

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

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

# Monday, December 6

7:00 AM	<b>Registration opens</b>	Lobby 20
7:00-8:15 AM	<b>Continental breakfast</b>	Sails Pavilion
7:00-8:15 AM	<b>Continental breakfast: First-time attendees</b> <i>All first-time conference attendees are welcome! Join this breakfast to connect and network with colleagues and hear from the PRIM&amp;R staff.</i>	Room 28ABCDE
8:15-8:30 AM	<b>Welcome and conference overview</b>	Ballroom 20
8:30-9:30 AM	<b>Keynote address: Francis Collins, MD, PhD, Director, U.S. National Institutes of Health</b>	Ballroom 20
	🕒 ✓	
9:30-10:30 AM	<b>Plenary: A Great Debate – Be It Resolved that Consent Forms are an Obstacle to Informed Consent and Should be Abolished</b> <b>Moderator:</b> Michele Russell-Einhorn <b>Debaters:</b> Leonard Glantz – pro, Jerry Menikoff – con	Ballroom 20
	🕒 ✓	
10:30-11:00 AM	<b>Coffee and “communing” time</b>	
11:00-11:45 AM	<b>Plenary: Rethinking the Research Regulations: Where Should We Go?</b> Ezekiel Emanuel, MD, PhD, Special Advisor for Health Policy to the Director of the Office of Management and Budget	Ballroom 20
	🕒 ✓	
11:45 AM-1:00 PM	<b>Common Ground Networking Lunch in the Conference Connection</b>	Sails Pavilion
11:45 AM-1:00 PM	<b>Lunch: What's New at the CITI Program?</b> <b>SOLD OUT!</b> 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.	Room 28ABCDE
1:00-1:15 PM	<b>Commuting time</b> (i.e. no food or beverage, just time to get to your sessions!)	

## 1:15-2:30 PM – Didactic Sessions and Workshop Series A

🕒 🗣️ A1	<b>A Dialogue with the Office for Human Research Protections (OHRP)</b> <i>(A Dialogue with the Feds I Track) Kristina Borrer, Mike Carome, Julie Kaneshiro, Melody Lin, Laura Odwazny, Irene Stith-Coleman, Elyse Summers</i>	Room 33A
🕒 🗣️ A2	<b>A Dialogue with the National Science Foundation (NSF)</b> <i>(A Dialogue with the Feds II Track) Kellina Craig-Henderson</i>	Room 27A
🕒 A3	<b>The Fundamentals of AAHRPP Accreditation for New Applicants</b> <i>(Accreditation of HRPPs Track) Sujatha Sridhar</i>	Room 31B
🕒 🗣️ A4 Advanced	<b>Delineating and Applying the Boundaries between Research and Practice: Public Health and Surveillance, Program Evaluation, and Quality Assurance/Quality Improvement (QA/QI)</b> <i>(Advanced Forum for Experienced IRB Professionals Track) Alex Capron, Patrick McNeilly, Rachel Nosowsky</i>	Room 6A
★ 🕒 A5	<b>The Making of a Principal Investigator (PI): The Essential Components of an Educational Program for PIs and Research Staff</b> <i>(Clinical Research Professionals Track) Mina Busch, Greg Koski</i>	Room 29B



