<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Location</th>
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<tbody>
<tr>
<td>7:00 AM-6:00 PM</td>
<td>Registration Open</td>
<td>Pre-Function C</td>
</tr>
<tr>
<td>7:00-8:30 AM</td>
<td>Continental Breakfast</td>
<td>Ballroom A</td>
</tr>
<tr>
<td>8:30 AM-4:30 PM</td>
<td><strong>Pre-Con I: Advanced Research Ethics</strong></td>
<td>Room 311</td>
</tr>
<tr>
<td>8:30 AM-4:30 PM</td>
<td><strong>Pre-Con II: Central Institutional Review Board (IRB) Models: Benefits, Challenges, and Role in Clinical Trial Networks</strong></td>
<td>Room 310</td>
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<tr>
<td>8:30 AM-4:30 PM</td>
<td><strong>Pre-Con III: Consent: Processes, Criteria, and Considerations for Obtaining Informed Consent</strong></td>
<td>Room 303</td>
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<tr>
<td>8:30 AM-5:00 PM</td>
<td><strong>Pre-Con IV: Contemporary Issues in Biobanking: Engagement, Governance, and Trust</strong></td>
<td>Room 302</td>
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<tr>
<td>8:30 AM-5:00 PM</td>
<td><strong>Pre-Con V: Ethical Issues in Global Research</strong></td>
<td>Room 300</td>
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<tr>
<td>8:30 AM-4:30 PM</td>
<td><strong>Pre-Con VI: Hot Topics for Institutional Officials</strong></td>
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<tr>
<td>8:30 AM-4:30 PM</td>
<td><strong>Pre-Con VII: IRB 101</strong></td>
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<tr>
<td>8:30 AM-4:30 PM</td>
<td><strong>Pre-Con VIII: IRB 201: An In-Depth Analysis of the Criteria for Review</strong></td>
<td>Room 312</td>
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<tr>
<td>8:30 AM-4:45 PM</td>
<td><strong>Pre-Con IX: IRB 202: Review and Application of the Regulatory Criteria for Approval</strong></td>
<td>Room 306</td>
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<tr>
<td>8:30 AM-5:00 PM</td>
<td><strong>Pre-Con X: Regulatory, Ethical, and Technical Challenges in Internet Research</strong></td>
<td>Room 304</td>
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<tr>
<td>8:30 AM-4:00 PM</td>
<td><strong>Pre-Con XI: Research Involving Children: Framing and Applying Additional Protections</strong></td>
<td>Room 313</td>
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<tr>
<td>4:00-6:00 PM</td>
<td><strong>Pre-Conference Programs Networking Reception</strong></td>
<td>Boylston Hallway, 3rd fl.</td>
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</table>

All those registered to attend a pre-conference program on November 6 are welcome to join us for a networking reception immediately following the conclusion of their program. Light refreshments will be served.
Thursday, November 7: 2013 AER Conference

7:00 AM-6:00 PM
Registration Open

7:00-8:00 AM
Continental Breakfast

7:00-8:00 AM
Continental Breakfast to Welcome First-Time Attendees
Hoping to connect and network with other first-time attendees before the conference starts? If so, please join us at this breakfast where you’ll have an opportunity to connect and network with colleagues, as well as hear answers to the top 10 most frequently asked questions about the conference from the PRIM&R staff. All first-time conference attendees are welcome, but in order to ensure there are enough seats and meals, we require attendees to sign up for this event in advance.

7:00-8:00 AM
Affinity Group (AG) Networking Continental Breakfast
Join your AG facilitators and fellow members before the conference starts to connect and network! All attendees registered for an AG are welcome, and the breakfast room will be divided by group. In order to ensure there are enough seats and meals, we require attendees to sign up for this event in advance. Please note that this event is sold out and you will not be able to sign up for it when registering.

7:15-7:45 AM
Book Signing with Author and Keynote Speaker Atul Gawande, MD, MPH
Join us at the onsite Bookstore in Pre-Function C for a book signing with author and keynote speaker Atul Gawande, MD, MPH. Copies of Dr. Gawande’s books are available online, as well as at the onsite Bookstore.

8:00-8:30 AM
Welcome and Presentation of PRIM&R’s ARENA Legacy Award to Daniel K. Nelson, MSc, CIP
Director, Office of Human Research Ethics; Professor of Social Medicine and Adjunct Professor of Pediatrics, University of North Carolina at Chapel Hill
Presented by Susan Z. Kornetsky, Co-Chair, 2013 AER Conference CCPC

8:30-9:15 AM
Keynote Address: The Century of the System
Atul Gawande, MD, MPH
Director, Ariadne Labs; General and Endocrine Surgeon, Brigham and Women’s Hospital; Professor of Surgery, Harvard Medical School; Professor in the Department of Health Policy and Management, Harvard School of Public Health

9:15-10:00 AM
Keynote Address: “Best Medical Care” vs. “Research” in an Era of Expanding Technologies: Blurred Lines and Best Intentions
George D. Demetri, MD
Director, Ludwig Center at Dana-Farber/Harvard Cancer Center and Center for Sarcoma and Bone Oncology; Senior Vice President for Experimental Therapeutics, Dana-Farber Cancer Institute; Professor of Medicine, Harvard Medical School

10:00-10:30 AM
Break
Join us in The Conference Connection for coffee.
Thursday, November 7 (cont.)

Didactic Sessions and Workshops Series A, 10:30–11:45 AM

A1
A Dialogue with the Office for Human Research Protections (OHRP)  
(A Dialogue with the Feds I Track)  
Kristina C. Borror, Julie Kaneshiro, Irene Stith-Coleman
This session will be led by representatives from OHRP. Attendees are encouraged to come with questions of interest to all. In this session, attendees will:
- Hear from OHRP representatives about evolving initiatives, issues, and guidance.
- Participate in an open discussion about topics relevant to OHRP stakeholders.
- Ask questions of OHRP representatives.

A2
A Dialogue with the National Science Foundation (NSF)  
(A Dialogue with the Feds II Track)  
Kellina M. Craig-Henderson
This session will be led by a representative from NSF. Attendees are encouraged to come with questions of interest to all. In this session, attendees will:
- Hear from a NSF representative about evolving issues, initiatives, and guidance.
- Participate in an open discussion topics relevant to NSF stakeholders.
- Ask questions of a NSF representative.

A3
Building a Comprehensive Human Research Protection Program (HRPP): An Overview of the  
Accreditation Process and Standards  
(Wesley Byerly, Sujatha Sridhar, Elyse I. Summers)
This session will focus on building the infrastructure of a comprehensive HRPP through accreditation. In this session, faculty will:
- Provide an overview of the accreditation standards related to the organization, the IRB or Ethics Committee, the researcher, and the research staff.
- Discuss the accreditation process and how to prepare for a site visit.
- Review how to develop effective HRPP programs and provide institutional guidance in this area to researchers.
- Outline how to meet the AAHRPP standards (Element I.4.B. and I.4.C.), including evaluating community outreach activities.

A4
Public Health Studies: Surveillance or Research? Models for Ethical Review  
(Activities Along the Boundaries Between Research and Practice Track)  
Nancy Ondruske, Walter L. Straus, Hugh Tilson, Laura Youngblood
In this session, faculty will:
- Explore the nature of public health studies, specifically the distinction between (and overlap of) surveillance and research.
- Explore the different ethical and regulatory implications and challenges of public health surveillance and public health research.
- Discuss tools for streamlining ethics review and encouraging investigators to engage in ethical reflection during project planning.
- Consider issues and potential solutions for ethics review during public health emergencies.

A5
Introducing “Essential Elements of Ethics”: A Rigorous Method for Ensuring Key Ethical Issues  
Have Been Incorporated into Your Protocol  
(Advanced Forum for IRB Professionals Track)  
Susana Callery D’Amico, David G. Forster, Rebecca Li, Maeve Luthin
In this session, faculty will:
- Identify essential ethical elements that should be considered and addressed in each clinical protocol.
- Describe the launch of a new and innovative “Essential Elements of Ethics” tool developed by Multi-Regional Clinical Trials (MRCT) and PRIM&R to facilitate crafting a dedicated ethics section of a protocol.
- Explain the rationale and methodology by which these essential ethical elements were derived and the potential impact this tool will have to raise the bar on clinical trials, especially those involving the developing world.
- Discuss survey data from a pilot study looking at the essential elements in clinical protocols submitted to IRBs.

A6
Educational Theory and Practice for 21st Century Adult Learning  
(Educating Research Teams Track)  
Joni K. Barnard, Francis DiMario
This session will present current best practices for teaching 21st century adult learners. A combination of theory and applied examples will be presented. In this session, faculty will:
- Discuss how to engage learners so that lessons and concepts presented are remembered and applied.
- Review the use of technology in making learning efficient and meaningful.
- Describe adult education principles as they relate to the characteristics of adult learners.
Thursday, November 7 (cont.)

Didactic Sessions and Workshops Series A, 10:30–11:45 AM

A7

How to Read the Empirical Ethics Literature (Ethical Issues Track)  
Paul S. Appelbaum, Paul Christopher  

In this session, faculty and attendees will:
- Discuss key aspects of research methods relevant to assessing empirical studies of ethical issues.
- Consider common logical fallacies in drawing conclusions from empirical data.
- Review and discuss an empirical study with a critical eye.

A8

Nontraditional Access to Investigational Drugs and Devices (FDA Regulations Track) Owen Faris, Richard Klein  

In this session, faculty will:
- Review the Food and Drug Administration (FDA) requirements related to nontraditional uses of FDA-regulated test articles.
- Discuss the similarities and differences in the expanded access provisions for investigational drugs, biologics, and medical devices.
- Provide an overview of the roles of the patient, doctor, sponsor, FDA, and the IRB.

A9

It Takes a Village: Models for Community Consultation in International Research (Global Research Track) Steven Wakefield  

In this session, faculty will:
- Review models for community engagement in international settings.
- Discuss mechanisms for interaction between community advisory groups and ethics review committees, including training on research ethics for community members.
- Outline considerations for population-based research when a target group is not represented on the IRB or ethics review committee through the use of HIV case studies.

A10

Informed Consent: Elevating the Process and Improving the Form (Informed Consent Track) Laura M. Beskow, Mina Busch, Elizabeth Senft  

In this session, faculty and attendees will:
- Review what research literature on informed consent tells us.
- Address how attending to comprehension can help elevate the informed consent process and lead to improvements in consent forms.
- Explore background issues such as: What is the state of health literacy? What works best for patients and subjects?
- Discuss general strategies to adjust consent forms for reading level, translation, and overall readability.
- Review recommendations for the development and formatting of easy-to-read and easy-to-comprehend informed consent forms.

A11

The “Sunshine” Act Regulations: Implications for Research and Human Subjects Protections (Institutional Officials Track) F. Lisa Murtha, Robyn S. Shapiro  

In this session, faculty will:
- Outline the final Physician Payment Sunshine Act regulations.
- Discuss the implications of the Sunshine Act (a core part of the 2010 Patient Protection and Affordable Care Act [PPACA]) on research.
- Identify strategies for research sites to assure compliance with the PPACA requirements.

