### Sunday, December 5—Pre-Conference Programs

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:00 AM</td>
<td>Registration opens</td>
<td>Lobby 20</td>
</tr>
<tr>
<td>7:00–8:30 AM</td>
<td>Continental breakfast</td>
<td>Sails Pavilion</td>
</tr>
<tr>
<td>8:30 AM–4:30 PM</td>
<td><strong>Advanced Research Ethics</strong></td>
<td>Room 33AB</td>
</tr>
<tr>
<td>8:30 AM–4:30 PM</td>
<td><strong>Advanced Tissue Banking</strong></td>
<td>Room 26AB</td>
</tr>
<tr>
<td>8:30 AM–12:30 PM</td>
<td><strong>Good Clinical Practice (GCP)—Everything You Always Wanted to Know, but Were Afraid to Ask!</strong></td>
<td>Room 24C</td>
</tr>
<tr>
<td>8:30 AM–4:30 PM</td>
<td><strong>Hot Topics for Institutional Officials</strong></td>
<td>Room 24A</td>
</tr>
<tr>
<td>8:30 AM–4:00 PM</td>
<td><strong>IRB 101™ - Biomedical Research</strong></td>
<td>Room 29AB</td>
</tr>
<tr>
<td>8:30 AM–4:00 PM</td>
<td><strong>IRB 101™ - Social, Behavioral, and Educational Research (SBER)</strong></td>
<td>Room 33C</td>
</tr>
<tr>
<td>8:30 AM–4:15 PM</td>
<td><strong>IRB 201: An In-Depth Analysis of the Criteria for Review</strong></td>
<td>Room 31ABC</td>
</tr>
<tr>
<td>8:30 AM–5:30 PM</td>
<td><strong>Listening to the Voices of Minorities and Researchers on Building Trust and Capacity for Respectful Engagement</strong></td>
<td>Room 23B</td>
</tr>
<tr>
<td>8:30 AM–4:30 PM</td>
<td><strong>Navigating Research Regulations and Research Ethics in the Internet Age</strong></td>
<td>Room 30AB</td>
</tr>
<tr>
<td>8:30 AM–5:00 PM</td>
<td><strong>The Buck Starts and Stops Here: Investigator Responsibilities for the Ethical Conduct of Research</strong></td>
<td>Room 23A</td>
</tr>
<tr>
<td>4:30–6:30 PM</td>
<td>Pre-conference program networking reception</td>
<td>Room 28ABCDE</td>
</tr>
</tbody>
</table>
# Conference Schedule

**Monday, December 6**

<table>
<thead>
<tr>
<th>Time</th>
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<tr>
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<td>Continental breakfast</td>
<td>Sails Pavilion</td>
</tr>
<tr>
<td>7:00-8:15 AM</td>
<td>Continental breakfast: First-time attendees</td>
<td>Room 28ABCDE</td>
</tr>
<tr>
<td></td>
<td><em>All first-time conference attendees are welcome! Join this breakfast to connect and network with colleagues and hear from the PRIM&amp;R staff.</em></td>
<td></td>
</tr>
<tr>
<td>8:15-8:30 AM</td>
<td>Welcome and conference overview</td>
<td>Ballroom 20</td>
</tr>
<tr>
<td>8:30-9:30 AM</td>
<td>Keynote address: Francis Collins, MD, PhD, Director, U.S. National Institutes of Health</td>
<td>Ballroom 20</td>
</tr>
<tr>
<td>9:30-10:30 AM</td>
<td>Plenary: A Great Debate – Be It Resolved that Consent Forms are an Obstacle to Informed Consent and Should be Abolished</td>
<td>Ballroom 20</td>
</tr>
<tr>
<td></td>
<td>Moderator: Michele Russell-Einhorn</td>
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<tr>
<td></td>
<td>Debaters: Leonard Glantz – pro, Jerry Menikoff – con</td>
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</tr>
<tr>
<td>10:30-11:00 AM</td>
<td>Coffee and “communing” time</td>
<td></td>
</tr>
<tr>
<td>11:00-11:45 AM</td>
<td>Plenary: Rethinking the Research Regulations: Where Should We Go?</td>
<td>Ballroom 20</td>
</tr>
<tr>
<td></td>
<td>Ezekiel Emanuel, MD, PhD, Special Advisor for Health Policy to the Director of the Office of Management and Budget</td>
<td></td>
</tr>
<tr>
<td>11:45 AM-1:00 PM</td>
<td>Common Ground Networking Lunch in the Conference Connection</td>
<td>Sails Pavilion</td>
</tr>
<tr>
<td>11:45 AM-1:00 PM</td>
<td>Lunch: What's New at the CITI Program?</td>
<td>Room 28ABCDE</td>
</tr>
<tr>
<td></td>
<td>CITI co-founder Karen Hansen will demonstrate new features that will help participants get the most from their use of the CITI Program, including site navigation, refresher modules, and non-English language capabilities.</td>
<td></td>
</tr>
<tr>
<td>1:00-1:15 PM</td>
<td>Commuting time <em>i.e. no food or beverage, just time to get to your sessions!</em></td>
<td></td>
</tr>
<tr>
<td>1:15-2:30 PM</td>
<td>Didactic Sessions and Workshop Series A</td>
<td></td>
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<tr>
<td></td>
<td>A1 A Dialogue with the Office for Human Research Protections (OHRP)</td>
<td>Room 33A</td>
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<tr>
<td></td>
<td><em>(A Dialogue with the Feds I Track) Kristina Borror, Mike Carome, Julie Kaneshiro, Melody Lin, Laura Odwazny, Irene Stith-Goleman, Elyse Summers</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>A2 A Dialogue with the National Science Foundation (NSF)</td>
<td>Room 27A</td>
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<tr>
<td></td>
<td><em>(A Dialogue with the Feds II Track) Kellina Craig-Henderson</em></td>
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<tr>
<td></td>
<td>A3 The Fundamentals of AAHRPP Accreditation for New Applicants</td>
<td>Room 31B</td>
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<tr>
<td></td>
<td><em>(Accreditation of HRPPs Track) Sujatha Sridhar</em></td>
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<tr>
<td></td>
<td>A4 Delineating and Applying the Boundaries between Research and Practice: Public Health and Surveillance, Program Evaluation, and Quality Assurance/Quality Improvement (QA/QI) <em>(Advanced Forum for Experienced IRB Professionals Track)</em></td>
<td>Room 6A</td>
</tr>
<tr>
<td></td>
<td>Alex Capron, Patrick McNeilly, Rachel Nosowsky</td>
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<tr>
<td></td>
<td>A5 The Making of a Principal Investigator (PI): The Essential Components of an Educational Program for PIs and Research Staff <em>(Clinical Research Professionals Track)</em></td>
<td>Room 29B</td>
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<tr>
<td></td>
<td>Mina Busch, Greg Koski</td>
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<tbody>
<tr>
<td>A6</td>
<td>Ethical Challenges When Conducting Research in Developing Countries: Case Studies in Vaccine Research (Ethical Issues Track)</td>
<td>Room 30A</td>
</tr>
<tr>
<td>A7</td>
<td>What Happens After the Protocol Is Approved: Amendments, Continuing Review, Modifications, Incident Reports, Unanticipated Problems, and Adverse Events (Federal Regulations I Track)</td>
<td>Room 29D</td>
</tr>
<tr>
<td>A8</td>
<td>FDA Expectations of IRBs When Making the Significant and Non-Significant Risk Determination in Device Investigations (Federal Regulations II Track)</td>
<td>Room 33B</td>
</tr>
<tr>
<td>A9</td>
<td>Cell and Gene Therapy Trials in Pediatric Research (Genetics, Stem Cells, and Repositories Track)</td>
<td>Room 31C</td>
</tr>
<tr>
<td>A10</td>
<td>CIA Interrogation Research (Hot Spots I Track)</td>
<td>Room 30E</td>
</tr>
<tr>
<td>A11</td>
<td>Research Using Mobile Health Devices (Hot Spots II Track)</td>
<td>Room 26A</td>
</tr>
<tr>
<td>A12</td>
<td>Understanding and Assembling the Components of an Effective HRPP (Hint: It’s the Institution Not the IRB!) (IRB Bootcamp Track)</td>
<td>Room 30B</td>
</tr>
<tr>
<td>A13</td>
<td>Determining What Needs IRB Review versus Exempt Research (IRB Operations and Tool Kit Track)</td>
<td>Room 32AB</td>
</tr>
<tr>
<td>A14</td>
<td>The Assent Process and Assessing Children’s Competence to Understand a Proposed Research Project (Informed Consent Track)</td>
<td>Room 28C</td>
</tr>
<tr>
<td>A15</td>
<td>Understanding the Elements of a Strong Compliance Program and Strategies for Implementation at Your Institution (Institutional Officials Track)</td>
<td>Room 33C</td>
</tr>
<tr>
<td>A16</td>
<td>“Going Buggy”: Ethical and Regulatory Issues When Exposing Human Subjects to Infectious Disease Vectors (International Research Track)</td>
<td>Room 25A</td>
</tr>
<tr>
<td>A17</td>
<td>What Factors and Questions do IRBs Look at When Reviewing a Protocol? (Issues for Pharma/Biotech Sponsors Track)</td>
<td>Room 24A</td>
</tr>
<tr>
<td>A18</td>
<td>How to Avoid Legal and Regulatory Pitfalls in International Research (Legal Track)</td>
<td>Room 25B</td>
</tr>
<tr>
<td>A19</td>
<td>National Cancer Institute (NCI) Central Institutional Review Board (CIRB) Open Forum (Oncology and Cancer Centers Track)</td>
<td>Room 24C</td>
</tr>
<tr>
<td>A20</td>
<td>A Great Debate Follow-Up: Be It Resolved that Consent Forms are an Obstacle to Informed Consent and Should be Abolished (Panel Follow-up Track)</td>
<td>Room 30C</td>
</tr>
<tr>
<td>A21</td>
<td>Developing Policies and Procedures to Conduct Clinical Trials in Vulnerable Populations in Resource Scarce Communities I Track)</td>
<td>Room 27B</td>
</tr>
</tbody>
</table>
Monday, December 6 (cont.)