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🕒 ↻ A6	<b>Ethical Challenges When Conducting Research in Developing Countries: Case Studies in Vaccine Research</b> ( <i>Ethical Issues Track</i> ) <i>Okyere Boateng, Robert Levine, Walter Straus</i>	Room 30A
🕒 🗣️ A7 Basic	<b>What Happens After the Protocol Is Approved: Amendments, Continuing Review, Modifications, Incident Reports, Unanticipated Problems, and Adverse Events</b> ( <i>Federal Regulations I Track</i> ) <i>Rob Bienvenu, Jeff Cooper, Janet Donnelly</i>	Room 29D
🕒 🗣️ A8	<b>FDA Expectations of IRBs When Making the Significant and Non-Significant Risk Determination in Device Investigations</b> ( <i>Federal Regulations II Track</i> ) <i>Fabienne Santel</i>	Room 33B
🕒 🗣️ A9	<b>Cell and Gene Therapy Trials in Pediatric Research</b> ( <i>Genetics, Stem Cells, and Repositories Track</i> ) <i>Susan Kornetsky, Robert Nelson, Celia Witten</i>	Room 31C
↻ A10	<b>CIA Interrogation Research</b> ( <i>Hot Spots I Track</i> ) <i>Allen Keller, Ivor Pritchard, Stephen Soldz</i>	Room 30E
🕒 🗣️ A11	<b>Research Using Mobile Health Devices</b> ( <i>Hot Spots II Track</i> ) <i>Karen Hale, Donna Spruijt-Metz</i>	Room 26A
🗣️ A12	<b>Understanding and Assembling the Components of an Effective HRPP (Hint: It's the Institution Not the IRB!)</b> ( <i>IRB Bootcamp Track</i> ) <i>Michael Roach, Lynn Smith</i>	Room 30B
🗣️ A13	<b>Determining What Needs IRB Review versus Exempt Research</b> ( <i>IRB Operations and Tool Kit Track</i> ) <i>Glen Drew, Ada Sue Selwitz</i>	Room 32AB
🕒 ↻ A14 Advanced	<b>The Assent Process and Assessing Children's Competence to Understand a Proposed Research Project</b> ( <i>Informed Consent Track</i> ) <i>Steve Joffe, Alex Kon</i>	Room 28C
🗣️ A15	<b>Understanding the Elements of a Strong Compliance Program and Strategies for Implementation at Your Institution</b> ( <i>Institutional Officials Track</i> ) <i>Delia Wolf, David Wynes</i>	Room 33C
🕒 ★ 🗣️ A16	<b>"Going Buggy:" Ethical and Regulatory Issues When Exposing Human Subjects to Infectious Disease Vectors</b> ( <i>International Research Track</i> ) <i>Yaw Afrane, Adriana Costero, Jim Lavery, Laura Youngblood</i>	Room 25A
🕒 🗣️ A17	<b>What Factors and Questions do IRBs Look at When Reviewing a Protocol?</b> ( <i>Issues for Pharma/Biotech Sponsors Track</i> ) <i>Sue Fish, Lindsay McNair</i>	Room 24A
🕒 🗣️ A18	<b>How to Avoid Legal and Regulatory Pitfalls in International Research</b> ( <i>Legal Track</i> ) <i>Mark Barnes, Justin McCarthy</i>	Room 25B
↻ A19	<b>National Cancer Institute (NCI) Central Institutional Review Board (CIRB) Open Forum</b> ( <i>Oncology and Cancer Centers Track</i> ) <i>Jeanne Adler, Jacquelyn Goldberg</i>	Room 24C
🕒 ↻ A20	<b>A Great Debate Follow-Up: Be It Resolved that Consent Forms are an Obstacle to Informed Consent and Should be Abolished</b> ( <i>Panel Follow-up Track</i> ) <i>Leonard Glantz, Jerry Menikoff</i>	Room 30C
🕒 🗣️ A21	<b>Developing Policies and Procedures to Conduct Clinical Trials in Vulnerable Populations in Resource Scarce Communities</b> ( <i>Populations Requiring Additional Protections I Track</i> ) <i>Robert Hood, David Resnik</i>	Room 27B



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- A22** **Equitable Selection of Research Subjects: Balancing the Enrollment of Non-English Speaking Subjects versus Applying the Justice Principle** Room 24B  
*(Populations Requiring Additional Protections II Track) George Gasparis, Seema Shah*
  
- A23** **The Nuts and Bolts of a QA/QI Routine Not-for-Cause Review** Room 30D  
*(QA/QI and Post-Approval Monitoring Track) Cindy Kern, Susan Rose*
  
- A24** **Responsible Conduct of Research 101** *(Responsible Conduct of Research Track)* Room 25C  
*Mike Kalichman*
  
- A25** **Advanced SBER Topics for IRB Chairs, Directors, and Institutional Officials** Room 29A  
*(SBER Advanced Track) Tracy Arwood, Jeff Cohen, Patti MacCubbin*
  
- A26** **Understanding How the Belmont Principles Can Help Us Implement the Regulations More Effectively** *(SBER Basic Track)* Room 23B  
*Helen McGough, Toby Schonfeld*
  
- A27** **The Basics of the Scientific Process** *(Science for the Non-scientist Track)* Room 23C  
*Cliff Gunthel, Yen-Hong Kuo, André Ivanoff*
  
- A28** **The Unique Challenges for IRBs at Community Hospitals** *(Small Research Institutions Track)* Room 31A  
*Adrianna Brigatti, Tanya Carrillo*
  
