Part 11 and Computer System Validation
FDA Regulations Track
Jan L. Hewett, James Riddle

A7 Room 23A
Different Models of Review: A Global Comparison
Global Research Track
Byung-in (B.I.) Choe, Barthalomew Wilson, Delia Y. Wolf, Rachel Zand

A8 Room 29C
The Certified IRB Professional (CIP®) Credential: How Do I Get Started?
Hot Topics Track
Michelle Francis Grienauer, Hallie Kassan, Lori Roesch

A9 Room 33AB
Not Less Work, But Different: Re-Engineering for Single IRB Review
Institutional Officials and HRPP Leadership Track
Nichelle Cobb, Megan Kasimatis Singleton, Kimberly K. Summers
Advanced

A10 Room 28DE
Back to Basics: Does My Project Fall Within the Scope of the Revised Common Rule?
IRB 101 Track
Jaime O. Hernandez

A11 Room 29A
Meeting Management for IRB Chairs
IRB Chairs Track
Francis J. DiMario Jr., Luke Gelinas

A12 Room 30AB
It's Not as New as You Think: Understanding How to Operationalize the Revised Common Rule
IRB Operations Advanced Track
Jeffrey A. Cooper, Kristin J. Craun, Jessica H. Huening, Heather H. Pierce

A13 Room 31A
ClinicalTrials.gov: How Academic Institutions Can Respond to New Clinical Trial Disclosure Requirements
Pharma/Biotech Perspectives Track
Sarah A. White, Rebecca J. Williams

A14 Room 30D
Legal and Regulatory Changes: A Year in Review
Legal Track
Mitchell E. Parrish, Michele Russell-Einhorn

A15 Room 27B
Defining Roles & Expectations for the Non-Scientist and Unaffiliated IRB Member: Deconstructing Regulatory and Research Terminology
Non-Scientist IRB Members Track
Glenn Ellis, Michelle M. Feige, Nancy A. Olson

A16 Room 25AB
Implementing NIH's Genomic Data Sharing Policy: Challenges and Solutions
Research Involving Data and Biospecimens Track
Shannon Sewards, Carrie D. Wolinetz

A17 Room 31B
Vulnerability Explored: Concepts and Applications
Populations Requiring Additional Protections Track
Bruce G. Gordon, Robert E. Nobles, II, David H. Strauss
Advanced

A18 Room 30C
Beyond Auditing and Monitoring of the IRB Towards Quality Improvement
QA/QI and Post-Approval Monitoring Track
John R. Baumann, Cheryl L. Byers, Mariette Marsh

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A19 Room 32AB
IRB Review of Big Data Research
Research Conducted in the Digital World Track
Jacob Metcalf, Laura Odwazny, Stephen J. Rosenfeld
CR CIP ✓ ▶ **Advanced**

A20 Room 21
Preparing Research Misconduct Committees to Succeed
Responsible Conduct of Research Track
Kate Gallin Heffernan, Ross A. Hickey
CIP ✓

A21 Room 23B
Challenges and Opportunities for Institutions With Small Research Programs
Small Research Programs Track
Andrea R. McDowell, John C. Smith
CIP

A22 Room 29D
Different Minimal Risk Review Models
SBER Track
Jeffrey M. Cohen, Cecilia Brooke Cholka, Erik Williams
★ New CR CIP ✓

A23 Room 30E
Risk Mitigation in Mixed SBER and Biomedical Research
SBER Track
Lara N. Sloboda, Matthew D. Stafford
★ New CIP ✓ ▶ **Advanced**

2:30-3:00 PM Second floor hallways
Beverage Break
Join us for coffee and cold drinks.

3:00-4:15 PM Breakout Session Series B

B1 Room 32AB
The Times, They Are A-Changing: Overview of the Latest NIH Changes and Their Implications on Research
A Dialogue With the Feds Track
Marylana Saadeh Helou, Carrie D. Wolinetz
★ CIP ✓ ▶

B2 Room 31C
The Generation and Utilization of Real-World Evidence: Ethical and Regulatory Considerations
FDA Regulations Track
Diana T. Chingos, Jacqueline Corrigan-Curay, Robert (Skip) M. Nelson, Jeremy Sugarman
New CIP ✓

B3 Room 28ABC
You'll Know It When You See It, or Will You? Defining "Human Subjects Research"
Boundaries and Balance Track
Misti Ault Anderson, Warren Capell, Dean R. Gallant
CR CIP ✓ **Advanced**