1:15-2:30 PM – Didactic Sessions and Workshop Series A (cont.)

- **A22** Equitable Selection of Research Subjects: Balancing the Enrollment of Non-English Speaking Subjects versus Applying the Justice Principle (Populations Requiring Additional Protections II Track) George Gasparis, Seema Shah
  
  Room 24B

- **A23** The Nuts and bolts of a QA/QI Routine Not-for-Cause Review (QA/QI and Post-Approval Monitoring Track) Cindy Kem, Susan Rose
  
  Room 30D

- **A24** Responsible Conduct of Research 101 (Responsible Conduct of Research Track) Mike Kalichman
  
  Room 25C

- **A25** Advanced SBER Topics for IRB Chairs, Directors, and Institutional Officials (SBER Advanced Track) Tracy Arwood, Jeff Cohen, Patti MacCubbin
  
  Room 29A

- **A26** Understanding How the Belmont Principles Can Help Us Implement the Regulations More Effectively (SBER Basic Track) Helen McGough, Toby Schonfeld
  
  Room 23B

- **A27** The Basics of the Scientific Process (Science for the Non-scientist Track) Cliff Gunthel, Yen-Hong Kuo, André Ivanoff
  
  Room 23C

- **A28** The Unique Challenges for IRBs at Community Hospitals (Small Research Institutions Track) Adrianna Brigatti, Tanya Carrillo
  
  Room 31A

- **A29** The Roles and Responsibilities of the Unaffiliated/Non-Scientific Member of the IRB (Unaffiliated/Non-Scientific Members Track) Melissa Frumin, Robert Reed Llewellyn, Gigi McMillan
  
  Room 26B

2:30-2:45 PM Commuting Time (i.e. no food or beverage, just time to get to your sessions!)

- **2:45-4:00 PM** Plenary: Panel I – Pushing the Envelope: Examining Campus-Based Research
  
  Moderator: Dean Gallant
  
  Panelists: Erik Fritsvold, Rachel Nosowsky, Janis Whitlock

  Room 6A

- **2:45-4:00 PM** Plenary: Panel II – Global Standards for Research Ethics: Is Uniformity Possible... Or Desirable?
  