- A29** **The Roles and Responsibilities of the Unaffiliated/Non-Scientific Member of the IRB** *(Unaffiliated/Non-Scientific Members Track)* Room 26B  
*Melissa Frumin, Robert Reed Llewellyn, Gigi McMillan*

**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** Room 6A  


**Moderator:** *Dean Gallant*  
**Panelists:** *Erik Fritsvold, Rachel Nosowsky, Janis Whitlock*
  
- 2:45-4:00 PM** **Plenary: Panel II – Global Standards for Research Ethics: Is Uniformity Possible... Or Desirable?** Room 6B  

**Moderator:** *Alex Capron*  
**Panelists:** *Nancy Kass, Caroline Kithinji, Jim Lavery*
  
- 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** Ballroom 20  

**Moderator:** *Ada Sue Selwitz*  
**Panelists:** *Nancy Dubler, David Strauss*

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

- B1** **Dialogue with the Food and Drug Administration (FDA)** *(A Dialogue with the Feds I Track)* Room 29B  
*Leslie Ball, Sonali Gunawardhana, Joanne Less, Diane Maloney, Kevin Prohaska*
  
- B2** **A Dialogue with the Environmental Protection Agency (EPA)** Room 23B  
*(A Dialogue with the Feds II Track) James Downing, Warren Lux*

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	🕒 B3	<b>Assuring the Scientific or Scholarly Validity of a Proposed Research Study (AAHRPP Element I.1.F)</b> ( <i>Accreditation of HRPPs Track</i> ) Karen Blackwell, Bertha deLanda	Room 29D
Advanced	🕒👉 B4	<b>Effective Practices for Reducing Administrative Burden in Human Subject Research</b> ( <i>Advanced Forum for Experienced IRB Professionals Track</i> ) Elizabeth Bankert, Lois Brako, Jane McCutcheon	Room 32AB
	🕒👉 B5	<b>Distinguishing Medical Practice from the Conduct of Research</b> ( <i>Clinical Research Professionals Track</i> ) Robert Levine, Rachel Nosowsky	Room 30A
Advanced	🕒🕒 B6	<b>Relativistic Ethics and Ethical Pluralism When Conducting Research Internationally</b> ( <i>Ethical Issues Track</i> ) Nandini Kumar, Joan Sieber, Alan Wertheimer	Room 31C
Advanced	🕒 B7	<b>Essential Documentation: IRB Membership, Documentation, Record Keeping, and Meeting Minutes</b> ( <i>Federal Regulations I Track</i> ) Jeff Cohen, Glen Drew, Jean Toth-Allen	Room 29C
	🕒👉 B8	<b>An Update from the SACHRP Subcommittee on Harmonization</b> ( <i>Federal Regulations II Track</i> ) Barbara Bierer, David Forster	Room 26A
	🕒👉 B9	<b>Genetic Research and Stored Biological Specimens</b> ( <i>Genetics, Stem Cells, and Repositories Track</i> ) Kate Gallin Heffernan, Nancy King, Pearl O'Rourke	Room 6B
	🕒👉 B10	<b>Data Monitoring Committees: Areas of Consensus and Controversy</b> ( <i>Hot Spots I Track</i> ) Susan Ellenberg, Hugh Tilson	Room 30E
	🕒👉🌟 B11	<b>Improving Collaboration and Resource Sharing Between IRBs for Multicenter Studies</b> ( <i>Hot Spots II Track</i> ) Todd Rice, Denise Roe	Room 31B
<b>NEW SESSION!</b>	🕒 B12	<b>ABCs of Basic and Continuing IRB Member Education</b> ( <i>IRB Bootcamp Track</i> ) Charlotte Coley, Yvonne Higgins, Elyse Summers	Room 33C
	🌟🕒 B13	<b>Administrative Pre-Review/Screening Processes for the IRB: From One Extreme to the Other—Where Do We Draw the Line?</b> ( <i>IRB Operations and Tool Kit Track</i> ) Donna Hoagland, Moira Keane, Paul Papagni	Room 6A
	🕒🕒 B14	<b>Criteria and Considerations for Waiving Requirements for Obtaining and Documenting Informed Consent</b> ( <i>Informed Consent Track</i> ) Karen Hale, Alisa Irwin	Room 29A
	🕒 B15	<b>Assessing and Providing Adequate Resources for Your HRPP</b> ( <i>Institutional Officials Track</i> ) Eric Allen, David Wynes	Room 24C
Advanced	🕒🕒 B16	<b>International Post-Trial Access: Ethical Issues and Responsibilities</b> ( <i>International Research Track</i> ) Rehab Abdelhai Ahmed, Jim Lavery, Walter Straus	Room 23C
	🕒👉 B17	<b>How to Resolve the Top 10 Concerns Sponsors Have About IRBs and IRB Review</b> ( <i>Issues for Pharma/Biotech Sponsors Track</i> ) Elizabeth Hohmann, Jennifer Webster	Room 25B
	🕒 B18	<b>HITECH Legal Developments in 2010 and Their Effects on Research</b> ( <i>Legal Track</i> ) Mark Barnes, Susan Stayn	Room 30B
Advanced	🕒🕒 B19	<b>Ethical Issues in Phase I Oncology Trials with Children</b> ( <i>Oncology and Cancer Centers Track</i> ) Steve Joffe, Robert Nelson, Amy Yamokoski	Room 33A
	🕒👉 B20	<b>Panel Follow-Up: Research Involving Adults with Decisional Impairments</b> ( <i>Panel Follow-Up Track</i> ) Susan Delano, Melissa Frumin, David Strauss	Room 25A



