November 14
Preconference Programs

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

Breakfast on your own.

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

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

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

4:30-5:30 PM  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

<table>
<thead>
<tr>
<th>Track</th>
<th>Descriptor</th>
<th>Sessions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A Dialogue With the Feds</td>
<td>This track will provide attendees with an opportunity to hear from and ask questions of federal agency representatives.</td>
</tr>
<tr>
<td>2</td>
<td>Boundaries and Balances</td>
<td>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.</td>
</tr>
<tr>
<td>3</td>
<td>Educating and Training</td>
<td>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.</td>
</tr>
<tr>
<td>4</td>
<td>Empirical Research Ethics</td>
<td>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.</td>
</tr>
<tr>
<td>5</td>
<td>FDA Regulations</td>
<td>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.</td>
</tr>
<tr>
<td>6</td>
<td>Global Research</td>
<td>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.</td>
</tr>
<tr>
<td>7</td>
<td>Hot Topics</td>
<td>This track includes sessions on topics that are current, complex, and/or late breaking.</td>
</tr>
<tr>
<td>8</td>
<td>Institutional Officials and HRPP Leadership</td>
<td>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.</td>
</tr>
<tr>
<td>9</td>
<td>IRB 101</td>
<td>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.</td>
</tr>
<tr>
<td>10</td>
<td>IRB Chairs</td>
<td>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.</td>
</tr>
<tr>
<td>11</td>
<td>IRB Operations Advanced</td>
<td>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.</td>
</tr>
<tr>
<td>12</td>
<td>Pharma/Biotech Perspectives</td>
<td>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.</td>
</tr>
<tr>
<td>Track</td>
<td>Descriptor</td>
<td>Sessions</td>
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<tr>
<td>13</td>
<td>Legal</td>
<td>A14, B14, C5, C14, D14, E14</td>
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<tr>
<td>14</td>
<td>Non-Scientist IRB Members</td>
<td>A15, C15, D15, E15</td>
</tr>
<tr>
<td>15</td>
<td>Research Involving Data and Biospecimens</td>
<td>A16, B16, C16, D16, E16</td>
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<tr>
<td>16</td>
<td>Populations Requiring Additional Protections</td>
<td>A17, B17, C17, D17, E17</td>
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<tr>
<td>17</td>
<td>QA/QI and Post-Approval Monitoring</td>
<td>A18, B18, C18, D18, E5, E18</td>
</tr>
<tr>
<td>18</td>
<td>Research Conducted in the Digital World</td>
<td>A19, B19, C19, D19, E8, E19</td>
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<tr>
<td>19</td>
<td>Responsible Conduct of Research (RCR)</td>
<td>A20, B20, C20, D20, E20</td>
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<tr>
<td>20</td>
<td>Small Research Program</td>
<td>A21, B21, C21, D21, E21</td>
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<tr>
<td>21</td>
<td>SBER</td>
<td>A22, A23, B22, B23, C22, C23, D22, D23, E22, E23</td>
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</table>
### Thursday, November 15

