Wednesday, November 15, 2006

7:00 AM  Registration Check-in Opens  
Atrium

Pre-Conference Educational Programs – Separate registration required.

8:30 AM – 5:30 PM  Advanced Research Ethics  
Cotillion Ballroom

8:30 AM – 4:15 PM  Embryonic Stem Cell Research Oversight Committees (ESCROs) and Institutional Review Boards (IRBs): Meeting the Challenges  
Washington 6

8:30 AM – 5:00 PM  Hot Topics for Institutional Officials  
Washington 5

8:30 AM – 5:00 PM  Institutional Biosafety Committee (IBC) Basics  
Delaware

8:30 AM – 4:00 PM  Institutional Review Board (IRB) 101™ – Biomedical Research  
Washington 4

8:30 AM – 4:00 PM  Institutional Review Board (IRB) 101™ – Social/Behavioral/Educational Research (SBER)  
Washington 3

8:30 AM – 4:15 PM  Institutional Review Board (IRB) 201  
Virginia

8:30 AM – 4:15 PM  Institutional Review Board (IRB) 250: Selected Topics  
Maryland

8:30 AM – 4:00 PM  What Does it Mean to Represent the Community? A Primer on Community Participation  
Washington 2

5:00 – 7:00 PM  Networking Reception & Membership Celebration in The Conference Connection  
Exhibit Hall C

7:00 – 8:15 PM  Liz Lerman Dance Exchange  
Liz Lerman will discuss, and dancers will perform excerpts from, Ferocious Beauty: Genome which was created to probe via movement and music what is occurring in the laboratories of genetic science, and what this kind of research will have on our lives. With grace, humor, and unforgettable images, Ferocious Beauty: Genome explores tough questions about how our lives may change as the genome revolution advances upon us. The project is the result of a three year collaboration among a national group of scientists, bioethicists, researchers, clergy, and artists who bring their best thinking to bear on the promise and threat of a new biological age.  
Marriott Ballroom Salon 1

Indicates didactic session (attendees mostly listen…)

 Indicates workshop (attendees talk too!)

 Indicates session will be captured for proceedings

 Receives CME Credit

Indicates a Double Session which includes both lecture and discussion
Thursday, November 16, 2006

7:00 AM     Registration Check-in Opens  Atrium

7:00 – 8:30 AM  Continental Breakfast  Exhibit Halls A & B South

8:15 – 8:30 AM  Welcome and Conference Overview  Marriott Ballroom

8:30 – 9:15 AM  Keynote Address:  Home Plate, the Cheese Lady, and Bad Sonnets:  On the Limitations of Regulation  Marriott Ballroom
Samuel Gorovitz

Moderator:  Jeremy Sugarman
Panelists:  Mindy Fullilove  Carol Levine  Larry Palmer

10:30 – 11:00 AM  Coffee and Commuting Time  Marriott, Cotillion, & Washington Foyers

**Series A: Didactic Sessions/Workshops**

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Location</th>
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<tbody>
<tr>
<td>11:00 AM – 12:15 PM</td>
<td><strong>Accreditation: What’s Involved, What’s Required?</strong>  (Accreditation Track)  John Mather, Lynn Smith</td>
<td>Cotillion Ballroom</td>
</tr>
<tr>
<td>11:15 AM – 12:15 PM</td>
<td><strong>An Introduction to IRBs: Purposes, Challenges, and Responsibilities</strong>  (Basics for Beginners Track)  Connie Lewin, Shirley Hicks, Don Workman</td>
<td>Marriott Ballroom</td>
</tr>
<tr>
<td>11:30 AM – 12:15 PM</td>
<td><strong>Evaluating the Conflict of Interest (COI) Issues While Conducting an IRB Review</strong>  (Chairs and IRB Members Track)  Elizabeth Bankert, Heather Fields</td>
<td>Washington 3</td>
</tr>
<tr>
<td>12:00 PM – 12:45 PM</td>
<td><strong>Human Research Protection Education for Investigators and Other Research Personnel: Who Should Do It and How?</strong>  (Education Track)  Michele Copersino, Brenda Ruotolo, Susan Rose</td>
<td>Washington 5</td>
</tr>
<tr>
<td>12:15 PM – 12:45 PM</td>
<td><strong>How to Assess an Individual’s Capacity During the Informed Consent Process</strong>  (Ethical Issues In….Track)  Paul Appelbaum, David Strauss</td>
<td>Maryland C</td>
</tr>
<tr>
<td>12:30 PM – 12:45 PM</td>
<td><strong>When and How to Seek an Emergency Exception to Informed Consent</strong>  (Hot Spots Track)  Sara Goldkind, Julie Kaneshiro, Robyn Shapiro, Jeremy Sugarman</td>
<td>Balcony B</td>
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| Indicates didactic session (attendees mostly listen….) | Indicates a Double Session which includes both lecture and discussion |
| Indicates workshop (attendees talk too!) | Indicates session will be captured for proceedings |
| Receives CME Credit |
Clinical Trial Registries and Databases: Problems and Solutions
(Industry Track) [Please note this is a double session and will end at 1:15 PM. A boxed lunch will be served. Pre-registration was required to attend this session.] Alexander Capron, An-When Chan, Celia Fisher, Owen Hughes, Pearl O'Rourke

Identifying and Addressing Conflicts of Interest for Academic and Hospital-Based Review Boards, As Well As for Independent IRBs
(Institutional Officials Track) David Korn, David Wynes

Practical Issues to Consider When Engaging in International Research: Industry-Sponsors, Non-Academic Institutions, and More
(International/Cross Cultural Track) [Please note this is a double session and will end at 1:15 PM. A boxed lunch will be served. Pre-registration was required to attend this session.] Clement Adegbamowo, David Borasky, Drew Lewis, Sergio Santillana, Walter Strauss

