### Friday, November 13

<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>Delta Foyer</td>
</tr>
<tr>
<td>7:00-8:30 AM</td>
<td>Continental breakfast</td>
<td>President’s Ballroom CDE</td>
</tr>
<tr>
<td>8:30 AM-4:30 PM</td>
<td>Advanced Research Ethics</td>
<td>Governor’s AE</td>
</tr>
<tr>
<td>8:30 AM-4:00 PM</td>
<td>Human Genetics Research: We Love the Knowledge, How We Fear the Data!</td>
<td>Delta D</td>
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<tr>
<td>8:30 AM-4:30 PM</td>
<td>Hot Topics for Institutional Officials</td>
<td>Governor’s D</td>
</tr>
<tr>
<td>8:30 AM-4:00 PM</td>
<td>IRB 101&lt;sup&gt;st&lt;/sup&gt; – Biomedical Research</td>
<td>Governor’s B</td>
</tr>
<tr>
<td>8:30 AM-4:00 PM</td>
<td>IRB 101&lt;sup&gt;st&lt;/sup&gt; – Social, Behavioral, and Educational Research (SBER)</td>
<td>Governor’s C</td>
</tr>
<tr>
<td>8:30 AM-4:15 PM</td>
<td>IRB 201: An In-depth Analysis of the Criteria for Review</td>
<td>Delta C</td>
</tr>
<tr>
<td>8:30 AM-4:00 PM</td>
<td>QA/QI 101: Fundamentals of Quality Assurance and Improvement in Human Subjects Research</td>
<td>Delta B</td>
</tr>
<tr>
<td>8:30 AM-5:30 PM</td>
<td>Strategies for Successful International Research: Lessons from Around the Globe</td>
<td>Ryman Ballroom CF</td>
</tr>
<tr>
<td>8:30-5:00 PM</td>
<td>What Does It Mean to Represent the Community? A Primer on Community Participation in Research – Morning Session</td>
<td>Ryman Ballroom AB</td>
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<tr>
<td></td>
<td>(Attendees will go to this morning session. The course will then break for lunch at 11:30 AM, and attendees will go to one of the two afternoon sessions listed below until 5:00 PM.)</td>
<td></td>
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<tr>
<td></td>
<td>Afternoon Session #1: Community Members</td>
<td>Ryman Ballroom AB</td>
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<tr>
<td></td>
<td>Afternoon Session #2: Community Research Advisory Boards</td>
<td>Ryman Ballroom DE</td>
</tr>
<tr>
<td>8:30 AM-5:00 PM</td>
<td>The Buck Starts and Stops Here: Investigator Responsibilities for the Ethical Conduct of Research</td>
<td>Delta Island ABC</td>
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<tr>
<td>4:30-6:30 PM</td>
<td>2009 Advancing Ethical Research Conference opening reception</td>
<td>Ryman Exhibit</td>
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<td>Hall B4-6</td>
</tr>
</tbody>
</table>
Saturday, November 14

7:00 AM  Registration opens

7:00-8:00 AM  Continental breakfast

8:00-8:15 AM  Welcome and award presentations

Presentation of the PRIM&R Lifetime Achievement Award to Al Jonsen, PhD.

Presentation of PRIM&R ARENA Legacy Award (ALA).

Presentation of PRIM&R Distinguished Service Award (DSA).

8:15-9:15 AM  Keynote address:  The FDA and Human Subjects

Joshua Sharfstein, MD
Principal deputy commissioner,
United States Food and Drug Administration (FDA)

9:15-10:30 AM  Panel I: Looking at Belmont with Fresh Eyes:

What’s Missing, What’s Wrong?

Moderator:  Alex Capron
Panelists:  Alex John London
            Albert Jonsen
            Lynnette Neufeld

10:30-11:00 AM  Coffee, commuting, and “communing” time

11:00 AM-12:15 PM  Living Room Conversation: Paying Research Subjects:

Fair Treatment or Unfair Inducement?

Moderator:  Alex Capron
Panelists:  Neal Dickert
            Ruth Grant
            Robert Helms
            Alex John London
            June Mervin
            Alan Wertheimer

11:00 AM-12:15 PM  Panel II: Bytes, Bots, and Avatars: SBER and Technology

Moderator:  J. Michael Oakes
Panelists:  Elizabeth Buchanan
            Ken Fleischmann
            Montana Miller

11:00 AM-12:15 PM  A Great Debate: Is the Era of Local IRBs Over, Particularly in the Setting of Multi-Site Research?

Moderator:  Ivor Pritchard
Debaters:  David Forster
          Daniel Nelson

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Indicates workshop (attendees talk too!)  Sessions labeled basic are for those new to the field or who are in need of a refresher.

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Indicates session was chosen from our invitation to contribute to program development process.
Common Ground Networking Lunch in the Conference Connection
Time to connect…over lunch! Meet peers for conversation and networking. Tables will also be available for those wishing to “just lunch.” The exhibition hall will be open during this time.

Research Ethics Book Group lunch
During this event, you can attend a vibrant discussion on Sentenced To Science: One Black Man’s Story of Imprisonment in America, by Allen Hornblum.

Luncheon with the Lifetime Achievement Award Recipient and SOLD OUT!
Drafter of the Belmont Report: Albert Jonsen, PhD

2:00-3:15 PM – Didactic Sessions and Workshop Series A

A1 Advanced
The Hous, Whats, and Whethers of Institutional Certification for Genome-Wide Association Studies (GWAS) (Advanced Forum for Experienced IRB Professionals Track) Susie Hoffman, Laura Lyman Rodriguez, Pearl O’Rourke

A2
A Dialogue with the Office of Human Research Protections (OHRP) (A Dialogue with the Federal Representatives I Track) Kristina Borror, Mike Carone, Julie Kaneshiro, Jerry Menikoff, Laura Oduwazny, Irene Stith-Coleman, Elyse Summers

A3 A Dialogue with the Office of Research Integrity (ORI): Context, Content, and Contemporary Challenges (A Dialogue with the Federal Representatives II Track) John Galland

A4 Going Electronic on a Shoestring: Tips and Tricks for Helping You Avoid the Need for a High-Priced System (Brother, Can You Spare a Dime? Track) Sarah Putney, Don Workman

A5 Strategies for Helping Your IRB Review Phase I Clinical Trials Ethically and Efficiently (Clinical Research Professionals Track) Cliff Gamthel, Nancy MP King