<table>
<thead>
<tr>
<th>Time</th>
<th>Event Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:00 AM-</td>
<td>On-Site Check-In</td>
</tr>
<tr>
<td>5:30 PM</td>
<td>Breakfast on your own.</td>
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<tr>
<td></td>
<td><strong>Ballroom 20A</strong></td>
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<tr>
<td>7:00-8:00 AM</td>
<td>Breakfast to Welcome First-Time Attendees</td>
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<tr>
<td></td>
<td>Attending the AER Conference for the first time can be exciting and overwhelming,</td>
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<tr>
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<td>which is why PRIM&amp;R invites all first-time attendees to participate in this special</td>
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<tr>
<td></td>
<td>breakfast. This event is a great opportunity for first-time attendees to ask</td>
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<td>questions of the PRIM&amp;R staff about the conference and PRIM&amp;R in general, and to</td>
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<td></td>
<td>learn about strategies and resources that can help them make the most of their</td>
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<tr>
<td></td>
<td>conference experience. Preregistration was required for this event.</td>
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<tr>
<td>7:15-8:00 AM</td>
<td>A Capella Musical Performance</td>
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<tr>
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<td>Join us before the conference starts for a musical performance by a local a capella</td>
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<td></td>
<td>group. PRIM&amp;R would like to thank Tech Software for supporting this performance.</td>
</tr>
<tr>
<td>8:00-8:15 AM</td>
<td>Conference Welcome Remarks from the Co-Chairs</td>
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<tr>
<td>8:15-8:40 AM</td>
<td>Remarks from PRIM&amp;R’s Executive Director, Elisa A. Hurley, PhD</td>
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<tr>
<td>8:40-9:00 AM</td>
<td>PRIM&amp;R Board Chair’s Address by Heather H. Pierce, JD, MPH</td>
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<tr>
<td>9:00-10:00 AM</td>
<td>Keynote Address by Timothy Caulfield, LLB, LLM, FRSC, FCAHS:</td>
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<tr>
<td></td>
<td>Celebrities, Science-y, and Pseudoscience: Tackling Misinformation in the</td>
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<td>Era of Health Noise</td>
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<tr>
<td>10:00-10:30 AM</td>
<td>Beverage Break with the Supporters and Exhibitors</td>
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<tr>
<td></td>
<td>Join us for coffee in the exhibit hall. PRIM&amp;R would like to thank Kinetiq for</td>
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<td></td>
<td>helping support this break.</td>
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<tr>
<td>10:30-11:45 AM</td>
<td>Concurrent Plenary Sessions</td>
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<tr>
<td></td>
<td><strong>Ballroom 20D</strong></td>
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<tr>
<td></td>
<td>Moderator: Cynthia A. Gómez</td>
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<tr>
<td></td>
<td>Panelists: Patrick M. Carter, Harold D. Cox, Zoe Grover</td>
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<td></td>
<td><strong>Ballroom 20BC</strong></td>
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<tr>
<td></td>
<td>Panel II: At the Crossroads of Hope and Hype: Recruiting the Desperately Ill</td>
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<td>for Clinical Trials</td>
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<td></td>
<td>Moderator: Alexander M. Capron</td>
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<td></td>
<td>Panelists: Andrea Denicoff, Betty R. Ferrell, Jodi Halper, Carol Juliet Weil</td>
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<tr>
<td></td>
<td><strong>Exhibit Hall H</strong></td>
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<tr>
<td></td>
<td>Panel III: The New Rule’s Identity Crisis: Should Identifiability Be Changed?</td>
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<tr>
<td></td>
<td>Moderator: Laura Odwazny</td>
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<tr>
<td></td>
<td>Panelists: William E. Grizzle, Suzanne M. Rivera</td>
</tr>
<tr>
<td>11:45 AM-</td>
<td>Networking Lunch Supported by CITI Program, a division of BRANY</td>
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<tr>
<td>1:00 PM</td>
<td>Time to connect…over lunch! Meet peers for conversation and networking. All are</td>
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<tr>
<td></td>
<td>welcome! PRIM&amp;R would like to thank CITI Program, a division of BRANY, for helping</td>
</tr>
<tr>
<td></td>
<td>support this lunch.</td>
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<tr>
<td>11:45 AM-</td>
<td>Research Ethics Discussion Luncheon: Fighting Health Myths With Stories, Art, and</td>
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<tr>
<td>1:00 PM</td>
<td>Fun</td>
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<tr>
<td></td>
<td>Moderator: Melissa E. Abraham</td>
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<tr>
<td></td>
<td>Author: Timothy Caulfield</td>
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<td>Note: A buffet lunch will be served in the session room. The formal presentation</td>
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<tr>
<td></td>
<td>will start at 12:00 PM.</td>
</tr>
</tbody>
</table>