The Relationship Between ESCROs and IRBs: Early Experiences and Best Practices
(Late-Breaking Topics Track) Julius Landwirth, Diane Lopez, Steve Peckman

Collaboration Agreements Between Local and Central IRBs: Pitfalls, Perils, and Policy Development
(Legal/Legislative Track) Gary Chadwick, Cami Gearhart, John Isidor

How to Write SOPs
(Operational Tips for IRB Professionals I Track) [Please note this is a double session and will end at 1:15 PM. A boxed lunch will be served. Pre-registration was required to attend this session.] George Gasparis, Daniel Nelson, Elyse Summers

Looking Beyond the Credentials When Hiring, Firing, and Managing the IRB Staff
(Operational Tips for IRB Professionals II Track) Tanna MacReynold, Camille Nebeker

Techniques for HRPP Post-Approval Monitoring: New Opportunities for Educating, Training, and Problem-Solving With Investigators and Key Research Personnel
(Oversight Monitoring Track) Jeff Cohen, Elizabeth Small

Re-Visioning and Revising Consent in Pediatric Clinical Trials: The Work of the Children’s Oncology Group
(Pediatrics and Other Special Populations Track) [Please note this is a double session and will end at 1:15 PM. A boxed lunch will be served. Pre-registration was required to attend this session.] Alan Fleischman, Steve Joffe, Maura O’Leary

Poster Presentations on Oversight of Research
(Poster Presentations & Abstracts Track) Moderator: Jerry Castellano plus poster presenters [Please refer to the Abstract Presentations section for a description of the posters to be presented in this session.]
A Social/Behavioral/Education Science Primer: The Fundamentals of Doing SBE Research  
(PRIMER’s Primer for Principal Investigators, Research Staff, and Contract Research Organization Staff Track)  
Felice Levine, Kate MacQueen

Chairing an Effective and Productive Meeting (And We’re Not Just Talking About IRB Meetings)  
(Professional Development Track)  
Elizabeth Hohmann

I’ve Always Wondered, but Never Had a Chance to Ask…
Conversations With Staff From the NIH About Federal and Local Review of Gene Transfer Clinical Trials  
(Q&A/Conversations with the Feds Track)  
Amy Patterson, Eugene Rosenthal, Allan Shipp

An Overview of the Federal Regulations for Human Research Protections: OHRP and FDA  
(Regulations/Federal Track)  
Carolyn Hommel, Lynda Lahl, Andrea Slavin, Mathew Thomas, Freda Yoder

Introduction to Component Analysis  
(Risk/Benefit Analysis/Scientific Design Track)  
Ernest Prentice, Charles Weijer

(SBER Basics Track)  
Tracy Arwood, Dean Gallant, Lorna Hicks

Scholars and Their Students: Studying Teaching and Learning in Your Own Post-Secondary School Classroom  
(SBER Best Practices Track)  
William Stokes

Biostatistics for the IRB Member  
(Science for the Non-Scientist Track)  
Susan Fish

Can a 35-Page Consent Form be Reduced to 3 Pages: How to Write Comprehensive and Comprehensible Consents Forms That Avoid Exculpatory Language  
(Show and Tell! Track)  
Howard Dickler, Erica Heath, Laura Odwazny

12:15 – 1:15 PM  
Luncheon  
Exhibit Halls A & B South

1:15 – 1:30 PM  
Commuting Time
1:30 – 2:45 PM  Panel II:  Identifying, Evaluating, and Communicating Risk in Social/Behavioral Research

Moderator:  Barbara Stanley
Panelists:  Celia Fisher
           David Strauss
           Charles Weijer

Panel III: In Their Own Voices – Research Subjects Speak

Moderator:  Gigi McMillan
Panelists:  Amy Farber
            James McNulty
            Thato Ntetha

2:45 – 3:00 PM  Coffee and Commuting Time

3:00 – 4:15 PM  Series B: Didactic Sessions/Workshops

B1 Accreditation: Learning From Those Who Have Gone Before Us (Accreditation Track)  Sharon Friend, Susan Stayn

B2 Exempt, Expedited, or Full-Committee Review? Which Review Process is Appropriate?  (Basics for Beginners Track)  Judith Brookshire, Glen Drew, Gwenn Oki

B3 Social/Behavioral/Educational Chairs’ Forum: It’s a Tough Job, but Somebody Has to Do It!  (Chairs and IRB Members Track)  Felice Levine, J. Michael Oakes

B4 The Balancing Act: Weighing Risks and Benefits, Science and Ethics, and the Needs of Subjects and Researchers When Reviewing a Protocol  (Community/Non-Affiliated Members Track)  Heather Butts, Amy Farber

B5 Responsible Conduct of Research Education Programs: Examples of Successful Models  (Education Track)  Frank Macrina

B6 The Uncertainty Principle: Is Clinical Equipoise an Ethical Mandate for Undertaking Clinical Trials Involving Human Subjects?  (Ethical Issues In… Track)  Frank Miller, Lee Seabrooke

B7 Ethical and Compliance Issues Raised by Research Involving Wards of the State  (Hot Spots Track)  George Gasparis, Susan Kornetsky

B8 Meet the “IRB-Sponsor Roundtable”  (Industry Track)  Felix Gyi, Maureen Hardwick, Owen Hughes, Daniel Nelson

B9 Clinical-Trial Contracts and Problematic Clauses: Subject Injury, Compensation, and Publication Delays  (Institutional Officials Track)  Todd Guttmann, Moira Keane

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Indicates a Double Session which includes both lecture and discussion
Global Human Subjects Protection: Interpreting and Applying Different Governmental and/or Agency Guidelines  (International/Cross Cultural Track)  Ames Dhai, Reidar Lie, Robert Levine  

Collaboration Between the IRB and the Institutional Biosafety Committee in the Review of Human Gene Transfer Research: Creating Synergy and Ensuring Optimal Protocol Review  (Late-Breaking Topics Track)  Kathryn Harris, Marcia Finucane  