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7:00-8:00 AM <b>SOLD OUT!</b>	<b>Continental breakfast: Learn more about the CIP® credentialing process</b> <i>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 Certification of IRB Professionals, network with fellow CIPs, ask questions of those already certified, etc.</i>	Room 28ABCDE
7:00-8:00 AM <b>SOLD OUT!</b>	<b>Continental breakfast: Post-IRB approval investigator audits networking</b> <i>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.</i>	Room 25ABC
8:00-8:15 AM	<b>Welcome and presentation of the ALA and DSA Awards</b>	Ballroom 20
8:15-9:15 AM ♫ ✓	<b>Keynote address: The Immortal Life of Henrietta Lacks</b> <i>Rebecca Skloot, science writer and author of “The Immortal Life of Henrietta Lacks”</i>	Ballroom 20
9:15-9:30 AM	<b>Commuting time</b> (i.e. no food or beverage, just time to get to your sessions!)	
9:30-10:45 AM ♫ ✓	<b>Plenary: Panel IV – Making Sense of Community Responses to Tissue Research</b> <b>Moderator:</b> Jeremy Sugarman <b>Panelists:</b> Chris Hempel, Carletta Tilousi	Ballroom 20
9:30-10:45 AM ♫ ✓	<b>Plenary: Panel V – Research in Complex Humanitarian Disaster Settings and War Zones</b> <b>Moderator:</b> Sangeeta Panicker <b>Panelists:</b> Jon Hubbard, Jerry Jacobs, Liesel Ritchie	Room 6B
9:30-10:45 AM ✓	<b>Plenary: Panel VI – Hot Off the Presses: Selected Abstracts on Innovative HRPP Programs and Research on Research Ethics</b> <i>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.</i> <b>Moderators:</b> David Borasky and Sue Fish <b>Topics and Panelists:</b> 1. <b>Evaluating the Quality of Information about Alternatives to Research Participation in Oncology Consent Forms</b> David Resnik, Dan Patrone, Shyamal Peddada 2. <b>Informed Consent in High-Throughput Genomic Research: Views of Health Plan Members</b> Susan Trinidad, Stephanie Fullerton, Gail Jarvik, Eric Larson, Wylie Burke 3. <b>Getting Started on the Right Foot: Study Start-up Consultations</b> Tracy Rightmer, Sandra Alfano, Kathleen Uscinski 4. <b>A Model of Building Trust for the Inclusion and Protection of Racial/Ethnic Populations in Research</b> Armida Ayala, Jeoma Nwachuku, Alva Moreno, Francisco Morales, Vonee So, Daria Galindo, Isabel Sanchez	Room 6A
10:45-11:15 AM	<b>Coffee, commuting, and “communing” time</b>	

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







♫ C1	<b>A Dialogue with the Department of Education</b> ( <i>A Dialogue with the Feds I Track</i> ) <i>Jeff Rodamar</i>	Room 27B
♫ C2 <b>NEW TITLE!</b>	<b>What’s New in VA Research Protections for Human Subjects</b> ( <i>A Dialogue with the Feds II Track</i> ) [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.] <i>Robert Brooks, Lynn Cates, Karen Jeans, Kevin Nellis, Joan Porter, Min-Fu Tsan</i>	Room 26B


