### Saturday, December 1, 2007

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
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<tbody>
<tr>
<td>7:00 AM</td>
<td>Registration Opens</td>
<td>Hynes Prefunction Hall C</td>
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<tr>
<td>7:00 – 8:30 AM</td>
<td>Continental Breakfast</td>
<td>Hynes Hall D</td>
</tr>
<tr>
<td>8:30 AM – 5:30 PM</td>
<td>Pre-Conference Educational Programs</td>
<td>Hynes</td>
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<td></td>
<td>Please refer to page 43 for more information.</td>
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<tr>
<td>5:30 – 7:30 PM</td>
<td>Welcome Reception and Commemoration of World AIDS Day</td>
<td>Hynes 3rd Floor</td>
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### Sunday, December 2, 2007

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<tr>
<th>Time</th>
<th>Event</th>
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<tr>
<td>7:00 AM</td>
<td>Registration Opens</td>
<td>Hynes Prefunction Hall C</td>
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<tr>
<td>7:00 – 8:15 AM</td>
<td>Continental Breakfast</td>
<td>Hynes Hall D</td>
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<tr>
<td>7:00 – 8:15 AM</td>
<td>Membership Orientation and Continental Breakfast</td>
<td>Constitution A</td>
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<tr>
<td></td>
<td>All are welcome! Learn more about PRIM&amp;R’s membership benefits and services, network with your peers, and ask questions of the Membership Committee and PRIM&amp;R Staff.</td>
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<tr>
<td>8:15 – 8:30 AM</td>
<td>Welcome and Conference Overview</td>
<td>Conference Co-chairs</td>
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<tr>
<td>8:30 – 9:15 AM</td>
<td>Keynote Address: What Is the Future of IRBs?</td>
<td>Hynes Veteran’s Auditorium</td>
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<td></td>
<td>Arthur Caplan</td>
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<tr>
<td>9:15 – 10:30 AM</td>
<td>Panel I: Do the Current Rules Work for All Types of Research?</td>
<td>Hynes Veteran’s Auditorium</td>
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<td>If Not, How Should the Rules Be Changed?</td>
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<td>Moderator: Leonard Glantz</td>
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<tr>
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<td>Panelists: Joanne Lynn, Mary Marshall Clark, Simon Whitney</td>
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<tr>
<td>10:30 – 11:00 AM</td>
<td>Coffee, Commuting, and “Communing” Time</td>
<td>Sheraton Prefunction Foyer &amp; Hynes Prefunction Hall C</td>
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</tbody>
</table>
Panel II: What Ethical Duties of Care and Caring do Researchers Owe their Subjects?

Moderator: Steve Joffe
Panelists: Haavi Moreim
Henry Richardson
Susan Wolf


Moderator: Barbara Stanley
Panelists: Mahzarin Banaji
Julius Landwirth
Kevin Ochsner

Luncheon for Conference Attendees

Networking Luncheon

If you are a First-Time Attendee or someone who might prefer more focused conversation during your lunch, please join the hosted lunch tables with the colorful tablecloths in the overflow dining area of The Conference Connection in the Hynes Convention Center. An experienced PRIM&R Member will be available at each table to make introductions and facilitate an informal discussion on the topics of interest to those at the table. Any questions you might have can also be posed at lunch. Everyone is welcome in this corner of the conference world, but if you are new to PRIM&R or a first-time attendee who could use some help getting acclimated to the PRIM&R Conference scene, we hope you will join us for this informal, and hopefully informative, luncheon. A boxed lunch will be served.

Public Policy Forum Luncheon

This session will provide an opportunity to discuss late breaking policy issues in a relaxed setting over lunch. Topics may include OHRP’s proposed changes to the Expedited Review Categories, OHRP’s Request for Information on Research That Involves Adult Individuals with Impaired Decision-making Capacity, and the IOG Report on FDA monitoring of clinical trials. This lunch is open to all attendees who are interested in any of these topics and are willing to share comments and ideas for shaping future policy in connection with these issues. This session will be of particular interest for people who want to learn how to participate in public policy activities initiated by PRIM&R, including the development of comments to federal agencies requesting feedback from the HRPP community. Background materials will be provided on PRIM&R’s online Conference Handout Center prior to the conference. There is no additional charge, but Pre-registration was required. A boxed lunch will be served.
12:15 – 1:05 PM Luncheon for Quality Improvement/Quality Assurance Initiatives and Programs

This ‘get-to-know-each-other’ lunch will be an opportunity to meet others involved in QI/QA initiatives and programs, and to discuss if there is an interest in developing a more organized network which attendees may continue to share ideas, materials, and support after the conference. Attendees are encouraged to bring questions, as well as any QI/QA program related materials they are willing to share (e.g. monitoring forms, program summaries). There is no additional charge, but Pre-registration was required. A boxed lunch will be served.

1:05 – 1:15 PM Commuting Time (i.e., no food, just time to get to your sessions!)

1:15 – 2:30 PM Panel IV: In Our Own Voices: Pediatric and Adolescent Research Subjects Share Their Stories

Moderator: Stuart Goldman
Panelists: Bryan Benfeld
Jeff Benfeld
Ziva Mann
Cindy Wolanin
Lee Wolanin

2:30 – 3:00 PM Coffee, Commuting, and Communing Time

This break is partially supported by BEC/IRBManager.

3:00 – 4:15 PM Didactic Sessions and Workshop Series A

A1 How Accreditation Changes Human Research Protection Programs (Accreditation Track)
Moira Keane, Peter Vasilenko, Candice Yekel

A2 A Conversation About How to Navigate the Federal Agencies Which Oversee and Affect Human Subjects Research (Ask the Federal Representatives I Track)
William Deniston, Glen Drew, Linda Tollefson

A3 NIH Review of Human Gene Transfer Protocols: Optimizing Science, Safety, and Ethics (Ask the Federal Representatives II Track)
Kathryn Harris, Eugene Rosenthal
[Please note: This was formerly session C9 and it has now been moved to the A series. The original session A3: A Conversation with The Office of Biotechnology Activities has been canceled.]

A4 Understanding and Applying the Ethical Principles When Reviewing Research (Basics for Beginners Track)
Susan Corl, Charles McCarthy

A5 Scientific Basics for the Non-Scientist (Community Track)
Robert Bienkowski, Terry Powell
A6  Orientation, Basic Education, and Continuing Education for IRB Members and Chairs  
( Education Track)  
Charlotte Coley, Brenda Ruotolo  
Independence East

(Ethical Issues Track)  
Miriam Kelty, Monika Markowitz  
Back Bay A

A8  Basic Review of HHS Regulations for Human Subject Protections, Including a Description of the Differences Between FDA’s Regulations and OHRP’s Guidance Documents  
( Federal Regulations I Track)  
Michelle Feige, Suzanne Fitzpatrick, Robert Nelson, Elyse Summers  
Hynes 306

A9  Hot Topics in Department of Education Research: Assent, Permissions, and Regulations (e.g., PPRA, FERPA) When Doing Research in Schools  
( Federal Regulations II Track)  
Lisa Abrams, William Stokes  
Fairfax

A10  Ethical and Practical Issues When Reviewing and Conducting Research on Terrorism  
( Hot Spots Track)  
Elana Newman, Joan Sieber  
Hynes 204