Injury, Insurance, and Indemnification: The Three “I’s” Every Site and Sponsor Need to Understand  (Legal/Legislative Track)  John Isidor, Heather Fields  

Continuation Reviews: When to Expedite and How to Be Thorough  (Operational Tips for IRB Professionals I Track)  Warren Ashe, Susie Corl, Thomas Foster, Farida Lada  

How to Streamline the IRB Process and How to Avoid Getting Bogged Down in the Procedural Minutiae  (Operational Tips for IRB Professionals II Track)  Elizabeth Cothran, Susan Fish  

Adverse Event Reporting: A Case Study  (Oversight Monitoring Track)  Barbara Stanley  

Reviewing Research Involving Adults with Impaired Decision-Making Capacity (Including a SACHRP Update)  (Pediatrics and Other Special Populations Track)  Paul Appelbaum, Alan Fleischman, David Strauss  

Poster Presentations on Research on Informed Consent  (Poster Presentations & Abstracts Track)  [Please refer to the Abstract Presentations section for a description of the posters to be presented in this session.]  

A Primer on Dealing Effectively With Your Local IRB  (PRIM&R’s Primer for Principal Investigators, Research Staff, and Contract Research Organization Staff Track)  Elizabeth Hohmann, Brad Noren  

Ask Us About Certification for IRB Professionals (CIP®): Types of Questions, How to Prepare, and How to Know if This Test’s For You!  (Professional Development Track)  Susan Delano, Tanna MacReynold  

I’ve Always Wondered, but Never Had a Chance to Ask…Conversations With Staff From OHRP  (Q&A/Conversations with the Feds Track)  Kristina Borror, Michael Carome, Shirley Hicks, Julie Kaneshiro, Melody Lin, Laura Odwazny, Bernard Schwetz, Irene Stith-Colemen  

Conducting Research Within the Department of Veterans Affairs  (Regulations/Federal Track)  Marisue Cody, Joan Porter, Thomas Puglisi  

Application of Component Analysis  (Risk/Benefit Analysis/Scientific Design Track)  Ernest Prentice, Charles Weijer  

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Receives CME Credit
School Rules: The Common Rule, FERPA, PPRA, and Bubblegum  
(SBER Basics Track)  Ivor Pritchard, Brenda Ruotolo  
Virginia A & B

Charity, Compensation, or Coercion: How Does Offering Money or Goods Affect the Researcher/Subject Relationship?  
(SBER Best Practices Track)  Loma Hicks, Kate MacQueen, Betsy Ripley  
Delaware B

Drug and Vaccine Development 101  
(Science for the Non-Scientist Track)  Glenn Siegmann, Dawn Sullivan  
Hoover

A Blueprint for Establishing a New IRB in an International Setting  
(Show and Tell! Track)  Edward Bartlett, Alexander Capron  
McKinley

4:15 – 4:45 PM  
Commuting Time

4:45 – 6:00 PM  
Concurrent

A Conversation with the NIH: New Directions in Research, Developments in Policy Harmonization, and Updates on Grants Management and Oversight  
Washington Rooms

Moderator:  Amy Patterson

Commentators:  Anna Barker, Joseph Ellis, Anthony Hayward, Vivian Ota Wang, Laura Lyman Rodriguez, Sam Shekar

Senior officials from key Institutes and Offices of the National Institutes of Health (NIH) will provide the latest headlines regarding programs and initiatives of importance to those concerned about clinical research and the protections of human subjects. Audience members will have ample opportunity to pose questions to the presenters, and a lively and informative interchange will be encouraged. Networking reception will follow.

4:45 – 6:00 PM  
Concurrent

International Town Meeting: Lessons Learned from Around the World  
Cotillion Ballroom

Moderator:  Karen Hansen

Commentators:  Alla Abou-Zeid, David Borasky, Alexander Capron, Marek Czarkowski, Ames Dhai, Derek Jones, Edwin Ramirez

Panelists representing different regions of the world will share their perspectives on international research. They will be asked to discuss unique ethical considerations for their culture/community and respond to questions from the audience. The session is intended to be interactive and offers the opportunity to promote dialogue and understanding for IRBs and researchers involved with global research activity. Networking reception will follow.

7:30 – 9:30 PM  
The World’s Largest Research Ethics Book Group  
Washington 1

All work and no reading makes IRB’ers dull folks! Therefore, please consider taking part in one of the largest research ethics book groups ever held! Choose either Flu: The Story Of The Great Influenza Pandemic by Keynote Speaker Gina Kolata, or Blood Done Sign My Name by Keynote Speaker Timothy B. Tyson, and join your conference colleagues in a spirited discussion of the relevant and challenging issues presented by each of these books. Dessert and coffee/tea will be served.
7:30 – 9:30 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 your 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 and so sit right down and see if it’s your lucky day (or night!). Dessert and coffee/tea will be served.

7:30 – 9:30 PM  Movie Night

It is not often that ethical issues related to human subjects research are the focus of a popular film. The Constant Gardener, directed by Fernando Meirelles, features a multinational pharmaceutical company conducting clinical trials of a tuberculosis drug in Kenya. The film touches on issues related to vulnerable subjects, conflicts of interest, and other more familiar themes of loss and love. The movie, based on a novel by John Le Carré, is an interesting film by any standards, but a must-see for the HRPP professional. Popcorn will be served.