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- **Common Rule**
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<tr>
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</table>
| 11:45 AM-1:00 PM   | 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   | 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   | 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   | Lunch Session: A Dialogue With the VA  
                    Kristina C. Borror, Richard D’Augusta, Charlotte K. Jeans, Molly M. Kline  
                    Note: Lunch will be served outside the session room. The formal presentation will start at 12:00 PM. |
| 12:15-12:35 PM     | Overview of the CIP® Exam  
                    Exhibit Hall FG  
                    Demo Theater |
| 12:30-1:00 PM      | Meet and Greet With the AER18 Supporters and Exhibitors  
                    Exhibit Hall FG |
| 12:30-1:00 PM      | Federal Agency/Accrediting Body Office Hours  
                    Exhibit Hall FG  
                    For the list of agencies participating in this office hours session, see the online agenda or the conference app. |
| 12:40-1:00 PM      | 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.  
                    Exhibit Hall FG  
                    Demo Theater |
| 1:15-2:30 PM       | Breakout Session Series A  
                    | A1  
                    A Dialogue With OHRP  
                    Misti Ault Anderson, Lisa R. Buchanan, Ivor A. Pritchard, Irene E. Stith-Coleman  
                    Room 28ABC |
|                    | A2  
                    Does Diversity Matter in the Conduct of a Clinical Trial?  
                    Barbara E. Bierer, Owen Garrick  
                    Room 23C |
|                    | A3  
                    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  
                    Room 29B |
|                    | A4  
                    Stories Matter: The Use of Narrative in IRB Member Education  
                    Educating and Training Track  
                    Michael Leary, Gianna McMillan  
                    Room 25C |
|                    | A5  
                    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  
                    Room 22 |

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<thead>
<tr>
<th>Session Code</th>
<th>Room</th>
<th>Session Title</th>
<th>Track</th>
<th>发言人</th>
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</thead>
<tbody>
<tr>
<td>A6</td>
<td>31C</td>
<td>Demystifying Part 11 and Computer System Validation</td>
<td>FDA Regulations Track</td>
<td>Jan L. Hewett, James Riddle</td>
</tr>
<tr>
<td>A7</td>
<td>23A</td>
<td>Different Models of Review: A Global Comparison</td>
<td>Global Research Track</td>
<td>Byung-in (B.I.) Choe, Bartholomew Wilson, Delia Y. Wolf, Rachel Zand</td>
</tr>
<tr>
<td>A8</td>
<td>29C</td>
<td>The Certified IRB Professional (CIP®) Credential: How Do I Get Started?</td>
<td>Hot Topics Track</td>
<td>Michelle Francis Grienauer, Hallie Kassan, Lori Roesch</td>
</tr>
<tr>
<td>A10</td>
<td>28DE</td>
<td>Back to Basics: Does My Project Fall Within the Scope of the Revised Common Rule?</td>
<td>IRB 101 Track</td>
<td>Jaime O. Hernandez</td>
</tr>
<tr>
<td>A11</td>
<td>29A</td>
<td>Meeting Management for IRB Chairs</td>
<td>IRB Chairs Track</td>
<td>Francis J. DiMario Jr., Luke Gelinas</td>
</tr>
<tr>
<td>A12</td>
<td>30AB</td>
<td>It's Not as New as You Think: Understanding How to Operationalize the Revised Common Rule</td>
<td>IRB Operations Advanced Track</td>
<td>Jeffrey A. Cooper, Kristin J. Craun, Jessica H. Huening, Heather H. Pierce</td>
</tr>
<tr>
<td>A13</td>
<td>31A</td>
<td>ClinicalTrials.gov: How Academic Institutions Can Respond to New Clinical Trial Disclosure Requirements</td>
<td>Pharma/Biotech Perspectives Track</td>
<td>Sarah A. White, Rebecca J. Williams</td>
</tr>
<tr>
<td>A14</td>
<td>30D</td>
<td>Legal and Regulatory Changes: A Year in Review</td>
<td>Legal Track</td>
<td>Mitchell E. Parrish, Michele Russell-Einhorn</td>
</tr>
<tr>
<td>A15</td>
<td>27B</td>
<td>Defining Roles &amp; Expectations for the Non-Scientist and Unaffiliated IRB Member: Deconstructing Regulatory and Research Terminology</td>
<td>Non-Scientist IRB Members Track</td>
<td>Glenn Ellis, Michelle M. Feige, Nancy A. Olson</td>
</tr>
<tr>
<td>A16</td>
<td>25AB</td>
<td>Implementing NIH’s Genomic Data Sharing Policy: Challenges and Solutions</td>
<td>Research Involving Data and Biospecimens Track</td>
<td>Shannon Seward, Carrie D. Wolinetz</td>
</tr>
<tr>
<td>A18</td>
<td>30C</td>
<td>Beyond Auditing and Monitoring of the IRB Towards Quality Improvement</td>
<td>QA/QI and Post-Approval Monitoring Track</td>
<td>John R. Baumann, Cheryl L. Byers, Mariette Marsh</td>
</tr>
</tbody>
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<th>Track</th>
<th>Speakers</th>
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</thead>
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<tr>
<td>A19</td>
<td>IRB Review of Big Data Research</td>
<td>Research Conducted in the Digital World Track</td>
<td>Jacob Metcalf, Laura Odwazny, Stephen J. Rosenfeld</td>
</tr>
<tr>
<td>A20</td>
<td>Preparing Research Misconduct Committees to Succeed</td>
<td>Responsible Conduct of Research Track</td>
<td>Kate Gallin Heffeman, Ross A. Hickey</td>
</tr>
<tr>
<td>A21</td>
<td>Challenges and Opportunities for Institutions With Small Research Programs</td>
<td>Small Research Programs Track</td>
<td>Andrea R. McDowell, John C. Smith</td>
</tr>
<tr>
<td>A22</td>
<td>Different Minimal Risk Review Models</td>
<td>SBER Track</td>
<td>Jeffrey M. Cohen, Cecilia Brooke Cholka, Erik Williams</td>
</tr>
<tr>
<td>A23</td>
<td>Risk Mitigation in Mixed SBER and Biomedical Research</td>
<td>SBER Track</td>
<td>Lara N. Sloboda, Matthew D. Stafford</td>
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</table>