A6 A Comprehensive History of Human Subjects Protections: From Tragedy to Outrage to Regulations (Community/NonScientific Members Track) Anne Dougherty, Ernie Prentice

A7 Basic
Basic and Continuing Education for IRB Members, Staff, and the Research Community: Tips, Tricks, and Resources (Education Track) Mina Busch, Melissa Fomin, Brenda Ruotolo


A9 Basic
What Happens After the Protocol Is Approved: Amendments, Continuing Review, Modifications, Incident Reports, and Unanticipated Problems and Adverse Events (Federal Regulations I Track) Jeff Cooper, Janet Donnelly, Susan Kornetsky

A10 NEW TITLE! Humanitarian Use Devices and Emergency and Compassionate Use of Unapproved Devices (Federal Regulations II Track) Michele Russell-Einhorn, Marian Serge

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A11 Effective Oversight of Human Gene Transfer Research: Coordinating and Creating Synergy in IRB and IBC Review (Hot Spots I Track)
LouAnn Burnett, Gwenn Oki, Allan Shipp

A12 Conducting Research Outside of Academic Centers: Issues to Consider… (Hot Spots II Track) Chris Backley, Leah Guidry, Hugh Tilson

A13 Sponsors and Accreditation: The Whats and Hows of Getting Accredited, and the Growing Trend Toward Selecting Accredited CROs and IRBs as Research Partners (IRB-Sponsor Relationships Track)
Stuart Horowitz, June Merwin

A14 The Only Guide You’ll Ever Need to Finding, Educating, Respecting, and Retaining Community Members of IRBs (IRB Operations and Tool Kit Track)
Charlotte Coley, Paula Knudson, Gigi McMillan

A15 Resources Available to Help Augment the Informed Consent Process and Form (Informed Consent Track)
Elizabeth Bankert, June Anne Insco, Robert Krell, Patrick McNeilly, Andrew Olnsted

A16 The Elements of Strong Compliance Programs: Creating the Culture, Promoting Education, Supporting Whistleblowers, Handling Consequences, and Everything Else You Need to Know to Avoid Coming Face to Face with a Federal Inspector (Institutional Officials Track)
Elizabeth Heitman, David Wynes

A17 The Ethical Review of Research: Understanding and Applying the Appropriate Ethical and Regulatory Guidelines in Different Cultures and Settings (International Track) Bob Levine, Swamalakshmi Singaravelu

A18 Privacy and Confidentiality: Legal Developments and Effects on Research (Legal Track) Amy Kearney, Susan Stayn

A19 Financial Considerations of Relevance to Subjects in Oncology and Other Research: Research Interventions and Who Pays for Them, Implications of the Medicare Secondary Payor Rules, and More* (Oncology and Cancer Centers Track) *Please note: anyone interested in the secondary payor rules is welcome to attend A19, as it is by no means limited to oncology research.
George Gasparis, Gustavo Montana, Richard Penson, Michael Roach

A20 Determining Whether Centralized Review Is Right for Your Institution (Panel Follow-Up Track) David Forster, Elizabeth Hohmann, Dan Nelson, Ivor Pritchard

A21 The Regulatory and Ethical Requirements of Conducting Research Involving Prisoners (Populations Requiring Additional Protections I Track)
Julia Gorey

A22 Lost in Translation: Using the Short Form With Verbal Translation for Subjects With Limited Literacy or Non-English Speaking/ESL Populations (Populations Requiring Additional Protections II Track)
Sue Fish, Cynthia Gomez

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3:15–3:30 PM  Coffee, commuting, and “communing” time

3:30–4:45 PM – Didactic Sessions and Workshop Series B

**A23** & What's Going on in the World of Not-For-Cause Audits and Post-IRB Approval Review Metrics (QA/QI and Post-IRB Approval Monitoring and Review Track) Kelly Domin-Koss, Ron Maio, Terry VandenBosch  
Ryman Studio MNO

**A24** & Research Involving Deception and Nondisclosure (SBER Advanced Track)  
Melissa Abraham, Barbara Davis Goldman, Corinne Rogers  
Bayou E

**A25** & Informed Consent: When, Why, and How? (SBER Basic Track)  
Ruth Fischbach, Monika Markowitz  
Ryman Ballroom F

**A26** & Understanding the Basics of the Scientific Process (Science for the Nonscientist Track) Bob Bienkowski  
Delta Island D

**A27** & How Accreditation Can Change Human Research Protection Programs (Self-Assessment and Accreditation of HRPPs Track)  
John Falletta, Helen Panagatos, Jody Power  
Ryman Ballroom D

**A28** & Ensuring Accountability for Private Investigators (PIs) Who are Not Employed by the Hospital, but Who Conduct Research There (Small Research Programs Track) Adriana Brigatti, David Vulcano  
Ryman Ballroom A

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Delta Island ABC

**B2** & A Dialogue with the United States Food and Drug Administration (FDA) (A Dialogue with the Federal Representatives I Track) Joanne Less, Diane Maloney, Michael Marcelli, Kevin Prohaska, Stephen Rhodes  
Governor’s C

**B3** & A Dialogue with the United States Environmental Protection Agency (EPA) (A Dialogue with the Federal Representatives II Track) Paul Lewis, Robert Trumkner  
Delta Island D

**B4** & Developing a Training Program on a Shoestring: Finding and Using Low- or No-Cost Resources on the Internet (Brother, Can You Spare a Dime? Track)  
Megan Kasimatis Singleton, Brenda Rnotolo  
Ryman Studio ABC

**B5** & Ethical and Practical Strategies for Enhancing Human Subjects Recruitment (Clinical Research Professionals Track) Michael McDonald  
Ryman Studio JK

**B6** & Let’s Review a Protocol! Recognizing and Addressing Key Issues (Community/Nonscientific Members Track) Bruce Gordon, Gigi McMillan, Cheryl Savini  
Canal C

**B7** & Developing Basic Education on the Nature of Research for Those Providing Daily Care to Patients/Subjects (Education Track)  
Elizabeth Hill, Chelle Yin  
Ryman Ballroom BE

**B8** & What Did the Belmont Drafters Mean by “Justice?” How IRBs Can Help Reclaim the Forgotten Principle (Ethical Issues Track)  
Alex John London, Suzanne Rivera, Alan Wertheimer  
Ryman Studio MNO