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**Friday, November 17, 2006**

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<tr>
<th>Time</th>
<th>Event</th>
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<tr>
<td>7:00 AM</td>
<td>Registration Check-in Opens</td>
<td>Atrium</td>
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<td>7:00 – 7:45 AM</td>
<td>Rise and Shine with Yoga – All levels are welcome!</td>
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<td>7:00 – 7:45 AM</td>
<td>Continental Breakfast</td>
<td>Exhibit Halls A &amp; B South</td>
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<td>7:45 – 8:15 AM</td>
<td>Welcome, Membership Update, &amp; Presentation of the Distinguished Service Award and ARENA Legacy Award</td>
<td>Marriott Ballroom</td>
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<td>8:15 – 9:15 AM</td>
<td>Keynote Address: Race Still Matters: The Impact of Race on Research Design and Review</td>
<td>Marriott Ballroom</td>
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<td>9:15 – 10:30 AM</td>
<td>Panel IV: Risk in Biomedical Research: How to Evaluate? How to Communicate?</td>
<td>Marriott Ballroom</td>
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<td>Moderator: Steven Joffé</td>
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<td>Panelists: Paul Appelbaum, Leonard Glantz, Nancy King, Charles Weijer</td>
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<td>9:15 – 10:30 AM</td>
<td>Panel V: The Challenges of Understanding and Engaging Racially and Ethnically Diverse Communities</td>
<td>Cotillion Ballroom</td>
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<td>Moderator: Cynthia Gómez</td>
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<td>Panelists: Robert Fullilove, Nancy Kass, Kate MacQueen, Patricia Tracey</td>
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<td>10:30 – 11:00 AM</td>
<td>Coffee and Commuting Time</td>
<td>Marriott, Cotillion, &amp; Washington Foyers</td>
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<td>Time</td>
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| 11:00 – 12:15 PM | How to Ensure That HRPP Organizational Components Are Effectively Communicating and Functioning *(Accreditation Track)*  
Denise Roe, David Wynes |
| 11:00 – 12:15 PM | Facilitating Ethical Research: How the IRB Can Use the Belmont Principles and Other Tools to Guide Investigator Conduct *(Basics for Beginners Track)* [Please note this is a double session and will end at 1:15 PM. A boxed lunch will be served. Pre-registration was required to attend this session.]  
Jeff Cohen, Monika Markowitz, Charles McCarthy |
| 11:00 – 12:15 PM | Biomedical IRB Chairs’ Forum: It’s a Tough Job, but Somebody Has to Do It! *(Chairs and IRB Members Track)* [Please note this is a double session and will end at 1:15 PM. A boxed lunch will be served. Pre-registration was required to attend this session.]  
Anne Dougherty, John Falletta, Thomas Foster, Bruce Gordon |
| 11:00 – 12:15 PM | The Community/IRB Partnership: The Psychology of an IRB Meeting *(Community/Non-Affiliated Members Track)*  
Gigi McMillan, Amy Farber |
| 11:00 – 12:15 PM | Orientation, Basic, and Continuing Education of IRB Members and Staff *(Education Track)*  
Charlotte Coley, Tanna MacReynold |
| 11:00 – 12:15 PM | What Are the Ethical Issues When Using Existing Research and Medical Records Data: How Do We Apply the Regulations? *(Ethical Issues In … Track)*  
Pearl O’Rourke, Alison Orkin |
| 11:00 – 12:15 PM | Alternative Models for IRB Review: The Ethics, the Liabilities, and What’s Lost or Gained When IRB Review is Shared or Outsourced? *(Hot Spots Track)*  
Leonard Glantz, Don Workman |
| 11:00 – 12:15 PM | Who is Responsible When a Pharmaceutical Company Contracts With a CRO on a Research Project? *(Industry Track)*  
Erica Heath, Lauren Sullivan |
| 11:00 – 12:15 PM | What Every IO Needs to Know About IRBs, Subject Protections, and Fiscal Compliance, Including Research Billing and Inappropriate Billing for Clinical Trials *(Institutional Officials Track)*  
Richard Bianco, Todd Guttman |
| 11:00 – 12:15 PM | Capacity Building for International Research: Training, Communication, and Post-Trial Considerations *(International/Cross-Cultural Track)* [Please note this is a double session and will end at 1:15 PM. A boxed lunch will be served. Pre-registration was required to attend this session.]  
Ames Dhai, Karen Hansen, Nancy Kass, Steve Wakefield |
| 11:00 – 12:15 PM | Update on SACHRP’s Subpart A Recommendations *(Late-Breaking Topics Track)*  
Felix Gyi, Daniel Nelson |

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What is Exempt When Conducting Social/Behavioral/Education Research: The “Regs,” Followed by a Case Study (SBER Basics Track)  Sangeeta Panicker, Ivor Pritchard

Ethical and Practical Issues in Ethnography Research: Quality Review of Qualitative Fieldwork (SBER Best Practices Track)  Kate MacQueen, Camille Nebeker

Scientific Issues in the Use of Randomization and Placebo-Controlled Trials (Science for the Non-Scientist Track)  Robert Levine

Role Playing: How To Communicate With Prospective Subjects During the Consent Process (Show and Tell! Track)  [Please note this is a double session and will end at 1:15 PM. A boxed lunch will be served. Pre-registration was required to attend this session.]  Susan Dorr Goold, Tammy Savencool, Terry VandenBosch

12:15 – 1:15 PM  Common Ground Luncheon  Time to connect! You are invited to meet with similarly situated professionals for conversation, networking, and lunch by looking for the tablecloth that matches the color of the name badge ribbon you selected during Registration. Don’t worry if you did not pre-select a ribbon! You are welcome to sit at the table of your choice. Find the light yellow tablecloths to have “just lunch.”

12:15 – 1:15 PM  Clinical Trials Registries Focus Group  The World Health Organization wants to know what those working in the IRB/HRPP fields think about Clinical Trial Registries, and thus we have scheduled a CTR Focus Group. If you are interested in discussing CTRs with Alexander Capron and An-Wen Chan of the WHO, please visit the Help Desk to pre-register for this event. Lunch will be served.