#### 2:30-3:00 PM
**Beverage Break**
Join us for coffee and cold drinks.

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

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<th>Session</th>
<th>Title</th>
<th>Track</th>
<th>Speakers</th>
</tr>
</thead>
<tbody>
<tr>
<td>B1</td>
<td>The Times, They Are A-Changing: Overview of the Latest NIH Changes and Their Implications on Research</td>
<td>A Dialogue With the Feds Track</td>
<td>Marylana Saadeh Helou, Carrie D. Wolinetz</td>
</tr>
<tr>
<td>B2</td>
<td>The Generation and Utilization of Real-World Evidence: Ethical and Regulatory Considerations</td>
<td>FDA Regulations Track</td>
<td>Diana T. Chingos, Jacqueline Corrigan-Curay, Robert (Skip) M. Nelson, Jeremy Sugarman</td>
</tr>
<tr>
<td>B3</td>
<td>You’ll Know It When You See It, or Will You? Defining “Human Subjects Research”</td>
<td>Boundaries and Balance Track</td>
<td>Misti Ault Anderson, Warren Capell, Dean R. Gallant</td>
</tr>
<tr>
<td>B4</td>
<td>An Educational Map to Being a Great Research Ethicist (or Just a Better One)</td>
<td>Educating and Training Track</td>
<td>Robert Hood, Dane C. Joseph</td>
</tr>
<tr>
<td>B5</td>
<td>Designing Trials for Completion</td>
<td>Empirical Research Ethics Track</td>
<td>Barbara E. Bierer, Luke Gelinas, Spencer Hey</td>
</tr>
<tr>
<td>B6</td>
<td>When Is an Investigational Device Exemption Needed for a Clinical Investigation of a Medical Device?</td>
<td>FDA Regulations Track</td>
<td>Soma Kalb</td>
</tr>
<tr>
<td>B7</td>
<td>Human Subjects Protections Across Borders</td>
<td>Global Research Track</td>
<td>Edward E. Bartlett (moderator), Byung-in (B.I.) Choe, Karen M. Hansen</td>
</tr>
</tbody>
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<th>Session Code</th>
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<th>Room/Location</th>
<th>Description</th>
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<tbody>
<tr>
<td>B8</td>
<td>Exploring and Enhancing Diversity Within Our Compliance Committees</td>
<td>Hot Topics Track</td>
<td>23C</td>
<td>Eric Allen, Owen Garrick, Tonya Ferraro</td>
</tr>
<tr>
<td>B9</td>
<td>Top Considerations for Institutional and HRPP Leadership When Accepting</td>
<td>Department of Defense Support of Research</td>
<td>29D</td>
<td>Institutional Officials and HRPP Leadership Track</td>
</tr>
<tr>
<td></td>
<td>1-800-RESEARCHLAWYER: Is Your Institution’s Legal Counsel on Speed Dial?</td>
<td>Legal Track</td>
<td>25C</td>
<td>Emily Chi Fogler, Kate Gallin Heffeman, Jesse A. Ripton</td>
</tr>
<tr>
<td>B10</td>
<td>Essential Documentation: IRB Records Documentation Requirements, Minutes,</td>
<td>IRB 101 Track</td>
<td>22</td>
<td>Lisa R. Buchanan, Janet C. Donnelly, Ada Sue Selwitz</td>
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<td></td>
<td>Written Procedures, and More</td>
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<tr>
<td>B11</td>
<td>The Evolving Role of the IRB Chair in the World of Single IRBs</td>
<td>IRB Chairs Track</td>
<td>30D</td>
<td>David C. Christiani, Susan C. Sonne</td>
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<tr>
<td></td>
<td>During and After Implementation of the Revised Common Rule</td>
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<tr>