A12

Essential Documentation: IRB Membership, Recordkeeping, Meeting Minutes, and More (IRB Bootcamp Track) Julia Gorey, Patrick McNeilly, Ada Sue Selwitz  

In this session, faculty and attendees will:
- Outline the basic federal requirements for IRB documents.
- Discuss federal requirements for maintenance of accurate, complete, and timely IRB records.
- Identify the components of a complete record of IRB meeting activities as reported in IRB meeting minutes.
in response to the Secretary's request.

The study of Bioethical Issues (the Bioethics Commission) to enumerate the ethical considerations of conducting pediatric clinical trials of MCMs, which are interventions to protect children in the event of a bioterrorism attack. The Department of Health and Human Services

Michelle Groman, Lisa

with

Pediatric Medical Countermeasure (MCM) Research: Enumerating Ethical Considerations to Aid with Policy Decisions (Populations Requiring Additional Protections Track)

This interactive session will use studies, concrete examples, and role-playing exercises. In this session, faculty and attendees will:

- Review techniques for delivering information (good or bad) to investigators in clear, concise, and tactful ways.
- Discuss strategies for using email more effectively to transmit IRB findings and stipulations.
- Explore the skills needed to diffuse frustration and resolve conflicts in a professional manner.

A14
Emerging Issues for Pharmaceutical/Biotechnology Companies and Contract Research Organizations in Research Conducted Abroad (Issues for Pharma/Biotech Track)

Albert J. Allen, Barry Mangum

This session will: Discuss the changing regulatory landscape as it pertains to conducting research abroad.

Address challenges in designing and conducting studies across different regions of the world.

Address if and how capacity-building needs across different continents have changed over the past five years.

A15
Taking the Ominous Out of the Omnibus Rule: Implications of the Final Health Insurance Portability and Accountability Act (HIPAA) Changes for Research (Legal Track)

Emily C. Fogler, Kate Gallin Heffernan, Christina Heide

As of September 2013, HIPAA-covered entities must be compliant with the Omnibus Final Rule. The final regulations contain a number of changes affecting clinical research activities. In this session, faculty will:

- Review the 2013 changes to the HIPAA regulations affecting human subjects research, including changes to the compound authorization rules and the ability to use protected health information (PHI) for future research, as well as the sale of PHI, the definition of breach, and other definitional changes.
- Discuss practical implementation issues and strategies for compliance.
- Offer the opportunity to hear the Office for Civil Rights’ perspective on the research-related changes.

A16
“Front Door” Consent: Making it Work (Out of Body Experiences: Research Involving Tissue and Data Track)

Mariani J. Bledsoe, Elizabeth Frank, Michele Russell-Einhorn, Nicole Sieffert

With the explosion of new technology and the need for high quality specimens for research, there is an increased level of interest in obtaining “front door” consent for the future use of specimens during the course of routine care. In this session, faculty will:

- Discuss when front-door mechanisms are feasible and what makes this approach to consent work.
- Address the ethical and regulatory responsibilities of an institution and its researchers.
- Review the challenges and benefits of an institution-wide biospecimen banking initiative and explore a practical approach to evaluating barriers, risks, and benefits in implementing “front door” consent.
- Discuss research subject perspectives, as expressed by a patient advocate.

A17
Pediatric Medical Countermeasure (MCM) Research: Enumerating Ethical Considerations to Aid with Policy Decisions (Population Requiring Additional Protections Track)

Michelle Groman, Lisa M. Lee, Jeremy Sugarman

Department of Health and Human Services (DHHS) Secretary Kathleen Sebelius asked the Presidential Commission for the Study of Bioethical Issues (the Bioethics Commission) to enumerate the ethical considerations of conducting pediatric clinical trials of MCMs, which are interventions to protect children in the event of a bioterrorism attack. The Bioethics Commission recently released its report, Safeguarding Children: Pediatric Medical Countermeasure Research, in response to the Secretary’s request. In this session, staff of the Bioethics Commission will:

- Outline the four ethical principles that form the ethical foundation of its deliberations—respect for persons, beneficence, justice, and democratic deliberation.
- Review its recommendations concerning trials conducted before an event occurs (pre-event), which involve a hypothetical condition with an unknown likelihood of occurring, and explain the Bioethics Commission’s conclusion that in pre-event MCM research with no prospect of direct benefit, children generally should not be exposed to research risks that are greater than those they would encounter in everyday life or routine medical examinations.
- Examine how the ethical considerations change if MCM research is conducted after the occurrence of an attack (post-event), when children could tangibly benefit from the knowledge resulting from such research, and review its recommendations concerning post-event studies.
- Describe how the Bioethics Commission offers a unique perspective on how advisory bodies can aid with difficult policy decisions such as the decision whether to conduct pediatric anthrax vaccine adsorbed trials.
A18  Streamlining IRB Review for Multi-Site Research: Results of a Randomized, Controlled Trial of Central Versus Local IRB Review (Potpourri Track) Daniel K. Nelson
Oversight of multicenter clinical trials is complicated by the traditional approach of redundant review of identical protocols by multiple local IRBs. There have been calls for streamlining this process, and some academic institutions are relying on a central IRB for these scenarios. However, this model has its own drawbacks, and there are few data to guide decisions. In this session, faculty will:
- Review the challenges presented by current system(s) for oversight of multicenter trials, and possible solutions.
- Describe a novel pilot project that employed a randomized, controlled, blinded study design to test reliance on any central IRB already involved with a multicenter trial, provided certain criteria were met.
- Present results from this pilot project, including data on efficiency and effectiveness of IRB processes, and summarize conclusions that can be applied more broadly.

A19  Nuts and Bolts of Setting up a QA/QI Program (QA/QI and Post-Approval Monitoring Track) Kelly Dornin-Koss, Sarah White
In this session, faculty will:
- Address the points to consider when developing a QA/QI program.
- Review basic auditing concepts.
- Discuss details involved in audits/onsite reviews including determining a sample size, advantages of standard observations, and follow up after the audit/onsite review.
- Compare and contrast how two established QA/QI programs work (audience participation and ideas encouraged).

A20  Finding Flexibility in the Federal Regulations: Basic Considerations and Applications (Regulatory Balance Track) Lois Brako, Cindy Shindledecker
In this session, faculty and attendees will:
- Review the multiple opportunities to find flexibility in the regulations.
- Explore the pros and cons of “unchecking the box.”
- Discuss the basic ways to use regulatory flexibility throughout the HRPP.

A21  Research Data Security: Protecting Human Subjects’ Identifiable Data in the University Setting (Research Involving the Internet & Social Networking Track) Adrienne Tanner, Leon Wong
Subjects volunteer to participate in research with the understanding that the researcher(s) will protect their identity and other personal information from inadvertent or inappropriate disclosure. The principle that the IRB upholds in assessing the benefits and risks of the research is expressed in The Belmont Report as “beneficence.” Issues surrounding data security, privacy, and confidentiality have become more complex since the advent of computers and the Internet, with the Cloud becoming common data storage space, and with more investigators utilizing software and networked devices. Thus, it is not clear whether users always understand the risks. In this session, faculty will:
- Address data security issues (with a special focus on data stored and transmitted electronically) concerning both social and behavioral and biomedical human subjects research.
- Review different methods and levels of data storage, including the appropriateness of these methods given the risks involved.
- Discuss ways to educate an institution’s research community about data security.

In this session, faculty will:
- Explore the concept of informed consent and the ethical principles that underlie it.
- Review when informed consent is mandatory, when it can be altered or waived, and how to implement an alteration or a waiver of documentation of consent.
- Examine the challenging issues of “passive consent,” minor assent, and short forms.
- Examine barriers to providing ethically valid consent arising from study subjects, researchers, and IRB members.
- Discuss best practices and innovations for providing a dynamic consent process for subjects who have diminished decisional or other cognitive capacities.
- Evaluate complex case studies to determine ways to improve the informed consent process.
**Thursday, November 7 (cont.)**

**Didactic Sessions and Workshops Series A, 10:30–11:45 AM**

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<tr>
<th>Track</th>
<th>Title</th>
<th>Presenter(s)</th>
<th>Description</th>
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| A23 | Aligning IRB Review with Community Cultural Ethics and Standards | Edward Bartlett, David A. Borasky | In this session, faculty will:  
- Review the human research regulations in various countries.  
- Explore responses to culturally sensitive concerns including those that arise regarding study design, study procedures and risk assessment, and community-engaged partnerships and accountability.  
- Examine the individual participation decisions of those with non-proxy status such as cultural leaders, e.g., a Samoan elder.  
- Outline the US regulatory requirements for waivers of assent and consent and associated documentation.  
- Discuss risk assessment factors including investigator skills and experience, study sites, security, etc. |
| A24 | Developing an HRPP at an Institution with a Small Social and Behavioral Research Portfolio | Shannon Harr, Patricia MacCubbin | This session will focus on the challenges of developing an effective HRPP at an institution with a small social and behavioral research program, and may be especially appropriate for attendees from small colleges or other institutions conducting primarily non-biomedical research. The interactive format will help attendees explore structural and operational aspects common in small HRPPs and identify solutions that work effectively in this environment. In this session, faculty and attendees will:  
- Discuss what makes small HRPPs unique.  
- Outline how to establish an effective HRPP in an institution with a small research program.  
- Identify strategies for engaging senior leadership, investigators, IRB members, and those who work in other components of the HRPP.  
- Review suggested action priority lists and time lines.  
- Identify effective institutional change agents, offices, mechanisms, etc. |
| A25 | The Roles and Responsibilities of the Unaffiliated and Non-Scientist Member of the IRB | Dahron Johnson, Susan L. Rose | As key members of the IRB, unaffiliated/non-scientist members join with the other IRB members to shape the culture and conduct of research within their institutions. In this session, faculty will:  
- Examine the ethical and regulatory responsibilities of the unaffiliated/non-scientist member.  
- Discuss recent academic articles about the perceptions of the role of the unaffiliated/non-scientist member.  
- Review research on and guidance for the unaffiliated/non-scientist member.  
- Provide an overview of the responsibilities and challenges of lay review in a variety of IRB scenarios. |
| A26 | Bioethics Funding at the National Institutes of Health (NIH) | Liza Dawson, Samuel Garner, Ann Hardy, Joseph Millum, Holly A. Taylor | Presenters of this session will include NIH program officers responsible for bioethics grants, and time will be allocated for questions and answers about the grant funding process. In this session, faculty and attendees will:  
- Review the NIH’s record of funding for bioethics research.  
- Explore currently available NIH bioethics funding opportunities.  
- Review the application process for NIH grants.  
- Discuss what types of empirical or conceptual bioethics projects are most informative for the human research oversight community, and what bioethics research topics and questions are of most interest and importance in the field. |

12:00–1:00 PM

**Common Ground Networking Lunch**

*Time to connect... over lunch! Meet peers for conversation and networking. The tables will be divided by institution type: University/College (Medical), University/College (Non-Medical), Hospital/Medical Center, Government Agency, Pharma/Biotech Company, and, Small Research Programs. We will also have tables available for those wishing to “just lunch.” The Supporter and Exhibitor booths located in The Conference Connection will be open during this time, and the posters will be available for viewing. All are welcome!*
Thursday, November 7 (cont.)