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</tr>
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<tbody>
<tr>
<td>B9</td>
<td>IRB Membership, Documentation, Record Keeping, and Meeting Minutes: Not Just Good Ideas; It's the Law! (Federal Regulations I Track)</td>
<td>Washington B</td>
</tr>
<tr>
<td>B10</td>
<td>FDA and OHRP Compliance Activities: If the “Yin” is Education, the “Yang” is Compliance (Federal Regulations II Track)</td>
<td>Bayou E</td>
</tr>
<tr>
<td>B11</td>
<td>When Is It Appropriate to Use an External or Independent IRB? Accountability and Reliance (Hot Spots I Track)</td>
<td>Ryman Studio HI</td>
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<tr>
<td>B12</td>
<td>Reducing Regulatory Burden: The University of Michigan Experience (Hot Spots II Track)</td>
<td>Governor's D</td>
</tr>
<tr>
<td>B13</td>
<td>Continuation of Experimental Treatments at the Conclusion of a Clinical Trial: Ethical and Practical Considerations for the IRB (IRB-Sponsor)</td>
<td>Canal D</td>
</tr>
<tr>
<td>B14</td>
<td>Electronic Data Capture, Documentation, and Storage: Ensuring Your Technology Takes into Account the Best Regulatory and Ethical Practices (IRB Operations and Tool Kit Track)</td>
<td>Canal A</td>
</tr>
<tr>
<td>B15</td>
<td>Criteria and Considerations for Waiving Requirements for Obtaining and Documenting Informed Consent (Informed Consent Track)</td>
<td>Canal E</td>
</tr>
<tr>
<td>B16</td>
<td>How Can I Do the Best Job Possible With the Money I Have? Guidance for Institutional Officials As They Fulfill Their Roles and Responsibilities in the Current Economic Landscape (Institutional Officials Track)</td>
<td>Ryman Ballroom D</td>
</tr>
<tr>
<td>B17</td>
<td>Issues to Consider When an IRB First Begins Working Internationally (International Track)</td>
<td>Delta Island F</td>
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<tr>
<td>B18</td>
<td>Informed Consent Forms: How to Minimize Legal Risks and Maximize Intelligibility (Legal Track)</td>
<td>Ryman Studio PQR</td>
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<tr>
<td>B19</td>
<td>Ethical Issues in Phase I Oncology Trials with Children (Oncology and Cancer Centers Track)</td>
<td>Lincoln C</td>
</tr>
<tr>
<td>B20</td>
<td>Consent of the Avatars: Virtual Human Subjects Research and Review (Panel Follow-Up Track)</td>
<td>Delta Island E</td>
</tr>
<tr>
<td>B21</td>
<td>Determining Decision-Making Capacity of Prospective Subjects: Case Studies on Strategies for Obtaining Consent (Populations Requiring Additional Protections I Track)</td>
<td>Canal B</td>
</tr>
<tr>
<td>B22</td>
<td>Ethical Issues in Research Involving Residual Blood Collected from Newborns (Populations Requiring Additional Protections II Track)</td>
<td>Ryman Ballroom A</td>
</tr>
<tr>
<td>B23</td>
<td>The Investigator Interview: How to Get the Information You Need (QA/QI and Post-IRB Approval Monitoring and Review Track)</td>
<td>Ryman Studio L</td>
</tr>
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Saturday, November 14 (continued)

🌟 🔺 B24 Advanced
IRB Review of Survey Research Protocols: Achieving a Balance Between Methodological Rigor and Subject Protections (SBER Advanced Track)
Ronald Langley, Michael Oakes

🌟 🔺 B25
Privacy and Confidentiality: Don’t Ask or Don’t Tell?
(SBER Basic Track) Moira Keane

Basic 🔺 B26
Statistics Without Tears: The Fundamentals and Vocabulary for Nonscientists (Science for the Nonscientist Track) Sue Fish, Yen-Hong Kuo

Basic 🔺 B27
Getting Started: A Guide to Surviving the Initial Stages of the Accreditation Process (Self-Assessment and Accreditation of HRPPs Track)
Sharon Friend, Helen Panageas

🔹 B28
You Are Not Alone (It Just Feels Like It): How to Build a Problem-Solving and Support Network Inside and Outside Your Institution (Small Research Programs Track) Elizabeth Cohan

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

5:00-6:30 PM Speed Mentoring
Join us for a networking event where you can ask HRPP professionals, the Feds, ethicists, and other experts those “everything-you’ve-always-wanted-to-know-but-didn’t-know-who-to-ask” questions. Light refreshments will be served.

5:30-7:00 PM Moderated abstract discussions
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!
Whether you wish to escape or engage, join us for a showing of Milk. Academy Award winner Sean Penn takes the title role in Gus Van Sant’s biopic tracing the last eight years in the life of Harvey Milk, the ill-fated politician and gay activist whose life changed history, and whose courage still inspires people.

8:00-10:00 PM Poker night with PRIM&R!
Join us for a sure-to-be-fun night of poker for all levels of players! Beginners can learn the game, “intermediates” can improve their play, and more advanced players can “strut their stuff.” Come one, come all, as this is a complimentary event and there are no entry fees.

Sunday, November 15

7:00 AM Registration opens

7:00-8:00 AM Continental breakfast

7:00-8:00 AM Member networking continental breakfast

All PRIM&R members are welcome! Attend this breakfast to connect with your colleagues, pick-up your member gift, and learn more about PRIM&R’s membership benefits. PRIM&R staff and members of the Membership Committee will be available to answer questions.