<td>B13</td>
<td>The European Union’s General Data Protection Regulation and US-Based Research:</td>
<td>Pharma/Biotech Perspectives Track</td>
<td>33AB</td>
<td>Mark Barnes, Karla Childers</td>
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<tr>
<td></td>
<td>Implications, Problems, and Potential Solutions</td>
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<tr>
<td>B14</td>
<td>New Data on Single IRBs: Implications for the Future</td>
<td>Hot Topics Track</td>
<td>30C</td>
<td>Robert Klitzman, Charles W. Lidz</td>
</tr>
<tr>
<td>B15</td>
<td>Research With Data and Biospecimens Under the Revised Common Rule: An</td>
<td>Research Involving Data and Biospecimens Track</td>
<td>20A</td>
<td>Marianna J. Bledsoe, Elizabeth A. Buchanan, Lauren Hartsmit</td>
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<tr>
<td></td>
<td>Overview of Changes and Challenges</td>
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<tr>
<td>B16</td>
<td>Conducting Research With Children: Complexities in Practice</td>
<td>Populations Requiring Additional Protections Track</td>
<td>25AB</td>
<td>Bruce G. Gordon, Susan Z. Kometsky</td>
</tr>
<tr>
<td>B17</td>
<td>Ideas and Practices for Compliance and Auditing of Single IRB Studies</td>
<td>QA/QI and Post-Approval Monitoring Track</td>
<td>31A</td>
<td>Nichelle Cobb, Sarah A. White</td>
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<tr>
<td>B18</td>
<td>Privacy and Security Risks in Research With Wearable Technology</td>
<td>Research Conducted in the Digital World Track</td>
<td>28DE</td>
<td>Megan Doerr, Sara Meeder</td>
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<tr>
<td>B19</td>
<td>Case Studies in Research Misconduct</td>
<td>Responsible Conduct of Research Track</td>
<td>29C</td>
<td>Ross A. Hickey, Fariba Houman</td>
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</tbody>
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For session descriptions, view the full agenda online or in the AER18 app

Icon Key

- Double Session
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# Thursday, November 15

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<tr>
<th>Session</th>
<th>Title</th>
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<tbody>
<tr>
<td>B21</td>
<td>How to Identify, Navigate, and Manage Conflicts of Interest at a Small Research Organization</td>
<td>Small Research Programs Track</td>
<td>Elizabeth A. Boyd, Heather H. Pierce</td>
</tr>
<tr>
<td>B22</td>
<td>College Students and Research: Challenges and Issues for IRBs</td>
<td>SBER Track</td>
<td>Andrea R. McDowell, Linda E. Petree</td>
</tr>
<tr>
<td>B23</td>
<td>Assessing and Mitigating Risk in SBER Research: A Case Study Approach</td>
<td>SBER Track</td>
<td>Amy Ben-Arieh, Alyssa Speier</td>
</tr>
</tbody>
</table>

### Schedule:

- **4:15-5:30 PM**
  - AER18 Welcome Reception
  - Drinks and light refreshments will be served.
- **5:10-5:30 PM**
  - Overview and Demonstration of PRIM&R’s New Ethical Research Oversight Course (E-ROC)
- **5:45-7:15 PM**
  - Young Professionals Networking Reception
  - While all attendees are welcome, complimentary drink tickets are only provided for young professional registrants.