B4 Room 31B
An Educational Map to Being a Great Research Ethicist (or Just a Better One)
Educating and Training Track
Robert Hood, Dane C. Joseph
★ New CIP ✓

B5 Room 24A
Designing Trials for Completion
Empirical Research Ethics Track
Barbara E. Bierer, Luke Gelinas, Spencer Hey
★ New CIP ✓

B6 Room 30E
When Is an Investigational Device Exemption Needed for a Clinical Investigation of a Medical Device?
FDA Regulations Track
Soma Kalb
New ✓ ▶ **Basic**

B7 Room 29B
Human Subjects Protections Across Borders
Global Research Track
Edward E. Bartlett (moderator), Byung-in (B.I.) Choe, Karen M. Hansen
CIP ✓

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B8 Room 23C
Exploring and Enhancing Diversity Within Our Compliance Committees
Hot Topics Track
Eric Allen, Owen Garrick, Tonya Ferraro

B9 Room 29D
Top Considerations for Institutional and HRPP Leadership When Accepting Department of Defense Support of Research
Institutional Officials and HRPP Leadership Track
Jean Barone, Kimberly Odam, T. Howard Stone
Advanced

B10 Room 22
Essential Documentation: IRB Records Documentation Requirements, Minutes, Written Procedures, and More
IRB 101 Track
Lisa R. Buchanan, Janet C. Donnelly, Ada Sue Selwitz
Basic

B11 Room 30D
The Evolving Role of the IRB Chair in the World of Single IRBs
IRB Chairs Track
David C. Christiani, Susan C. Sonne

B12 Room 30AB
The After Party: Tools and Techniques for the Assessment of IRB Operations During and After Implementation of the Revised Common Rule
IRB Operations Advanced Track
Meghan K. Scott, Jeanne Velders

B13 Room 33AB
The European Union's General Data Protection Regulation and US-Based Research: Implications, Problems, and Potential Solutions
Pharma/Biotech Perspectives Track
Mark Barnes, Karla Childers

B14 Room 25C
1-800-RESEARCHLAWYER: Is Your Institution's Legal Counsel on Speed Dial?
Legal Track
Emily Chi Fogler, Kate Gallin Heffernan, Jesse A. Ripton

B15 Room 30C
New Data on Single IRBs: Implications for the Future
Hot Topics Track
Robert Klitzman, Charles W. Lidz

B16 Ballroom 20A
Research With Data and Biospecimens Under the Revised Common Rule: An Overview of Changes and Challenges
Research Involving Data and Biospecimens Track
Marianna J. Bledsoe, Elizabeth A. Buchanan, Lauren Hartsmith

B17 Room 25AB
Conducting Research With Children: Complexities in Practice
Populations Requiring Additional Protections Track
Bruce G. Gordon, Susan Z. Kornetsky
Advanced

B18 Room 31A
Ideas and Practices for Compliance and Auditing of Single IRB Studies
QA/QI and Post-Approval Monitoring Track
Nichelle Cobb, Sarah A. White

B19 Room 28DE
Privacy and Security Risks in Research With Wearable Technology
Research Conducted in the Digital World Track
Megan Doerr, Sara Meeder
Basic

B20 Room 29C
Case Studies in Research Misconduct
Responsible Conduct of Research Track
Ross A. Hickey, Fariba Houman
Basic

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B21 Room 24C	**How to Identify, Navigate, and Manage Conflicts of Interest at a Small Research Organization** Small Research Programs Track *Elizabeth A. Boyd, Heather H. Pierce*	CIP **Basic**
B22 Room 29A	**College Students and Research: Challenges and Issues for IRBs** SBER Track *Andrea R. McDowell, Linda E. Petree*	CIP **Basic**
B23 Room 24B	**Assessing and Mitigating Risk in SBER Research: A Case Study Approach** SBER Track *Amy Ben-Arieh, Alyssa Speier*	CIP
4:15-5:30 PM Exhibit Hall FG	**AER18 Welcome Reception** Drinks and light refreshments will be served.	
5:10-5:30 PM Exhibit Hall FG Demo Theater	**Overview and Demonstration of PRIM&R's New Ethical Research Oversight Course (E-ROC)**	
5:45-7:15 PM Half Door Brewing Company (off-site)	**Young Professionals Networking Reception** While all attendees are welcome, complimentary drink tickets are only provided for young professional registrants.	