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8:00-8:15 AM  Welcome, updates, and PRIM&R’s 35th anniversary  
8:15-9:15 AM  Keynote address: Hot Topics in Research Using Biorepositories  
   Ellen Wright Clayton, MD, JD  
   Rosalind E. Franklin Professor of Genetics and Health Policy;  
   professor of pediatrics; professor of law; and Director, Center for  
   Biomedical Ethics and Society, Vanderbilt University  
8:15-9:15 AM  Keynote address: Predictably Irrational  
   Professor Dan Ariely  
   James B. Duke Professor of Behavioral Economics  
   Duke University  
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  Panel III: Conflicts of Interest: What’s New? Why Worry?  
   Moderator: Jeremy Sugarman  
   Panelists: Mark Hall  
   Robin Fretwell Wilson  
   Jane Jordan  
9:30-10:45 AM  Panel IV: Biobanking: If, When, and How to Return Research Results  
   Moderator: Ellen Wright Clayton  
   Panelists: S. Malia Fullerton  
   Pearl O’Rourke  
   Joan Scott  
9:30-10:45 AM  Panel V: How to Successfully Review New and Uncommon Methodologies  
   in SBER  
   Moderator: André Ivanoff  
   Panelists: Dan Ariely  
   Lise Dobrin  
   Robert Fullilove  
10:45-11:15 AM  Coffee, commuting, and “communing” time  
11:15 AM-12:30 PM  Didactic Sessions and Workshop Series C  
   Advanced  C1  Finding the Right Balance Between Compliance and Ethics: Helping  
   Your IRB Move Beyond “Ethics by Checklist”  
   (Advanced Forum for  
   Experienced IRB Professionals Track) Ann Dougherty, Nancy MP King, Sarah Putney  
   C2  A Dialogue with the Department of Education  
   (A Dialogue with the Federal Representatives ITrack) Jeff Rodamar  
   C3  A Dialogue with the Department of Veterans Affairs Office of Research  
   Oversight (ORO): Hot Topics, Thorny Problems, and Practical  
   Solutions – Research Safety and Animal Welfare Auditing  
   (A Dialogue with the Federal Representatives II 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.] Michael Fallon, Susan Harper  

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C5 Anyone Can be a PI, Right?! Certification Standards for Investigators (Clinical Research Professionals Track) Greg Koski, David Vulano

C6 Let’s Review a Protocol! An Interactive “How-To” for Members of the Community and/or the Nonscientist (Community/Nonscientific Members 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.] Kip Kantelo, Emily Largent

C7 A Gathering for Those Interested in Exploring the Certified IRB Professional (CIP®) Credential: Your Chance to Ask Us About the Certification Process (Education Track) Susan Delano, Felix Gyi, Corinne Rogers

C8 Relativistic Ethics and Ethical Pluralism When Conducting Research Internationally: Are the Belmont Principles Universally Appropriate? (Ethical Issues 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.] David Borasky, Alan Wertheimer

C9 Navigating the World of Research Oversight: What Regulations Apply and When? When Is an Assurance and/or Registration Needed? When Is an Activity “Human Subjects Research?” What Is Exempt? What Does It Mean to Be “Engaged?” (Federal Regulations I 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.] Mike Carome, Susie Hoffman, Alisa Irwin

C10 The End of Your Search for Information on the FDA's Investigational New Drug (IND) and Investigational Device Exemption (IDE) Regulations (Federal Regulations II 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.] Jeff Cooper, Christine Drabick, Tejashri Purohit-Sheth, Stephen Rhodes, Ada Sue Selzvitz

C11 Managing Specimen Repositories: Tools and Strategies (Hot Spots I 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.] Marianna Beddoo, Malia Fullerton, Julie Kaneshiro

C12 Distinguishing Health Care Practice from Health Care Research: When Is IRB Review Required? (Hot Spots II Track) Barbara Bierer, Jeff Botkin, Warren Lux


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14. How to Achieve Greater Efficiency and Cooperation Without Compromising Protections for Subjects: The University of Texas Experience and How It Can Work for Your Institution (IRB Operations and Tool Kit Track) Peter Davies, Lisa Leiden, Sujatha Sridhar

15. Eschew Obfuscation! Plain Talk About the Need for Plain Language in Consent Forms (Informed Consent 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.] Howard Mann, Betsy Ripley

16. Identifying, Reducing, and Managing Conflicts of Interest Involving IRB Members, Researchers, and Institutions (Institutional Officials Track) Stuart Horowitz, Suzanne Rivera

17. International Research Capacity Building: Ethical and Practical Issues (International 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.] Ronald Heslegrave, Reidar Lie, Siti Sundar, Kasem Tantiphalakha, Julia Welch

18. FDA: Areas of Risk for Institutions and Investigators (Legal Track) Karen Cooper, John Mills

19. Data and Safety Monitoring Plans and Boards: NCI Requirements and IRB Responsibilities (Oncology and Cancer Centers 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.] Amanda Hammond, John Kuttlesch, Gwenn Oki


21. When and How Can Emergency Research Be Carried Out Without Informed Consent? The Rapid Anticonvulsant Medications Prior to Arrival Trial (RAMPART) Study and Beyond (Populations Requiring Additional Protections I Track) Tom Foster, Deneil Kolk, Katherine Lamond, Robert Silbergliet

22. The IRB’s Role in Helping Prospective Research Subjects Who Are Critically Ill Avoid the Therapeutic Misconception (Populations Requiring Additional Protections II Track) Bob Levine

23. The Nuts and Bolts of a QA/QI Review (QA/QI and Post-IRB Approval Monitoring and Review 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.] Cindy Kern, Linda Triemer, Delia Wolf

24. Advanced SBER Topics for IRB Chairs and Directors, and Institutional Officials (SBER Advanced 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.] Jeff Cohen, Patricia MacGubbin, Michael Oakes

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Indicates workshop (attendees talk too!)

Indicates session will be recorded.

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Receives CME Credit.

Indicates session was chosen from our invitation to contribute to program development process.
**Sunday, November 15 (continued)**

**C25**  
**Basic**  
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 1:45 PM. A boxed lunch will be served before the session begins. Pre-registration is required to attend this session.]  
Kristina Boron, Loma Hicks, Laura Odwazny  
*Canal D*

**C26**  
**Basic**  
Common Study Designs, Including Controlled Clinical Trials (Randomized and Placebo-Controlled), and How Protocols for Each Are Reviewed (Science for the Nonscientist 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.]  
Cliff Gunthel  
*Jackson C*

**C27**  
**Basic**  
Re-Accreditation: How to Prepare and What to Expect (Self-Assessment and Accreditation of HRPPs Track)  
Sharon Friend, Elan Czeisler  
*Lincoln B*

**C28**  
**Basic**  
Educating Your Institutional Official, Compliance Officer, Finance VP, Business Office, and Legal Counsel About Your Program’s Needs (Small Research Programs Track)  
Eric Allen, Bob Bienkowski  
*Delta Island D*

**12:30-1:45 PM**  
**Lunch in the Conference Connection**  
*Ryman Exhibit Hall B4-6*

**12:30-1:45 PM**  
**Lunch: What's New at the CITI Program?**  
*Governor’s AE*

During this event, CITI co-founder Dr. Paul Braunschweiger will demonstrate new features that will help participants get the most from their use of the CITI program, including CITI Program Course site navigation, refresher modules, and non-English language capabilities.