12:00-1:00 PM
Research Ethics Book Group Lunch: The Professional Guinea Pig: Big Pharma and the Risky World of Human Subjects
Participate with your peers in a vibrant discussion of The Professional Guinea Pig: Big Pharma and the Risky World of Human Subjects by Roberto Abadie. Copies of Professor Abadie’s book are available in print and for Kindle via Amazon.com, and they will also be available for purchase at the onsite Bookstore. In order to ensure there are enough seats and meals, we require attendees to sign up for this event in advance.

12:00-1:45 PM
Meet and Greet the Conference Supporters, Exhibitors, and Poster Presenters
Network with this year’s conference Supporters, Exhibitors, and Poster Presenters in The Conference Connection during or after lunch!

1:00-1:15 PM
Demonstration of PRIM&R’s Online Course
Join us in the PRIM&R Booth for a demonstration of our interactive online resource—Ethical Research Oversight Course (E-ROC). A 15 minute presentation on E-ROC will provide you with an introduction to utilizing this tool to strengthen your understanding of human subjects protections.

Panel I and “Innovations in…” Series, 2:00–3:15 PM
During this time, attendees have the option to attend Panel I: When Research Offends: Ethics, IRB Review, and the Risk of Stigma, or one of the four panel presentations in our new “Innovations in…” series. Drawn from a rich pool of submissions, the “Innovations in…” series will feature poster authors whose cutting-edge research and practices are furthering the field of human subjects protections. Learn more about this new series by visiting our webpage.

Moderator: David H. Strauss
Panelists: Walter Bockting, Carl Hart, Susan Brown Trinidad
Are there scientific questions, which by their very nature risk offending subject populations and therefore should not be asked? What are the obligations of the IRB around protecting groups of subjects from stigma or burden resulting from research findings and their application? This panel will examine research and the role of research oversight in relation to stigma and stereotype with a focus on race, ethnicity, and sexuality.

Innovations A: Innovations in Research on Controversial Topics
Moderator: Steven Joffe
Panelists: Hila Berger, Lindsay McNair, Holly A. Taylor, Dorothy E. Vawter
The Belmont Report outlines three basic ethical principles as particularly relevant to research with human subjects: respect for persons, beneficence, and justice. In the most straightforward settings, balancing these principles requires careful consideration. When research is conducted on controversial topics or in sensitive settings about which there may be limited literature, deliberations about how to balance ethical principles can be particularly complex. This panel will highlight the ethical and practical challenges of conducting controversial research using four examples: protocols using sex offenders as subjects, surgical innovation and research, placebo and lesion controlled surgical trials, and research conducted in disaster settings.

Innovations B: Innovations in Genomics and Biobanking
Moderator: Paul S. Appelbaum
Panelists: Francesca Gould, Dina Paltoo, Jennifer Shaw
Research involving the use of biospecimens is becoming more prevalent, yet many questions about best practices remain. For instance, what are the implications of the possibility of genomic findings when the biospecimens are those of children? How is pharmacogenomics research perceived in communities where past research has cultivated and perpetuated harm? What best practices exist for biorepositories and how might an accreditation program improve the quality of biorepositories? Using these questions as a framework, this panel will share examples and make suggestions for how the panelists’ experiences and knowledge can inform the practice of attendees.

Innovations C: Innovations in Influences on Research Participation
Moderator: Jeffrey R. Botkin
Panelists: Mary Cataletto, Karen Leggett Dugosh, Rosemary Musesengwa
The public is often presented with mixed messages regarding research participation. Contrary findings across clinical trials and conflicts of interest among investigators performing pharmaceutical studies cast a negative light on the research enterprise for some, while others remain committed to participating in and lobbying for more clinical research. What ultimately tips the scales and convinces members of the public that they should or should not participate in research? What is the role of voluntariness in the decision-making process? How are the benefits of research perceived? Can the demographics of the researcher affect participation, and how? The panelists will address these and related questions using their own research findings.

ICON KEY

Didactic session
Pre-registration required
CME accredited
Interactive workshop
Call for Session Proposal
Double session
Recorded session
CIP eligible
Thursday, November 7 (cont.)
Panel I and “Innovations in…” Series, 2:00–3:15 PM

**Innovations D: Innovations in Communication with Research Subjects**

**Moderator:** Cynthia A. Gómez

**Panelists:** Leah R. Eisenberg, A. Robert Schleipman, Sharon L. Zack

Clear communication with subjects regarding all aspects of their participation in research is a necessary condition for performing ethical research. Considerable efforts are undertaken by research teams and IRBs to ensure subjects are fully informed of the relevant details of their participation, including risks, benefits, privacy, confidentiality, and more. Yet many questions remain about how best to communicate with research subjects. For example, what do subjects want to know about radiation risks? How can we ensure youth subjects understand what they are assenting to? Can complex information such as that contained in the HIPAA Notice of Privacy Practices be communicated effectively in comic form? This panel will address these questions while also highlighting how attendees might apply the presented methodologies at their own institution.

**3:15-3:45 PM**

**Break**

Join us in The Conference Connection for coffee.

**3:15-3:45 PM**

**Book Signing with Author and Panelist Carl Hart, PhD**

Join us at the onsite Bookstore in Pre-Function C after Panel I for a book signing with panelist and author Carl Hart, PhD. Copies of Professor Hart’s book, High Price: A Neuroscientist’s Journey of Self-Discovery That Challenges Everything You Know About Drugs and Society, are available online, as well as at the onsite Bookstore.

**Concurrent Plenary Sessions, 3:45-5:15 PM**

**Panel II: Internet Research: Is it Different? Is it “Special”? Points to Ponder for Social and Behavioral Investigators, IRBs, and Subjects**

**Moderator:** Laura Odwazny

**Panelists:** Jeffrey M. Cohen, Joseph A. Konstan, B.R. Simon Rosser

The internet is a research tool of enormous potential in the social and behavioral sciences. Yet many IRBs and investigators worry about the conduct of internet research, risks to subjects (known or unknown), and whether some research is appropriate—or even possible—using the internet. During this session, panelists will present specific examples of internet research, including surveys, data harvesting, experimental research, and ethnographic research, and will explore strategies for understanding and addressing ethical and technical concerns regarding such research. Other IRB review considerations will also be discussed.

**Panel III: The Increasingly Blurry Distinction Between Medical Research and Practice: Implications for Ethical Oversight**

**Moderator:** Robert J. Levine

**Panelists:** Thomas L. Beauchamp, Alexander M. Capron, Ruth R. Faden, Nancy E. Kass

*(Please note that in order to provide our slate of speakers adequate time to cover this complex topic, this panel will run from 3:45 to 5:30 PM)*

In a special supplement to *The Hastings Center Report* titled, “Ethical Oversight of Learning Healthcare Systems,” a team from The Johns Hopkins University argues that the traditional distinction between research and treatment, and the human subjects protections framework that rests on and reinforces it, are no longer tenable within the larger category of activities that the Institute of Medicine calls “learning healthcare systems.” Furthermore, they argue, we need a new ethical framework for overseeing the sorts of activities conducted within those systems. Some are seeing these proposed changes as a radical paradigm shift in thinking about human subjects research. PRIM&R has recently addressed similar issues, at a more practical level, through its project on the Boundaries Between Research and Practice. In this session, representatives from both projects will discuss the following questions: What are the salient features of a healthcare learning system, and how does it blend the roles of researcher/health care provider and patient/research subject? Which activities should continue to be reviewed by IRBs, which might better be referred to alternative committees for ethical review, and which do not require ethical review beyond the regular mechanisms provided by professional organizations? Should participation in some of these activities be considered obligatory and carried out without informed consent? And, what are the implications for the definition of “research”? 
Panel IV: Applying the Belmont Principles Across Borders and Cultures

Moderator: Eric M. Meslin

Panelists: Clement Adebamowo, Sara Lavinia Brair, Sana Loue, Masayuki Yoshida

This panel will feature speakers from diverse global settings who will discuss how the Belmont principles are understood and applied in those settings and contexts, and contrast them with traditional Western interpretations and applications of the principles. Topics to be highlighted include the role of gender, religion, and class in understanding the principles; the practical realities of interpreting and making relevant ethical concepts such as autonomy, beneficence, and justice in non-Western settings; and the challenges of putting the principles into practice in diverse contexts (e.g., the informed consent process). The panel will also include a discussion of the role of local research ethics committees as the standard-bearers for ethical research, as well as their capacity for implementing effective research review.

5:15-7:00 PM

2013 AER Conference Welcome Reception

Join us in The Conference Connection to celebrate the opening of the 2013 AER Conference, toast the kick-off of PRIM&R’s 40th year, and extend your best wishes to Joan Rachlin, PRIM&R’s longtime executive director, who will be retiring in early 2014. You’ll also be able to meet our Conference Supporters and Exhibitors, view the Poster Presentations, and receive a complimentary mini-massage. Light refreshments will be served.

5:30-5:45 PM

Demonstration of PRIM&R’s People and Perspectives (P&P)

Join us in the PRIM&R Booth for a demonstration of our newest interactive online initiative—People and Perspectives (P&P). P&P is an online archive that seeks to uncover, collect, catalogue, preserve, and share the stories of those performing the essential work of advancing ethical research. P&P features both the oral histories and reflections of those “in the trenches,” as well as information about the field’s founders, shared via video, audio and text stories. This 15-minute presentation will introduce you to some of the stories and participants on the site so far, and give a brief overview on how to contribute your own story to this living archive!

7:00 PM

WIRB-Copernicus Group Evening Reception

The WIRB-Copernicus Group is pleased to host their signature celebration at PRIM&R’s 2013 AER Conference. All PRIM&R attendees are invited to join the WIRB-Copernicus Group for an evening of cocktails, light supper, and entertainment at the Sheraton Boston Hotel, located just steps from the Hynes Convention Center. More information about the WIRB-Copernicus Group, a 2013 AER Conference Platinum Supporter, can be found here.
Friday, November 8: 2013 AER Conference

7:00 AM-5:30 PM
Registration Open

7:00-8:00 AM
Continental Breakfast

7:00-8:00 AM
Certified IRB Professional (CIP®) Continental Breakfast
Interested in earning your CIP credential? Want to connect with other “CIPs?” Attend this continental breakfast to learn more about the credential, meet representatives of the Council for Certification of IRB Professionals, network with fellow CIPs, and ask questions of those already certified.

Concurrent Plenary Sessions, 8:00-9:30 AM

Moderator: Jeremy Sugarman
Panelists: Leonard Glantz, Robert D. Truog
In March 2013, OHRP issued a compliance oversight determination letter about the Surfactant, Positive Pressure, and Oxygenation Randomized Trial (SUPPORT) conducted at 22 sites with 1,300 subjects. Because, even after years of research and practice, clinicians did not know how much oxygen to provide to extremely low birth weight infants to minimize retinopathy of prematurity without increasing impaired brain development or death, the SUPPORT study randomized extremely low birth weight infants to lower or higher levels of oxygen saturation, all within the range of oxygenation provided by clinicians as standard care at the institutions at which the research was conducted. The consent documents for the study did not include information about the risks of retinopathy of prematurity, impaired brain development, or death posed by receiving either low or high oxygen saturation levels. On this basis, OHRP found that consent was deficient and violated the regulatory requirements. More generally, pragmatic clinical trials comparing interventions already in use in clinical care are proliferating in the effort to find more effective and less expensive therapies. OHRP’s view of such research when it involves randomization to “standard of care” interventions, as evidenced by the determinations made regarding the SUPPORT study, may not be shared widely within the research community. The months of heated controversy that followed OHRP’s original determination and subsequent letter suspending all compliance actions against the SUPPORT sites reveal a lack of consensus within the research community around many of the ethical issues underlying the conduct of research randomizing subjects to two or more “standard of care” interventions. This session will use a moderated debate format to explore these contentious issues, including how IRBs should assess this type of clinical trial design, how the risks of the “standard of care” interventions should be evaluated if subjects would be receiving these “standard of care” interventions as treatment outside of the research, and whether informed consent is ethically necessary.