A11  Financial Conflicts of Interest: What IRBs and HRPPs Need to Know  
( Industry Track)  
Richard Bianco  
Back Bay C

A12  Research Participants’ Reactions to Standard Informed Consent Language: The Results of an Empirical Study  
( Informed Consent Track)  
Alice Fortune-Greeley, Chantelle Hardy, Jan Lawlor, Jeremy Sugarman  
Hynes Veteran’s Auditorium

A13  What Institutional Officials Need to Know About IRBs, Subject Protections, and About Their Role as a Signatory Official on HHS-Supported and Other Research  
( Institutional Officials Track)  
Shirley Hicks, David Wynes  
Berkeley

A14  The Ethical Review of Research: Understanding and Applying the Relevant Ethical and Regulatory Guidelines in Different Cultures and Settings  
( International/Cross-Cultural Track)  
Amaboo Dhai, Robert Levine  
Independence West

A15  Everything You Need to Know If You’re a New IRB Chair, From Robert’s Rules to Nikita Khrushchev’s Shoe!  
( IRB Chairs Track)  
Thomas Foster, Elizabeth Hohmann, Reese Jones  
Hynes 202

A16  The Art of Writing Minutes That Comply With Federal Requirements  
( IRB Operations Track)  
Kevin Nellis, Ada Sue Schwitz  
Hynes Ballrooms A-C

A17  Electronic IRB Systems: The Pleasures, the Pitfalls, the Promise, and the Price  
( IRB Professionals – Advanced Track)  
Daniel Nelson, David Mulder, Gwenn Oki  
Hynes 200

Indicates session will be taped for CD-ROM Proceedings  
Receive CME Credit
Indicates didactic session (attendees mostly listen…)
Indicates workshop (attendees talk too!)
Indicates a Double Session which includes both lecture and discussion  
Indicates an abstract submission accepted for presentation
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<thead>
<tr>
<th>Session</th>
<th>Title</th>
<th>Location</th>
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<tbody>
<tr>
<td>A18</td>
<td>“I Know I Turned It in on Time!” Continuing Reviews – Policies, Issues, Consequences, and Best Practices (IRB Tool Kit Track)</td>
<td>Hampton</td>
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<tr>
<td>A19</td>
<td>What IRBs Need to Know About Evidence-Based Medicine and Health Technology Assessment (Late Breaking Track)</td>
<td>Hynes 205</td>
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<tr>
<td>A20</td>
<td>The ABCs of Clinical Trial Agreements for IRBs and Institutional Officials: Regulatory Requirements and AARPP Considerations (Legal/Legislative Track)</td>
<td>Liberty A</td>
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<tr>
<td>A21</td>
<td>Developing and Maintaining a Program That Meets Federal Compliance Expectations (Oversight Monitoring Track)</td>
<td>Gardner</td>
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<td>A22</td>
<td>Opportunities, Obligations, and Restrictions When Conducting Research on Women’s Health: The Inclusion of Pregnant Women, Contraception Research, and More (Populations Requiring Additional Protections Track)</td>
<td>Clarendon</td>
</tr>
<tr>
<td>A23</td>
<td>Poster Presentation – Research About Researchers and Research Ethics (Poster Abstracts Track)</td>
<td>Kent</td>
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<tr>
<td>A24</td>
<td>A Primer on Data and Specimen Repositories: How to Establish and Manage Repositories, and How to Ensure That They Are HIPAA-Compliant (Principal Investigators and the Research Team Track)</td>
<td>Hynes 203</td>
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<tr>
<td>A26</td>
<td>What’s Different About Research With Children? They’re Not Just Small Adults! (Research With Children Track)</td>
<td>Dalton</td>
</tr>
<tr>
<td>A27</td>
<td>Responsibilities of the HRPP and IRB With Respect to Developing and Responding to Information for, and From, Subjects (e.g., Investigational Drug Brochures, Management of Subject Complaints, Adverse Events, Unanticipated Problems, and IND Safety Reports) (Risk-Benefit Track)</td>
<td>Hynes 206</td>
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<td>4:15 – 4:30 PM</td>
<td><strong>Commuting Time</strong> (i.e., no food, just time to get to your sessions!)</td>
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<tr>
<td>4:30 – 5:45 PM</td>
<td><strong>Didactic Sessions and Workshop Series B</strong></td>
</tr>
<tr>
<td>B1</td>
<td>The Self-Assessment and Application Process <em>(Accreditation Track)</em></td>
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<tr>
<td></td>
<td>Jeffrey Cohen, Yvonne Higgins</td>
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<tr>
<td>B2</td>
<td>A Conversation With the FDA Center for Devices and Radiologic Health, Including a Discussion of Expanded Access for Devices and Post-Marketing Approval Studies <em>(Ask the Federal Representatives I Track)</em></td>
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<tr>
<td></td>
<td>Robert Bienkowski, Sally Hojvat, Stephen Rhodes, Marian Serge</td>
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<tr>
<td>B3</td>
<td>A Conversation With The National Science Foundation (NSF) <em>(Ask the Federal Representatives II Track)</em></td>
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<tr>
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<td>Kellina Craig-Henderson</td>
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<tr>
<td>B4</td>
<td>Crafting a Fair and Responsive Consent Process, Including the Identification of Legally-Authorized Representatives <em>(Basics for Beginners Track)</em></td>
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<tr>
<td></td>
<td>Susan Delano, Laura Odwazny</td>
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<tr>
<td>B5</td>
<td>From Then 'Til Now: Community Member Involvement in the Research Review Process <em>(Community Track)</em></td>
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<tr>
<td></td>
<td>Glen Ellis, Steve Peckman</td>
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<tr>
<td>B6</td>
<td>Subject Protection Education for Investigators, Coordinators, and Other Research Personnel <em>(Education Track)</em></td>
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<tr>
<td></td>
<td>Elizabeth Beattie, Charlotte Coley, Kathleen Uscinski</td>
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<tr>
<td>B7</td>
<td>Setting up an ESCRO - The Mission, the Mechanics, and the Multiple Oversight Committees Involved (e.g., IRBs and IACUCs) <em>(Ethical Issues Track)</em></td>
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<tr>
<td></td>
<td>Kate Heffernan, Steve Jaffe, Pearl O’Rourke</td>
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<tr>
<td></td>
<td>Jeffrey Cooper, Freda Yoder</td>
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<tr>
<td>B9</td>
<td>What the Subparts Say About Vulnerable Subjects, and Translating the Mandates Into Institutional Policies <em>(Federal Regulations II Track)</em></td>
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<tr>
<td></td>
<td>Lynda Lahl, Elana Newman, Barbara Stanley</td>
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<tr>
<td>B10</td>
<td>How IRBs Should Handle Incidental Findings <em>(Late Breaking Track)</em></td>
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<td></td>
<td>Elizabeth Hohmann, David Strauss</td>
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<tr>
<td>B12</td>
<td>Informed Consent in Phase I Oncology Research: What Are the Obligations to the Subject, and How Detailed Must the Consent Be? (Informed Consent Track)</td>
</tr>
<tr>
<td>B13</td>
<td>Fiscal Compliance for Institutional Officials, Including the New Rules for Medicare Coverage for Clinical Trials and Their Impact on Research (Institutional Officials Track)</td>
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<tr>
<td>B14</td>
<td>Community Advisory Boards: Their Purpose, Their Role in Research, and Ways to Maximize Their Effectiveness (International/Cross-Cultural Track)</td>
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<tr>
<td>B15</td>
<td>Biomedical IRB Chairs’ Forum: It’s a Tough Job, but Somebody Has to Do It! (IRB Chairs Track)</td>
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<tr>
<td>B16</td>
<td>The Basics of Operating an IRB Office (IRB Operations Track)</td>
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<tr>
<td>B17</td>
<td>Senior IRB Professionals Forum: A Q&amp;A to Help Develop Solutions for Common Challenges Faced by Experienced Administrators (IRB Professionals – Advanced Track)</td>
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<tr>
<td>B18</td>
<td>Encouraging Researchers to Use Plain Language: Strategies, Tools, and Resources for Creating Readable Consent Forms and Other Participant Materials (IRB Tool Kit Track)</td>
</tr>
<tr>
<td>B19</td>
<td>IBCs and IRBs in the Oversight of Human Gene Transfer Research: Creating Synergy and Optimizing both the Protocol Review and Consent Processes (Late Breaking Track)</td>
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<tr>
<td>B20</td>
<td>A Survey of the Essential Laws and Policies: Ensuring Privacy Protections for Research Subjects (Legal/Legislative Track)</td>
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<tr>
<td>B21</td>
<td>Post-Approval Monitoring: Effective Models From Small, Mid-Sized, and Large Institutions (Oversight Monitoring Track)</td>
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<tr>
<td>B22</td>
<td>Developing Ethics Guidelines for HIV Prevention Research With Drug Users (Populations Requiring Additional Protections Track)</td>
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</table>
Poster Presentation – Bang for the Buck? Juice for the Squeeze? Getting the Most Out of Your IRB (Poster Abstracts Track) Kent
Moderator: David Borasky
[Please note: This track includes those posters and/or abstracts judged to be of high interest and/or utility to the attendees.]