**12:30-1:45 PM**  
**Lunch: Open house for the National Cancer Institute (NCI) Central Institutional Review Boards (CIRBs) participants**  
*Delta Island ABC*

Are you enrolled in NCI CIRB? If so, attend this event to meet the leaders and staff of the CIRB, network with others using the CIRB, and ask questions about SOPs, facilitated review, and anything else on your mind. The anticipated format will be a brief presentation, questions from the audience, and breakouts for one on one questions. This event is open to participating sites only.

**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**  
**Living Room Conversation: A Discussion with Research Subjects and Their Advocates**  
*Delta CD*

**Moderator:**  
Leonard Glantz  
**Panelists:**  
Roberto Abadie  
Robert Helms  
Jen Levine-Fried  
Gigi McMillan  
Suzanne Pattee

**2:00-3:15 PM**  
**Panel VI: Ethics in Research: Who’s Minding the Store... The IRB, the REC, and/or the Investigator?**  
*Delta A*

**Moderator:**  
Steven Joffe  
**Panelists:**  
Mildred Cho  
Susan Kornetsky  
Malcolm Smith

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**Sessions labeled basic are for those new to the field or who are in need of a refresher.**

**Receives CME Credit.**
2:00-3:15 PM  Panel VII: Risk Management in SBER  

Moderator:  J. Michael Oakes  
Panelists:  Scott Bradner  
Barbara Davis Goldman  
Elana Newman  

3:15-3:30 PM  Coffee, Commuting, and “Communing” Time  

3:30-4:45 PM  Town Hall Meeting: Making HHS More Transparent, But Not Invisible: A Dialogue with FDA, NIH, and OHRP  

Moderator:  Ivor Pritchard  
Panelists:  Phil Budashewitz, Mike Carone, Joanne Less, Diane Maloney, Jerry Menikoff, Kevin Prohaska  

3:30-4:45 PM  Panel VIII: The Implications and Application of the Belmont Principles in SBER Today  

Moderator:  Ada Sue Schwartz  
Panelists:  Richard Barke  
Helen McGough  
J. Michael Oakes  

3:30-4:45 PM  A Great Debate: Should All Minimal Risk Research be Exempt from Coverage by the Regulations for the Protection of Human Subjects?  

Moderator:  Bob Levine  
Debaters:  Jeffrey Cohen  
Scott Kim  

4:45-5:00 PM  Commuting time (i.e. no food or beverage, just time to get to your sessions!)  

5:00-6:15 PM - Didactic Sessions and Workshop Series D  

D1 Advanced  Does Your IRB Office Function as an Internal Research Consultant for Your Research Community or Is This Valuable Institutional Resource Untapped? How to Foster Effective Communication Between Your Institution’s Research Community and the IRB  (Advanced Forum for Experienced IRB Professionals Track)  
Paula Kudason, Susan Kornetsky  

D2  The VA Central IRB (A Dialogue with the Federal Representatives ITrack)  
Annette Anderson, Lynn Cates  

D3  A Dialogue with the National Institutes of Health (NIH)  (A Dialogue with the Federal Representatives II Track)  
Mariani Bledsoe, Phil Budashewitz, Jaci Goldberg, Donna McCloskey  

D4  IRB Administration on a Shoestring: How Do You Maintain Compliance with Minimal Staff? (Brother, Can You Spare a Dime? Track)  
Elizabeth Cothran  

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Receives CME Credit.  

Indicates workshop (attendees talk too!)  

Indicates session will be recorded.  

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<thead>
<tr>
<th>Session</th>
<th>Track</th>
<th>Description</th>
<th>Location</th>
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</thead>
<tbody>
<tr>
<td>D5</td>
<td>Advanced</td>
<td>When the IRB Suspends Your Clinical Study: Making Lemonade from Lemons (Clinical Research Professionals Track) Chris Carter, Suzanne Fitzpatrick</td>
<td>Ryman Ballroom F</td>
</tr>
<tr>
<td>D6</td>
<td>Basic</td>
<td>Eliciting, Respecting, Validating, and Following-Up on the Ideas of the Nonscientists at the Table (Community/Nonscientific Members Track) Cheryl Dubeneck, Dorothy Hilmann, Susan Rose, Rosemarie Sore</td>
<td>Ryman Ballroom D</td>
</tr>
<tr>
<td>D7</td>
<td>Basic</td>
<td>Education for Those Teaching Human Research Protections in the Classroom: Curriculum Design and Development (Education Track) Melissa Frumin, Brian Gladue, Barbara Goldman, Michael McDonald</td>
<td>Governor's B</td>
</tr>
<tr>
<td>D8</td>
<td>Basic</td>
<td>Protections Afforded by the Belmont Report, the Declaration of Helsinki, and Good Clinical Practice: What's the Same and What's Different? (Ethical Issues Track) Elizabeth Heitman, Ernie Prentice</td>
<td>Canal D</td>
</tr>
<tr>
<td>D9</td>
<td>Basic</td>
<td>Viva la Difference: A Comparison of the DHHS and FDA Regulations for the Protection of Human Subjects (Federal Regulations ITrack) Janet Donnelly, Julia Gorey, Alisa Irwin</td>
<td>Ryman Studio PQR</td>
</tr>
<tr>
<td>D10</td>
<td>Basic</td>
<td>FDA Expectations of IRBs When Making the Significant and Non-Significant Risk Determination in Device Investigations (Federal Regulations II Track) Stephen Rhodes, Fabienne Santel</td>
<td>Washington B</td>
</tr>
<tr>
<td>D11</td>
<td>Basic</td>
<td>Research on Infectious Outbreaks, Disasters, and Complex Emergencies (Hot Spots I Track) Bob Levine, William New</td>
<td>Governor's D</td>
</tr>
<tr>
<td>D12</td>
<td>Basic</td>
<td>IRB Accountability: Heightened Concerns about Human Research Protections in the Wake of the GAO Investigation (Hot Spots II Track) Chris Backley, Suzanne Rivera</td>
<td>Ryman Studio ABC</td>
</tr>
<tr>
<td>D13</td>
<td>Advanced</td>
<td>Compensation for Research-Related Injury: Negotiated Terms with Sponsors, Concurrence Between Contracts and Consent Forms, the Limits of Insurance Coverage, and the Ethics of Not Offering Compensation (IRB-Sponsor Relationships Track) Jill Alvarez, Anne Dougherty, Tom Foster</td>
<td>Canal C</td>
</tr>
<tr>
<td>D14</td>
<td>Basic</td>
<td>Take a Letter to My Sweetheart: The Dos and Don'ts of Writing Concise, Coherent, and Compliant Minutes (IRB Operations and Tool Kit Track) Moira Keane, Elyse Summers</td>
<td>Bayou E</td>
</tr>
<tr>
<td>D15</td>
<td>Basic</td>
<td>Suggested Language to Include in Consent Documents Involving Genetic Testing, Tissue Banking, and Registries (Informed Consent Track) Cathy McCarty, Kate Gallin Heffernan, Laura Lyman Rodriguez</td>
<td>Governor’s C</td>
</tr>
<tr>
<td>D16</td>
<td>Basic</td>
<td>An Advanced Institutional Official Forum with OHRP (Institutional Officials Track) Ivor Pritchard</td>
<td>Ryman Ballroom A</td>
</tr>
<tr>
<td>D17</td>
<td>Advanced</td>
<td>Future Uses of Biologic Specimens Derived from Multi-Site International Research (International Track) Malia Fullerton, Nancy MP King, James Lavery, Karuna Rameshikumar</td>
<td>Ryman Studio L</td>
</tr>
</tbody>
</table>
Sunday, November 15 (continued)