1:15 – 1:30 PM  Commuting Time


1:30 – 2:45 PM  Panel VII:  From Anecdote to Evidence: Toward a More Effective System of Protections Using Evidence-Based Practice SBER/BIOMED  Moderator:  Joan Sieber  Panelists:  Nancy Kass  Jeff Rodamar  Mary Simmerling

2:45 – 3:00 PM  Coffee and Commuting Time

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<tbody>
<tr>
<td>D1</td>
<td>Accreditation Checklist: The How To’s of Self-Assessment</td>
<td>Maryland C</td>
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<tr>
<td></td>
<td>(Accreditation Track) Lisa Korcuska, Lisa Leiden</td>
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<tr>
<td>D2</td>
<td>The Elements of Informed Consent in the Federal Regulations</td>
<td>Cotillion Ballroom</td>
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<td>(Basis for Beginners Track) Edward Bartlett, Susan Delano, Betsy Ripley</td>
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<td>D3</td>
<td>Non-Compliance Reports: Investigation and Resolutions</td>
<td>Washington 3</td>
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<td>(Chairs and IRB Members Track) John Falletta, Bruce Gordon, Susan Kornetsky</td>
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<td>D4</td>
<td>The Community/IRB Partnership: Ask the Chair</td>
<td>Virginia C</td>
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<td>(Community/Non-Affiliated Members Track) Gigi McMillan, Karen Schwener</td>
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<td>D5</td>
<td>Ensuring that HRPP Personnel Understand Their Responsibilities</td>
<td>Balcony C &amp; D</td>
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<td>vis-à-vis Continuing Reviews, Amendments, Serious Adverse Events, “Verifications,” Protocol Violations, and More</td>
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<td>(Education Track) George Gasparis, Michele Russell-Einhorn</td>
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<td>D6</td>
<td>Conflict of Interest Notification Study (COINS) – What to Do,</td>
<td>Coolidge</td>
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<td>What to Say, Whom to Train</td>
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<td>(Ethical Issues In… Track) Jennifer Allsbrook, Michaela Dinan, Joelle Friedman, Jeremy Sugarman, Kevin Winfurst</td>
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<tr>
<td>D7</td>
<td>Investigator Non-Compliance and the IRB: How to Handle?</td>
<td>Washington 5</td>
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<td>What to Report?</td>
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<td>(Hot Spots Track) Heather Fields, David Gan, Sharon Gershon, Karen Hale, Carol Weil</td>
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<td>D8</td>
<td>Adverse Event Reports, IND Safety Reports, and “Dear Investigator” Letters: An IRB-Industry Dialogue</td>
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<td>(Industry Track) Cami Gearhart, Leslie Williams</td>
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<td>D9</td>
<td>Different Models of Compliance Offices: Finding the Right Fit for Your Institution</td>
<td>Wilson A</td>
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<td>(Institutional Officials Track) Elizabeth Bankert, David Wynes</td>
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<tr>
<td>D10</td>
<td>Establishing and Maintaining Collaboration, Partnership, and Trust in International Research</td>
<td>Kennedy</td>
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<tr>
<td></td>
<td>(International/Cross Cultural Track) David Borasky, Pauline Mwinzi, Steve Wakefield</td>
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<tr>
<td>D11</td>
<td>Race, Genechips, and Individualized Medicine: BiDil and Beyond</td>
<td>Maryland B</td>
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<td></td>
<td>(Late-Breaking Topics Track) Heather Butts</td>
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<tr>
<td>D12</td>
<td>Coping with Crises: Effective Strategies in Compliance Investigations and Other Challenging Situations</td>
<td>Harding</td>
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<td></td>
<td>(Legal/Legislative Track) Leslie Ball, John Mills, Laura Odwazny, Mathew Thomas</td>
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</tbody>
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- Indicates didactic session (attendees mostly listen…)
- Indicates workshop (attendees talk too!)
- Indicates session will be captured for proceedings
- Receives CME Credit

Indicates a Double Session which includes both lecture and discussion
NEW TITLE

What IRB Professionals Need to Know About the Challenges of Specimen Banking (Operational Tips for IRB Professionals I Track)
Marianna Bledsoe, Sharon Friend, Sally Hojvat, Rose Mary Padberg  
Washington 6

When is it “Human Subjects Research?” QA, QI, Oral History, Documentary Film, Ethnography… (Operational Tips for IRB Professionals II Track)  
Michael Carome, Jeffrey Cohen, Julie Kaneshiro  
Marriott Ballroom

When and What Should the IRB Report to the Feds? (Oversight Monitoring Track)  
Kristina Borror, Charlotte Coley  
Wilson C

Research Involving Adolescents: Their Rights and the Researcher’s Responsibilities (Pediatrics and Other Special Populations Track)  
Leonard Glantz, Monika Markowitz  
Washington 2

Poster Presentations on Ask the Subjects: Risk, Trust, Integrity (Poster Presentations & Abstracts Track)  
Moderator: Suzy Fitzpatrick plus poster presenters  
[Please refer to the Abstract Presentations section for a description of the posters to be presented in this session.]  
Johnson

A Primer on Clinical Trial Networks: How They Operate and Assist in Subject Protection (PRIME&R’s Primer for Principal Investigators, Research Staff, and Contract Research Organization Staff Track)  
William Harmon  
Balcony A

Mentoring Principal Investigators and Other Research Personnel (Professional Development Track)  
Thomas Foster, Bernard Schwetz  
Washington 1

I’ve Always Wondered, but Never Had a Chance to Ask… Conversations with the NIH Office of Biotechnology Activities About the National Science Advisory Board for Biosecurity and Emerging Policy Regarding the Oversight of Dual Use Research (Q&A/Conversations with the Feds Track)  
Amy Patterson  
Taft

DSMPs, DSMBs, Interim Safety Committees, and Safety Monitoring: What Is Appropriate and When? (Regulations/Federal Track)  
Susan Ellenberg, Robert Levine  
Delaware A