  Moderator: Alex Capron
  
  Panelists: Nancy Kass, Caroline Kithinji, Jim Lavery

  Room 6B

- **2:45-4:00 PM** Plenary: Panel III – When Research Includes the Most Vulnerable Subjects: Key Considerations in IRB Review of Research with Adults Who Cannot Consent for Themselves
  
  Moderator: Ada Sue Selwitz
  
  Panelists: Nancy Dubler, David Strauss

  Ballroom 20

4:00-4:30 PM Commuting and “communing” time

4:30-5:45 PM – Didactic Sessions and Workshop Series B

- **B1** Dialogue with the Food and Drug Administration (FDA) (A Dialogue with the Feds I Track) Leslie Ball, Sonali Gunawardhana, Joanne Less, Diane Maloney, Kevin Prohaska
  
  Room 29B

- **B2** A Dialogue with the Environmental Protection Agency (EPA) (A Dialogue with the Feds II Track) James Downing, Warren Lux
  
  Room 23B
### Monday, December 6 (cont.)

4:30-5:45 PM - Didactic Sessions and Workshop Series B

<table>
<thead>
<tr>
<th>Session</th>
<th>Title</th>
<th>Track</th>
<th>Room</th>
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</thead>
<tbody>
<tr>
<td>B3</td>
<td>Assuring the Scientific or Scholarly Validity of a Proposed Research Study (AAHRPP Element I.1.F)</td>
<td>Accreditation of HRPPs Track</td>
<td>Room 29D</td>
</tr>
<tr>
<td>B4</td>
<td>Effective Practices for Reducing Administrative Burden in Human Subject</td>
<td>Advanced Forum for Experienced IRB Professionals Track</td>
<td>Room 32AB</td>
</tr>
<tr>
<td>B5</td>
<td>Distinguishing Medical Practice from the Conduct of Research</td>
<td>Clinical Research Professionals Track</td>
<td>Room 30A</td>
</tr>
<tr>
<td>B6</td>
<td>Relativistic Ethics and Ethical Pluralism When Conducting Research</td>
<td>Ethical Issues Track</td>
<td>Room 31C</td>
</tr>
<tr>
<td>B7</td>
<td>Essential Documentation: IRB Membership, Documentation, Record Keeping, and Meeting Minutes</td>
<td>Federal Regulations I Track</td>
<td>Room 29C</td>
</tr>
<tr>
<td>B8</td>
<td>An Update from the SACHRP Subcommittee on Harmonization</td>
<td>Federal Regulations II Track</td>
<td>Room 26A</td>
</tr>
<tr>
<td>B9</td>
<td>Genetic Research and Stored Biological Specimens</td>
<td>Genetics, Stem Cells, and Repositories Track</td>
<td>Room 6B</td>
</tr>
<tr>
<td>B10</td>
<td>Data Monitoring Committees: Areas of Consensus and Controversy</td>
<td>(Hot Spots I Track)</td>
<td>Room 30E</td>
</tr>
<tr>
<td>B11</td>
<td>Improving Collaboration and Resource Sharing Between IRBs for Multicenter Studies</td>
<td>(Hot Spots II Track)</td>
<td>Room 31B</td>
</tr>
<tr>
<td>B12</td>
<td>ABCs of Basic and Continuing IRB Member Education</td>
<td>IRB Bootcamp Track</td>
<td>Room 33C</td>
</tr>
<tr>
<td>B13</td>
<td>Administrative Pre-Review/Screening Processes for the IRB: From One Extreme to the Other—Where Do We Draw the Line?</td>
<td>IRB Operations and Tool Kit Track</td>
<td>Room 6A</td>
</tr>
<tr>
<td>B14</td>
<td>Criteria and Considerations for Waiving Requirements for Obtaining and Documenting Informed Consent</td>
<td>Informed Consent Track</td>
<td>Room 29A</td>
</tr>
<tr>
<td>B15</td>
<td>Assessing and Providing Adequate Resources for Your HRPP</td>
<td>Institutional Officials Track</td>
<td>Room 24C</td>
</tr>
<tr>
<td>B16</td>
<td>International Post-Trial Access: Ethical Issues and Responsibilities</td>
<td>International Research Track</td>
<td>Room 23C</td>
</tr>
<tr>
<td>B17</td>
<td>How to Resolve the Top 10 Concerns Sponsors Have About IRBs and IRB Review</td>
<td>Issues for Pharma/Biotech Sponsors Track</td>
<td>Room 25B</td>
</tr>
<tr>
<td>B18</td>
<td>HITECH Legal Developments in 2010 and Their Effects on Research</td>
<td>(Legal Track)</td>
<td>Room 30B</td>
</tr>
<tr>
<td>B19</td>
<td>Ethical Issues in Phase I Oncology Trials with Children</td>
<td>Oncology and Cancer Centers Track</td>
<td>Room 33A</td>
</tr>
<tr>
<td>B20</td>
<td>Panel Follow-Up: Research Involving Adults with Decisional Impairments</td>
<td>Panel Follow-Up Track</td>
<td>Room 25A</td>
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Monday, December 6 (cont.)

4:30-5:45 PM - Didactic Sessions and Workshop Series B


B22 Research with Prisoners (Including Incarcerated Minors) Basic (Populations Requiring Additional Protections II Track) Julia Corey, Pat Houser

B23 There’s Not Just One Right Answer: Corrective Action for Common Findings from QI Not-for-Cause Reviews (QA/QI and Post-Approval Monitoring Track) Eunice Newbert, Lynn Smith

B24 Responsible Conduct of Research: What Does a Great Mentor Do? (Responsible Conduct of Research Track) Betsy Holmes, Mike Kalichman

B25 Panel Follow-Up: Pushing the Envelope: Examining Campus-Based Research (SBER Advanced Track) Erik Fritsvold, Janis Whitlock

B26 Ask or Don’t Ask, Tell or Don’t Tell: Privacy versus Anonymity versus Confidentiality versus Disclosure/Public Recognition (SBER Basic Track) Suzanne Holguin, Alison Orkin

B27 Comparing and Contrasting Research Norms: Biomedical versus SBE Research (Science for the Non-Scientist Track) Bob Bienkowski, Cliff Gunthel, Sangeeta Panicker

B28 Developing an Education Program with Limited Resources (Small Research Institutions Track) Scott Lipkin, Brenda Ruotolo

B29 Understanding and Honoring the Spirit of Informed Consent: Form versus Process (Unaffiliated/Non-Scientific Members Track) Bruce Gordon, Gigi McMillan

5:45-7:00 PM Meet and greet the exhibitors! Sails Pavilion

5:45-7:00 PM Speed Mentoring Sails Pavilion

Join us for a one-on-one networking event where you can connect with HRPP professionals, the Feds, ethicists, and other experts to receive personalized answers to your regulatory, ethical, and/or operational questions. Light refreshments will be served.