D18 Clinical Trial Agreements: Identifying and Resolving Challenging Issues
(Legal Track) Elena Adolphus, Julie Ozier, Heather Pierce

 Lincoln B

D19 Ethical, Scientific, and Policy Issues Surrounding Access to
Advanced Investigational Cancer Drugs (Oncology and Cancer Centers Track)
Bruce Gordon, Richard Klein

 Lincoln C

D20 Best Practices and Policies on Subject Incentive Payments:
The University of Michigan Experience (Panel Follow-Up Track)
Judy Birk, Jan Hewett

Ryman Ballroom BE

D21 Case Studies on the IRB’s Role in Subpart B, C, and D Determinations
Basic (Populations Requiring Additional Protections ITrack)
Yvonne Higgins, Irene Stith-Coleman

 Jackson C

D22 Research with Subjects who Lack Capacity to Consent: SACHRP's Final
NEW SESSION! Recommendations for Investigators, IRBs, and Institutions
(Populations Requiring Additional Protections II Track) Barbara Bierer, David Strauss

Delta Island E

D23 No One Right Answer: Corrective Action for Common Findings from
QI Not-For-Cause Reviews (QA/QI and Post-IRB Approval Monitoring and
Review Track) Bob Bienkowski, Kelly Dornin-Koss, George Gasparis

Ryman Studio MNO

D24 International SBER: An Interactive Discussion about Best Practices and
Ongoing Challenges (SBER Advanced Track) David Borasky, Kate MacQueen

Ryman Studio HI

D25 School Rules: The Common Rule, the Family Educational Rights and
Basic Privacy Act (FERPA), and the Protection of Pupil Rights Amendment
(PPRA) (SBER Basic Track) Jonathan Miller, Jeff Rodamar

Canal B

D26 Research Data Security Policies and Practices:
The Harvard University Experience (Science for the Nonscientist Track)
Basic
NEW TITLE! Scott Bradner

Ryman Ballroom G

D27 A Users' Guide to the Revised Standards and Elements for Accreditation
Basic (Self-Assessment and Accreditation of HRPPs Track) Peter Vasilenko

 Delta Island F

D28 Managing the Workload: Tapping External Resources, Using Central
IRBs, and Avoiding Mission Creep (Small Research Programs Track)
Erica Heath, Michael Roach

 Delta Island D

D29 The Office of Human Research Protection’s (OHRP’s) New Draft Guidelines
NEW SESSION! on Continuing Review and Conditional IRB Approval
(Federal Regulations I Track) Mike Carone

 Delta CD

7:00 PM-10:00 PM PRIM&R’s 35th Anniversary Birthday Party
Join us for great music—we've hired New South to play your favorite 60s, 70s, and 80s
throwbacks—amazing food—top round of roast beef infused with elephant garlic, tortellini,
radiator, and seven-grain penne pastas, salads, gourmet cupcakes—games, trivia, fantastic
prizes, and more!

Delta B

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Monday, November 16

7:00 AM  Registration opens  
7:00-8:00 AM  Continental breakfast  

7:00-8:00 AM  Continental breakfast: Learn more about the CIP® credentialing process  
Interested in earning your CIP® (Certified IRB Professional) Credential? Want to connect with “CIPers?” Stop by this breakfast to learn more and to meet representatives of the Council for Certification of IRB Professionals.

8:00-8:15 AM  Welcome, tribute to Sen. Edward M. Kennedy, and membership news  
PRIM&R will posthumously award the Special Lifetime Public Service Award to the late Senator Edward M. Kennedy.

Membership news presented by David Borasky, Chair, PRIM&R’s Membership Committee.

8:15-9:15 AM  Keynote address: Community Health Research Reform: Ensuring IRB Members are Aligned with Evolving Strategies for Engaging Underserved Communities  
Keith Norris, MD  
Interim President, Charles Drew University of Medicine and Science  

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  Panel IX: Ethical Issues in Multinational Trials  
**Moderator:** Bob Levine  
**Panelists:** Michael Clayman, James Lavery, Robert “Skip” Nelson  

9:30-10:45 AM  Panel X: The Changing Concept of Privacy in SBER  
**Moderator:** Philip Rubin  
**Panelists:** Dwayne Dixon, Robert Gellman, Harry Lewis  

9:30-10:45 AM  A Great Debate: Should IRBs Consider Broader Social Implications of Research?  
**Moderator:** David Borasky  
**Debaters:** Jonathan Rackoff, Seema Shah  

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

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

**El**  Identifying, Communicating, and Reaching Out to the Community Served by Your IRB (Advanced Forum for Experienced IRB Professionals Track)  
Keith Norris  

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Monday, November 16 (continued)

**E2**  A Dialogue with the Secretary's Advisory Committee on Human Research Protections (SACHRP) (A Dialogue with the Federal Representatives I Track) Barbara Bierer, Dan Nelson