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Friday, November 16

7:00 AM-5:30 PM
Exhibit Hall FG Foyer

On-Site Check-In
Breakfast on your own.

7:15-8:00 AM
Exhibit Hall FG and Exhibit Hall H

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.

8:00-8:30 AM
Exhibit Hall H

Welcome and Presentation of PRIM&R's Distinguished Service Award to P. Pearl O'Rourke, MD, Director, Human Research Affairs, Partners Healthcare System Inc.; Associate Professor, Pediatrics, Harvard Medical School, and Presentation of PRIM&R's ARENA Legacy Award to Jerry Castellano, BS, PharmD, CIP, Corporate Director, IRBs, Christiana Care Health System

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8:30-9:30 AM
Exhibit Hall H

Keynote Address by Michelle M. Mello, JD, PhD: Clinical Trial Data Sharing: Perspectives From Participants

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9:30-10:00 AM
Exhibit Hall FG

Beverage Break With the Supporters and Exhibitors
Join us for coffee in the exhibit hall. *PRIM&R would like to thank Prime Review Board for helping support this break.*

10:00-11:00 AM

Explorations In... Panel Series

Research and scholarly exploration is how progress is made in any field; the field of research ethics and oversight is no exception. The Explorations In… panel series spotlights selected scholarly works submitted to this year's AER Conference Poster Presentation Program and offers an opportunity to hear about some of the current work impacting our field. Authors will present their work in a research-conference-style format, followed by a brief question and answer period. For the full abstracts, check page 59 of this guide.

Exhibit Hall H

Explorations A: Explorations in Optimizing Informed Consent and Assent
Moderator: *Ryan Spellecy*

- **Poster #6: A Novel Approach to Engage Stakeholders in Creating Educational Tools for Future Human Subjects: The "What Is Research?" Video**
  Jessica Macha
- **Poster #20: Prototype Checklist for Informed Consent in Clinical Trials With Pregnant Women: An Engagement-Informed Tool to Support Ethical Inclusion**
  Kristen Sullivan
- **Poster #66: Developing a Novel App to Educate Children on the Human Subjects Assent Process**
  Moore Rhys

Ballroom 20BC

Explorations B: Explorations in Navigating the Single IRB Mandate
Moderator: *Michael J. Linke*

- **Poster #24: Success With a Single Reviewing IRB Serving a Federally-Funded Consortium**
  Jeanette Bailey
- **Poster #33: Local Context Assessment: A Mixed-Methods Study of an IRB's Process**
  Adrianne Haggins
- **Poster #38: Evaluating Local Context Review: Early Data From the Implementation of Local Context Review**
  Megan Kasimatis Singleton

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Ballroom 20D **Explorations C: Explorations in Engaging Communities to Promote Ethical Research**
Moderator: *Lauren Hartsmith*

- **Poster #3: Amplifying the Voices of Participants and Their Communities: Developing an Independent Community Oversight Board on Research With Human Participants**
  Bethany Hansen
- **Poster #4: Reciprocity as a Guiding Principle When Returning Scientific Results to the Community**
  Katie Huber
- **Poster #14: Enhancing the Ethical Conduct of HIV Research With Migrant Sex Workers: Empirical Research on Human Rights, Policy, and Social Contextual Considerations**
  Shira Goldenberg

11:15 AM-12:30 PM Breakout Session Series C

C1 Room 30C **A Dialogue With the Department of Defense (DOD): Updates for DOD and DOD-Sponsored Research Protections Personnel**
A Dialogue With the Feds Track
Stephanie Bruce, Monique E. Hawkins, Kim London, T. Howard Stone

C2 Room 29C **A Dialogue With the Secretary's Advisory Committee on Human Research Protections**
A Dialogue With the Feds Track
David A. Borasky, Jr., David G. Forster, Julia G. Gorey, Nancy M.P. King

C3 Ballroom 20D **Standard of Care, Medical Innovation, or Research: How Should We Decide?**
Boundaries and Balance Track
Stephanie S. Cargill, Jeremy J. Corsmo
Advanced

C4 Room 30D **Advancing Yourself as a Regulatory Professional: Education, Cooperation, and Self-Advocacy**
Educating and Training Track
Charlotte H. Coley, Karen M. Hansen, Margaret Rankovic
Basic