6:00-7:00 PM Moderated Abstract Discussions Sails Pavilion

Please join us for an informal opportunity to learn about how your colleagues are supporting the advancement of ethical research. Attend one of four discussions with the authors of select abstracts. Each discussion promises to provide important and original ideas in a relaxed and interactive environment. Light refreshments will be served.

8:00-10:00 PM Movie night with PRIM&R: To Kill A Mockingbird Marriott Hotel – Salon E

Join us for a screening of Harper Lee’s masterpiece on the 50th anniversary of the book’s release. We hope the elements of justice, respect, and difficult choices addressed in this story serve as both a timeless inspiration and an opportunity to reflect on the topics featured during the 2010 AER Conference. All are welcome!

Tuesday, December 7

7:00 AM Registration opens Lobby 20

7:00-8:00 AM Continental breakfast Sails Pavilion
Tuesday, December 7 (cont.)

7:00-8:00 AM  Continental breakfast: Learn more about the CIP® credentialing process  Room 28ABCDE
SOLD OUT!
Interested in earning your Certified IRB Professional (CIP®) credential? Want to connect with other “CIPers”? Attend this breakfast to learn more about the credential, meet representatives of the Council for IRB Professionals, network with fellow CIPs, ask questions of those already certified, etc.

7:00-8:00 AM  Continental breakfast: Post-IRB approval investigator audits networking  Room 25ABC
SOLD OUT!
Join the University of Michigan Human Subjects Compliance Office to discuss common challenges and to strategize ways that academic human subjects compliance and QA/QI offices might develop more consistent, effective networking on the current state of post-IRB approval compliance reviews. This activity is known by various names including auditing, not for cause review, QA/QI, etc., and is conducted separately from IRB submissions.

8:00-8:15 AM  Welcome and presentation of the ALA and DSA Awards  Ballroom 20

8:15-9:15 AM  Keynote address: The Immortal Life of Henrietta Lacks  Ballroom 20
Rebecca Skloot, science writer and author of “The Immortal Life of Henrietta Lacks”

9:15-9:30 AM  Commuting time (i.e. no food or beverage, just time to get to your sessions!)

9:30-10:45 AM  Plenary: Panel IV – Making Sense of Community Responses to Tissue Research  Ballroom 20
Moderator: Jeremy Sugarman
Panelists: Chris Hempel, Carletta Tilousi

9:30-10:45 AM  Plenary: Panel V – Research in Complex Humanitarian Disaster Settings and War Zones  Room 6B
Moderator: Sangeeta Panicker
Panelists: Jon Hubbard, Jerry Jacobs, Liesel Ritchie

9:30-10:45 AM  Plenary: Panel VI – Hot Off the Presses: Selected Abstracts on Innovative HRPP Programs and Research on Research Ethics  Room 6A
Research professionals and researchers will present innovative, empirical “research on research ethics,” as well as concrete tools and strategies designed to improve the effectiveness of IRBs/HRPPs.

Moderators: David Borasky and Sue Fish
Topics and Panelists:
1. Evaluating the Quality of Information about Alternatives to Research Participation in Oncology Consent Forms  David Resnik, Dan Patrone, Shyamal Peddada
2. Informed Consent in High-Throughput Genomic Research: Views of Health Plan Members  Susan Trinidad, Stephanie Fullerton, Gail Jarvik, Eric Larson, Wylie Burke
3. Getting Started on the Right Foot: Study Start-up Consultations  Tracy Rightmer, Sandra Alfano, Kathleen Uschinski
4. A Model of Building Trust for the Inclusion and Protection of Racial/Ethnic Populations in Research  Armida Ayala, Jeoma Nwachuku, Alva Moreno, Francisco Morales, Vonee So, Daria Galindo, Isabel Sanchez

10:45-11:15 AM  Coffee, commuting, and “communing” time

11:15 AM-12:30 PM Didactic Sessions and Workshop Series C

느 C1  A Dialogue with the Department of Education  (A Dialogue with the Feds I Track)  Room 27B
Jeff Rodamar

느 C2  What’s New in VA Research Protections for Human Subjects  (A Dialogue with the Feds II Track)  Room 26B
NEW TITLE!  [Please note this is a double session and will end at 1:45 PM. Please pick-up your boxed lunch in the Sails Pavilion before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.]  Robert Brooks, Lynn Cates, Karen Jeans, Kevin Nellis, Joan Porter, Min-Fu Tsan

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C3 Outreach to and Involvement of the Community in HRPPs (AAHRPP Standard 1-4) (Accreditation of HRPPs Track) Monika Markowitz, Peter Vasilenko

C4 Strengthening Your IRB’s Approach to Incidental Findings (Advanced Forum for Experienced IRB Professionals Track) Libby Holmann, Susan Kornetsky, Pearl O’Rourke

C5 Towards Ensuring Research Integrity: Appropriate Communication and Delegation of Responsibilities by the Principal Investigator (Clinical Research Professionals Track) Greg Koski, David Van Houten

C6 Ethical Issues in Deception Research (Ethical Issues Track) Rebecca Armstrong, George Gasparis, Yvonne Higgins

C7 Navigating the World of Research Oversight: Who Must Register? What Regulations Apply? When is Research Exempt? Why are Assurances Required? How Do I Become Engaged? (Federal Regulations I Track) [Please note this is a double session and will end at 1:45 PM. Please pick-up your boxed lunch in the Sails Pavilion before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.] Dan Nelson, Brenda Ruotolo, Irene Stüth-Coleman

C8 The End of Your Search for Information on FDA’s Investigational New Drug (IND) and Investigational Device Exemption (IDE) Regulations (Federal Regulations I Track) [Please note this is a double session and will end at 1:45 PM. Please pick-up your boxed lunch in the Sails Pavilion before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.] Jeff Cooper, Christine Drabick, Lynn Henley, Tejashri Puroit-Sheth

C9 PRIM&R's Primer on the Ethical and Regulatory Issues Relevant to the Use of Biospecimens in Research (Genetics, Stem Cells, and Repositories Track) [Please note this is a double session and will end at 1:45 PM. Please pick-up your boxed lunch in the Sails Pavilion before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.] Marianna Bledsoe, Julie Kaneshiro, Ada Sue Selwitz

C10 Hot Spots in Public Health Research: Intervention Trials, Disease Registries, and Disaster Planning and Response (Hot Spots I Track) [Please note this is a double session and will end at 1:45 PM. Please pick-up your boxed lunch in the Sails Pavilion before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.] Robert Hood, Hugh Tilson