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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* Room 31C
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**C4 Strengthening Your IRB's Approach to Incidental Findings** (*Advanced Forum for Experienced IRB Professionals Track*) *Libby Hohmann, Susan Kornetsky, Pearl O'Rourke* Room 29B
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**C5 Towards Ensuring Research Integrity: Appropriate Communication and Delegation of Responsibilities by the Principal Investigator** (*Clinical Research Professionals Track*) *Greg Koski, David Van Houten* Room 26A
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**C6 Ethical Issues in Deception Research** (*Ethical Issues Track*) *Rebecca Armstrong, George Gasparis, Yvonne Higgins* Room 29D
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**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 Stith-Coleman* Room 31A
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**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* Room 6A
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**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* Room 33A
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**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* Room 30D
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**C11 Ethical Engagement of Minorities in Research** (*Hot Spots II Track*) *David Barnard, Jonas Chaney, Meleah Himber, Sandra Quinn, Stephen Thomas* Room 30A
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**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 Gorey, Amanda Hammond, Lynn Smith, Elyse Summers* Room 29A
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**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* Room 30E

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-  **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* Room 33B
-   **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* Room 33C
-   **C16** **How to Find and Work With an IRB Outside the United States** (*International Research Basic* Track) *Peggy Coyle, Sharon Freitag, Dao Duc Giang, Melody Lin, Julia Welch* Room 25B
-   **C17** **The “Other” Federal Agency: What Sponsors of FDA-Regulated Studies Need to Know About OHRP** (*Issues for Pharma/Biotech Sponsors* Track) *Kristina Borrer, Kate Gottfried, Lindsay McNair* Room 23B
-   **C18** **Legal Issues in Secondary-Use Research: A Dialogue Between Industry and Institutions** (*Legal* Track) *Mark Barnes, Justin McCarthy, Laura Odwazny* Room 30C
-   **C19** **Financial Considerations of Relevance to Subjects in Oncology Research** (*Oncology and Cancer Centers* Track) *Paul Papagni* Room 24A
-   **C20** **Panel Follow-Up: Subject Attitudes Towards Specimen and Data Research** (*Panel Follow-up* Track) *Bill Freeman, Jody Harland, Steve Peckman* Room 27A
-   **C21** **Considerations and Concerns When Using Student Research Pools** (*Populations Requiring Additional Protections I* Track) *Michael Carome, Susan Rose, Joan Sieber* Room 30B
-   **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* Room 24B
-  **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* Room 29C  
**NEW TITLE!**
-  **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* Room 24C
-  **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* Room 32AB
-   **C26** **Informed Consent: When, Why, and How?** (*SBER Basic* Track) *Suzanne Holguin, Alison Orkin* Room 31B

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- 🔊 C27 **Statistics Without Tears: To Dream the Impossible Dream?** Room 25C  
(*Science for the Non-Scientist* Track) Sue Fish, Yen-Hong Kuo
- 🔊 C28 **Self-Assessment and Quality Improvement Procedures** Room 25A  
(*Small Research Programs* Track) Eric Allen
-  C29 **PRIM&R's Primer for the "Newbie" Unaffiliated/Non-Scientific Member/Reviewer** Room 23C  
Basic (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

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

12:30-1:45 PM **Research Ethics Book Group lunch** Room 28ABCDE  
**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.

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** Ballroom 20  
🔊 ✓  
**Moderator:** Cynthia Gomez  
**Panelists:** John Jackson, Robert Levine, Kate MacQueen


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

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** Room 6B  
🔊 ✓  
**Moderator:** Susan Kornetsky  
**Commentators:** Rebecca Dresser, Brian Gladue, Greg Manship, Paula Radmacher

3:15-3:45 PM **Commuting and "Communing" Time**

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

- 🔊 D1 **A Dialogue With The VA Central IRB** (A Dialogue with the Feds I Track) Room 30B  
Annette Anderson, Lynn Cates
- 🔊 D2 **Dialogue with the Department of Energy** (A Dialogue with the Feds II Track) Room 23B  
Libby White
- 🔊 D3 **Negotiating Contracts to Protect Human Participants in Research (AAHRPP Standard 1-8)** (Accreditation of HRPPs Track) Room 25C  
Mont Brownlee, Martha Nielsen
- 🔊 ★ D4 **Balancing Respect for Autonomy versus the Public Health Benefits of Research** Room 33A  
Advanced (Advanced Forum for Experienced IRB Professionals Track) Robert Hood, Michael McDonald
- 🔊 D5 **The Clinical Laboratory Improvements Act (CLIA) and its Impact on Research** Room 25A  
(Clinical Research Professionals Track) Brad Noren, Michele Russell-Einhorn