IRBs’ Experience with the FDAs’ Emergency Research Waiver of Informed Consent Rule (Risk/Benefit Analysis/Scientific Design Track)  
Sara Goldkind, Joanne Less, Diane Maloney  
Wilson B

Privacy and Confidentiality: Don’t Ask, or Don’t Tell? (SBER Basics Track)  
Tracy Arwood, Sangeeta Panicker  
Virginia A & B

Research Involving Deception and Non-Disclosure in Research With Human Subjects: Respecting Subjects’ Autonomy While Doing Good Science (SBER Best Practices Track)  
Lorna Hicks, Frank Miller  
Delaware B

Epidemiology for the Non-Scientist (Science for the Non-Scientist Track)  
Walter Straus  
Hoover

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Receives CME Credit
Indicates a Double Session which includes both lecture and discussion
Conflict Resolution for IRBs: Strategies for Removing the Roadblocks in Interactions with Researchers and Subjects
(Show and Tell! Track) Judith Brookshire, David Clark

4:15 – 4:30 PM
Commuting Time

4:30 – 5:45 PM
The Federal Forum: Q & A with the Federal Agencies

Moderators: Ivor Pritchard and Ada Sue Schwitz

Dr. Bernard Schwetz of OHRP and Dr. Ernest Prentice, Chair of SACHRP, will each provide introductory comments. Following the brief updates, there will be a Q & A session from a wide array of federal agencies including OHRP, the FDA, the CDC, the Dept. of Defense, the Dept. of Education, the National Science Foundation, USAID, the Veteran’s Administration, and other Common Rule agencies. Questions will be taken both from the floor and from those submitted prior to the event.

7:30 – 9:30 PM
Light Fare and Lots of Laughs!
Join PRIM&R for a belly full of delicious dishes and laugh out loud fun! Back by popular demand is Washington, D.C.’s own Capitol Steps, “The Only Group In Washington That’s Funnier Than Congress!” The cost of this event is not included in your registration fee and tickets are $40 each, and can be purchased onsite at the Help Desk until Thursday at 12:00 PM.

Saturday, November 18, 2006

7:00 AM
Registration Opens

7:00 – 7:45 AM
Rise and Shine with Yoga – All levels are welcome!

7:00 – 8:30 AM
Continental Breakfast

8:30 – 9:15 AM
Keynote Address: Responsible Reporting When Research Stories Hit the Headlines
Hit the Headlines
Gina Kolata

9:15 – 9:30 AM
Commuting Time

9:30 – 10:45 AM
Panel VIII: Access to Subjects and Their Data in Epidemiological and Health Services Research: Considerations for IRBs

Moderator: Susan Fish
Panelists: Laura Beskow, Ulrika Kreicbergs, Pearl O’Rourke

Marriott Ballroom

Indicators:
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Indicates a Double Session which includes both lecture and discussion
### 9:30 – 10:45 AM

**Panel IX: Trauma, Tragedy, and Terror: Ethical Conundrums When Conducting Research With Disaster Victims**

**Moderator:** Felice Levine

**Panelists:** Alan Fleischman, Shirley Laska, Roxane Silver

**Cotillion Ballroom**

### 10:45 – 11:15 AM

**Coffee and Commuting Time**

**Marriott, Cotillion, & Washington Foyers**

### 11:15 AM – 12:30 PM

#### Series E: Didactic Sessions/Workshops

<table>
<thead>
<tr>
<th>Session</th>
<th>Title</th>
<th>Location</th>
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<td>E1</td>
<td>Accreditation Checklist: The How To’s of Self-Assessment</td>
<td>Maryland C</td>
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<tr>
<td>E2</td>
<td>What Happens After the Protocol is Approved? Continuations, Modifications, Adverse Events, Advertisements, and Post-Approval Monitoring</td>
<td>Cotillion Ballroom</td>
</tr>
<tr>
<td>E3</td>
<td>Assessing Minimal Risk in Pediatric Studies: The New SACHRP Recommendations</td>
<td>Marriott Ballroom</td>
</tr>
<tr>
<td>E4</td>
<td>The Community/IRB Partnership: Do Community Members Add to the Protection of Vulnerable Populations?</td>
<td>Wilson C</td>
</tr>
<tr>
<td>E5</td>
<td>A Day in the Life of A Science Writer: What Warrants Writing About?</td>
<td>Balcony C &amp; D</td>
</tr>
<tr>
<td>E6</td>
<td>Dial “E” for Ethics: Helping PIs with Ethical Dilemmas Identified in Protocol Review, or After the Research Is Underway</td>
<td>Washington 3</td>
</tr>
<tr>
<td>E8</td>
<td>Informed Consent: What IRBs Want Industry to Know and What Industry Wants IRBs to Know</td>
<td>Coolidge</td>
</tr>
<tr>
<td>E9</td>
<td>What Do We Mean by Integrated Compliance: How to Harmonize the IRB, Compliance Office, and the IBC (Institutional Biosafety Committee)</td>
<td>Virginia C</td>
</tr>
<tr>
<td>E10</td>
<td>The Ethical Issues of Doing HIV/AIDS Research in Resource Scarce Settings</td>
<td>Kennedy</td>
</tr>
</tbody>
</table>

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**Indicates workshop (attendees talk too!)