C11 Ethical Engagement of Minorities in Research (Hot Spots II Track) David Barnard, Jonas Chaney, Meleah Himber, Sandra Quinn, Stephen Thomas

C12 The Magnificent Seven and Beyond: How a Robust Set of Policies and Procedures Can Strengthen Your Human Subject Protections Program (IRB Bootcamp Track) [Please note this is a double session and will end at 1:45 PM. Please pick-up your boxed lunch in the Sails Pavilion before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.] Julia Garey, Amanda Hammond, Lynn Smith, Elyse Summers

C13 Gathering for Those Interested in Exploring the CIP® Credential: Your Chance to Ask Us About the Certification Process (IRB Operations and Tool Kit Track) Jaime Arango, Susan Delano, David Forster
Tuesday, December 7 (cont.)
11:15 AM - 12:30 PM - Didactic Sessions and Workshop Series C

C14 Improving Informed Consent (Informed Consent Track) [Please note this is a double session and will end at 1:45 PM. Please pick-up your boxed lunch in the Sails Pavilion before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.] Laura Beskow, David Borasky, Heather Pierce

C15 Alternative Models for IRB Review (Institutional Officials Track) [Please note this is a double session and will end at 1:45 PM. A boxed lunch will be served before the session begins. Pre-registration is required to attend this session.] Barbara Bierer, Dawn DeFazio, Erica Heath, Don Workman

C16 How to Find and Work With an IRB Outside the United States (International Research Track) Peggy Coyle, Sharon Freitag, Dao Duc Giang, Melody Lin, Julia Welch

C17 The “Other” Federal Agency: What Sponsors of FDA-Regulated Studies Need to Know About OHRP (Issues for Pharma/Biotech Sponsors Track) Kristina Borror, Kate Gottfried, Lindsay McNair

C18 Legal Issues in Secondary-Use Research: A Dialogue Between Industry and Institutions (Legal Track) Mark Barnes, Justin McCarthy, Laura Odwazny

C19 Financial Considerations of Relevance to Subjects in Oncology Research (Oncology and Cancer Centers Track) Paul Papagni

C20 Panel Follow-Up: Subject Attitudes Towards Specimen and Data Research (Panel Follow-up Track) Bill Freeman, Jody Harland, Steve Peckman

C21 Considerations and Concerns When Using Student Research Pools (Populations Requiring Additional Protections I Track) Michael Carome, Susan Rose, Joan Sieber

C22 Ethical Issues When Conducting Research on Residual Newborn Screening Blood Samples (Populations Requiring Additional Protections II Track) Susan Burner Bankowski, Nancy King, Robert Nelson, Radhika Rao

C23 Behind the Review: Tools and Methods to run a QA/QI Office More Efficiently! (QA/QI and Post-Approval Monitoring Track) Ann Meeker-O’Connell, Sarah White

C24 Responsible Conduct of Research: Identifying and Implementing Best Practices for Responsible Collaborative Research (Responsible Conduct of Research Track) [Please note this is a double session and will end at 1:45 PM. Please pick-up your boxed lunch in the Sails Pavilion before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.] John Galland

C25 Shifting Ground in the Qualitative Research Fields: Ethnography, Oral Histories, Internet Communities, and More (SBER Advanced Track) [Please note this is a double session and will end at 1:45 PM. Please pick-up your boxed lunch in the Sails Pavilion before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.] Helen McGough, Montana Miller

C26 Informed Consent: When, Why, and How? (SBER Basic Track) Suzanne Holguin, Alison Orkin
Tuesday, December 7 (cont.)

11:15 AM-12:30 PM - Didactic Sessions and Workshop Series C

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Statistics Without Tears: To Dream the Impossible Dream?  
(Science for the Non-Scientist Track) Sue Fish, Yen-Hong Kuo  
Room 25C

c28

Self-Assessment and Quality Improvement Procedures  
(Small Research Programs Track) Eric Allen  
Room 25A

C29

PRIM&R’s Primer for the “Newbie” Unaffiliated/Non-Scientific  
Member/Reviewer (Unaffiliated/Non-Scientific Members Track) [Please note this is a double  
session and will end at 1:45 PM. Please pick-up your boxed lunch in the Sails Pavilion before  
proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be  
included on your name badge.]  
Bruce Gordon, Gigi McMillan  
Room 23C

12:30-1:45 PM Lunch in the Conference Connection  
Sails Pavilion

12:30-1:45 PM Research Ethics Book Group lunch  
SOLD OUT!  
Participate in a vibrant discussion about “The Immortal Life of Henrietta Lacks,” by keynote speaker  
Rebecca Skloot. Attendees will have the opportunity to discuss the book with their peers and the author.  
Room 28ABCDE

1:45-2:00 PM Commuting time (i.e. no food or beverage, just time to get to your sessions!)

2:00-3:15 PM Plenary: Panel VII – Going Global or Staying Local? Research Ethics in a Culturally  
Diverse World  
Moderator: Cynthia Gomez  
Panelists: John Jackson, Robert Levine, Kate MacQueen  
Ballroom 20

2:00-3:15 PM Plenary: Panel VIII – Biological Specimens, Biobanking, and Informed Consent Issues  
Moderator: Pearl O’Rourke  
Panelists: Laura Beskow, Dan Nelson, Radhika Rao  
Room 6A

2:00-3:15 PM Plenary: Living Room Conversation – In Their Own Voices: A Discussion with Research  
Subjects Who Also Work in the Field of Subject Protections  
Moderator: Susan Kometsky  
Commentators: Rebecca Dresser, Brian Gladue, Greg Manship, Paula Radmacher  
Room 6B

3:15-3:45 PM Commuting and “Communing” Time

3:45-5:00 PM - Didactic Sessions and Workshop Series D

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A Dialogue With The VA Central IRB (A Dialogue with the Feds I Track)  
Annette Anderson, Lynn Cates  
Room 30B

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Dialogue with the Department of Energy (A Dialogue with the Feds II Track)  
Libby White  
Room 23B

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Negotiating Contracts to Protect Human Participants in Research (AAHRPP  
Standard 1-8) (Accreditation of HRPPs Track) Mont Brownlee, Martha Nielsens  
Room 25C

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Balancing Respect for Autonomy versus the Public Health Benefits of Research  
(Advanced Forum for Experienced IRB Professionals Track) Robert Hood, Michael McDonald  
Room 33A

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The Clinical Laboratory Improvements Act (CLIA) and its Impact on Research  
(Clinical Research Professionals Track) Brad Noren, Michele Russell-Einhorn  
Room 25A

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registration is required. Double sessions are held over lunch and a boxed lunch will be  
served before the start of each session. Please see the program for end time.