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- D6** **Reserved for Late-Breaking** (*Ethical Issues* Track) Room 29D
- D7** **Vive la Différence: A Comparison of the DHHS and FDA Regulations for the Protection of Human Subjects** (*Federal Regulations I* Track) Room 33B  
*Janet Donnelly, Glen Drew, Amanda Hammond, Don Workman*
- D8** **Unanticipated Problems Involving Risks to Subjects or Others: OHRP and FDA Regulations and Guidance** (*Federal Regulations II* Track) Room 6A  
*Kristina Borrer, Kevin Prohaska, Chelle Yin*
- D9** **An Update from the National Academies' Human Embryonic Stem Cell Research Advisory Committee** (*Genetics, Stem Cells, and Repositories* Track) Room 30A  
*Steve Peckman*
- D10** **Building Trust Between Minorities and Researchers: Findings from the NIH Bioethics Research Infrastructure Initiative** (*Hot Spots I* Track) Room 29A  
*James Butler, Craig Fryer, Mary Garza, Sandra Quinn, Stephen Thomas*
- D11** **Practical Strategies for Strengthening IRB Review of Community-Engaged Research** (*Hot Spots II* Track) *Sarena Seifer, Nancy Shore* Room 30D
- D12** **“Tea and Conversation” with the IRB/HRPP Experts: Ask Us Anything!** (*IRB Bootcamp* Track) *Mike Carome, Charlotte Coley, Yvonne Higgins, Nancy Olson* Room 25B
- D13** **Managing Student Research** (*IRB Operations and Tool Kit* Track) Room 32AB  
*Donna Eaton, Lane Fischer, Karen Smith-Gratto*
- D14** **Substituted Judgment: Obtaining Informed Consent from the Legally Authorized Representatives of Decisionally-Impaired Individuals Involved in Research** (*Informed Consent* Track) *Alex Capron, Elizabeth Small, David Straus* Room 33C
- D15** **Having it All: Strategies for Balancing the Need for IRB Efficiency with the Need for Compliance** (*Institutional Officials* Track) *Gary Chadwick, Susan Miller* Room 26B
- D16** **Navigating the Different Review and Approval Systems When Doing Research in Multiple Countries** (*International Research* Track) Room 24A  
*Edward Bartlett, Jim Lavery, Swarnalakshmi Singaravelu*
- D17** **PRIM&R's Primer for Sponsors on Genetics and Tissue Banking** (*Issues for Pharma/Biotech Sponsors* Track) *Mary Ellen Allen, Eric Mah* Room 27A
- D18** **What Attorneys and Other Stakeholders Should Know About FDA Regulations and Enforcement** (*Legal* Track) *Sonali Gunawardhana, Kate Gallin Heffernan* Room 24C
- D19** **Palliative Care Research** (*Oncology and Cancer Centers* Track) Room 26A  
*Scott Irwin, Steve Oppenheim*  
**NEW TITLE!**
- D20** **Panel Follow-Up: More on Biospecimen Research: If, When, and How to Return Research Results** (*Panel Follow-up* Track) Room 31A  
*Lynn Dressler, Emily Namey, Nicole Lockhart, Carol Weil*



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- D21 Challenges of Research with Adolescent Populations** (*Populations Requiring Additional Protections I Track*) *Rob Bienvenu, Okyere Boateng, Robert Frenck* Room 31B
- D22 Genetic Research in Families: On the Trail of Inherited Disorders** (*Populations Requiring Additional Protections II Track*) *Ruth Fischbach, Judy Norsigian, Gwenn Oki* Room 30E
- D23 QA/QI Metrics: Utilizing Findings and Observations to Improve Your Research Program** (*QA/QI and Post-Approval Monitoring Track*) *Kelly Dornin-Koss, Ron Maio, Sarah White* Room 31C
- D24 An Update from the Office of Research Integrity (ORI)** (*Responsible Conduct of Research Track*) *John Galland, Sandy Titus* Room 30C
- D25 Panel Follow-Up: Going Global or Staying Local: Research Ethics in a Culturally Diverse World** (*SBER Advanced Track*) *Kate MacQueen* Room 24B  
 Advanced
- D26 School-Based Research and the Common Rule: The How-Tos** (*SBER Basic Track*) *Alison Orkin, Jeff Rodamar* Room 29B  
 Basic
- D27 Personalized Medicine: What Does it Mean and How Close are We to Seeing its Everyday Application?** (*Science for the Non-Scientist Track*) *Bob Bienkowski, Gary Cohen* Room 23C
- D28 The Dynamics of HRPPs at Predominantly Undergraduate Institutions** (*Small Research Programs Track*) *Eric Allen* Room 27B
- D29 Let's Review a Protocol: A Guide for Beginners** (*Unaffiliated/Non-Scientific Members Track*) *Kip Kantelo, Adelaide Siegl, Matt Stafford* Room 29C  
 Basic
- 5:15-6:30 PM Member networking reception** Sails Pavilion  
*PRIM&R members, we're thrilled you're part of our community! Please join us at this special networking reception, so we can extend our gratitude in person! Connect with your colleagues, relax, and chat with PRIM&R Board and committee members, as well as PRIM&R staff.*