**E3**  A Dialogue with the National Science Foundation (NSF) (Dialogue with the Federal Representatives II Track) Kellina Craig-Henderson

**E4**  Continuous Quality Improvement on a Shoestring: Working With the IRB and Investigators (Brother, Can You Spare a Dime? Track) Julia Gorey, Delia Wolf

**E5**  Everything You Always Wanted to Know about What the FDA Expects and Requires of Clinical Investigators (Clinical Research Professionals Track) George Gasparis, Tejashri Purohit-Sheth

**E6**  Ensuring Diversity on the IRB: Finding, Educating, and Honoring Members Who Represent Vulnerable Populations, Different Ethnic Groups, and Others in the Community (Community/Nonscientific Members Track) Bill Freeman, Francine Gachupin

**E7**  Education for Research Coordinators: Internal Training Programs, External Certification Programs (e.g. Those Available from SoCRA and/or ACRP), and Everything in Between! (Education Track) Gail Mayo, Paul Papagni

**E8**  Desperately Seeking Subjects... So Why Are We Discouraging Them from Participating in Research? (Ethical Issues Track) Michael McDonald, Lindsay McNair

**E9**  Developing a Robust Set of Policies and Procedures That Will Help Strengthen Your Human Subjects Protections Program (Federal Regulations I Track) Suzanne Fitzpatrick, Karen Hansen, Elyse Summers

**E10**  Adverse Events and Unanticipated Problems: FDA and OHRP Regulations and Guidance (Federal Regulations II Track) Mike Carone, Jeff Cooper, Ernie Prentice, Kevin Prohaska

**E11**  The Oversight of Human Embryonic and Induced Pluripotent Stem Cells: The Role of the IRB and the Effect of the New NIH Guidelines (Hot Spots I Track) [Please note this is a double session and will end at 1:30 PM. A boxed lunch will be served before the session begins. Pre-registration is required to attend this session.] Sandy Alfano, Julie Kaneshiro, Pearl O’Rourke, Susan Stayn

**E12**  Communicating with Research Subjects: Returning Results, Clinicaltrials.gov, and Incidental Findings (Hot Spots II Track) Howard Mann, Michele Russell-Einhorn


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**E4** Indicates didactic session (attendees mostly listen…)

**E6** Indicates workshop (attendees talk too!)

**E8** Indicates session will be recorded.

**E9** Reaches CME Credit.

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<tr>
<td>E14</td>
<td>Been There, Done That, and Want to Help You Learn From My Missteps: How to Prepare for – and Lessons Learned From – an eIRB Conversion (IRB Operations and Tool Kit Track)</td>
<td>Ryman Studio ABC</td>
</tr>
<tr>
<td>E15</td>
<td>Improving the Consent Process and Reformatting the Form (Informed Consent Track)</td>
<td>Governor’s D</td>
</tr>
<tr>
<td>E16</td>
<td>Issues Faced by Universities and Hospitals When Using Central IRBs (Institutional Officials Track)</td>
<td>Canal D</td>
</tr>
<tr>
<td>E17</td>
<td>Avoiding Therapeutic Misconception When Conducting Research in Developing Countries (International Track)</td>
<td>Jackson C</td>
</tr>
<tr>
<td>E18</td>
<td>How to Have Your Say: The Public Comment Process (Legal Track)</td>
<td>Delta Island D</td>
</tr>
<tr>
<td>E19</td>
<td>National Cancer Institute (NCI) Clinical Trials Reporting: A Status Report on Its Purpose, Focus, and Implementation (Oncology and Cancer Centers Track)</td>
<td>Delta Island F</td>
</tr>
<tr>
<td>E20</td>
<td>“Reproducing” Risk: Ethical Issues in Research Involving Women (Panel Follow-Up Track)</td>
<td>Ryman Ballroom A</td>
</tr>
<tr>
<td>E21</td>
<td>Research Involving Children or Minors: Concepts and Values Relating to the Rights of Minors, Research with Adolescents, and the “Rule of 7” (Populations Requiring Additional Protections I Track)</td>
<td>Canal C</td>
</tr>
<tr>
<td>E22</td>
<td>The Multi-Regional Clinical Trial (MRCT) Project: Global Trials and Ethical Challenges for Trials in the Developing World (Populations Requiring Additional Protections II Track)</td>
<td>Ryman Ballroom G</td>
</tr>
<tr>
<td>E23</td>
<td>“You’re Telling Me I Did What Wrong?!” How to Discuss Noncompliance with Investigators and the Research Community (QA/QI and Post-IRB Approval Monitoring and Review Track)</td>
<td>Washington B</td>
</tr>
<tr>
<td>E24</td>
<td>Into the Matrix: Wrestling with the Concept of Vulnerability and Paternalism in SBER (SBER Advanced Track)</td>
<td>Lincoln C</td>
</tr>
<tr>
<td>E25</td>
<td>Issues for the IRB to Consider When Reviewing Qualitative Research, Oral History, Ethnography, and More! (SBER Basic Track)</td>
<td>Canal A</td>
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**Session Levels:**
- **Basic**: Sessions labeled basic are for those new to the field or who are in need of a refresher.
- **Advanced**: Sessions labeled advanced are for those with more experience.
E26  An Introduction to Genetics and Personalized Medicine  (Science for the Nonscientist Track) Ingrid Holm  Ryman Studio PQR

E27  Qualitative Methods and Quantitative Metrics for Assessing HRPPs and IRB/Ethics Committee Review  (Self-Assessment and Accreditation of HRPPs Track) Elan Czeisler, Susan Rose  Canal B

E28  A Moderated Forum for Those Everything-You-Always-Wanted-To-Know-But-Didn't-Know-Where-To-Ask-Questions  (Small Research Programs Track) Kristina Borror, Susan Delano  Ryman Ballroom BE

12:30-1:30 PM  Lunch  Ryman Exhibit Hall B4-5


This event is for those interested in learning the basics about the NCI CIRB, i.e. the enrollment and implementation process, the facilitated review model, the benefits and challenges, etc. You may also ask questions and get answers.


Interested in learning more about the old and new AAHRPP Evaluation Instruments? If so, attend this lunch session to review the overall summary of the changes and to learn more about the requirements for written materials that were removed and that are new; the elements modified to allow a greater degree of flexibility; the regulatory requirements not covered in the new Evaluation Instrument; and clarifications from AAHRPP. Individuals preparing applications for accreditation or re-applications for accreditation who need to follow the new standards should attend this session. Please note this lunch is open to attendees on a first come, first serve basis and limited seating is available. Jeff Cooper.