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† Receives Continuing Medical Education (CME) Credit

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program development process.
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<th>Session</th>
<th>Title</th>
<th>Room</th>
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<tr>
<td>D6</td>
<td>Reserved for Late-Breaking (Ethical Issues Track)</td>
<td>29D</td>
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<tr>
<td>D7</td>
<td>Vive la Différence: A Comparison of the DHHS and FDA Regulations for the Protection of Human Subjects (Federal Regulations I Track)</td>
<td>33B</td>
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<td>Janet Donnelly, Glen Drew, Amanda Hammond, Don Workman</td>
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<tr>
<td>D8</td>
<td>Unanticipated Problems Involving Subjects or Others: OHRP and FDA Regulations and Guidance (Federal Regulations II Track)</td>
<td>6A</td>
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<td>Kristina Borror, Kevin Prohaska, Chelle Yin</td>
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<tr>
<td>D9</td>
<td>An Update from the National Academies’ Human Embryonic Stem Cell Research Advisory Committee (Genetics, Stem Cells, and Repositories Track)</td>
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<td>Steve Peckman</td>
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<td>D10</td>
<td>Building Trust Between Minorities and Researchers: Findings from the NIH Bioethics Research Infrastructure Initiative (Hot Spots I Track)</td>
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<td>James Butler, Craig Fryer, Mary Garza, Sandra Quinn, Stephen Thomas</td>
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<td>D11</td>
<td>Practical Strategies for Strengthening IRB Review of Community-Engaged Research (Hot Spots II Track)</td>
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<td>Sarena Seifer, Nancy Shore</td>
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<td>D12</td>
<td>“Tea and Conversation” with the IRB/HRPP Experts: Ask Us Anything! (IRB Bootcamp Track)</td>
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<td>Mike Carone, Charlotte Coley, Yvonne Higgins, Nancy Olson</td>
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<td>D13</td>
<td>Managing Student Research (IRB Operations and Tool Kit Track)</td>
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<td>Donna Eaton, Lane Fischer, Karen Smith-Gratto</td>
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<td>D14</td>
<td>Substituted Judgment: Obtaining Informed Consent from the Legally Authorized Representatives of Decisionally-Impaired Individuals Involved in Research (Informed Consent Track)</td>
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<td>Alex Capron, Elizabeth Small, David Strauss</td>
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<td>D15</td>
<td>Having it All: Strategies for Balancing the Need for IRB Efficiency with the Need for Compliance (Institutional Officials Track)</td>
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<td>Gary Chadwick, Susan Miller</td>
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<td>D16</td>
<td>Navigating the Different Review and Approval Systems When Doing Research in Multiple Countries (International Research Track)</td>
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<td>Edward Bartlett, Jim Lavery, Swarnalakshmi Singaravelu</td>
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<td>D17</td>
<td>PRIM&amp;R’S Primer for Sponsors on Genetics and Tissue Banking (Issues for Pharma/Biotech Sponsors Track)</td>
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<td>Mary Ellen Allen, Eric Mah</td>
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<td>D18</td>
<td>What Attorneys and Other Stakeholders Should Know About FDA Regulations and Enforcement (Legal Track)</td>
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<td>Sonali Gunawardhana, Kate Gallin Heffern</td>
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<td>D19</td>
<td>Palliative Care Research (Oncology and Cancer Centers Track)</td>
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<td>Scott Irwin, Steve Oppenheim</td>
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<td>D20</td>
<td>Panel Follow-Up: More on Biospecimen Research: If, When, and How to Return Research Results (Panel Follow-up Track)</td>
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<td>Lynn Dressler, Emily Namey, Nicole Lockhart, Carol Weil</td>
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Wednesday, December 8 (cont.)

9:30-10:45 AM  \(\bigvee\) Plenary: Panel X – Research that Seeks to Build Community Involvement  
Moderator: Sarena Seifer  
Panelists: Saida Abdi, Heidi Ellis, Loretta Jones, Stephen Thomas  
Room 6B

9:30-10:45 AM  \(\bigvee\) Plenary: A Great Debate – Be It Resolved There Is an Obligation to Participate in Research  
Moderator: Alan Wertheimer  
Debaters: Rebecca Dresser, Steve Joffe  
Room 6A

10:45-11:15 AM  
Coffee, communting, and “communing” Time

11:15 AM-12:30 PM - Didactic Sessions and Workshop Series E

\(\bigvee\) E1 A Dialogue with the Department of Defense (DOD): Ethical Issues When Conducting Research in a Military Setting  
(A Dialogue with the Feds I Track) Molly Klotz, Patty Decot  
Room 30B

\(\bigvee\) E2 A Dialogue with the National Institutes of Health (NIH)  
(A Dialogue with the Feds II Track) Dan Davis, Ann Hardy, Steven Hirschfeld, Laura Lyman Rodriguez  
Room 30D

\(\bigvee\) E3 Reporting Requirements for Researchers (AAHRPP Element III.2.D)  
(Accreditation of HRPPs Track) Shelley Bizila, Jenice Longfield  
Room 23C

\(\bigvee\) E4 Advanced Evolving Challenges of First-in-Humans Trials  
(Advanced Forum for Experienced IRB Professionals Track) Susan Miller, Richard Penson  
Room 30A

\(\bigvee\) E5 Understanding the Differences Between the International Committee on Harmonization (ICH) Guidelines and the FDA’s Good Clinical Practice (GCP) Regulations  
(Clinical Research Professionals Track) George Gasparis, Ann McKeer-O’Connell  
Room 30C

\(\bigvee\) E6 Payment to Research Subjects: Preliminary Findings of the NIH Survey  
(Ethical Issues Track) Alan Wertheimer  
Room 29C

\(\bigvee\) E7 Basic FDA and OHRP Compliance Activities  
(Federal Regulations I Track) Kristina Borror, Karena Cooper  
Room 31C

\(\bigvee\) E8 Advanced Nontraditional Access to Investigational Drugs and Devices: Single Patient INDs, Expanded Access, and Humanitarian Devices  
(Federal Regulations II Track) [Please note this is a double session and will end at 1:30 PM. Please pick-up your boxed lunch in the Sails Pavilion before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.] Karen Hale, Lynn Henley, Richard Klein  
Room 33A