**Indicates session will be captured for proceedings**

**Receives CME Credit**

**Indicates a Double Session which includes both lecture and discussion**
<table>
<thead>
<tr>
<th>Session</th>
<th>Title</th>
<th>Track/Track(s)</th>
<th>Location</th>
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<tbody>
<tr>
<td>E11</td>
<td>Trends in OHRP Determination Letters</td>
<td>Late-Breaking Topics Track</td>
<td>Maryland B</td>
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<tr>
<td>E12</td>
<td>High Profile Legal Cases and Their Effect on IRBs</td>
<td>Legal/Legislative Track</td>
<td>Washington 6</td>
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<tr>
<td>E13</td>
<td>Improving the IRB/Investigator Relationship</td>
<td>Operational Tips for IRB Professionals I Track</td>
<td>Harding</td>
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<tr>
<td>E14</td>
<td>Writing Minutes That Comply With Federal Requirements</td>
<td>Operational Tips for IRB Professionals II Track</td>
<td>Washington 4</td>
</tr>
<tr>
<td>E15</td>
<td>Show Me the Money! Determining the Adequacy of Resources to Complete a Proposed Research Project</td>
<td>Oversight Monitoring Track</td>
<td>Washington 2</td>
</tr>
<tr>
<td>E16</td>
<td>Challenging Cases for Subpart D Determinations: Is It 405 or 406?</td>
<td>Pediatrics and Other Special Populations Track</td>
<td>Maryland A</td>
</tr>
<tr>
<td>E17</td>
<td>Poster Presentations on Managing Adverse Event Reporting</td>
<td>Poster Presentations &amp; Abstracts Track</td>
<td>Johnson</td>
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<tr>
<td>E18</td>
<td>A Primer on Available Technology to Augment the Consent Process</td>
<td>PRIM&amp;R’s Primer for Principal Investigators, Research Staff, and Contract Research Organization Staff Track</td>
<td>Balcony A</td>
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<tr>
<td>E19</td>
<td>Essentials for IRB Professionals: Writing Skills</td>
<td>Professional Development Track</td>
<td>Taft</td>
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<tr>
<td>E20</td>
<td>I’ve Always Wondered, but Never Had a Chance to Ask … Conversations With Staff From CDC, EPA, NSF, Department of Education, and Department of Defense</td>
<td>Q&amp;A/Conversations with the Feds Track</td>
<td>Wilson A</td>
</tr>
<tr>
<td>E21</td>
<td>An Update on Federal Activities Related to Adverse Event Reporting</td>
<td>Regulations/Federal Track</td>
<td>Delaware A</td>
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<tr>
<td>E22</td>
<td>DSMB Assessment of Benefits and Harms</td>
<td>Risk/Benefit Analysis/Scientific Design Track</td>
<td>Wilson B</td>
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<tr>
<td>E23</td>
<td>Informed Consent in Social, Behavioral, and Education Research</td>
<td>SBER Basics Track</td>
<td>Virginia A &amp; B</td>
</tr>
</tbody>
</table>
2:00 – 2:15 PM Didactic Session (SBER Best Practices Track)
J. Michael Oakes, Kevin Prohaska

2:15 – 2:30 PM Workshop (Science for the Non-Scientist Track)
Barbara Handelin, Ingrid Holm

9:00 – 9:15 AM Concurrent Plenary Address: Why IRBs Are Peer-Review Systems
J. Michael Oakes

2:45 – 4:00 PM Concurrent Panel X: Data and Safety Monitoring in Research
BIOMED
Moderator: Robert Levine
Panelists: David DeMets, Susan Ellenberg, Lawrence Friedman

2:45 – 4:00 PM Concurrent PANEL XI: Abstract Presentations
Moderator: David Borasky and Susan Fish

Title: Determination of IND Requirements for Investigator-Initiated Studies: A Comprehensive Cancer Center’s Approach to Compliance
Author: Chicquita Hatten, MSN
Affiliation: The University of Texas M. D. Anderson Cancer Center, Houston, Texas

Title: Disaster Preparedness and Recovery: Lessons Learned with Hurricane Katrina
Author: Joseph Breault, MD, CIP
Affiliation: Ochsner Health Systems, New Orleans, LA

Title: Assessment of Parental Permission for Research Participation with Neonates
Author: Robert M. Nelson, MD, PhD
Affiliation: Center for Research Integrity, The Children’s Hospital of Philadelphia and the Department of Anesthesiology and Critical Care, University of Pennsylvania School of Medicine

12:30 – 1:30 PM Luncheon

1:30 – 1:45 PM Commuting Time

1:45 – 2:30 PM Plenary Address: Why IRBS Are Peer-Review Systems
J. Michael Oakes

2:30 – 2:45 PM Commuting Time

2:45 – 4:00 PM Concurrent Panel XI: Abstract Presentations
Moderator: David Borasky and Susan Fish

Title: Determination of IND Requirements for Investigator-Initiated Studies: A Comprehensive Cancer Center’s Approach to Compliance
Author: Chicquita Hatten, MSN
Affiliation: The University of Texas M. D. Anderson Cancer Center, Houston, Texas

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Author: Joseph Breault, MD, CIP
Affiliation: Ochsner Health Systems, New Orleans, LA

Title: Assessment of Parental Permission for Research Participation with Neonates
Author: Robert M. Nelson, MD, PhD
Affiliation: Center for Research Integrity, The Children’s Hospital of Philadelphia and the Department of Anesthesiology and Critical Care, University of Pennsylvania School of Medicine
Title: Perceived Quality of Care for Insured and Uninsured Participants in Clinical Trials: Qualitative Results from the EPIC (Experiences of Participants in Clinical Trials) Study
Author: Carrie Thiessen
Affiliation: Department of Clinical Bioethics, National Institutes of Health, Harvard University, and Yale School of Medicine

2:45 – 4:00 PM  Panel XII: New Technologies, New Risks: Behavioral Genetics, Privacy, Data Security, and More  SBER
Moderator: Jeffrey Cohen
Panelists: Scott Bradner, Barbara Goldman, Vivian Ota Wang