Panel VI: The Ethics of Research Without Consent
Moderator: Alan Wertheimer
Panelists: Neal Dickert, Patricia A. Marshall, Franklin G. Miller
The purpose of this panel is to examine whether and when it is justifiable to engage in research with human subjects without their valid consent. Although the Common Rule specifically allows for the waiver of informed consent when certain criteria are met, there is no standard account of whether and when it is morally justifiable to engage in research without seeking consent, or with deceived consent, for instance, in the context of observational research, emergency research, and “mystery shopping” studies. Panelists will discuss each of these examples. The central questions to be addressed are: Does the Common Rule get it basically right and, if so, why? Does it exempt too much? Does it exempt too little? And, what is properly exempted under these criteria?

Friday, November 8 (cont.)
Panel VII: Data Sharing on Steroids: Demands for Transparency of Subject-Level Research Data

Moderator: Mark Barnes

Panelists: Elizabeth Hohmann, Justin P. McCarthy, Sharon F. Terry

There is increasing demand for transparency in clinical research. The expansion of clinical trial registries means more public access to both research studies open to participation and to reporting of aggregate research results from protocols. The demand for transparency of research data has now expanded to include access to individual-level raw data. Perhaps the most publicized example of this push is a recent initiative from the European Medicines Agency. Some pharmaceutical/biotechnology industry sponsors have also started their own transparency initiatives that involve sharing of data. The primary goals of these initiatives include not only review and monitoring of completed research, but the possibility of secondary use of the data collected. While the current focus of discussion about "big data" sharing is on industry-sponsored research, it is important to consider the potential expansion of scope to include all research. The panel will begin with an overview of several concrete initiatives and proposals under development. Representatives from a patient advocacy group, the pharmaceutical/biotech industry, and an institutional oversight body will then discuss the potential benefits as well as concerns of such transparency.

9:30-9:45 AM

Break

Concurrent Plenary Sessions, 8:00-9:30 AM

Panel VII: Data Sharing on Steroids: Demands for Transparency of Subject-Level Research Data

Moderator: Mark Barnes

Panelists: Elizabeth Hohmann, Justin P. McCarthy, Sharon F. Terry

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9:30-9:45 AM

Break

Concurrent Welcomes, Membership Updates, & Keynote Addresses, 9:45-11:00 AM

9:45-10:15 AM

Welcome and Membership Update

10:15-11:00 AM

Keynote Address: Social Science Research and the Fight Against Poverty

Esther Duflo, PhD

Abdul Latif Jameel Professor of Poverty Alleviation and Development Economics, Massachusetts Institute of Technology; Director, Abdul Latif Jameel Poverty Action Lab

9:45-10:15 AM

Welcome and Membership Update

10:15-11:00 AM

Keynote Address: Therapeutic Misconception in Clinical Research: A 30-Year Retrospective

Paul S. Appelbaum, MD

Dollard Professor of Psychiatry, Medicine, and Law; Director, Division of Law, Ethics, and Psychiatry; and Director, Center for Research on Ethical, Legal, and Social Implications of Psychiatric, Neurologic, and Behavioral Genetics, Department of Psychiatry, Columbia University College of Physicians and Surgeons

11:00-11:15 AM

Break

Join us in The Conference Connection for coffee.

Didactic Sessions and Workshops Series B, 11:15 AM-12:30 PM

B1

A Dialogue with the Department of Defense (DOD): Updates for DOD-Funded Researchers

(A Dialogue with the Feds I Track) Laura Ruse Brosch, Jessica Candia, L. Andrew Jones

This session will be led by representatives from the DOD, and is for researchers who have or are seeking extramural DOD funding. Attendees are encouraged to come with questions of interest to all. In this session, attendees will:

- Hear from DOD staff about policies affecting the conduct of DOD-funded research.
- Ask questions about current issues and initiatives.
- Participate in an open discussion about DOD-related topics relevant to the research community.

B2

A Dialogue with the Presidential Commission for the Study of Bioethical Issues

(A Dialogue with the Feds II Track) Michelle Groman, Lisa M. Lee

This session will be led by representatives from the Bioethics Commission. Attendees are encouraged to come with questions of interest to all. In this session, faculty and attendees will:

- Review the Bioethics Commission's latest work.
- Discuss topics relevant to Bioethics Commission stakeholders, such as the federal research protections regulations that informed the Bioethics Commission's recent recommendations on pediatric MCM research, the Human Subjects Research Landscape Project – Analysis Dataset posted for public use on bioethics.gov, and Bioethics Commission educational materials.
- Participate in a question and answer session with Bioethics Commission staff.

Friday, November 8 (cont.)
**B3**
**Improving Relationships Between Researchers and the IRB** (Accreditation of HRPPs Track)
*John R. Baumann, Eifaang Li, Elyse I. Summers*

This session will focus on how to achieve effective communication between researchers and IRB members. In this session, faculty will:
- Share ideas on the pre-submission advising of researchers (the example of an initiative started at Cedars-Sinai will be used);
- Discuss transparent and clear policies and standards, enhanced communication techniques, and improving efficiency;
- Highlight innovative research from Indiana University concerning proven relationship-strengthening strategies.

**B4**
**Cutting Edge Science in the Operating Room: Ethical Issues in Surgical Innovation and Research** (Activities Along the Boundaries Between Research and Practice Track) *Lindsay McNair, Sean Philpott*

Clinical research in operating rooms shares many ethical concerns with other types of biomedical research. However, additional ethical considerations arise in studies involving invasive surgical interventions. This session will review current definitions, policies, and practices with respect to surgical innovation and research, including recent recommendations from the Society of University Surgeons on the establishment and role of institutional Surgical Innovation Committees. In this session, faculty and attendees will:
- Define surgical practice, innovation, and research as described in the current literature;
- Discuss particular challenges around study design and assessment of surgical research studies, including the innovation versus research distinction and deviation from standard of care, informed consent, randomization to receive invasive and often irreversible surgical procedures, use of control groups (including sham surgery), and the feasibility of post-trial access to interventions that demonstrate benefit;
- Examine existing and proposed methods of ethical oversight for surgical innovation and research;
- Explore issues in clinical study design and conduct that may have unique ethical implications in surgical research compared to other types of biomedical research.

**B5**

This session will provide attendees with an opportunity to:
- Review when an activity is considered “research” and when that activity involves “human subjects,” as defined in the DHHS and FDA regulations;
- Examine the federally mandated exemption categories and the differences between the DHHS and FDA regulations with regard to exempt research;
- Use case studies to explore in depth the nuances around these crucial decisions and the impact of personal and institutional attitudes on such determinations.

**B6**
**The Making of a Successful Research Team: Essential Components of an Educational Program** (Educating Research Teams Track) *Donna Buckley, Mina Busch*

In this session, faculty and attendees will:
- Discuss activities for facilitating educational programs for researchers, including mentoring of research students by faculty;
- Compare elements of a structured educational program for researchers;
- Identify job aids and tools that provide value to researchers;
- Review what “current” means in clinical research training.

**B7**
**Assessing the Prospect of Direct Benefit in Pediatric Studies and Component Analysis** (Ethical Issues Track) *Susan Z. Kornetsky, Robert “Skip” Nelson*

In this session, faculty and attendees will:
- Examine the process for reviewing research interventions that offer the prospect of direct benefit to a pediatric population;
- Discuss the application of component analysis in the IRB’s review of pediatric studies;
- Outline the expectations for documenting the prospect of direct benefit and use of component analysis during the review of pediatric studies.

*Please note this is a double session and will end at 1:45 PM.*
### B8
**An Overview of FDA’s Investigational New Drug (IND) Regulations: Understanding the Sponsor’s Responsibilities** *(FDA Regulations Track)*

Diane M. Maloney, Walter L. Straus

In this session, faculty will:
- Examine the federal regulations for INDs (21 CFR 312).
- Review sponsor and investigator responsibilities for IND studies.
- Present IND issues unique to the FDA’s Center for Biologics Evaluation and Research (CBER).

### B9
**New Policies for Clinical Trials in India: Promises and Pitfalls** *(Global Research Track)*

Lester J. Arnold, Mark Barnes, Jeremy Sugarman

India has become an international hub for clinical research. Earlier this year, as part of an effort to address ethical concerns about some of this research, India introduced the Drug and Cosmetics (First Amendment) Rules 2013. The new policy, which is aimed at protecting human subjects in research, is generating much discussion both within India and worldwide. In this session, faculty will:
- Review the research context and climate in India that led to the creation of the new policy.
- Outline the new policy’s central features, including the provision of compensation for research injuries and the required registration of ethics review committees.
- Examine the implications of the new policy, including the unintended consequences of potentially reducing valuable research activities and capacity in India.
- Discuss international responses and implications for clinical research conducted in other global settings.

### B10
**Informed Consent: To Waive or Not to Waive** *(Informed Consent Track)*

Elizabeth Bankert, Marcella Banks-Shields, Jeffrey A. Cooper

In this session, faculty and attendees will:
- Discuss the appropriate use of waivers for obtaining informed consent.
- Review the regulatory applicability of waivers.
- Explore a variety of cases in which a waiver would add more protections and help facilitate research.

*Please note this is a double session and will end at 1:45 PM.*

### B11
**Operationalizing the Public Health Service (PHS) Financial Conflict of Interest (FCOI) Rule** *(Institutional Officials Track)*

Wayne Patterson, Robyn S. Shapiro

In this session, faculty will:
- Provide a brief summary of the major changes to the regulation including those regarding the definition of significant financial interests, disclosure thresholds, accessibility of information to the public, and investigator training.
- Discuss ways in which universities and hospitals have implemented the PHS FCOI rule.
- Address difficulties that institutions have experienced when implementing the new requirements.

### B12
**The Basics and Beyond: Research with Prisoners, Pregnant Women and Fetuses, and Children** *(IRB Bootcamp Track)*

Paul Christopher, Julia Gorey, Josiah D. Rich

In this session, faculty will:
- Review the DHHS regulations governing research with prisoners, children, pregnant women, fetuses, i.e., 45 CFR 46 subparts B, C, and D.
- Outline best practices for research with these populations and discuss other relevant guidance.
- Discuss challenges and ethical considerations for research involving prisoners.