## Wednesday, December 8

- 7:00 AM Registration opens** Lobby 20
- 7:00-8:00 AM Continental breakfast** Sails Pavilion
- 8:00-8:15 AM Welcome** Ballroom 20
- 8:15-9:15 AM Keynote address: Ethics in Medicine: Lessons from Mengele's Lab** Ballroom 20  


*Eva Mozes Kor, Founder, CANDLES Holocaust Museum*
- 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 IX – How Do We Measure Quality? Identifying New Metrics for Evaluating HRPPs and IRBs** Ballroom 20  

**Moderator:** *David Borasky*  
**Panelists:** *David Dilts, Charles Lidz, Stephen Rosenfeld*



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- 9:30-10:45 AM **Plenary: Panel X – Research that Seeks to Build Community Involvement** Room 6B  
 ☺ ✓ **Moderator:** Sarena Seifer  
**Panelists:** Saida Abdi, Heidi Ellis, Loretta Jones, Stephen Thomas
- 9:30-10:45 AM **Plenary: A Great Debate – Be It Resolved There Is an Obligation to Participate in Research** Room 6A  
 ☺ ✓ **Moderator:** Alan Wertheimer  
**Debaters:** Rebecca Dresser, Steve Joffe







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


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


- ☺ ☞ 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) Room 30B  
 Molly Klote, Patty Decot
- ☺ ☞ E2 **A Dialogue with the National Institutes of Health (NIH)** (A Dialogue with the Feds II Track) Room 30D  
 Dan Davis, Ann Hardy, Steven Hirschfeld, Laura Lyman Rodriguez
- ☺ ☞ E3 **Reporting Requirements for Researchers (AAHRPP Element III.2.D)** (Accreditation of HRPPs Track) Room 23C  
 Shelley Bizila, Jenice Longfield
- ☺ ★ ☞ E4 **Evolving Challenges of First-in-Humans Trials** (Advanced Forum for Experienced IRB Professionals Track) Room 30A  
 Advanced Susan Miller, Richard Penson
- ☺ ☞ 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) Room 30C  
 George Gasparis, Ann Meeker-O’Connell
- ☺ ☞ E6 **Payment to Research Subjects: Preliminary Findings of the NIH Survey** Room 29C  
 (Ethical Issues Track) Alan Wertheimer
- ☺ ☞ E7 **FDA and OHRP Compliance Activities** (Federal Regulations I Track) Room 31C  
 Basic Kristina Borrer, Karena Cooper
- ☺ ★ 🚌 E8 **Nontraditional Access to Investigational Drugs and Devices: Single Patient INDs, Expanded Access, and Humanitarian Devices** (Federal Regulations II Track) Room 33A  
 Advanced 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
- ☺ ☞ E9 **Stem Cell Research Post Lamberth: Implications for Policy and Oversight** Room 25A  
 NEW TITLE! (Genetics, Stem Cells, and Repositories Track) Hank Greely, Russell Korobkin, Jeanne Loring
- ☺ ★ 🚌 E10 **Facebook, Twitter, and YouTube: Wrangling with New Ethical Ropes, as Internet Research Gallops Forward** (Hot Spots I Track) Room 6A  
 [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
- ★ 🚌 E11 **Privacy, Confidentiality, and Research Using Electronic Health Records** Room 32AB  
 (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