Strategies for Dealing Effectively With Your Local IRB (Principal Investigators and the Research Team Track) Brad Noren

Advanced Survival Skills for IRB Professionals: Avoiding Burnout and Keeping Your Job Manageable (Professional Development Track) Michelle Christiano, Elizabeth Cothran

Research Involving Adolescents: Rights, Responsibilities, and Special Issues (Research With Children Track) Bruce Gordon, John Santelli, Susan Sniderman

The Interpretation and Application of “Prospect of Direct Benefit” in Emergency Research Under 21 CFR 50.24 and Pediatric Research under 21 CFR 50.52 (Risk-Benefit Track) Sara Goldkind, Robert Nelson

Back to School: “Lessons” in Reviewing and Monitoring School-Based Research (SBER I Track) Tracy Arwood, William Stokes


Understanding Common Study Designs and How Protocols for Each Are Reviewed (Science for the Non-Scientist Track) J. Michael Oakes

5:45 – 7:00 PM Peruse Our Posters, Meet Our Exhibitors, and Join Us for a “Focus on the Feds” Curbstone Reception in The Conference Connection! Don’t Miss the “Best Practices Poster Parade” and the chance to meet our federal friends and exhibitors!

7:00 – 8:15 PM Dinner on Your Own The Greater Boston Convention & Visitors Bureau will be on hand to make dining recommendations and reservations for attendees. This service is complimentary to HRPP attendees.
### Movie Night

Whether you wish to escape or engage, join your HRPP colleagues at a showing of either The Doctor or Hairspray.

The Doctor, starring William Hurt, is the story of an arrogant surgeon who is mean to his patients, until he is diagnosed with throat cancer and gets a “taste of his own medicine.”

Hairspray, the 2007 musical film, is an adaptation of the Tony Award-winning 2002 Broadway musical of the same name. Set in 1962 Baltimore, the film follows a “pleasantly plump” teen named Tracy Turnblad as she simultaneously pursues stardom as a dancer on a local TV show and rallies against racial segregation. Popcorn will be served at these complimentary movies.

### Research Ethics Book Group

Please join PRIM&R for its second annual Research Ethics Book Group! This year’s selection, Allegra Goodman’s award-winning novel Intuition, portrays the struggles of researchers in the fictional, under funded Philpott Institute, who are seemingly on the brink of discovering a possible cure for cancer. Discussion questions will be provided, and dessert and coffee will be served at this complimentary event.

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### Monday, December 3, 2007

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<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>7:00 AM</td>
<td>Registration Opens</td>
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<tr>
<td>7:00 – 8:00 AM</td>
<td>Continental Breakfast for Conference Attendees</td>
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<td><em>This breakfast is partially supported by Huron Consulting Group.</em></td>
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<tr>
<td>7:00 – 8:00 AM</td>
<td>Continental Breakfast for Those Interested in Learning More About the CIP Certification Credentialing Process</td>
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<td><em>Interested in earning your CIP® (Certification of IRB Professionals)? Want to connect with “CIPers”? Stop by the CIP Breakfast to learn more and to meet representatives of the Council for Certification of IRB Professionals.</em></td>
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<tr>
<td>8:00 – 8:15 AM</td>
<td>Welcome &amp; Presentation of ARENA Legacy Award</td>
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<td><em>Susie Hoffman</em></td>
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<tr>
<td>8:15 – 9:00 AM</td>
<td>Keynote Address: Special Challenges Facing IRBs When Reviewing Genetic Research</td>
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<td><em>Wylie Burke</em></td>
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<td>9:00 – 9:15 AM</td>
<td>Commuting Time (i.e., no food, just time to get to your sessions!)</td>
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<tr>
<td>9:15 – 10:30 AM</td>
<td>Panel V: Desperately Seeking Experimental Therapies: Compassionate Use and Expanded Access</td>
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<tr>
<td>Concurrent</td>
<td>Moderator: Jeremy Sugarman</td>
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<td>Panelists: George Demetri, Steve Walker, Mark Wilenzick</td>
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<tr>
<td>Concurrent</td>
<td>Moderator: Robert Levine</td>
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<td>Debaters: Phil Rubin, Jerry Menikoff</td>
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<td>10:30 – 11:00 AM</td>
<td>Coffee, Commuting, and “Communing” Time</td>
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<td>This break is partially supported by Click Commerce.</td>
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<tr>
<td>11:00 AM – 12:15 PM</td>
<td>Didactic Sessions and Workshop Series C</td>
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<tr>
<td>C1</td>
<td>What Are the Most Challenging Issues in Becoming Accredited?</td>
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<tr>
<td>(Accreditation Track)</td>
<td>Lisa Ballance, Karen Hale</td>
</tr>
<tr>
<td>C2</td>
<td>A Conversation With NIH: New Directions in Research, Developments in Policy Harmonization, and Updates on Grants Management and Oversight (Ask the Federal Representatives I Track)</td>
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<td>Sarah Carr, Alan Fleischman, Amy Patterson, Laura Rodriguez</td>
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<td>[Please note this is a double session and will end at 1:05 PM. A boxed lunch will be served. Pre-registration was required to attend this session.]</td>
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<tr>
<td>C3</td>
<td>A Conversation with the Department of Veterans Affairs Office of Research and Development, Including an Update on the VA Central IRB and Accreditation (Ask the Federal Representatives II Track)</td>
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<td>Lynn Cates, Marisue Cody</td>
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<td>[Please note this is a double session and will end at 1:05 PM. A boxed lunch will be served. Pre-registration was required to attend this session.]</td>
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<tr>
<td>C4</td>
<td>Exempt, Expedited, or Full Board? Which Type of Review Is Appropriate? (Basics for Beginners Track)</td>
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<td>Deborah Barnard, Betsy Ripley, Lisa Rooney, Ada Sue Selwitz</td>
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<tr>
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<td>[Please note this is a double session and will end at 1:05 PM. A boxed lunch will be served. Pre-registration was required to attend this session.]</td>
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Let’s Review a Protocol! An Interactive “How-To” for the Non-Scientist (Community Track)  
Judith Brookshire, Kip Kantelo 
[Please note this is a double session and will end at 1:05 PM. A boxed lunch will be served. Pre-registration was required to attend this session.]