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  Town Hall Meeting: Federal Forum on Accountability  Governor's B

Moderators:  Jeff Cohen and Michele Russell-Einhorn

Panelists:  Laura Brosch, Lynn Cates, John Galland, Warren Lux, Michael McDonald, Joan Porter, Jeff Rodamar, Sandra Titus

1:45-3:00 PM  Panel XI: Ethical, Regulatory, and Practical Issues in Research  Delta B

Moderator:  Judy Norsigian

Panelists:  Anne Lyperly
Douglas Taylor
Kathleen Uhl

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Receive CME Credit.

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Panel XII: Hot Off the Presses: Selected Abstracts on Innovative HRPP Programs and Research on Research Ethics
Come learn about best practices for your IRBs and HRPPs! During this session, research professionals and researchers will present innovative, empirical “research on research ethics” and will provide audience members with concrete tools and strategies designed to improve the effectiveness of IRBs/HRPPs.

Moderators: David Borasky and Sue Fish

Topics and Panelists:

1. Parental Attitudes Toward Pediatric Biobanks
   Jody Harland, Lucy Miller, Eric Meslin, James Wolf, Scott Denne

2. Informed Consent: Hollywood Style
   Rebecca Flores Stella, Nancy Danielov, Jessica Spotts, Keren Dunn

3. Information Overload: The Effect of a Shorter Form on the Quality of Informed Consent
   Leanne Stunkel, Meredith Shannon Benson, Gabriella Bedarida, Ezekiel Emanuel, Christine Grady

4. From Shut Down to AAHRPP Full Accreditation in 10 short Years: A Case Study of the Operational and Organizational Changes at the Duke University Health System IRB
   Charlotte Coley, Chelle Yin

3:00–3:15 PM  Coffee, commuting, and “communing” time

3:15–4:30 PM – The Grand Finale!

A Session for Experienced IRB Professionals: The Pros and Cons of Using the Short Form
Respect for persons, as described in the Belmont Report, requires that subjects, “to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.” The purpose of this roundtable session is to (1) consider the ethical issues of enrolling subjects when a language barrier exists; (2) examine the limitations of the short form; and (3) identify ways to enhance the informed consent process when a short form is used. David Borasky, Jeff Cooper, Amanda Hammond.

Citizen Scientists Film Screening and Discussion Session
Citizen Scientists is a documentary that explores the world of advocacy and rare genetic diseases, focusing on Hermansky-Pudlak Syndrome (HPS). The film profiles the HPS advocacy group, individual patients, and researchers and physicians, all of whom are involved in the Phase III clinical trial designed to slow the progression of a fatal symptom of HPS. This session will encourage contemplation of such ethical and societal issues as: What are the lived experiences of patients and research subjects? What conflicts are raised for researchers who develop emotional relationships with their subjects? How is research study design impacted by input from advocacy groups? This film was created by Maren Grainger-Monsen, MD and Nicole Newham of the Center for Integration of Research on Genetics and Ethics (CIRGE) at Stanford University. This session will be led by Mildred Cho and Jennifer Ladd.
Creative Solutions to Managing Staff and Budgets at Large Research Institutions
This session will allow those working at large research institutions a chance to share best practices for managing staff and budgets. The session will begin with a presentation that focuses on developing the types of reports needed to support funding for the appropriate staffing level, the establishment of performance standards for staff, ways to increase efficiency, methods for motivating staff (beyond salary), and effective approaches to promoting and instituting change. Plenty of time will be allotted for attendees to share their own ideas, ask questions, and discuss concerns with the group. Sharon Friend, George Gasparis, Don Workman.

Creative Solutions to Managing Staff and Budgets at Small Research Entities, Including Research Organizations, Colleges, and Hospitals
This session will afford those working in small research entities a chance to participate in a facilitated brainstorming session about how to design a high quality/low budget educational program in human research protections for staff; how to prepare for the certified IRB professional (CIP) credential on your own; how to increase your professional qualifications; how to save time and money by transitioning to a (semi-)paperless program; how to reach out and identify mentors and advisors; and more! Attendees are encouraged to come with ideas, questions, and concerns to share with the group. Bob Bienkowski, Corinne Rogers.

★ IRB Stakeholders: Collaboration or Conflict?
This session will focus on the conflict and cooperation between three of the primary stakeholders in the research endeavor: research ethics boards, researchers, and participants. Informed consent issues have become central to the discussion and conflict between IRB’s and researchers. The emerging trend of community based participatory research (CBPR) highlights the value of collaborative approaches between the researcher and the community being studied. Using a CBPR model with community defined as these primary stakeholders in the research endeavor, this session will involve the attendees in focus group discussions. Darla Beaty.

★ A Facilitated Forum for Public Health IRBs
IRBs associated with State’s Departments of Health are responsible for reviewing a wide range of research including, but not limited to epidemiology, public health intervention trials, disease registries, and disaster planning and response. This research may be conducted in a setting of public and media scrutiny, statutory and regulatory constraints, and may involve public health officials and academics. This session will present a forum for those participating in this review process, as well as those conducting research at Departments of Health, to discuss common concerns and novel approaches to problems. Bruce Gordon, Robert Hood.

Current and Future Needs for Bioethics Research, Training, and Translation
This session will describe a current effort underway at the NIH to review NIH’s investment in bioethics research, training, and translation; develop a long-range, strategic plan to enhance the integration of ethical inquiry and practice into the conduct of research across the research spectrum; and seek input from participants on the status of the field of bioethics and current and future needs for bioethics research, training, and translation. The NIH will be seeking public comment on its draft strategic plan in the spring of 2010. Marianna Bledsoe, Phil Budashewitz, Sarah Carr.

4:30-5:30 PM  Closing reception and fond farewells!

Symbols:
- 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.
- Indicates didactic session (attendees mostly listen…)
- ★ Indicates workshop (attendees talk too!)
- ¦ Indicates session will be recorded.
- Sessions labeled advanced are for those with more experience.
- Sessions labeled basic are for those new to the field or who are in need of a refresher.
- ★ Indicates CME Credit.
- ☆ Indicates session was chosen from our invitation to contribute to program development process.
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