\(\bigvee\) E9 NEW TITLE! Stem Cell Research Post Lamberth: Implications for Policy and Oversight  
(Genetics, Stem Cells, and Repositories Track) Hank Greely, Russell Korobkin, Jeanne Loring  
Room 25A

\(\bigvee\) E10 Advanced Facebook, Twitter, and YouTube: Wrangling with New Ethical Ropes, as Internet Research Gallops Forward  
(Hot Spots I Track) [Please note this is a double session and will end at 1:30 PM. Please pick-up your boxed lunch in the Sails Pavilion before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.] Elizabeth Buchanan, Montana Miller, Laura Odwazny  
Room 6A

\(\bigvee\) E11 Privacy, Confidentiality, and Research Using Electronic Health Records  
(Hot Spots II Track) [Please note this is a double session and will end at 1:30 PM. Please pick-up your boxed lunch in the Sails Pavilion before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.] Marianna Bledsoe, Rex Chisholm, Rachel Nosowsky  
Room 32AB

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\(\bullet\) Receives Continuing Medical Education (CME) Credit
Let’s Review a Protocol! Recognizing and Addressing Key Issues (IRB Bootcamp Track) [Please note this is a double session and will end at 1:30 PM. Please pick-up your boxed lunch in the Sails Pavilion before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.] Jerry Castellano, Glen Drew, Cheryl Savini

Best Practices and Other Strategies for Managing IRBs/HRPPs (IRB Operations and Tool Kit Track) Charlotte Coley, Brenda Ruotolo

Facilitating Informed Consent in Non-Western Cultures (Informed Consent Track) Edward Bartlett, Caroline Kithinji, Swamalakshmi Singaravelu

Identifying, Reducing, and Managing Conflicts of Interest (Institutional Officials Track) [Please note this is a double session and will end at 1:30 PM. Please pick-up your boxed lunch in the Sails Pavilion before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.] Kate Gottfried, Emie Prentice, Elyse Summers

Reviewing International Research When Time Is of the Essence: Pandemics, Infectious Diseases, and More (International Research Track) Ali Khan, Barbara DeCausey, Amy Sandul

Getting to Yes: Negotiating Subject Injury and Compensation Language that is Acceptable to Both Sponsors and IRBs (Issues for Pharma/Biotech Sponsors Track) Lester Arnold, Anne Dougherty, Nancy Olson

When Is the Ball in My Court? Distinguishing Between Institutional Decisions and IRB Decisions (Legal Track) Emily Fogler, Don Workman

PRIM&R’s Primer on Genes and Oncology Research (Oncology and Cancer Centers Track) Naynesh Kamani, Santosh Kesari

Panel Follow-Up: How Do We Measure Quality? Identifying New Metrics for Evaluating IRBs and HRPPs (Panel Follow-up Track) [Please note this is a double session and will end at 1:30 PM. Please pick-up your boxed lunch in the Sails Pavilion before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.] David Borasky, David Dilts, Stephen Rosenfeld

“Race for a Cure”: Subject Advocacy versus Therapeutic Misconception (Populations Requiring Additional Protections I Track) Robert Levine, Lindsay McNair

Inclusion of Persons with Disabilities in Clinical Research (Populations Requiring Additional Protections II Track) Jeremy Block

The Reviewer, Auditor, Monitor, and Inspector: Who’s Looking at the Study Data and Why? (QA/QI and Post-Approval Monitoring Track) Eunice Newbert, Terry VandenBosch

Responsible Conduct of Research: Building Cultural Awareness When Conducting Research (Responsible Conduct of Research Track) Okyere Boateng, John Galland

Beyond the Basics in Education Research: Difficult Issues from Pre-school to Grad School (SBER Advanced Track) [Please note this is a double session and will end at 1:30 PM. Please pick-up your boxed lunch in the Sails Pavilion before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.] Tracy Anwood, Ivor Pritchard
Wednesday, December 8 (cont.)

11:15 AM-12:30 PM - Didactic Sessions and Workshop Series E

**E26** Finding Flexibility in the Federal Regulations: Exemptions, Expedited Review, Waivers, and Defining Research Involving Human Subjects (SBER Basic Track) [Please note this is a double session and will end at 1:30 PM. Please pick-up your boxed lunch in the Sails Pavilion before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.] Jeff Cohen, Julia Gorey, Irene Stith-Coleman

**E27** The ABCs of Research Data Security (Science for the Non-Scientist Track) [Please note this is a double session and will end at 1:30 PM. Please pick-up your boxed lunch in the Sails Pavilion before proceeding to the session room. Pre-registration is required to attend and a lunch ticket will be included on your name badge.] Bob Bienkowski, Jeff Cooper

**E28** Building a Support Network for IRBs/HRPPs at Small Research Institutions (Small Research Programs Track) Elizabeth Cothran

**E29** The Dynamics of an IRB Meeting: How to Encourage Dialogue, Minimize Disruptions, and Foster a Cooperative Environment (Unaffiliated/Non-Scientific Member Track) Rob Bienvenu, Tanya Carrillo

12:30-1:30 PM Lunch in the Conference Connection

1:30-1:45 PM Commuting time (i.e. no food or beverage, just time to get to your sessions!)

1:45-3:00 PM Plenary: Panel XI – Protecting “Vulnerable” Participants in Research: The Tension Between Justice and Respect for Persons

Moderator: Andre Ivanoff
Panelists: Hank Greely, Michael McDonald, Alan Wertheimer

1:45-3:00 PM Plenary: Panel XII – Distinguishing Between Biomedical and Non-Biomedical Research in a Trans-Disciplinary World: An Increasingly False Dichotomy?

Moderator: Robert Levine
Panelists: Dale Hammerschmidt, Jamie Ostroff

1:45-3:00 PM Plenary: Panel XIII – Research on Pregnancy: A Necessary Risk?

Moderator: Judy Norsigian
Panelists: Sara Goldkind, Toby Schonfeld, Hugh Tilson

3:00-3:30 PM Commuting and “communing” time

3:30-4:45 PM – The Grand Finale!