Educating IRB Administrators and Members About the Methods Used in Social and Behavioral Research (Education Track)  
Jonathan Miller, Nancy Shore

The “Higher Good:” Balancing Regulatory Compliance and Ethical Decision-Making... Case Studies at the Edge (Ethical Issues Track)  
Charles McCarthy, Don Workman

Required Criteria for IRB Approval of Research (Federal Regulations I Track)  
Lauren Privitera, Freda Yoder

Science for the Non-Scientist: Controlled Clinical Trials, Including Randomized and Placebo-Controlled Designs

Robert Levine 
[Please note: The session on the NIH Review of Human Gene Transfer Protocols has been moved to A3. The new topic is a late addition to the program and has been included in the Federal Regulations II Track even though it will not address federal regulations.]

A Guide for the Perplexed: Navigating OHRP’s, FDA’s and NIH’s Expectations for Reporting Adverse Events and Unanticipated Problems (Hot Spots Track)  
Mike Carome, Sara Goldkind, Amy Patterson 
[Please note this is a double session and will end at 1:05 PM. A boxed lunch will be served. Pre-registration was required to attend this session.]

Ancestry Can Be Revealed in Our Genome: Is This a Risk or Benefit to Clinical Trial Subjects? (Industry Track)  
Barbara Handelin 
[Please note this is a double session and will end at 1:05 PM. A boxed lunch will be served. Pre-registration was required to attend this session.]

Strategies for Improving Consent Forms: Reducing the Length, Enhancing the Readability, Appropriately Characterizing the Risks, and More! (Informed Consent Track)  
Mari-Lynn Drainoni, Michael Paasche-Orlow 
[Please note this is a double session and will end at 1:05 PM. A boxed lunch will be served. Pre-registration was required to attend this session.]

Indicates session will be taped for CD-ROM Proceedings  
Indicates didactic session (attendees mostly listen…)  
Indicates a Double Session which includes both lecture and discussion  
Indicates workshop (attendees talk too!)  
Indicates an abstract submission accepted for presentation  
Receives CME Credit
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<tr>
<td>C13</td>
<td>Institutional Alternatives to Local IRBs: Central IRBs, Consortia, Commercial IRBs, and Other Models for Research Review</td>
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<td>C14</td>
<td>Ethical Guidance in HIV Prevention Trials</td>
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<tr>
<td>C15</td>
<td>Dealing With Difficult People: Anger Management (Yours and Theirs), and Oral and Written Communication Skills</td>
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<td>C16</td>
<td>Special HRPP/IRB Concerns for Small and Mid-Sized Institutions (i.e., Those Reviewing Fewer Than 500 Protocols per Year)</td>
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<td>C17</td>
<td>Facilitating Cooperative Research: Managing IRB Authorization Agreements and Unaffiliated Investigator Agreements</td>
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<td>C18</td>
<td>Finding Flexibility in the Regulations When Reviewing and Conducting Social, Behavioral, and Educational Research</td>
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<td>C19</td>
<td>Challenges in Research Involving Human Tissues, Other Specimens, and Data Repositories</td>
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<td>C20</td>
<td>The Growth of Research Compliance Offices and Their Relationship to the IRB, the Institution's Legal Office, and the Institutional Official</td>
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<tr>
<td>C21</td>
<td>The Nuts and Bolts of Conducting an Audit</td>
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</table>
C22 Reviewing Research Involving Adults With Impaired Decision-Making Capacity (Including a SACHRP Update)  
(Populations Requiring Additional Protections Track)  
Paul Andreason, Paul Appelbaum, Julia Gorey, David Strauss  
[Please note this is a double session and will end at 1:05 PM.  
A boxed lunch will be served. Pre-registration was required to attend 
this session.]  

C23 Poster Presentation – Research about IRB Members  
(Poster Abstracts Track) Moderator: Suzanne Fitzpatrick  
[Please note: This track includes those posters and/or abstracts judged to 
be of high interest and/or utility to the attendees.]  

C24 Institutional Strategies for Facilitating Ethical and Regulatory Compliance of Investigators  
(Principal Investigators and the Research Team Track)  
Leslie Ball, Karena Cooper, Tejashri Purohit-Sheth, Kirstin Rochford  

C25 Ask Us About Certification for IRB Professionals (CIP®): Types of Questions, How to Prepare, and How to Know If This Test Is For You!  
(Professional Development Track)  
Gary Chadwick, Susan Delano  

C26 Assent to Pediatric Clinical Research: Ethics, Regulations, and Innovation  
(Research With Children Track)  
Steve Joffe, Elyse Summers  

C27 How Does the Risk-Benefit Assessment Apply to Social, Behavioral, and Educational Research?  
(Risk-Benefit Track)  
Lorna Hicks, Simon Whitney  

C28 The Great Debate! The Tension Between IRB Review and Academic Freedom/the First Amendment (Debate Follow-Up)  
(SBER I Track)  
Jerry Menikoff, Phil Rubin  

C29 Ethical and Practical Challenges Facing the IRB When Reviewing Action-Based Research in Schools  
(SBER II Track)  
Erica Heath, William Stokes  

C30 Understanding the Basics of the Scientific Process: The Science of Thinking Scientifically  
(Science for the Non-Scientist Track)  
Joan Sieber  

12:15 – 1:15 PM Luncheon for Conference Attendees
12:15 – 1:15 PM Luncheon for Users, or Potential Users, of the National Cancer Institute’s Central IRB (CIRB) Constitution A

Moderators: Susan Corl, Jacquelyn Goldberg, Bruce Gordon, Gwenn Oki

This session will provide a facilitated forum for a dialogue among those who administer, chair, or otherwise have an interest in the adult or pediatric NCI CIRB. The session will cover best practices in hopes of ensuring that institutions joining the NCI CIRB do not have to reinvent policies and procedures for implementation of the facilitated review process. This luncheon will also provide an opportunity for networking and shared problem-solving. There is no additional charge, but Pre-registration was required. A boxed lunch will be served.

1:15 – 1:30 PM Commuting Time (i.e., no food, just time to get to your sessions!)