### B13
**Protocol Rage and Meeting Fatigue: Therapeutic Options for IRB Chairs** *(IRB Operations and Toolkit Track)*

Melissa E. Abraham, Elizabeth Hohmann

In this session, faculty will:
- Review common problems with protocols submitted for IRB review.
- Share strategies for working with difficult Investigators.
- Explore best practices for managing the challenges and stressors that come with being an IRB chair.
In this session, faculty will:

- Review the results and recommendations of the CTTI Use of Central IRBs for Multicenter Clinical Trials project.
- Describe the purpose and utility of the Considerations Document, a CTTI developed guide to support communication and contractual relationships between institutions and a central IRB.
- Share case examples of the successful adoption of the recommendations and use of the Considerations Document.

**B15**

“State” it Like it Is: The Impact of State Laws on Informed Consent and Other Aspects of Research

(Out of Body Experiences: Research Involving Tissue and Data Track) Valerie Gutmann Koch, Susie A. Han, Laura Odwazny – OHRP Resource Person

State laws can complicate the requirements imposed on researchers and institutions in many ways. New York state laws may be utilized as examples and case studies, which may highlight the categories of state laws that IRBs and investigators often have to consider when engaged in certain types of research. In this session, faculty will:

- Explore state law issues that should be analyzed in connection with any federal Common Rule and FDA requirements, including state law requirements that impact the content of informed consent, research involving vulnerable populations, surrogate appointment, and more.
- Review the interaction between overlapping state and federal requirements, for example: research involving donated biospecimens, including issues related to state and federal genetic privacy laws and newborn screening programs.
- Discuss the challenges of various research requirements, such as: how to define who is a research participant for purposes of consent/assent; issues raised by the increase of social media and internet research; and issues around what constitutes the “standard of care” in clinical research.

Please note this is a double session and will end at 1:45 PM.

**B16**

Beyond the Genome: Data Security and Privacy Concerns Surrounding Genomic Research

(Issues for Pharma/Biotech Track) Sara Calvert, Cynthia Hahn

The CTTI Use of Central IRBs for Multicenter Clinical Trials project published results and recommendations in January 2013. Implementation of these recommendations may increase the quality and efficiency of clinical trials. In this session, faculty will:

- Discuss an expanded view of vulnerability beyond that outlined in the human subjects protections regulations, reframe vulnerability in the context of laws, policies, and processes in other fields.
- Provide examples of different types of vulnerability, such as homelessness and disability, and explore how to think about these examples in the context of clinical research.
- Review the threshold questions an IRB should address before permitting research with these subjects.
- Discuss examples of risks to subjects that may be different in nature or frequency for these subjects.

**B17**

Redefining Vulnerability: People with Disabilities and Beyond

(Populations Requiring Additional Protections Track) Jeremy Block, Susan Delano, Michelle Feige – OHRP Resource Person

In this session, faculty will:

- Discuss an expanded view of vulnerability beyond that outlined in the human subjects protections regulations, reframe vulnerability in the context of laws, policies, and processes in other fields.
- Provide examples of different types of vulnerability, such as homelessness and disability, and explore how to think about these examples in the context of clinical research.
- Review the threshold questions an IRB should address before permitting research with these subjects.
- Discuss examples of risks to subjects that may be different in nature or frequency for these subjects.
In this session, faculty and attendees will:

- Examine different techniques for identifying and recruiting unaffiliated and/or non-scientist IRB members from the local community.
- Review how to integrate unaffiliated and/or non-scientist IRB members onto the board and retain them once they are recruited.
- Consider ways to pay, thank, and reward unaffiliated and/or non-scientist IRB members in ways that keep them interested in continued membership.

B19

Making Your QA/QI Program Work for You (QA/QI and Post-Approval Monitoring Track)

Leslie Howes, Delia Wolf

In this session, faculty will:

- Provide an overview of the elements needed to develop and customize a QA/QI program that fits your institution’s needs and available resources.
- Describe a wide range of QA/QI activities and services specific to different types of research, from social and behavioral to biomedical/clinical, and from domestic to international.
- Discuss how to identify, establish, and evaluate benchmarks to assess the quality of your HRPP.
- Describe strategies for developing effective education and training opportunities for your investigators.
- Share and discuss QA/QI sample documents, including onsite review/audit checklists, QA/QI report templates, and various study management tools.

*Please note this is a double session and will end at 1:45 PM.*

B20

Finding and Applying Flexibility in the Federal Regulations: Cooperative Review Agreements and Other Advanced Considerations (Regulatory Balance Track)

Irene Stith-Coleman, Laura Youngblood, Tracy Ziolek

This advanced session will explore various procedures that incorporate flexibilities within the regulations while providing equivalent protections to research subjects. In this session, faculty and attendees will:

- Review the flexibilities in Subpart B, including the definition of “pregnancy” as an important decision point in assessing Subpart applicability.
- Consider the flexibilities in Subpart C, including the circumstances under which a subject is a “prisoner,” and a prisoner is a “subject.” Use of a DHHS Secretarial Waiver for inclusion of prisoners in epidemiology will also be discussed.
- Examine the flexibilities in Subpart D, including the regulatory definition of a “child,” and issues around assent, parental permission, and documentation of assent/permission.
- Discuss best practices for forming and utilizing cooperative review agreements with partner institutions, even on a small scale, using the existing University of Pennsylvania/The Children's Hospital of Philadelphia agreement as a case study.

B21

Informed Consent Realities and Possibilities in Internet Research (Research Involving the Internet & Social Networking Track) Elizabeth Buchanan, Donna Spruijt-Metz

This session will focus on the elements of consent and internet research, with a review of the different types of internet research. In this session, faculty and attendees will:

- Identify specific internet research settings and conditions for consent.
- Examine how to apply the Common Rule regulatory requirements for informed consent to internet research and review regulatory flexibilities applicable to consent in such research.
- Consider parental consent and child assent in internet research involving minors.
- Discuss the applicability of informed consent waivers and/or waivers of documentation.
- Share sample language for informed consent documents for internet research that emphasizes data security and confidentiality of research-related information.

*Please note this is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please register online or email us, and we’ll be sure to save you a seat! For those who pre-register, a lunch ticket will be included on your name badge. Please use this to pick up your boxed lunch, which will be located outside of the session room.*
**Friday, November 8 (cont.)**

**Didactic Sessions and Workshops Series B, 11:15 AM-12:30 PM**

**B22**

**Speed it Up: Exempt... Expedite... Relax!** *(SBER I – Basic Track)*

*Jeffrey M. Cohen, Dean R. Gallant, Samantha Smith – OHRP Resource Person*

In this session, faculty and attendees will:
- Discuss the procedural review process for social, behavioral, and educational research through a sequence of questions including: Is this activity research? Does it involve human subjects? Is my institution engaged? Is the research exempt? And may review be expedited?
- Use test scenarios to explore each of the aforementioned questions.
- Identify regulatory flexibilities that can be used while still assuring research is conducted ethically.

*Please note this is a double session and will end at 1:45 PM.*

**B23**

**Scientific Merit, Generalizability, and the Risks Associated with Qualitative Research Methodologies (QRM)** *(SBER I – Advanced Track)*

*Ellen Marakowitz, Julie Simpson, Karen Szala-Meneok*

In this session, faculty will:
- Explain and illustrate QRM.
- Explore the IRB review process for assessing scientific merit and risk minimization in QRM studies.
- Engage the audience in a discussion of how to assess scientific merit and risk minimization in QRM studies.

*Please note this is a double session and will end at 1:45 PM.*

**B24**

**Outsourcing IRB Review While Maintaining a Robust HRPP at an Institution with a Small Research Program** *(Small Research Programs Track)*

*Felix A. Khin-Maung-Gyi, Scott Lipkin*

This session will describe how an institution with a small research program can maintain an effective HRPP while outsourcing IRB review, and it will be appropriate for individuals from institutions that self-identify as having a small research program according to any of the criteria laid out in the track descriptor. During the session, faculty will:
- Explore the considerations associated with outsourcing IRB review to a central or single partner IRB.
- Review the delineation of responsibilities, accountabilities, and liabilities between the institution and the independent IRB when protocol review is outsourced.
- Discuss how to measure and maintain an effective HRPP when protocol review is outsourced.

**B25**

**Statistics Without Tears** *(Unaffiliated and Non-Scientist IRB Members Track)*

*Susan S. Fish, Janice Weinberg*

This session will explain the intimidating statistical terms that make your eyes glaze over! To begin, attendees will review the statistical basics and then, half-way through, the group will split so those who need more study of the basics can obtain that information, while others ready for the next level can move on to more advanced topics. In this session, faculty and attendees will:
- Review the basic concepts of testing.
- Discuss different ways to be right and wrong, e.g., type 1 and type 2 errors.
- Review the concept of “power,” the types of statistical tests, and when to bring in a statistician.
- Explore the relationship between statistics and ethics.
- Apply statistical vocabulary.

*Please note this is a double session and will end at 1:45 PM.*
Panel VIII: Taking Control: Ethical Challenges for Participant-Centered and Participant-Led Research

**Moderator:** Susan Z. Kornetsky

**Panelists:** Greg Biggers, P. Pearl O'Rourke, Sharon F. Terry

Social media and digital technologies have facilitated the formation of online communities engaged in establishing and conducting health research projects. In these scenarios, participants become the driving force behind the initiation and sometimes conduct of research projects such as self-surveillance, analyses of genomic data, genome-wide association studies (GWAS), data collection, formal studies, and even “citizen science.” This form of research therefore represents a bottom-up approach, often by lay individuals, as opposed to a top-down approach, led by traditional scientists. Potential benefits of such research may include more representative and broader participation of the public, outcomes-focused research, enhancement of personal autonomy and empowerment of the research community, transparency and openness about research, accelerated research, and lack of profit-seeking and career-enhancing motives for conducting research. While this research approach may be innovative and valuable, it raises many logistical, regulatory, and ethical questions from the perspective of human subjects protections. This panel will address some of those questions, including: What are the requirements for ethical oversight? Are the "principal investigators" and the "research participants” one and the same, or is a continuum possible? Are "research sponsors" indistinguishable from "research participants?” Can standard processes around “informed consent” bear the weight of these new interactions? For example, do the Terms of Agreement used on a social networking site suffice as informed consent, is one-time static consent sufficient, or should consent be responsive to context and changing lifespan values? Are the norms and mechanisms for regulating standard biomedical research applicable to participant-led research? And, to what extent is IRB review suitable for participant-centered research?
Panel IX: Nearly Unavoidable: Cluster Randomized Trials in Social and Behavioral Research

Moderator: Dean R. Gallant

Panelists: John Y. Baker, Rachel Glennerster

Social and behavioral research studies sometimes involve interventions designed to influence behavior and are delivered at a group, institutional, or community level. Individuals who are the objects of the interventions may be unaware of their participation in research. Even when they are aware, it may be difficult or impossible for them to avoid those interventions. In addition, individual consent is often impracticable. The decision to field such trials is often made at a political level through negotiations between investigators and gatekeepers controlling the means to deliver the interventions to the targeted populations. Community consultation of some kind may or may not occur. Depending on the source of funding and the type of intervention, the trial may or may not require IRB review and, consequently, may or may not need to satisfy such criteria as minimizing risks, equitable selection of subjects, or justifiable waiver of informed consent. Panelists will discuss different types of research “clusters,” including issues such as whether these features of cluster randomized trials are inevitable, given their design, and whether and when those features are problematic from a human research protections perspective.