C5 Room 30E **The Pressing Need for IRB Precedent**
Legal Track
Barbara E. Bierer, Holly Fernandez Lynch, Stephen J. Rosenfeld

C6 Room 23A **The Rise of the Patient Voice at FDA**
FDA Regulations Track
Andrea Furia-Helms, Salina P. Miller

C7 Room 23C **Research Passport: Regulatory and Ethics Review Implications for International Participants in US-Based Clinical Trials**
Global Research Track
Jessica Huening, Aarthi Iyer

C8 Room 30AB **Developments Regarding the Federal "Right-to-Try" Law and its Impact on the FDA's Expanded Access Program**
Hot Topics Track
Marylana Saadeh Helou, Richard Klein, Marjorie A. Speers, Walter L. Straus

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Friday, November 16

C9 Room 33AB
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
Ann Johnson, Michele Kennett, Robert E. Nobles, II
Note: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.
Advanced

C10 Room 28ABC
Let's Review a Protocol: Reviewing Research That Requires Expedited or Full Board Review
IRB 101 Track
Warren Capell, Andrew Hedrick, Amy C. Waltz
Note: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.

C11 Room 22
IRB Chairs Forum: A Structured Discussion for IRB Chairs
IRB Chairs Track
Robert W. Frenck, Jr., R. Peter Iafrate, Geeta K. Swamy
Note: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.

C12 Room 29B
Creative Solutions for Serving as a Reviewing IRB
IRB Operations Advanced Track
Joseph Datko, Michael J. Linke, P. Pearl O'Rourke (moderator), Julie Ozier, Susan C. Sonne
Note: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.

C13 Room 23B
Scientific and Ethical Considerations in Choosing a Study Control Group
Pharma/Biotech Perspectives Track
Robert (Skip) M. Nelson, Albert J. Allen

C14 Ballroom 20A
Just When You Thought You Understood the Health Insurance Portability and Accountability Act of 1996: What's New and What We Still Need to Worry About
Legal Track
Marissa Gordon-Nguyen, Susie R. Hoffman, Nadine Peters
Note: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.

C15 Room 21
Scientific Aspects of Study Design: A Primer for Non-Scientists
Non-Scientist IRB Members Track
Susan S. Fish, Lindsay McNair
Note: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.

C16 Room 28DE
Considerations for Return of Results Under the Revised Common Rule
Research Involving Data and Biospecimens Track
Angela Bradbury, Michelle Francis Grienauer, Jody M. Shoemaker Roberts
Note: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.
Advanced

C17 Room 29A
Situational Vulnerability: Considerations and Safeguards When Exploring Gender Identity, Social/Economic Challenges, and At-Risk Behavior
Populations Requiring Additional Protections Track
Amy Ben-Arieh, Jeanette Bowles, Mary L. Gray
Note: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.

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C18 Room 25C
Advanced Investigator Post-Approval Monitoring Issues
QA/QI and Post-Approval Monitoring Track
Mary-Tara Roth, Alyssa Speier
Note: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.

C19 Room 32AB
The Intersections of Data Security, Privacy, Confidentiality, and Compliance in Digital Health and Mobile Health Research
Research Conducted in the Digital World Track
Jeremy N. Block, Brenda L. Curtis
Note: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.
Basic

C20 Room 31B
The Regulatory Intersection of Research Misconduct and Human Subjects Protections
Responsible Conduct of Research Track
Lisa R. Buchanan, Kate Gallin Heffernan, Scott J. Moore

C21 Room 24C
Flying Solo: A Moderated Discussion on Challenges Encountered by Single Staff IRB Offices
Small Research Programs Track
April V. Baker, Andrea R. McDowell, Rachel Zand
Note: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.
Basic

C22 Room 31A
Research in K-12 Settings
SBER Track
Shannon Sewards, Julie Slayton
Basic

C23 Room 29D
Understanding and Applying Family Educational Rights and Privacy Act Guidelines
SBER Track
Bethany L. Johnson, Nalinee D. Patin
Advanced

12:30-1:30 PM Exhibit Hall FG
Networking Lunch

1:00-1:20 PM Exhibit Hall FG Demo Theater
Overview and Demonstration of PRIM&R's New Ethical Research Oversight Course (E-ROC)