1:30 – 2:45 PM Panel VII: Autonomy and Voluntariness – Current Controversies Regarding Informed Consent in Research Hynes Veteran’s Auditorium

Moderator: Alex Capron
Panelists: Paul Appelbaum, Alan Wertheimer, Simon Whitney

1:30 – 2:45 PM Panel VIII: Beyond the Subparts: The Impact of an Expanded View of Vulnerable Populations on Social, Behavioral, and Educational Research Hynes Ballrooms A-C

Moderator: Sangeeta Panicker
Panelists: Andre Ivanoff, Elana Newman, David Strauss

2:45 – 3:15 PM Coffee, Commuting, and “Communing” Time

This break is partially supported by iMedRIS Data Corporation.

3:15 – 4:30 PM Didactic Sessions and Workshop Series D

D1 After the Site Visit: The Organization’s Response (Accreditation Track) Lisa Ballance, Gary Chadwick Hynes 201

D2 A Conversation With the Food and Drug Administration (Ask the Federal Representatives I Track) Leslie Ball, David Lepay, Joanne Less, Diane Maloney, Michael Marcarelli, Robert Nelson Berkeley

D3 A Conversation with the Department of Defense: “So You’re Engaged In Research with the DoD – Now What?” An Update on DoD Human Subjects Protection Requirements (Ask the Federal Representatives II Track) DOD representatives Hynes 200

D4 Examining and Enhancing the Consent Process When Conducting Research With Vulnerable Populations (Basics for Beginners Track) Paul Appelbaum, Nancy Kass Back Bay D

✓ Indicates session will be taped for CD-ROM Proceedings
✓ Indicates workshop (attendees talk too!)
✓ Indicates an abstract submission accepted for presentation
✓ Indicates a Double Session which includes both lecture and discussion

Indicates didactic session (attendees mostly listen…)

Receives CME Credit
The “Psychology” of An IRB Meeting  (Community Track)  
Kenneth Von Kluck, Don Workman  
Hynes 202

Educating Biomedical IRB Administrators and Members About the Social and Behavioral Aspects of Medical Protocols  
(Education Track)  Dale Hammerschmidt, Miriam Kelty  
Hynes 205

Autonomy Versus Beneficence in Protocol Review: Where Is the Balance?  
(Ethical Issues Track)  Celia Walker, Alan Wertheimer  
Back Bay A

Regulatory Considerations for IRBs: Documentation Requirements, Including IRB Determinations, IRB Membership, Quorum Requirements, Minutes, and Other Record-Keeping Procedures  
(Federal Regulations I Track)  Kevin Nellis, Richard Wagner  
Hynes 210

A Conversation With the Office for Human Research Protections  
(Federal Regulations II Track)  Kristina Borror, Mike Carome, Shirley Hicks, Julie Kaneshiro, Melody Lin, Laura Odwazny, Irene Stith-Coleman  
Fairfax

Internet Research: Doing “Virtual” Research Virtuously  
(Hot Spots Track)  Jeffrey Cohen, Simon Rosser  
Hynes 306

Strategies for Enhancing Relationships Between IRBs and Industry: A Dialogue with Members of the IRB-Industry Roundtable  
(Industry Track)  Maureen Hardwick, Lindsay McNair, Brad Noren  
Dalton

Ensuring Full and Ethical Disclosure of Investigator Conflicts of Interest as Part of the Informed Consent Process  
(Informed Consent Track)  Chris Clark, Heather Fields  
Commonwealth

What Do We Mean by “Integrated Compliance:” How to Harmonize the IRB, the Compliance Office, the IACUC, and the IBC  
(Institutional Officials Track)  Elizabeth Bankert, Richard Bianco  
Hynes 203

The Expanding Scope of International Trials: Developing Appropriate Ethical Oversight When Doing Research in Emerging Markets  
(International/Cross-Cultural Track)  Karen Hansen, Justin McCarthy, Walter Strauss  
Hynes 204

Social, Behavioral, and Educational Chairs’ Forum: It’s a Tough Job, but Somebody Has to Do It!  
(IRB Chairs Track)  David Bernhardt, Andre Ivanoff, Ann Nichols-Casebolt  
Gardner

Emergency Exception to Informed Consent: When and How?  
(IRB Operations Track)  Sara Goldkind, Paula Knudson, Ron Maio  
Republic A

✓ Indicates session will be taped for CD-ROM Proceedings  ☑ Receives CME Credit
☑ Indicates didactic session (attendees mostly listen…)  ◕ Indicates workshop (attendees talk too!)
✑ Indicates a Double Session which includes both lecture and discussion  🌱 Indicates an abstract submission accepted for presentation
D17 Processes for Handling Data or Specimen-Related “Not-Human-Subjects Research:” Determining Who Is Engaged, and When Coded Data/Specimen Use Is or Is Not “Research Involving Human Subjects” (IRB Professionals – Advanced Track)
Mark Barnes, Pearl O’Rourke, Elyse Summers

Hynes Veteran’s Auditorium

D18 HRPP Quality Improvement Programs in Action: What Are the Different Kinds of Monitoring Forms and Tools Developed for Use in QI Programs? (IRB Tool Kit Track)
Eunice Newbert, Susan Rose

Hynes 206

D19 Protecting Confidentiality, Including the NEW “Confidential Information Protection and Statistical Efficiency Act” (CIPSEA) (Late Breaking Track)
George Gasparis, Brian Harris-Kojetin, Caroline Miner

Independence West

D20 Handling Investigator Non-Compliance/Poor Compliance (Legal/Legislative Track)
James Kim, Sarah Putney, Delia Wolf

Hynes Ballrooms A-C

D21 External and Self-Assessment of IRB Compliance and Processes: It's Never Easy, but You'll Be Glad You Did It! (Oversight Monitoring Track)
Deborah Barnard, Anne Marie Hobson

Back Bay B

D22 Advanced Directives for Research (Populations Requiring Additional Protections Track)
Melissa Frumin

Exeter

D23 Poster Presentation – “We’re From the IRB and We’re Here to Help” – Improving the IRB’s Relationship with the Research Community (Poster Abstracts Track) Moderator: Jerry Castellano
[Please note: This track includes those posters and/or abstracts judged to be of high interest and/or utility to the attendees.]

Kent

D24 Obtaining Multiple IRB Approvals for a Single-Site Clinical Trial: Experiences and Recommendations (Principal Investigators and the Research Team Track)
Sharina Reyes, Jose Mendoza-Silveiras

Clarendon

D25 Handling Difficult Interactions with Subjects, Researchers, and/or Other Colleagues (Professional Development Track)
Simon Whitney

Independence East

D26 Talking and Listening to Parents of Research Subjects (Research With Children Track)
Insoo Hyun, Gigi McMillan

Beacon D

D27 The Use of Deception in Biomedical Research (Risk-Benefit Track)
Howard Mann

Back Bay C

D28 Beyond the Subparts: The Impact of an Expanded View of Vulnerable Populations on Social, Behavioral, and Educational Research (Panel Follow-up) (SBER I Track)
Elana Newman, Saneepta Panicker, David Strauss

Liberty C

Dean Gallant, Ivoir Pritchard

Liberty A/B

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Receives CME Credit
Welcome to the “Brave New World:” An Introduction to Genetics (Science for the Non-Scientist Track)
Barbara Handelin, Ingrid Holm

4:30 – 4:45 PM  Commuting Time (i.e., no food or drink, just time to get to your sessions!)