C1

A Dialogue with the FDA (A Dialogue with the Feds I Track)

Owen Faris, Joanne Less, Diane M. Maloney, Catherine Parker

This session will be led by representatives from the FDA. Attendees are encouraged to come with questions of interest to all. In this workshop, attendees will:
- Hear from representatives of the FDA about new and evolving issues, initiatives, regulations, and guidance.
- Participate in an open discussion about topics relevant to FDA stakeholders.
- Ask questions about evolving issues at the FDA, including warning letters.

C2

Applying the Definition of Children and State Law to Biomedical and Social-Behavioral Research

Laura Odwazny, Peter Vasilenko

The federal regulations related to the definition of children defers to state and local laws as to who qualifies as a child; however, who is legally considered a child varies from state to state, and state law definitions of who may be considered a child or an emancipated minor are complicated. Thus, determining whether subjects are children and whether they are children is problematic for IRBs reviewing multi-site studies. This session will highlight the challenges of applying the various definitions of “children” to biomedical and social-behavioral research and provide a strategy for investigators and IRBs seeking to address these issues. In this session, faculty and attendees will use case studies to:
- Review the federal regulatory definition of children and discuss how OHRP interprets the various components of that definition.
- Examine how the federal definition of children operates in relation to state law.
- Discuss an analytic framework investigators and IRBs can use to work through these issues.

C3

Using Metrics for Quality Improvement of HRPPs (Accreditation of HRPPs Track)

David G. Forster, Jeremy Corsmo

In this session, faculty will:
- Review the AAHRPP-collected metrics for 2012.
- Outline how to collect performance metrics in both large and small HRPPs.
- Discuss how to use performance metrics to drive quality improvement.
- Explore specific information on measuring and maintaining high quality, efficient HRPPs using the metrics collected by AAHRPP.

C4

QA/QI/Program Evaluation: Is it or is it Not “Research”? (Activities Along the Boundaries Between Research and Practice Track) George Gasparis, Sean Philpott

In this session, faculty will:
- Use case studies to highlight distinctions between QA/QI, program evaluation, and research.
- Address how to determine whether an activity is human subjects research, and discuss generalizability.
- Discuss the issues raised by an investigator’s involvement in another institution’s QA/QI research, including whether, in such cases, the home institution is engaged in research.
C5

Future Trends in the Relationship Between Central/Independent IRBs and Research Institutions: Risk/Benefit Ratio (Advanced Forum for IRB Professionals Track)

Barry B. Bercu, Ernest D. Prentice

Innovation and progress in pharmaceutical drug development is stifled by redundancy, inefficiency, and rising and exorbitant costs. Despite several recent documents by DHHS, FDA, and NIH suggesting central IRB review is logical, appropriate, and efficient, there is still resistance by many academic institutions. Why is this? And, what can be done to keep the US IRB infrastructure competitive in this global marketplace? In this session, faculty and attendees will:

- Discuss the genesis of nonprofit and for-profit independent IRBs, as well as the events that led to the first academic health science center using a commercial IRB.
- Contrast the characteristics, complexities, and subtleties of an academic health science center IRB with those of a commercial IRB.
- Identify the advantages and disadvantages of an academic health science center using a commercial IRB for its protocol review.
- Review the Advance Notice of Proposed Rulemaking (ANPRM) recommendations on the use of one IRB for multicenter clinical trials.

C6

The CIP® Credential: What’s it About? (Educating Research Teams Track)

Jaime Arango, Gregorio Lim, Kelley O’Donoghue

During this session, attendees and faculty will:

- Discuss the CIP credential and the steps involved in pursuing it.
- Review eligibility and recertification requirements.
- Outline the types of questions on the CIP exam.
- Share exam preparation strategies.

C7

Looking Beyond Responsible Conduct of Research: Ethical Research from Design to Data Collection to Dissemination of Results (Ethical Issues Track) Philip M. Alberti

In this session, faculty will:

- Describe how a clinical trial conducted entirely in accordance with Responsible Conduct of Research guidelines for review, approval, and oversight might still fall short of ethical responsibilities in the broader social contract of research.
- Discuss how the conduct of research fits along a continuum from concept and funding through the dissemination of results, and what other entities bear responsibility for ensuring the results of research reach those populations that could benefit most.
- Review the ethical implications of health disparities.

C8

Emergency Research and Exception from Informed Consent (EFIC): Interesting Challenges and Lessons Learned About Community Consultation from a Multicenter Network (FDA Regulation Track) Michelle Biros, Neal Dickert, Sara F. Goldkind, Deniel Harney

In this session, faculty and attendees will:

- Discuss a combination of interesting experiences and lessons learned through the first two EFIC trials conducted through Neurological Emergencies Treatment Trials (NETT), a multicenter network of 17 hub sites funded to conduct clinical trials of interventions to address neurological emergencies.
- Review data collected on investigator and study coordinator perspectives of community consultation.
- Discuss network-wide data regarding community consultation, subjects’ perspectives on EFIC research and NETT studies, and network-wide experiences using different methods of community consultation.

C9

Telling it Like it Is: Challenges in Informed Consent in International Settings (Global Research Track)

David A. Borasky, Caroline Kithinji

In this session, faculty will:

- Review the international standards for informed consent and documentation of consent.
- Describe challenges around obtaining meaningful informed consent, such as varying degrees of literacy, translation issues, and differences in cultural norms.
- Review measures taken to adapt the Western informed consent model to international settings.
Friday, November 8 (cont.)
Panels VIII and IX, and Didactic/Workshops Series C, 2:00-3:15 PM

C10
Regulatory Requirements and Ethical Considerations Regarding Pediatric Assent in Research
(Informed Consent Track) Lisa Buchanan, Robert W. Frenck, Steven Joffe
In this session, faculty will:
- Review the regulatory requirements for child assent and waivers of assent.
- Discuss developmental issues, with an emphasis on determining when a child acquires the capacity to provide assent and consent.
- Explore ethical issues, including how to proceed when there is a disagreement between children and their parents or legal guardians about research participation.

C11
Identifying, Reducing, and Managing Institutional Conflicts of Interest (Institutional Officials Track)
Mark Barnes, Jennifer Kulynych
In this session, faculty will:
- Discuss how to create and maintain an organizational culture that understands, acknowledges, and addresses potential institutional conflicts of interest.
- Review how to handle institutional conflicts of interest, including those that arise when institutional officials don’t follow HRPP/IRB policies.

C12
Writing Stellar Standard Operating Procedures (SOPs) (IRB Bootcamp Track)
Karen Hale, Elyse I. Summers
In this session, faculty and attendees will:
- Discuss the components of comprehensive and effective HRPP/IRB SOPs.
- Understand the resources, input, and/or approvals needed to develop specific SOPs.

C13
Evaluating and Improving IRB Operations (IRB Operations and Toolkit Track)
Melissa Epstein, Cheryl Savini
In this session, faculty and attendees will:
- Review techniques such as evaluating the “life” of a protocol, identifying bottlenecks and inefficiencies, conducting desk audits, analyzing IRB metrics, evaluating staff morale and workload, evaluating resources, and obtaining feedback from investigators.
- Discuss ways to improve operations and streamline processes, including using a computer-based recordkeeping system, maximizing staff efficiency, using flexibility in the regulations, and adopting written SOPs.
- Bring and share solutions that have worked at their respective institutions.

C14
Flexible Adaptive Clinical Trial Designs: Understanding Such Designs, and Implications for Informed Consent and IRB Review (Issues for Pharma/Biotech Track)
Scott Berry, William J. Meurer
In this session, faculty will:
- Provide a general overview of the why, when, and how of adaptive clinical trial designs.
- Present a case study of an actual trial for discussion of the clinical, logistical, and ethical issues.
- Discuss some of the challenges of preparing an informed consent form for, and conducting IRB review of, an adaptive clinical trial protocol.

C15
“Research Free or Die”: Legal Protections Against Challenges to Academic Freedom in Research (Legal Track) Ann Hardy, Julia Hesse, Ellen Marakowitz
The recent litigation concerning whether researchers from Boston College must release tapes to Great Britain from an oral history research project related to murders allegedly committed by the Irish Republican Army has brought to light the legal challenges that can be associated with researchers’ academic freedom. In this session, faculty will:
- Define best practices for structuring institutional policies and research agreements to defend against similar challenges.
- Discuss the scope of legal protection and privilege afforded to researchers under Certificates of Confidentiality (CoC) and considerations around when it would be prudent to obtain a CoC.
C16 The Impact of the NIH’s Draft Genomic Data Sharing (GDS) Policy on the IRB’s Role in Reviewing Genetic Research (Out of Body Experiences: Research Involving Tissue and Data Track)
Laura Lyman Rodriguez, Dina N. Paltoo
Rapid advances in DNA sequencing and other high-throughput technologies have increased the volume, complexity, and types of data generated in genomic studies. To ensure the full value of genomic data in light of this growth, the NIH has drafted the GDS Policy, which updates and expands on the 2007 NIH Policy for Sharing of Data Obtained in NIH-Supported or NIH-Conducted GWAS. The draft NIH GDS Policy is founded on the principle of maximizing public benefit by facilitating broad data sharing to advance the understanding of public health needs, while ensuring the responsible oversight of genomic data sharing. In this session, faculty will:

- Review the scope of the draft NIH GDS Policy and how it differs from current NIH Policy for Sharing of Data Obtained in NIH-Supported or NIH-Conducted GWAS.
- Discuss the NIH public consultation process for obtaining public comment and testimony on the draft NIH GDS Policy.
- Review a summary of the comments received and their impact on revising the draft Policy and potential data management strategies.
- Outline the expected processes and procedures for data submission and access to NIH genomic data repositories when the NIH GDS Policy is implemented.

C17 Research Involving Native American Populations (Populations Requiring Additional Protections Track)
William Freeman, Scarlett Hopkins, Cynthia Pearson
In this session, faculty will:

- Review the unique training challenges for the responsible conduct of community-engaged research in general and in Native American (including American Indian/Alaskan Native) communities in particular.
- Identify elements of and strategies for developing and maintaining long-term and trusting relationships with rural and Native American communities.
- Discuss the importance of establishing an ongoing dialogue and fostering cultural sensitivity in research with Native American populations.
- Explore methods for adapting the Collaborative IRB Training Initiative (CITI) Program modules to the needs of ethnic minorities.
- Examine the case of the Center for Alaska Native Health Research, a community-based participatory research center aimed at understanding risk and protective factors for obesity and related chronic disease in native Alaskans living in Southwest Alaska.

C18 Forming Medical and Non-Medical Data Repositories: Review and Oversight Responsibilities for the IRB (Potpourri Track) Julie Kaneshiro, Andrew Rusczek
In this session, faculty will identify key regulatory issues (including issues related to confidentiality and privacy) involved with building medical and non-medical data repositories for research purposes. During this session, faculty will:

- Review when the collection of institutional evaluative data becomes research.
- Address how the IRB decides whether the collection of new types of data constitutes “research” as defined by the federal regulations, and how these activities compare with quality assurance projects in medical settings.
- Discuss how the IRB reviews data repositories formed by ongoing, prospective non-research for research purposes.
- Outline the issues that arise when merging data from different sources into a data repository.
- Define what confidentiality and privacy protections should be required by the IRB.
- Review what the IRB should consider in determining whether consent must be obtained.