1:45-3:00 PM Concurrent Plenary Sessions

Ballroom 20BC
Panel IV: What Do Patients Want: Does Majority Rule?
Moderator: *Neal W. Dickert, Jr.*
Panelists: *Diana T. Chingos, Jonathan D. Jackson, Matthew McCoy*

Ballroom 20D
Panel V: Ethical Challenges in HIV Cure Research
Moderator: *Stephanie S. Cargill*
Panelists: *Nir Eyal, Rowena Johnston, Jeremy Sugarman*

Exhibit Hall H
Panel VI: To Participate or Not to Participate, That Is the Question
Moderator: *Ivor A. Pritchard*
Panelists: *Celia B. Fisher, Jonathan M. Green, Ada Sue Selwitz*

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Friday, November 16

3:00-3:30 PM **Beverage Break**
Second floor hallways
Join us for coffee. *PRIM&R would like to thank CITI Program, a division of BRANY, for helping support this break.*

3:30-4:45 PM Breakout Session Series D

D1 Room 30C
A Dialogue With the FDA
A Dialogue With the Feds Track
Jan L. Hewett, Soma Kalb, Joanne R. Less, Diane M. Maloney, Kevin A. Prohaska

D2 Room 24AB
Pharmacogenetics and Precision Medicine: Partnering to Enable DNA Research in Global Clinical Trials
Pharma/Biotech Perspectives Track
Linda M. Coleman, Feng Hong, Anita J. Nelsen

D3 Room 30AB
Tissue Repositories and Data Banks in the Era of the Revised Common Rule
Boundaries and Balance Track
Mark Barnes, Julie Kaneshiro, Susan Stayn

D4 Room 29B
Paving the Road to Success: Meeting the Challenges of Investigator and Study Team Education
Educating and Training Track
Kelly Unsworth, Michael Voth

D5 Room 31B
Promises and Perils of HIV Phylogenetics Research
Empirical Research Ethics Track
Susan J. Little, Jeremy Sugarman, Jeff Taylor

D6 Room 29A
FDA's Oversight of ClinicalTrials.gov Requirements
FDA Regulations Track
Anthony Keyes, Patrick J. McNeilly
Basic

D7 Room 31C
Lessons From the Trenches: Avoiding Legal and Operational Pitfalls in International Research Studies
Global Research Track
David A. Borasky, Jr., Andrew P. Rusczek
Basic

D8 Room 31A
Public Health Emergencies, Research, and Bioethics
Hot Topics Track
Nicole (Nicky) J. Cohen, Christine Grady

D9 Room 30D
How to Investigate, Mitigate, Report, and Learn from Noncompliance: Avoiding Pitfalls and Seizing Opportunities for Improvement
Institutional Officials and HRPP Leadership Track
Kate Gallin Heffernan, Scott J. Lipkin

D10 Room 33AB
Writing and Updating Standard Operating Procedures With the Revised Common Rule in Mind
IRB 101 Track
Elizabeth A. Bankert, Lauren Hartsmith, Cheryl A. Savini

D11 Room 28DE
The Revised Common Rule: Operational Considerations for the IRB Chair
IRB Chairs Track
Jeremy J. Corsmo, R. Peter Iafrate

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D12 Room 32AB
Single IRB: The Next Generation
IRB Operations Advanced Track
Daniel Alderson, Jenni Beadles, Aaron Kirby
Advanced

D13 Room 21
Post-Trial Access: A Look at the Challenges of Ensuring Continued Access to Investigational Medicine
Pharma/Biotech Perspectives Track
Ariella Kelman, Robert Klitzman, Walter L. Straus

D14 Room 25AB
Wrangling IRB Reliance Agreements: How to Implement Flexible Terms and Addenda and Execute Necessary Agreements
Legal Track
Nichelle Cobb, Ann Johnson, Megan Kasimatis Singleton

D15 Room 24C
Recruiting, Educating, and Retaining Non-Scientist and Unaffiliated IRB Members
Non-Scientist IRB Members Track
Charlotte H. Coley, Glenn Ellis

D16 Room 28ABC
Assessing Plans to Maintain Confidentiality: How IRBs Can Determine Whether Data Security and Management Plans Are Sufficient
Research Involving Data and Biospecimens Track
Gretchen L.J. Anding, John R. Baumann, Elizabeth A. Buchanan

D17 Room 29D
Looking Through the Bars: Responsible Research With Prisoners
Populations Requiring Additional Protections Track
Wayne Carriker, Julia G. Gorey