4:45 – 6:00 PM  Town Hall Meeting: Research Involving Decisionally Impaired Adults: What Can and Cannot Be Done in the Absence of Specific Federal Rules?
Moderator: David Strauss
Commentators: Sandra Alfano, Paul Appelbaum, Anne Donahue, Laurie Flynn, David Forster, Ramy Mahmoud, David Shore

4:45 – 6:00 PM  Town Hall Meeting: An Update on Clinical Trial Registries
Moderator: Alex Capron
Commentators: Pearl O’Rourke, Kathleen Uscinski, Deborah Zarin

This Town Hall Meeting will provide a chance to learn-and ask questions about-the new requirements related to clinical trial registries. The recent passage of Public Law 110-85 requires the registration of all phase 2 through 4 drug studies (regardless of sponsor) and all non-feasibility device studies with ClinicalTrials.gov, effective December 26, 2007. In addition, as of September 26, 2008, trial sponsors must submit summary results data, both published and unpublished, for trials of approved drugs or devices within 12 months of the trial completion date. Civil and monetary penalties, as well as administrative sanctions, apply for non-compliance. This meeting will include the perspectives of medical journal editors, who have their own expectations and issues regarding trial registrations and representatives from research institutions, who will explore the impact of registry requirements on local investigators, IRBs, DSMBs and compliance offices. Come discuss how you will grapple with this new set of obligations and explore a complex set of new topics, such as institutional policies for studies not covered by PL 110-85, collaborative trials with international partners from countries developing their own CTRs, responding to global standards set by WHO or state legislative initiatives in the face of federal preemption, and the relationship to DSMB processes.

4:45 – 6:00 PM  Speed Mentoring
Join us for a networking event at which you can ask experienced HRPP professionals those “everything-you’ve-always-wanted-to-know-but-didn’t-know-where-to-ask” questions. The room will be ringed with tables with a mentor seated at each one. You will start at a randomly assigned table, and will move through several different mentor tables throughout the event, thereby allowing you to interact with several mentors during a short period of time. This informal “speed mentoring” (“speed dating” ain’t got nothing on us!) will enable you to ask questions and get advice from knowledgeable and high profile professionals with decades of experience in the HRPP field. All are welcome! Light refreshments will be served.
8:00 – 10:00 PM  
**Texas Hold ’Em**  
*If you enjoy, or think you might enjoy, Texas Hold ‘Em, please join us for a sure-to-be-fun night of poker for all levels of players! Beginners can learn the game, intermediates can improve theirs, and more advanced players can “strut their stuff.” Come one, come all, as this is an entirely complimentary event and there are no entry fees. There are, though, prizes for the winners of each table so sit right down and see if it’s your lucky day (or night)!. Please sign-up at Help Desk in the Hynes Prefunction Hall C by 12:00 on Monday in order to reserve your seat at a table!!  
Dessert and coffee/tea will be served.

8:00 – 10:30 PM  
**Karaoke, Dancing, and DJ**  
*Join us for an evening of dancing, karaoke, and FUN! This event is complimentary and dessert and coffee will be served.*

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**Tuesday, December 4, 2007**

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<th>Time</th>
<th>Event</th>
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<tr>
<td>7:00 AM</td>
<td>Registration Opens</td>
<td>Hynes Prefunction Hall C</td>
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<tr>
<td>7:15 – 8:15 AM</td>
<td>Continental Breakfast</td>
<td>Hynes Hall D</td>
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</tbody>
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| 8:15 – 9:00 AM| Keynote Address: *Race, Ethnicity, and Disease in the Age of Genetic Medicine*  
*Keith Wailoo* | Hynes Veteran’s Auditorium                                           |
| 9:00 – 9:15 AM| Commuting Time (i.e., no food or drink, just time to get to your sessions!) |                           |
| 9:15 – 10:30 AM| **Panel IX: What Do We Know About How HRPPs Work?**                 | Hynes Veteran’s Auditorium |
|               | **Concurrent**                                                       |                           |
|               | Moderator: *Ivor Pritchard*                                          |                           |
|               | Panelists: *Raymond De Vries, Jan Jaeger, Charles Lidz*              |                           |
| 9:15 – 10:30 AM| **Panel X: Social Behavioral Research In and With the Community**   | Hynes Ballrooms A-C       |
|               | **Concurrent**                                                       |                           |
|               | Moderator: *Nancy Shore*                                             |                           |
|               | Panelists: *Sarah Flicker, Simon Rosser, Scyatta Wallace*            |                           |
| 10:30 – 11:00 AM| Coffee, Commuting, and “Communing” Time                             | Sheraton Foyer & Hynes Prefunction Hall C |

11:00 AM – 12:15 PM  
**Didactic Sessions and Workshop Series E**  

**E1**  
**Re-Accreditation - Has It Been Three Years Already?**  
*(Accreditation Track)* *Denise Roe*  

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A Conversation With the Office for Human Research Protections  [Please note: This is a repeat of session D9.]  
(Ask The Federal Representatives I Track)  
Kristina Borror, Mike Carome, Shirley Hicks, Julie Kaneshiro, Melody Lin, Irene Stith-Coleman, Ivor Pritchard  

A Conversation with the Department of Defense: Achieving Economies in DoD Human Research Review  
(Ask the Federal Representatives II Track)  
DOD representatives  

What Happens After the Protocol is Approved? Understanding and Handling Continuations, Modifications, Adverse Events, Advertisements, and Post-Approval Monitoring  
(Basics for Beginners Track)  
Brenda Ruotolo, Carol Weil  

A Common Identity Crisis for Community Members: Which Part of the “Community” Are We Supposed to Represent?  
(Community Track)  
David Bernhardt, Glen Ellis  

Implementing Quality Improvement Recommendations: How to Effectively Translate Findings From Specific Reviews/Assessments to Your Institution’s Research Community  
(Education Track)  
Eunice Newbert, Delta Wolf  

The Practical Implications of Informed Consent’s Ethical Underpinnings  
(Ethical Issues Track)  
Matt DeCamp, Toby Schonfeld  

A Conversation with the Department of Veterans Affairs Office of Research Oversight  
(Federal Regulations I Track)  
Joan Porter, Thomas Puglisi, Paula Waterman  
[Please note this is a double session and will end at 1:05 PM. A boxed lunch will be served. Pre-registration was required to attend this session.]  

The FDA’s Investigational New Drug (IND) and Investigational Device Exemption (IDE) Regulations  
(Federal Regulations II Track)  
Patricia Holobaugh, Tejashri Purohit-Sheth, Stephen Rhodes  
[Please note this is a double session and will end at 1:05 PM. A boxed lunch will be served. Pre-registration was required to attend this session.]  