C19 An IRB-Based Clinical Research Quality Assurance (QA) Program (QA/QI and Post-Approval Monitoring Track) Rebecca Dahl, Pramod M. Lad
Despite the acknowledged importance of QA in the clinical research process, the problem of how such a program should be implemented at the level of an academic teaching hospital or a similar institution has not been adequately addressed. In addition, although QA is expected in programs that accredit IRBs, very little is known about the role of the IRB in programs of clinical research QA. In this session, faculty will:

- Review the definition of clinical research QA and the types of programs designed to achieve it.
- Identify key elements of a QA program, including education at the site level (with both mandatory and voluntary components), and an auditing and monitoring program, which reinforces education on QA.
- Analyze audits related to patient safety, patient rights, regulatory compliance, and data quality and integrity, including audits of the informed consent process.
- Discuss corrective measures for noncompliance.
- Explore the pros and cons of an IRB-based QA program.
Friday, November 8 (cont.)
Panels VIII and IX, and Didactic/Workshops Series C, 2:00-3:15 PM

C20
You’ll Know it When You See it: Defining “Human Subjects Research” Under the DHHS Regulations
(Regulatory Balance Track) Christina Booth, Cheri Pettey, Samantha Smith – OHRP Resource Person
Evaluating whether an investigator is engaging in research involving human subjects has many important ramifications for both the institution and the investigator in terms of cost, time, and requirements for the activity. Since interpretation of key definitions in the regulations – including “systematic,” “generalizable,” “engaged,” and “human subject” – can be tricky, thorough consideration is needed to ensure appropriate application of the regulations. In this advanced session, faculty will use case examples to:
- Outline a process and set of criteria for determining whether an activity is research involving human subjects according to the federal regulations.
- Explore key decision points for determining that one is “engaged” in a research activity, and the impact of institutional determinations on other institutions/investigators involved in the project.
- Discuss when evaluation of data or specimens involves human subjects, with attention to what constitutes “identifiable” data without the use of a non-disclosure agreement.

C21
Ethical Challenges for Evaluating Research Using Internet-Based Social Media
(Research Involving the Internet & Social Networking Track) Brenda Curtis, Celia B. Fisher
The expanding use of social media in human subjects research is posing major challenges for IRBs. Participants will discuss specific case examples of social media research recruitment for HIV risk behaviors and drug use research. In this session, faculty and attendees will:
- Review the most recent forms of internet-based research recruitment utilizing Google, Facebook, and other popular social media sites.
- Discuss how social media websites are currently used for recruitment for legally and socially sensitive research, and identify the specific challenges this presents for privacy and confidentiality, informed consent, and validity of data collection.
- Explore current guidelines and strategies for protecting privacy and confidentiality, providing adequate consent information, and validating the nature of data collected.
- Use case studies to explore how to develop IRB decisional strategies for reviewing legally and socially sensitive research that utilizes social media for recruitment.

C22
What You Need to Know about Privacy and Confidentiality (SBER I – Basic Track)
Joseph A. Konstan, Lauren B. Solberg
In this session, faculty will:
- Discuss the question of public versus private behavior, including what counts as a reasonable expectation of privacy.
- Review identifiable versus anonymous participation and data.
- Address the tension between the public recognition of research participation and de-identification of results to ensure that subjects are not individually identifiable.
- Examine the adequacy of confidentiality protections and procedures designed to avoid or minimize privacy invasion.

C23
Ethical Issues with Introductory Psychology Subject Pools (SBER II – Advanced Track)
Robert Henderson
In this session, faculty will:
- Address risk of harm to regular and at-risk college students from emotional upset, distress, anxiety, etc. in research on personal behaviors (self-harm, sex, drug use, etc.), thoughts about one’s own death, partner violence, etc.
- Review the respective roles and qualifications of undergraduate research assistants and principal investigators.
- Discuss the risk of informational harm (privacy, confidentiality, data security) in research involving sensitive, personally identifiable information.
- Examine the value of participation in studies for teaching research ethics to undergraduate students.
- Outline how to avoid conflict of interest when the researcher is the instructor.
- Explore alternatives to participating in subject pools.
- Discuss research participation as service learning.
- Review waivers of consent for minors.
Friday, November 8 (cont.)

Panels VIII and IX, and Didactic/Workshops Series C, 2:00-3:15 PM

C24
Managing the HRPP in an Institution with a Small Research Portfolio (Small Research Programs Track) Shannon Harr, Lori Roesch
This session will focus on addressing the HRPP management challenges that are unique to institutions with small research programs, and is appropriate for individuals from institutions that self-identify as having a small research program according to any of the criteria laid out in the track descriptor. During this session, faculty and attendees will:
- Outline effective HRPP management strategies in institutions with small research programs.
- Discuss effective ways to provide investigator, IRB member, and community education.
- Examine inter-institutional agreements and quality-improvement activities.
- Discuss the value of developing meta-activities such as program assessments and HRPP metrics.
- Explore processes for managing conflicts of interest, noncompliance, post-approval monitoring, and unanticipated problems.

C25
Let’s Review a Protocol!! Regulatory Considerations in the Approval Process
(Unaffiliated and Non-Scientist IRB Members Track) Kristina C. Borr, Dario Kuzmanovic, Matthew Stafford
In this session, faculty and attendees will:
- Review the regulatory criteria for approval.
- Discuss fundamental strategies and tools used to facilitate protocol review.
- Systematically review sample protocols and participate in the decision-making process that leads to approval or request for revisions.

3:15-5:15 PM
Networking Reception in The Conference Connection
Meet and greet the Supporters and Exhibitors and view this year’s Poster Presentations. Light refreshments will be served.

3:30-3:45 PM
Demonstration of PRIM&R’s Online Course
Join us in the PRIM&R Booth for a demonstration of our interactive online resource—Ethical Research Oversight Course (E-ROC). A 15 minute presentation on E-ROC will provide you with an introduction to utilizing this tool to strengthen your understanding of human subjects protections.

3:30-4:45 PM
Speed Mentoring
Gather with your colleagues for a one-on-one networking event where you can connect with HRPP professionals, the Feds, ethicists, and other experts to receive answers to your regulatory, ethical, and/or operational questions. Light refreshments will be served.

4:00-4:15 PM
Demonstration of PRIM&R’s People and Perspectives (P&P)
Join us in the PRIM&R Booth for a demonstration of our newest interactive online initiative—People and Perspectives (P&P). P&P is an online archive that seeks to uncover, collect, catalogue, preserve, and share the stories of those performing the essential work of advancing ethical research. P&P features both the oral histories and reflections of those “in the trenches,” as well as information about the field’s founders, shared via video, audio and text stories. This 15-minute presentation will introduce you to some of the stories and participants on the site so far, and give a brief overview on how to contribute your own story to this living archive!

5:30-7:00 PM
The Drama of DNA: An Interactive Play Exploring the Ethical, Legal, and Psychosocial Implications of Genomic Research and Medicine with Children
Moderators: Lynn W. Bush and Karen H. Rothenberg
This interactive session weaves together audience participation with an original, four-act genomics play that illuminates ethical, psychological, social, legal, and policy concerns surrounding the attaining and sharing of the massive amounts of information generated by next-generation sequencing, particularly when used with “unaffected” children and pregnant women. The fictional vignettes that make up each act evolve from an audience-driven and then to the disclosure of incidental findings. Between each act, the audience and bioethicist actor-panelists will engage in lively discussion around a focused, ethically oriented question. Following the play, the actor-panelists will join the moderators to explore with attendees the complex implications of genomic information, delving further into controversial research ethics issues brought to life in the play including how much and what should be reported to whom, and under what circumstances.
Young Professionals (YPs) Networking Reception

Calling all YPs! Connect with other YPs interested in research ethics, talk about current issues and experiences in the field, and relax after a busy day in Boston at this fun, after-hours reception. This event will take place in the Champions Sports Bar, located in the Boston Marriott Copley Place Hotel.
Saturday, November 9: 2013 AER Conference

7:00 AM-12:00 PM
Registration Open

7:00-8:00 AM
Continental Breakfast

7:00-8:00 AM
What’s New at the CITI Program? Continental Breakfast
Staff members from the CITI Program at the University of Miami will demonstrate new features that will help participants get the most from their use of the CITI Program, including site navigation, refresher modules, and non-English language capabilities. PRIM&R would like to thank the CITI Program at the University of Miami for supporting this breakfast.

7:30-7:45 AM
Demonstration of PRIM&R’s People and Perspectives (P&P)
Join us in the PRIM&R Booth for a demonstration of our newest interactive online initiative—People and Perspectives (P&P). P&P is an online archive that seeks to uncover, collect, catalogue, preserve, and share the stories of those performing the essential work of advancing ethical research. P&P features both the oral histories and reflections of those “in the trenches,” as well as information about the field’s founders, shared via video, audio and text stories. This 15-minute presentation will introduce you to some of the stories and participants on the site so far, and give a brief overview on how to contribute your own story to this living archive!

8:00-8:30 AM
Welcome and Presentation of PRIM&R’s Lifetime Achievement Award for Excellence in Research Ethics to Joan Rachlin, JD, MPH, Executive Director, PRIM&R
Presented by Alexander M. Capron, Chair, PRIM&R Board of Directors

8:30-9:15 AM
Keynote Address: PRIM&R and the Field of Research Ethics: Passages, Linkages, and Villages
Joan Rachlin, JD, MPH
Executive Director, PRIM&R

9:15-9:30 AM
Break

Didactic Sessions and Workshops Series D, 9:30-10:45 AM

D1
A Dialogue with the NIH (A Dialogue with the Feds I Track)
Valery M. Gordon, Christine Grady, Dina N. Paltoo, Meredith Temple-O’Connor
This session will be led by representatives from the NIH. Attendees are encouraged to come with questions of interest to all. In this workshop, attendees will:
- Hear from representatives of the NIH Office of Science Policy, the NIH Office of Extramural Research, and the National Cancer Institute about activities that are pertinent to clinical research policy and the protection of human subjects in research.
- Participate in an open discussion about topics relevant to NIH stakeholders.
- Ask questions about new and ongoing initiatives at the NIH.

D2
A Dialogue with the Department of Energy (DOE) (A Dialogue with the Feds II Track)
Lindsay Motz, Elizabeth White *Please note this presentation will be given via Skype.
This session will be led by representatives from the DOE. Attendees are encouraged to come with questions of interest to all. In this workshop, attendees will:
- Learn about DOE’s Human Subjects Research Database.
- Participate in an open discussion of issues relevant to DOE stakeholders.
- Ask questions about new and ongoing initiatives at the DOE.
In this session, faculty will:

- Identify the ethical principles that guide all community-engaged research.
- Define community-based research (CBR)/community-based participatory research (CBPR).
- Outline the innovative ways some organizations are a) enhancing understanding of research by subjects and the community at large, and b) understanding and conducting CBR/CBPR.
- Discuss options for recalibrating risk and evaluating how to make changes in practice.
- Discuss how to measure risk tolerance in IRB administration and review.
- Identify deficient knowledge, according to the research.
- Review recommended elements for researcher training programs.
- Explore one model of certification for clinical investigators.