For session descriptions, view the full agenda online or in the AER18 app.
## Friday, November 16

### 7:00 AM - 5:30 PM  
**On-Site Check-In**  
Exhibit Hall FG Foyer  
**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**

### 8:30-9:30 AM  
**Exhibit Hall H**  
**Keynote Address by Michelle M. Mello, JD, PhD: Clinical Trial Data Sharing: Perspectives From Participants**

### 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  
**Exhibit Hall H**  
**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.

#### Exhibits Hall H  
**Explorations A: Explorations in Optimizing Informed Consent and Assent**  
**Moderator: Ryan Spellecy**  
  *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  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  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  Standard of Care, Medical Innovation, or Research: How Should We Decide?
Boundaries and Balance Track
Stephanie S. Cargill, Jeremy J. Corsmo

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

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

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

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

C8  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

For session descriptions, view the full agenda online or in the AER18 app
Friday, November 16

C9 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.

C10 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 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 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 Scientific and Ethical Considerations in Choosing a Study Control Group
Pharma/Biotech Perspectives Track
Robert (Skip) M. Nelson, Albert J. Allen

C14 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 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 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.

C17 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.

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

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

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

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

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

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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| 3:00-3:30 PM | **Beverage Break**  
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 |
| **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 |
| **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 Hefferman, 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  Single IRB: The Next Generation
Room 32AB
IRB Operations Advanced Track
Daniel Alderson, Jenni Beadles, Aaron Kirby

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

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

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

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

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

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

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

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

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

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

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

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

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4:45-6:00 PM  Meet the AER18 Poster Authors  
Exhibit Hall FG

4:45-6:00 PM  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.
Exhibit Hall FG

4:50-5:15 PM  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.
Demo Theater

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**7:00 AM - 12:30 PM**
**On-Site Check-In**
Exhibit Hall FG Foyer

**Breakfast on your own.**

**7:15-8:00 AM**
**A Capella Musical Performance**
Exhibit Hall FG and Exhibit Hall H

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**
**Welcome and PRIM&R Membership and CIP® Updates**
Exhibit Hall H