Cancer Centers: How Do They Conduct Scientific Review and IRB Review, and Where Is There Overlap and Redundancy?  
(Hot Spots Track)  
Paul Papagni, Michele Russell-Einhorn  

The IRB’s Role in Negotiating and Monitoring Contracts and Budgets: How Involved Are Most IRBs in the Financial Details?  
(Industry Track)  
Geoff Grant, Heather Fields  

Can Informed Consent Be Obtained for Future Unspecified (Data and/or Specimen) Research?  
(Informed Consent Track)  
Clement Adebamowo, Sally Hojvat
The Role of the Institution and the Institutional Official in Handling a Federal Inquiry  
(Institutional Officials Track) 
Elizabeth Bankert, David Clark, Lisa Rooney

Strategies for Success and Issues for Consideration for U.S. IRBs New to International Research  
(International/Cross-Cultural Track) 
David Borasky

The Role of an IRB Chair in the Regulatory Review of Emergency or Urgent Approvals  
(IRB Chairs Track) 
Anne Dougherty, Thomas Foster

So You Think You Could Do Expedited Review as Well as Non-Staff Members? Well You Can!  
(IRB Operations Track) 
Moira Keane, Carol Siegel

Your Chance to “Fool with the Common Rule:” An Update on SACHRP’s Subpart A Recommendations and an Opportunity for Input on Regulatory Interpretations  
(IRB Professionals – Advanced Track) 
Karen Hale, Susie Hoffman, Daniel Nelson 
[Please note this is a double session and will end at 1:05 PM. A boxed lunch will be served. Pre-registration was required to attend this session.] 

Challenges Presented By Exiting Faculty: Ownership of…Intellectual Property Rights, Confidential Patient/Subject Information, HIPAA Concerns, Tissue Samples, Etc.  
(IRB Tool Kit Track) 
Susan Stayn, Howard Mann

What Every IRB Needs to Know About the Genome Wide Association (GWAS) Policy  
(Late Breaking Track) 
Marianna Bledsoe, Pearl O’Rourke, Laura Lyman Rodriguez 
[Please note this is a double session and will end at 1:05 PM. A boxed lunch will be served. Pre-registration was required to attend this session.] 

Readability Versus Liability in Consent Forms: Removing Exculpatory Language and Ensuring That Consent Documents Are Not Confused With Clinical Trial Agreements  
(Legal/Legislative Track) 
Todd Guttman, John Mills

IRB Review of Data Safety Monitoring Plans: What Should the IRB Look for in a Plan, and How Much Leverage Does the IRB Really Have?  
(Oversight Monitoring Track) 
Robert Bienkowski, John Isidor
Biomedical and Social/Behavioral Research With Prisoners: Subpart C, SACHRP Recommendations, the NAS/IOM Report, and Perspectives From the Field (Populations Requiring Additional Protections Track)
Julia Gorey, Elizabeth Mendelsohn, Virginia Morrison, Wendy Visscher
[Please note this is a double session and will end at 1:05 PM. A boxed lunch will be served. Pre-registration was required to attend this session.]

Poster Presentation – Research about Informed Consent (Poster Abstracts Track) Moderator: Melissa Epstein
[Please note: This track includes those posters and/or abstracts judged to be of high interest and/or utility to the attendees.]

Conflicts of Interest Go Beyond Dollars! How Financial and Non-Financial Conflicts of Interest Can Cause a PI to Compromise or Lose Objectivity (Principal Investigators and the Research Team Track) Mark Barnes, Ruth Fischbach

Economic Issues for IRBs: Ensuring Efficient Administration, Operation, Function, and Appropriate Staffing and Activity Levels (Professional Development Track) Tanna MacReynold, Kathleen Uscinski

Applying Subpart D and the SACHRP Report to Difficult Cases (Research With Children Track)
Susan Kornetsky, Kevin Prohaska, Mark Schreiner

The Hidden Alternative: Are Consent Forms Disclosing the Option of Getting a New Treatment Without Participating in the Study? (Risk-Benefit Track) Jerry Menikoff

Social Behavioral Research In and With the Community (Panel Follow-Up) (SBER I Track)
Sarah Flicker, Simon Rosser, Nancy Shore, Scyatta Wallace

The Kids are Alright! Research On and By Students (SBER II Track) J. Michael Oakes, Celia Walker
[Please note this is a double session and will end at 1:05 PM. A boxed lunch will be served. Pre-registration was required to attend this session.]

Social and Behavioral Research: What’s Different and What’s the Same Irrespective of the Type of Research or the Type of IRB? (Science for the Non-Scientist Track)
Monika Markowitz, Betsy Ripley

12:15 – 1:05 PM Luncheon

1:05 – 1:15 PM Commuting Time (i.e., no food or drink, just time to get to your sessions!)
1:15 – 2:30 PM  Panel XI: *Assessing and Reviewing Intercultural Research from Multi-National Perspectives*  
**Hynes Veteran’s Auditorium**  
**Moderator:** Patricia Marshall  
**Panelists:** Clement Adebamowo  
Joe Carrese  
Nancy Kass  
Robert Ssekubugu

1:15 – 2:30 PM  Panel XII: *Law and Order: The IRB and Criminal Justice Research*  
**Hynes Ballrooms A-C**  
**Moderator:** J. Michael Oakes  
**Panelists:** Thomas Grisso  
Angela Robertson

2:30 –3:00 PM  Coffee, Commuting, and “Communing” Time  
This break is partially supported by IRBNet (Research Dataware, LLC).

3:00 – 4:15 PM  Didactic Sessions and Workshop Series F

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<td><strong>Overseeing Change Control of Written Procedures During the</strong></td>
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<td><strong>AAHRPP Accreditation Process</strong></td>
<td><strong>Hynes 200</strong></td>
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<td>F2</td>
<td><strong>Check Out the Office of Research Oversight’s Checklists for the</strong></td>
<td><strong>Fairfax</strong></td>
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<td><strong>Protection of Human Subjects: An Interactive “Show and Tell”</strong></td>
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<td><strong>About Tools for Research Compliance</strong></td>
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<td><em>(Ask the Federal Representatives I Track)</em></td>
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<td><strong>Joan Porter, Thomas Puglisi, Paula Waterman</strong></td>
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<td>F3</td>
<td><strong>Late Breaking! What the Federal Register Notice on Proposed</strong></td>
<td><strong>Beacon D</strong></td>
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<td><strong>Changes to the Expedited Review Categories Means for IRBs and</strong></td>
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<td><strong>Research</strong> <em>(Ask the Federal Representatives II Track)</em></td>
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<td><strong>Susan Fish</strong></td>
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<td><strong>Conversation With the Department of Energy session will not be held</strong></td>
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<td><strong>this year. The new topic is a late addition to the program.]</strong></td>
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<td>F4</td>
<td><strong>Q&amp;A for Beginners (You Provide the Questions and Seasoned</strong></td>
<td><strong>Hampton</strong></td>
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<td><strong>IRB Administrators Will Provide the Answers)</strong></td>
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<td><em>(Basis for Beginners Track)</em></td>
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<td><strong>Tracy Arwood, Michelle Christiano, Cynthia Edmonds</strong></td>
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<td>F5</td>
<td><strong>Ask the IRB Chair: A Wide-Ranging Q&amp;A on What the</strong></td>
<td><strong>Clarendon</strong></td>
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<td><strong>“Typical” Chair Expects from the “Typical” Community</strong></td>
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<td><strong>Member</strong> <em>(Community Track)</em></td>
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<td><strong>David Bernhardt, Anne Dougherty</strong></td>
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<td>F6</td>
<td><strong>Educating the Community About Human Subjects Protections</strong></td>
<td><strong>Hynes 206</strong></td>
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<td><strong>and Clinical Trial Participation</strong> <em>(Education Track)</em></td>
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<td><strong>Kate MacQueen, Brenda Ruotolo</strong></td>
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**Indicators:**  
✓ Indicates session will be taped for CD-ROM Proceedings  
✓ Indicates didactic session (attendees mostly listen…)  
✓ Indicates workshop (attendees talk too!)  
✓ Indicates a Double Session which includes both lecture and discussion  
✓ Indicates an abstract submission accepted for presentation  
✓ Indicates didactic session (attendees mostly listen…)  
✓ Indicates workshop (attendees talk too!)  
✓ Indicates a Double Session which includes both lecture and discussion  
✓ Indicates an abstract submission accepted for presentation
F7 Reviewing and Approving Informed Consent Processes and Forms in Cultures with Limited Literacy, or in Non-English Speaking/ESOL Populations (Ethical Issues Track)
Monika Markowitz, Betsy Ripley