**E26** “We Are the World:” Sharing Strategies and Solving Problems for Those Reviewing and/or Conducting International Research

This session will offer attendees an opportunity to continue the conversation about overcoming barriers, enhancing communication, improving policies and procedures, and otherwise streamlining/harmonizing the IRB/REC/REB review processes. Rehab Abdelhai Ahmed, David Borasky, Swarnalakshmi Singaravelu, Julia Welch

**E26** A Documentary Film About Protecting Human Subjects – Centering the Human Subject: Disseminating Study Results through Drama, Poetry, Song, and Visual Arts

Join us for a screening of this unique and creative documentary in which researchers worked collaboratively with artists to render stories arising from interview transcripts about the experiences of human subjects in health research into multi-media “re-tellings.” Susan Cox, Darquise Lafrenière
3:30-4:45 PM As the Virtual World Turns... A Recap of Recent Episodes and Current Issues in Internet Research
The session will afford attendees an opportunity to catch up on key issues covered at the pre-conference program, Navigating Research Regulations and Research Ethics in the Internet Age, and double session E10: Facebook, Twitter, and YouTube. In addition, the audience will learn what other PRIM&R attendees are experiencing in regard to tricky issues in Internet research, as well as possible best approaches/solutions for their IRBs.
Elizabeth Buchanan, Montana Miller

Room 6A

3:30-4:45 PM A Video on the Responsible Conduct of Research from the Office of Research Integrity (ORI): THE LAB: Avoiding Research Misconduct
Join ORI staff members ORI to view an educational video on reporting ethical issues in research. Attendees will watch this interactive film and be engaged in a discussion about how to make ongoing decisions when choosing to report or stay silent. Betsy Holmes, Sandy Titus

Room 32AB

3:30-4:45 PM “I’ve learned A LOT at the 2010 AER Conference! Now What?”
All of us leave educational gatherings with the best of intentions regarding how to translate what we learned into relevant and customized policies for our respective programs. Instead, we return to a longer than usual “to do” list and the game of catch-up takes over. This session is designed to ease that problem. Let’s come together and develop individual plans for applying the knowledge gained and skills acquired before leaving San Diego. Go home with more than an overloaded brain. Subject matter experts and writing assistance will be available to help you develop a policy, procedure, newsletter article, or training document for the folks back home. Edward Bartlett, Charlotte Coley, Scott Lipkin, Ron Maio, Gigi McMillan, Brad Noren

Room 26AB

3:30-4:45 PM Small is Beautiful! A “Last Licks” Gathering for Small Research Programs
This session will afford those working in small research entities a chance to participate in facilitated networking sessions on compliance; education of stakeholders in the human research protection program; or continuing education of human research protections professionals. Additional or alternate groups can be organized, depending on the interests of the attendees. Participants are encouraged to come with ideas, questions, and concerns to share with the group. Ideas for continued networking after the conference will be discussed. Eric Allen, Bob Bienkowski, Tanya Carrillo

Room 25AB

3:30-4:45 PM Ask the Experts! Basic Topics in SBER
New to the field of SBER and/or IRB review? Still have a nagging question regarding SBER? Join us for this session where SBER subject matter experts will be available to take questions on basic topics in SBE research. Attendees will divide into small groups to help facilitate highly interactive discussions. Come with ideas, questions, and concerns to share with the group. Tracy Anwood, Jeff Cohen, Patti MacCubbin, Sangeeta Panicker, Cheryl Savini

Room 27AB

3:30-4:45 PM Current and Future Needs for Bioethics Research, Training, and Translation
The National Institutes of Health (NIH) is engaged in an effort to develop a strategic plan for its future investments in the field. During this session, NIH staff will present a set of provisional priorities for bioethics funding. These priorities are the heart of the plan and need thoughtful review, discussion, and input before they are finalized and the planning process can proceed. This session is an opportunity to contribute reactions and ideas, and inform strategic planning in bioethics at NIH. NIH welcomes the views of PRIM&R attendees! Marianna Bledsoe, Dan Davis

Room 24BC

4:45-5:45 PM Closing reception and fond farewells!

Room 28ABCDE
Boston University School of Medicine
Continuing Medical Education (CME) Accreditation Statement

This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of Boston University School of Medicine and PRIM&R. Boston University School of Medicine is accredited by the ACCME to provide Continuing Medical Education (CME) for physicians.

Boston University School of Medicine designates this educational activity for a maximum of 18.75 AMA PRA Category 1 Credits™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

This program meets the criteria of the Massachusetts Board of Registration in Medicine for risk management study.

Course director: Leonard Glantz, JD, Associate Dean Emeritus, Academic Affairs; Professor, Health Law, Bioethics, and Human Rights

Target audience: Professionals who work with or administer Human Subjects Protection Programs including Institutional Review Board members, administrators, chairs; investigators, institutional officials, regulators, compliance officers, those charged with overseeing "responsible conduct of research" programs, hospital/university attorneys, patient advocates, representatives of voluntary health organizations, industry and biotechnology representatives, and those in science policy.

Educational objectives: A participant in this activity will be able to: (1) Develop strategies for managing successful human research protection programs; (2) participate in a user-friendly learning environment; and (3) gain cutting-edge information and skills in order to reach professional excellence.

Needs addressed statement: The purpose of the meeting is to create a “user-friendly” learning environment in which the assorted stakeholders in the IRB/HRPP and research processes may come together to teach and learn from each other; to present attendees with both basic and cutting-edge information on how best to do their jobs; and to energize those involved in human subjects research about the value of their work and to be optimistic about their ability to do it even better than before. There will be more networking opportunities for all who come so that they can assist each other in between PRIM&R meetings.

Faculty disclosure statement:
Boston University School of Medicine asks all individuals involved in the development and presentation of Continuing Medical Education (CME) activities to disclose all relationships with commercial interests. This information is disclosed to CME activity participants. Boston University School of Medicine has procedures to resolve any apparent conflicts of interest. In addition, faculty members are asked to disclose when any unapproved use of pharmaceuticals and devices is being discussed. A detailed copy of the disclosure statement may be obtained onsite at the CME Desk located in Lobby 20.

Indicates a Double Session which includes both lecture and discussion. Pre-registration is required. Double sessions are held over lunch and a boxed lunch will be served before the start of each session. Please see the program for end time.

 Festooned with a pictogram of a double decker bus, an indicator of a Double Session which includes both lecture and discussion. Pre-registration is required. Double sessions are held over lunch and a boxed lunch will be served before the start of each session. Please see the program for end time.

 Session labeled **advanced** are for those with more experience.
 Session labeled **basic** are for those new to the field or who are in need of a refresher.
 Session labeled **CME Credit** receives Continuing Medical Education (CME) Credit.
 Session labeled **Invited** indicates session was chosen from our invitation to contribute to the program development process.