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

**9:30-10:00 AM**
**Beverage Break With Supporters and Exhibitors**
Exhibit Hall FG

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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<td>E7</td>
<td>Applying US Human Research Protections Regulations and Embedded Cultural Values to Research Conducted in Different Cultures: Challenges, Cultural Considerations, Collaborations, and Experiences</td>
<td>30D</td>
<td>Global Research Track &lt;br&gt; <em>Edward E. Bartlett (moderator), Derek Englis, A. Roxana Lescano, Sophea Sout</em></td>
<td>Global Research Track</td>
<td>Advanced</td>
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<tr>
<td>E8</td>
<td>User Agreements in Human Subjects Research During the Burgeoning Technology Age</td>
<td>25AB</td>
<td>Research Conducted in the Digital World Track &lt;br&gt; <em>Eric Allen, Linda M. Coleman, Megan Doerr</em></td>
<td>Research Conducted in the Digital World Track</td>
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<tr>
<td>E9</td>
<td>Ethical and Operational Issues Related to Clinical Trial Billing: What HRPPs and IRBs Should Consider</td>
<td>25C</td>
<td>Institutional Officials and HRPP Leadership Track &lt;br&gt; <em>Keren R. Dunn, F. Lisa Murtha, Ann Rodavitch</em></td>
<td>Institutional Officials and HRPP Leadership Track</td>
<td>Basic</td>
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<td>E10</td>
<td>IRB Review of Informed Consent: Moving Beyond the Form</td>
<td>33AB</td>
<td>IRB 101 Track &lt;br&gt; <em>Elizabeth A. Bankert, Joshua Fedewa, Jamie O. Hernandez</em></td>
<td>IRB 101 Track</td>
<td>Advanced</td>
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<tr>
<td>E11</td>
<td>The Role of the IRB Chair in Protocol Exceptions, Violations, Noncompliance, and Unanticipated Problems</td>
<td>28DE</td>
<td>IRB Chairs Track &lt;br&gt; <em>Madelon V. Baranoski, Jeremy J. Corsmo</em></td>
<td>IRB Chairs Track</td>
<td>Advanced</td>
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<tr>
<td>E13</td>
<td>Designing and Implementing Expanded Access Programs</td>
<td>31C</td>
<td>Pharma/Biotech Perspectives Track &lt;br&gt; <em>Erika L. Segar Johnson, Richard Klein, Marjorie A. Speers, Walter L. Straus</em></td>
<td>Pharma/Biotech Perspectives Track</td>
<td>Advanced</td>
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<tr>
<td>E14</td>
<td>From Shield to Sword? How the 21st Century Cures Act and NIH Policy Have Altered Certificates of Confidentiality</td>
<td>24AB</td>
<td>Legal Track &lt;br&gt; <em>Catherine Sutherland, Leslie E. Wolf, Carrie D. Wolinetz</em></td>
<td>Legal Track</td>
<td>Advanced</td>
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<tr>
<td>E15</td>
<td>Considerations and Strategies for Maximizing IRB Contributions from Non-Scientist and Unaffiliated Members</td>
<td>24C</td>
<td>Non-Scientist IRB Members Track &lt;br&gt; <em>Nathalia Henry, Stephen Poppel</em></td>
<td>Non-Scientist IRB Members Track</td>
<td>Basic</td>
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<td>E16</td>
<td>Building a Better Biobank: Promise and Challenges of the National Cancer Institute Cancer Moonshot Biobank</td>
<td>29C</td>
<td>Research Involving Data and Biospecimens Track &lt;br&gt; <em>Janet Freeman-Daily, Helen Moore</em></td>
<td>Research Involving Data and Biospecimens Track</td>
<td>Basic</td>
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<tr>
<td>E17</td>
<td>Tribal Research Futures: Resources to Strengthen Governance, Trust, and Culture in Research Partnerships</td>
<td>23A</td>
<td>Populations Requiring Additional Protections Track &lt;br&gt; <em>Julie Lucero, Yvette Roubideaux</em></td>
<td>Populations Requiring Additional Protections Track</td>
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<td>E18</td>
<td>Nuts and Bolts of Investigator Site Audits</td>
<td>QA/QI and Post-Approval Monitoring</td>
<td>Room 29D</td>
<td>David A. Borasky, Jr., Stefanie deRijke, Kelly Dornin-Koss</td>
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<tr>
<td>E20</td>
<td>Data Acquisition and Management: Concepts Every Researcher and Research Administrator Should Know</td>
<td>Responsible Conduct of Research</td>
<td>Room 23C</td>
<td>Carolyn Broccardo</td>
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<tr>
<td>E21</td>
<td>Managing Small Research Programs in Healthcare Settings</td>
<td>Small Research Programs</td>
<td>Room 31B</td>
<td>Delilah Ofosu-Barko, Jennifer L. Pacheco</td>
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<tr>
<td>E22</td>
<td>How to Create an Undergraduate Research Training Program</td>
<td>SBER</td>
<td>Room 30E</td>
<td>Jonathan M. Girard, Shannon Sewards</td>
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**12:45-2:30 PM**

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<thead>
<tr>
<th>Session</th>
<th>Title</th>
<th>Track</th>
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<td></td>
<td>Closing General Session Luncheon: Research Ethics, Race, and Opioids—The Evolution of the Perfect Epidemic</td>
<td></td>
<td>Exhibit Hall H</td>
<td>Elizabeth A. Buchanan, Brenda L. Curtis, Alexis Roth, Ekow N. Yankah</td>
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Note: Lunch will be served during this session. The formal presentation will begin at 1:15 PM.

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