F8 The Department of Health and Human Services and the Food and Drug Administration Waivers of Informed Consent (Federal Regulations I Track)
Susan Corl, Glen Drew, Suzanne Fitzpatrick, Michele Russell-Einhorn

F9 Regulatory Requirements for Informed Consent: How to Bring “Life” to the Process (Federal Regulations II Track)
Judith Forman, Richard Klein, Lynda Lahl

F10 When Should Clinical Innovations Be Subjected to Scientific Validation and Thus Come Under the Jurisdiction of the IRB? Surgeons and Beyond! (Hot Spots Track)
Mary Simmerling

F11 The Good Clinical Practice Program (GCP) and the IRB (Industry Track)
Paula Bistak, Carlotta Rodriguez

F12 How Consent Forms Commonly Fail to Adequately Provide Appropriate Information to Subjects, and Suggested Remedies for This Problem (Informed Consent Track)
Leonard Glantz, Jerry Menikoff

F13 Identifying and Addressing Both Individual Investigator and Institutional Conflicts of Interest (Institutional Officials Track)
Ronald Newbower, Julie Zadinsky

F14 Future Uses of Biologic Specimens Derived from Multi–Site International Research (International/Cross-Cultural Track)
David Borasky, Don Workman

F15 Recruitment and Retention Strategies: Achieving Diversity and Stability in IRB Membership (IRB Chairs Track)
Elizabeth Beattie, Elizabeth Hohmann

F16 Checking (or Unchecking) the Boxes: Pros and Cons of Applying the Federalwide Assurance to All Research (IRB Operations Track)
Dean Gallant, Susan Rose

F17 A Look Ahead: What Will Keep IRB Professionals Awake in the Wee Hours of 2008, and How to Minimize the Insomnia (IRB Professionals – Advanced Track)
Nancy Olson, Pearl O’Rourke

F18 Case Study: Summa Health System’s Adoption of IRBNet’s Electronic System for IRB Submissions, Approvals, Post-Approvals, and Audit Activities (IRB Tool Kit Track)
Rebecca Garner, Andrew Olmsted
(Late Breaking Track)  Casey Bush, Karen Moe

What Your Institution Needs to Know About Medicare’s Clinical Trial Policy  
(Legal/Legislative Track)  Christina Davis, Madeline Williams

Crafting and Implementing Effective Corrective Action Plans  
(Oversight Monitoring Track)  Karena Cooper, George Gasparis

Research in Critically Ill Populations: The “Therapeutic Misconception,” Substituted Judgment, and Other Ethical Issues  
(Populations Requiring Additional Protections Track)  Steven Davis

Poster Presentation – Enhancing Informed Consent  
(Poster Abstracts Track)  Moderator: Mark Hughes  
[Please note: This track includes those posters and/or abstracts judged to be of high interest and/or utility to the attendees.]

Ethical Issues in the Recruitment of Research Subjects  
(Principal Investigators and the Research Team Track)  Jean Amoura, Bruce Gordon, Toby Schonfeld

The Silent Majority: Raise Your Voice and Add Value to Your HRPP  
(Professional Development Track)  Suzanne Holguin, Mary Richards

Research Involving Vulnerable Populations of Children, Including Those Who are Abused (or Suspected of Being Abused), Wards of the State, Incarcerated, or Homeless  
(Research With Children Track)  Amaboo Dhai, William Freeman

Environmental Exposure Studies: Can They Be Ethically and Safely Done?  
(Risk-Benefit Track)  Warren Lux, Bob Truckner

Law and Order: The IRB and Criminal Justice Research  
(Panel Follow-Up)  (SBER I Track)  Thomas Grisso, Angela Robertson

Research Review for Social, Behavioral, and Educational Research Outside the United States  
(SBER II Track)  Edward Bartlett, Lorna Hicks

Ethical Issues in Qualitative/Non-Traditional Research That Is Otherwise Exempt from the Federal Regulations  
(Science for the Non-Scientist Track)  Michael Nurok

4:15 – 4:30 PM  Commuting Time  (i.e., no food or drink, just time to get to your sessions!)
4:30 – 5:45 PM  Panel XIII: *Introducing our Abstract Winners*

**Concurrent**

This plenary session will be made up of six or seven concurrent “mini-panels,” representing those presentations selected by the Planning Committee from abstracts that were submitted for panel presentation. We’re thrilled to be bringing our audience great strategies from you and for you!

**Panelists and Topics:**

1. **Ethical Issues With Human Embryonic Stem Cell Research:**
   *Beyond the Moral Status of the Embryo* – Sandra Alfano, Insoo Hysun, Patrick Taylor  
   Hynes 202

2. **Behavioral Trials: Understanding the Safety Risks** – Kathleen Carroll, Felix Gyi, Peter Kaufmann, Robert Lindblad  
   Hynes 203

3. **The Challenges of Integrating Research Oversight Programs of the Army, Navy, Air Force Medical Centers and Uniformed Services University in the National Capital Area** – Audrey Chang, Eileen Dauer, Deborah J. Kenny, Mary Klote, Sarathy Komandouri, Jeff Lenert, Charles McQueen  
   Hynes 302

4. **Is a Comprehensive Adverse Event Reporting System in Human Subject Research a Realistic Possibility?** – Joan M. Caron, Nicholas A. DeMartinis, Gustavo Fernandez, David Silverman, Richard Simon  
   Hynes 304

5. **Eliminating Disparities in Clinical Trials: An Ethical, Economic, and Scientific Imperative** – Dan Bustillos, Barbara Pence, James Powell, Armin Weinberg  
   Hynes 306

4:30 – 5:45 PM  Panel XIV: *Hot Topics in Social, Behavioral, Educational Research*

**Concurrent**

**Moderator:** Joan Rachlin  
**Panelists and Topics:**

1. Research With Military Personnel – Tora Bikson  
2. Subject Pools – J. Michael Oakes  
3. International Student Research – Sumiaa Al-Fadil

5:45 – 7:00 PM  Closing Reception – Wine, Cheese, and Fond Farewells!

**Boylston Street Hall**  
Hynes 3rd Floor