4:00 – 4:15 PM  Coffee and Commuting Time

4:15 – 5:30 PM  Series F: Didactic Sessions/Workshops

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<th>Session</th>
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<th>Track</th>
<th>Room</th>
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<tbody>
<tr>
<td>4:15</td>
<td>F1</td>
<td>What Happens After the Site Visit? The Organizational Response</td>
<td>Accreditation Track</td>
<td>Maryland C</td>
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<td>(Pearl O’Rourke, Susan Kometsky)</td>
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<tr>
<td>4:15</td>
<td>F2</td>
<td>Q&amp;A for Beginners (You Provide the Questions and Seasoned IRB Administrators Will Provide the Answers)</td>
<td>Basics for Beginners Track</td>
<td>Maryland A</td>
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<td>(Susan Delano, Susie Hoffman, Nancy Olson)</td>
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<tr>
<td>4:15</td>
<td>F3</td>
<td>NIH’s Proposal for Data Sharing in Genomic Studies: Exploring the Implications for Participants, Investigators, and IRBs</td>
<td>Chairs and IRB Members Track</td>
<td>Marriott Ballroom</td>
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<td>(Laura Beskow, Barbara Handelin, Laura Lyman Rodriguez)</td>
<td>Salon 2 &amp; 3</td>
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<tr>
<td>4:15</td>
<td>F4</td>
<td>The Community/IRB Partnership: Finding Strength-in-Numbers by Organizing a Network of Community Members – A Call-to-Action!</td>
<td>Community/Non-Affiliated Members Track</td>
<td>Wilson C</td>
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<td>(Gigi McMillan, Terry Powell)</td>
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<tr>
<td>4:15</td>
<td>F5</td>
<td>How to Design GCP/GMP/ICH/DSMB/IBC Educational/Training Programs</td>
<td>Education Track</td>
<td>Balcony C &amp; D</td>
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<td>(Deborah Barnard, Michelle Christiano, Sheila Noone)</td>
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<tr>
<td>4:15</td>
<td>F6</td>
<td>Communicating Research Results to Research Participants: When is a Little Knowledge a Dangerous Thing?</td>
<td>Ethical Issues In… Track</td>
<td>Washington 5</td>
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<td>(Derek Jones, Mary Lou Smith)</td>
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<tr>
<td>4:15</td>
<td>F7</td>
<td>Epidemiological Research and Long-Term Follow-Up</td>
<td>Hot Spots Track</td>
<td>Balcony B</td>
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<td>(Kui Huang, Nataliya Volkova)</td>
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<tr>
<td>4:15</td>
<td>F8</td>
<td>Demystifying the Sponsor/IRB Relationship</td>
<td>Industry Track</td>
<td>Coolidge</td>
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<td>(Greg Koski)</td>
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<td>4:15</td>
<td>F9</td>
<td>Can We Do That? Enhancing Institutional Awareness of Proposed Research Activities</td>
<td>Institutional Officials Track</td>
<td>Virginia C</td>
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<td>(Richard Bianco, Lee Seabrooke)</td>
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Indicates a Double Session which includes both lecture and discussion
Clinical Research in “Emerging Markets”  (International/Cross Cultural Track)  Munish Mehra, Andy Lee, Sergio Santillana

How to Handle the Findings and/or Deficiencies Uncovered in QI Reviews  (Late-Breaking Topics Track) Eunice Newbert, Delia Wolf

Breaking the Bottleneck in — and Otherwise Improving — Clinical Trial Agreements  (Legal/Legislative Track) John Counts

Managing Off-Site Studies: Who Are the People Engaged in the Research, and What Type of Assurances and Agreements Are Needed?  (Operational Tips for IRB Professionals Track) Hal Blatt, Irene Stith-Coleman, Ada Sue Schwartz, Lisa Voss

IRBs at Small and Mid-Sized Institutions: This One’s for You!  (Operational Tips for IRB Professionals Track) Barbara Bigby, Guenn Oki

IRB Self-Assessment: Monitoring Ourselves  (Oversight Monitoring Track) Warren Ashe, Yvonne Higgins


Poster Presentations on Assessing IRB Review  (Poster Presentations & Abstracts Track) Moderator: Sanford Ghodosh plus poster presenters

[Please refer to the Abstract Presentations section for a description of the posters to be presented in this session.]

A Primer on Minimizing Coercion and Undue Influence in Subject Recruitment  (PRIM&R’s Primer for Principal Investigators, Research Staff, and Contract Research Organization Staff Track) Laura Brosch, Robert Nelson

Essentials for IRB Professionals: Listening and Speaking Skills  (Professional Development Track) Moira Keane

I’ve Always Wondered, but Never Had a Chance to Ask … Conversations With the Staff From the FDA’s Center for Devices and Radiologic Health Including Humanitarian Device Exemptions  (Q&A/Conversations with the Feds Track) Joanne Less, Marian Serge

Federal Regulatory Site Visits: For-Cause and Not-For-Cause  (Regulations/Federal Track) Roy Blay, Karena Cooper, Brad Noren, Andrea Slavin

Post-Marketing Surveillance at FDA’s Center for Biologics Evaluation and Research  (Risk/Benefit Analysis/Scientific Design Track) Craig Zinderman

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F23  |  SBE Research Outside the United States  (SBER Basics Track)  
    |  David Borasky, Cynthia Gómez  

F24  |  Internet Research: Doing “Virtual” Research Virtuously  
    |  (SBER Best Practices Track)  Ruth Fischbach, Dean Gallant  

F25  |  Survey Design and Research Methods, Including Sampling  
    |  (Science for the Non-Scientist Track)  Lawrence Friedman, Dale Hammerschmidt  

F26  |  How to Implement an Electronic IRB System: Lessons From the Battlefield  
    |  (Show and Tell! Track)  Mary Banks, Scott Bradner, Rosemary Kelso  

5:30 – 6:30 PM  |  Closing Reception and Fond Farewells!  

See you next year at the  
2007 Annual HRPP Conference,  
December 1-4, at the Sheraton Hotel and  
Hynes Convention Center in Boston, MA!