D18 Room 22
Nuts and Bolts of Assessing IRB Compliance
QA/QI and Post-Approval Monitoring Track
Lisa Denney, Keren R. Dunn

D19 Ballroom 20A
Social Media in Research: Recruitment, Subject Communication, and Data Source
Research Conducted in the Digital World Track
Emily Largent, Holly Fernandez Lynch, Michelle N. Meyer

D20 Room 29C
Agents and Rogues: The Limits of Agency, Institutional Engagement, and Institutional Responsibility
Responsible Conduct of Research Track
Robert S. Bienkowski, Joseph Crossno, Lynn E. Smith

D21 Room 23C
How to Maintain Institutional Memory at a Small Research Program
Small Research Programs Track
Sharon C. Freitag, Jennifer L. Pacheco
Advanced

D22 Room 25C
Clinical Trials in the SBER Context
SBER Track
Melissa E. Abraham, Cynthia S. Shindledecker, Wendy J. Weber

D23 Room 30E
Navigating Uncertainty: Research With Undocumented/Unauthorized Immigrants
SBER Track
Gene Gloeckner, Elizabeth Jach, Colleen Kohashi

4:45-6:00 PM Exhibit Hall FG
Networking Reception With the Supporters and Exhibiters
Light refreshments will be served, and a cash bar will be available.

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Friday, November 16

4:45-6:00 PM
Exhibit Hall FG

Meet the AER18 Poster Authors

4:45-6:00 PM
Exhibit Hall FG

Federal Agency/Accrediting Body Office Hours

For a full list of agencies participating in this office hours session, see the online agenda and conference app.

4:50-5:15 PM
Exhibit Hall FG
Demo Theater

Simplifying Research Compliance With Cayuse IRB

Join us for a discussion in the demo theater of the many features of Cayuse IRB that help institutions reduce the burdensome process of completing, submitting, and reviewing IRB studies. During this overview, we will look at how Cayuse IRB truly "simplifies" compliance with innovative features like role-based dashboards, configurable electronic applications, automatic messaging and reminders, and centralized meeting management – all in a secure, cloud-based environment. Decrease your turnaround time and risk using the tools provided by Cayuse IRB.

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Saturday, November 17

7:00 AM-12:30 PM
Exhibit Hall FG Foyer
On-Site Check-In
Breakfast on your own.

7:15-8:00 AM
Exhibit Hall FG and Exhibit Hall H
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.

8:00-8:30 AM
Exhibit Hall H
Welcome and PRIM&R Membership and CIP® Updates

8:30-9:30 AM
Exhibit Hall H
Keynote Address by Vickie M. Mays, PhD, MSPH

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

10:00-11:15 AM Concurrent Plenary Sessions

Ballroom 20BC
Panel VII: IRB Decision-Making From a Behavioral Economics Perspective
Moderator: *Christine Grady*
Panelists: *Charles W. Lidz, Ivor A. Pritchard, Michele Russell-Einhorn*

Exhibit Hall H
Panel VIII: Big Data: Who's Minding the Store?
Moderator: *Brenda L. Curtis*
Panelists: *Matthew J. Bietz, Mary L. Gray, Mark MacCarthy*

Ballroom 20D
Panel IX: Is a Misconception Always a Misconception?
Moderator: *John D. Lantos*
Panelists: *Monica Mita, Sally Okun*

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

E1
Room 29B
A Dialogue With AAHRPP, Inc.
A Dialogue With the Feds Track
Michelle M. Feige, Robert Hood, M. Oscar Platero, Elyse I. Summers, Kate Vulakovich

E2
Room 22
Two Offices Divided by a Common Goal: Conflict of Interest and IRB
Institutional Officials and HRPP Leadership Track
John R. Baumann, Heather H. Pierce

E3
Room 30AB
The Seven Habits of Highly Effective and Flexible IRBs
Boundaries and Balance Track
Cecilia Brooke Cholka, Jeffrey A. Cooper, Jonathan M. Green

E4
Room 31A
Building Bridges Through IRB Education Outreach
Educating and Training Track
Mina P. Busch, Colleen P. Gilrane, Belinda Smith

E5
Room 32AB
Correcting and Avoiding Noncompliance: Examining Real-Life Cases
QA/QI and Post-Approval Monitoring Track
Charlotte H. Coley, Martha Jones