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-  **E12** **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* Room 33B  
 Basic
-  **E13** **Best Practices and Other Strategies for Managing IRBs/HRPPs** (*IRB Operations and Tool Kit Track*) *Charlotte Coley, Brenda Ruotolo* Room 29D
-   **E14** **Facilitating Informed Consent in Non-Western Cultures** (*Informed Consent Track*) *Edward Bartlett, Caroline Kithinji, Swarnalakshmi Singaravelu* Room 25B
-   **E15** **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, Ernie Prentice, Elyse Summers* Room 29A
-   **E16** **Reviewing International Research When Time Is of the Essence: Pandemics, Infectious Diseases, and More** (*International Research Track*) *Ali Khan, Barbara DeCausey, Amy Sandul* Room 26A
-   **E17** **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* Room 24A
-  **E18** **When Is the Ball in My Court? Distinguishing Between Institutional Decisions and IRB Decisions** (*Legal Track*) *Emily Fogler, Don Workman* Room 31A
-  **E19** **PRIM&R's Primer on Genes and Oncology Research** (*Oncology and Cancer Centers Track*) *Naynesh Kamani, Santosh Kesari* Room 23B  
 Basic
-  **E20** **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* Room 29B
-   **E21** **"Race for a Cure": Subject Advocacy versus Therapeutic Misconception** (*Populations Requiring Additional Protections I Track*) *Robert Levine, Lindsay McNair* Room 24C
-   **E22** **Inclusion of Persons with Disabilities in Clinical Research** (*Populations Requiring Additional Protections II Track*) *Jeremy Block* Room 27B
-   **E23** **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* Room 30E
-   **E24** **Responsible Conduct of Research: Building Cultural Awareness When Conducting Research** (*Responsible Conduct of Research Track*) *Okyere Boateng, John Galland* Room 24B
-  **E25** **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 Arwood, Ivor Pritchard* Room 26B  
 Advanced

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 **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* Room 33C  
Basic


 **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* Room 25C  
Basic


 **E28** **Building a Support Network for IRBs/HRPPs at Small Research Institutions** (Small Research Programs Track) *Elizabeth Cothran* Room 27A


 **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* Room 31B

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

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** Ballroom 20  
**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?** Room 6A  
**Moderator:** *Robert Levine*  
**Panelists:** *Dale Hammerschmidt, Jamie Ostroff*





1:45-3:00 PM  ✓ **Plenary: Panel XIII – Research on Pregnancy: A Necessary Risk?** Room 6B  
**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!

3:30-4:45 PM **“We Are the World:” Sharing Strategies and Solving Problems for Those Reviewing and/or Conducting International Research** Room 33ABC  
*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*

3:30-4:45 PM **A Documentary Film About Protecting Human Subjects – Centering the Human Subject: Disseminating Study Results through Drama, Poetry, Song, and Visual Arts** Room 6B  
*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*

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- 3:30-4:45 PM As the Virtual World Turns... A Recap of Recent Episodes and Current Issues in Internet Research** Room 6A  
*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*
- 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** Room 32AB  
*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*
- 3:30-4:45 PM “I’ve learned A LOT at the 2010 AER Conference! Now What?”** Room 26AB  
*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*
- 3:30-4:45 PM Small is Beautiful! A “Last Licks” Gathering for Small Research Programs** Room 25AB  
*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*
- 3:30-4:45 PM Ask the Experts! Basic Topics in SBER** Room 27AB  
*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 Arwood, Jeff Cohen, Patti MacCubbin, Sangeeta Panicker, Cheryl Savini*
- 3:30-4:45 PM Current and Future Needs for Bioethics Research, Training, and Translation** Room 24BC  
*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 PRIMR attendees! Marianna Bledsoe, Dan Davis*
- 4:45-5:45 PM Closing reception and fond farewells!** Room 28ABCDE

 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.	Sessions labeled <b>advanced</b> are for those with more experience (sessions not labeled are open to all audiences).
 Indicates didactic session (attendees mostly listen...)	Sessions labeled <b>basic</b> are for those new to the field or who are in need of a refresher (sessions not labeled are open to all audiences).
 Indicates workshop (attendees talk too!)	 Receives Continuing Medical Education (CME) Credit
 Indicates session will be recorded for conference proceedings.	 Indicates session was chosen from our invitation to contribute to the program development process.

# PRIM&R Advancing Ethical Research Conference

## 2010 Uniting People, Principles, and Practices

December 6-8 | San Diego, CA | Pre-Conference Programs December 5

### 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.

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