E6
Room 29A
FDA Clinical Holds and 21 CFR 50 Subpart D
FDA Regulations Track
David G. Forster, Kevin A. Prohaska, Donna L. Snyder

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E7 Room 30D
Applying US Human Research Protections Regulations and Embedded Cultural Values to Research Conducted in Different Cultures: Challenges, Cultural Considerations, Collaborations, and Experiences
Global Research Track
Edward E. Bartlett (moderator), Derek Englis, A. Roxana Lescano, Sophea Sout
Advanced

E8 Room 25AB
User Agreements in Human Subjects Research During the Burgeoning Technology Age
Research Conducted in the Digital World Track
Eric Allen, Linda M. Coleman, Megan Doerr

E9 Room 25C
Ethical and Operational Issues Related to Clinical Trial Billing: What HRPPs and IRBs Should Consider
Institutional Officials and HRPP Leadership Track
Keren R. Dunn, F. Lisa Murtha, Ann Rodavitch
Basic

E10 Room 33AB
IRB Review of Informed Consent: Moving Beyond the Form
IRB 101 Track
Elizabeth A. Bankert, Joshua Fedewa, Jamie O. Hernandez
Basic

E11 Room 28DE
The Role of the IRB Chair in Protocol Exceptions, Violations, Noncompliance, and Unanticipated Problems
IRB Chairs Track
Madelon V. Baranoski, Jeremy J. Corsmo
Advanced

E12 Room 30C
Overlapping Roles of Data Safety Monitoring Boards and IRBs in the Protection of Human Subjects
IRB Operations Advanced Track
Roger J. Lewis, Michael J. Linke, Robert Silbergleit, Megan Kasimatis Singleton

E13 Room 31C
Designing and Implementing Expanded Access Programs
Pharma/Biotech Perspectives Track
Erika L. Segear Johnson, Richard Klein, Marjorie A. Speers, Walter L. Straus
Advanced

E14 Room 24AB
From Shield to Sword? How the 21st Century Cures Act and NIH Policy Have Altered Certificates of Confidentiality
Legal Track
Catherine Sutherland, Leslie E. Wolf, Carrie D. Wolinetz

E15 Room 24C
Considerations and Strategies for Maximizing IRB Contributions from Non-Scientist and Unaffiliated Members
Non-Scientist IRB Members Track
Nathalia Henry, Stephen Poppel

E16 Room 29C
Building a Better Biobank: Promise and Challenges of the National Cancer Institute Cancer Moonshot Biobank
Research Involving Data and Biospecimens Track
Janet Freeman-Daily, Helen Moore

E17 Room 23A
Tribal Research Futures: Resources to Strengthen Governance, Trust, and Culture in Research Partnerships
Populations Requiring Additional Protections Track
Julie Lucero, Yvette Roubideaux

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Saturday, November 17

E18 Room 29D
Nuts and Bolts of Investigator Site Audits
QA/QI and Post-Approval Monitoring Track
David A. Borasky, Jr., Stefanie deRijke, Kelly Dornin-Koss

E19 Ballroom 20A
Intersection of Research and Electronic Health Records With Privacy and Confidentiality Concerns: Considerations for IRB Review
Research Conducted in the Digital World Track
Gretchen L.J. Anding, Judith Birk
Advanced

E20 Room 23C
Data Acquisition and Management: Concepts Every Researcher and Research Administrator Should Know
Responsible Conduct of Research Track
Carolyn Broccardo

E21 Room 31B
Managing Small Research Programs in Healthcare Settings
Small Research Programs Track
Delilah Ofosu-Barko, Jennifer L. Pacheco
Basic

E22 Room 30E
How to Create an Undergraduate Research Training Program
SBER Track
Jonathan M. Girard, Shannon Sewards
Basic

E23 Room 28ABC
You Want to Do What? Developing Best Practices for IRB Review of Research Investigating Illegal/Illicit Behaviors
SBER Track
Jeffrey M. Cohen, Dean R. Gallant, Sarah Trautz
Advanced

12:45-2:30 PM Exhibit Hall H
Closing General Session Luncheon: Research Ethics, Race, and Opioids—The Evolution of the Perfect Epidemic
Moderator: *Elizabeth A. Buchanan*
Panelists: *Brenda L. Curtis, Alexis Roth, Ekow N. Yankah*
Note: Lunch will be served during this session. The formal presentation will begin at 1:15 PM.

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