**Clinical Databases and Electronic Medical Records: When Do They Become Research?** (Activities Along the Boundaries Between Research and Practice Track)

*Richard Platt, Sebastian Schneeweiss, Walter L. Straus, Hugh Tilson*

Electronic medical records present a large amount of data for potential study. In this session, faculty will:

- Discuss when examination of electronic medical records crosses the line from quality improvement to research.
- Review how to manage clinical databases to ensure they are appropriately used for quality improvement or research.
- Examine management and tracking strategies for these uses.

**Making Subpart Determinations When Reviewing Research Involving Vulnerable Populations: Case Studies** (Advanced Forum for IRB Professionals Track)

*Jeremy Block, Bruce Gordon, Irene Stith-Coleman – OHRP Resource Person*

In this session, faculty and attendees will:

- Use case studies to examine research protections for vulnerable populations in biomedical and behavioral studies.
- Examine the protections that must be in place in order to include vulnerable populations in research.
- Review the ethical and regulatory guidelines for including these groups in research.

**Anybody Can Be an Investigator, Right?** (Educating Research Teams Track)

*Greg Koski*

The skills necessary to be a good researcher are neither innate nor part of most graduate curricula, especially in medical school, and the risks to subjects can be great. Yet, prior certification is required of clinicians who use new clinical procedures or new techniques and instruments. Is this asymmetry reasonable? This session will review the preliminary results of a pilot study to ascertain the need for certification of clinical investigators. In this session, faculty will:

- Explore the need for training and certification programs for clinical researchers based on study data.
- Identify deficient knowledge, according to the research.
- Review recommended elements for researcher training programs.
- Explore changes in practice while maintaining regulatory compliance.

**FDA’s Investigational Device Exemption (IDE) Decisions and Communications: What You Need to Know** (FDA Regulations Track)

*Owen Faris*

In this session, faculty will:

- Discuss the FDA’s device classification, what an IDE is, and the different types of IDE studies.
- Discuss the FDA’s decision-making process for determining IDEs.
- Discuss the regulatory requirements for risk determination of medical device studies.
In this session, faculty will:

- Explore how discussions of issues such as tiered consent, return of results to subjects, sharing of coded genomic data sets, and scope of research differ between academic and commercial settings, given the latter does not maintain ongoing relationships with patients participating in clinical trial specimen collection and storage.
- Review how changes in global regulations are driving discussions about how commercial companies will structure specimen collection procedures in the future.

**D10**

**Empowering Terminally Ill Subjects Through the Informed Consent Process** *(Informed Consent Track)*  
Lauren B. Solberg

When conducting and reviewing research with terminally ill subjects, researchers and IRBs are faced with a variety of issues that must be carefully considered. The consent process can be particularly complicated with terminally ill subjects, as it is especially important for them to understand whether the study offers any potential therapeutic benefit. For terminally ill people who enroll in research and subsequently lose medical decision-making capacity, researchers may be challenged with seeking surrogate consent for their continued participation. The regulatory requirements around informed consent appear to be sufficient to ensure that terminally ill subjects receive the information necessary to make an informed decision about whether to participate. In this session, faculty will:

- Discuss the potential vulnerabilities of terminally ill individuals who may enroll in research.
- Examine landmark cases and statutes that govern the rights of, and thus empower, terminally ill individuals.
- Identify strategies that researchers and IRBs can implement as a part of the informed consent process to ensure terminally ill individuals are empowered as well as adequately protected.

**D11**

**Academic-Industry Partnerships: Maximizing Benefits and Reducing Inefficiencies While Promoting Ethical Research** *(Institutional Officials Track)*  
Barbara E. Bierer, Kate Gallin Heffernan

In this session, faculty will:

- Define the areas where the research interests and missions of academia and industry intersect and complement one another, and how these synergies can be maximized.
- Review the ways in which principled partnerships between industry and academia can be undermined through frictions, miscommunications, and inefficiencies.
- Discuss common ground and solutions to the identified challenges to maximize the benefits of these principled partnerships without sacrificing the quality or ethics of the research under collaboration.

**D12**

**The Ins and Outs of IRB Offices** *(IRB Bootcamp Track)*  
Sharon Freitag, Hallie Kassan, Brenda Ruotolo

In this session, faculty and attendees will:

- Explore the different ways of processing IRB submissions through an IRB office.
- Identify responsibilities of different staff in an IRB office.
- Review processes that work well for IRB offices in facilitating the approval process.

**D13**

**Evaluating Member Performance** *(IRB Operations and Toolkit Track)*  
Yvonne Higgins, Tara Moore, Melissa Schlenker

Evaluating IRB member performance may benefit institutions. In this session, faculty will:

- Review what to do if a performance issue is found with an IRB member.
- Address how to include IRB members in the solution so as to enhance the relationship and make IRB members feel appreciated, which, in turn, could benefit the HRPP.
- Discuss how ongoing education for IRB members is a way to keep members informed, as well as reinforce their responsibilities.
D15

When Noncompliance Processes Collide: How to Manage Multiple Different Internal Investigations of an Event (Legal Track) Megan Kasimatis Singleton, Andrew Rusczek

One allegation or problem in a clinical study, such as a concern that a researcher has falsified research data, can invoke multiple requirements and policies for investigation and resolution. In this session, faculty will:

- Identify the various institutional policies and processes that may be triggered by a noncompliance event, including IRB serious/continuing noncompliance investigations, research misconduct proceedings, HIPAA privacy/security breach determinations, conflict of interest reviews, human resources investigations, risk management and morbidity/mortality peer reviews, and IBC reviews.
- Help institutional representatives recognize the ways in which the requirements and standards applicable to different processes may overlap or be in tension.
- Discuss appropriate roles for individuals and oversight boards involved in these processes.
- Suggest strategies for coordinating and conducting multiple investigations in a way that maximizes efficiency, but also maintains the integrity of the various processes.

D16

Unique Challenges in Pediatric Biobanking (Out of Body Experiences: Research Involving Tissue and Data Track) Julia Gorey, Steven Joffe, Carol Weil

This session will explore the ethical and regulatory issues surrounding pediatric donors of biological specimens and the implications that arise when those donors reach the age of majority. In this session, faculty will:

- Provide a working knowledge of the regulatory requirements for parental permission and child assent in the context of pediatric biobanking protocols.
- Address the ethical and legal issues involved in seeking consent from former pediatric biospecimen donors at age of majority.
- Review the ethical and regulatory controversies surrounding the return of research results for pediatric biospecimen donors.

D17

Populations on the Edge: The Homeless, Substance Abusers, and More (Populations Requiring Additional Protections Track) Christina Booth, Jeffrey M. Cohen

There are many populations that have vulnerabilities related to their marginalized status. Thus, it is important for IRBs to understand the expertise needed to review studies with these populations and some of the special or heightened concerns related to these groups. In this session, faculty and attendees will:

- Identify vulnerable populations beyond those addressed by the federal regulations who are nonetheless vulnerable because of homelessness, substance abuse, or other issues.
- Examine the special considerations that study teams should address when designing a study involving these populations, and that IRBs should be aware of when reviewing these studies, such as payment and undue influence.
- Review the threshold questions an IRB should address before permitting research with these subjects.
- Discuss complex issues such as how to assure confidentiality, balancing concerns about criminal liability with the need to protect subjects and conduct valuable research, the need for assistance to avoid individual harm, and whether Certificates of Confidentiality should be a prerequisite for these studies.
- Explore how to recruit and maintain contact with subjects from these populations.

D18

Alleged Misconduct in Clinical Research: Challenges for IRBs and Research Integrity Officers (RIOs) (Potpourri Track) Mark Barnes, Kristina C. Borror, George Gasparis, Kristen Grace

Alleged misconduct in clinical research presents challenges for both IRBs and RIOs. The Secretary’s Advisory Committee on Human Research Protections (SACHRP), the Office of Research Integrity, and OHRP have all addressed such challenges. In this session, faculty and attendees will:

- Explore the challenges of alleged misconduct in clinical research.
- Review potential solutions by which both IRBs and RIOs can perform their duties in a manner that will not compromise each office’s ability to fulfill their oversight responsibilities.

D19

Developing Effective Corrective Action (QA/QI and Post-Approval Monitoring Track) Marinna Banks-Shields, Eunice Yim Newbert, Jessica Randall-Aprea

In this session, faculty and attendees will:

- Identify and develop effective and novel corrective actions and corrective action plans (CAPs) depending on the noncompliance identified.
- Discuss common pitfalls with the CAPs researchers provide.
- Explore how to build educational elements into each CAP to help ensure the specific noncompliance finding doesn’t happen again.
**Beyond the Regulations: Strategies for Obtaining Informed Consent** 
(Regulatory Balance Track) Elizabeth Bankert, Susie Hoffman

Researchers continue to struggle with the consent form and process, and they are looking for practical methods to improve both in order to obtain truly informed consent. In this session, faculty will:

- Review methods and concepts to improve the consent form and process.
- Discuss the components of the Valid Optimization of Informed Consent Evaluation (VOICE) Program.

**Internet Research with Minors** 
(Research Involving the Internet & Social Networking Track) 
Laura Odwazny, Donna Spruijt-Metz

In this session, faculty will:

- Review the basic ethical and regulatory elements of research with minors.
- Discuss unique issues with internet research involving minors and age verification.
- Provide suggestions and guidance for researchers and IRBs in preparing and executing informed consent and assent with minors in internet settings.

**School Rules! Conducting Research in Elementary and Secondary Public Schools** 
(SBER I – Basic Track) Eric Allen, Jonathan Miller

In this session, faculty and attendees will:

- Discuss the investigator’s role in facilitating the development of local school district policies/practices in regard to communication with parents about the authority to conduct research.
- Review the use of consent alterations and waivers at schools with historically low parental involvement and high student absence.
- Explore special considerations for research involving students engaged in distance learning.
- Discuss how the interpretation of what constitutes “routine educational practices” (exempt category 1) evolves over time, e.g., videotaping in classrooms.
- Distinguish exemption eligibility factors related to different research designs, e.g., whether the generalizable knowledge sought is focused on (i) teachers; (ii) students; or (iii) effectiveness/satisfaction of innovative learning techniques.

**Identifying, Assessing, and Resolving Issues in Greater than Minimal Risk Social, Behavioral, and Educational Research** 
(SBER II – Advanced Track) Monika S. Markowitz, Cynthia J. Monahan

In this session, faculty will:

- Identify the need for and mechanisms of IRB review relevant to the following: risk identification and minimization applied to individual research subjects, groups, and the subjects’ community; post-approval harm monitoring and reporting procedures; and post-facto risk determination (for similar future studies).
- Examine examples of greater than minimal risk social, behavioral, and educational research, including: FOIA-mediated survey research (in which there is no voluntary consent and inappropriate or non-responders may face disciplinary action); survey or interview research in vulnerable and at-risk populations; psychology 100 research involving very sensitive information about students; and research about topics such as domestic violence, academic dishonesty, recreational drug use, and varsity athlete gambling.
- Define minimal risk in research involving first time offender and recidivist prisoners.

**Institutional Memory: How Did We Handle this the Last Time? Consistency in Protocol Review Procedures and Approval Standards When Reviewing Low Volume Protocol Submissions Involving Greater than Minimal Risk** 
(Small Research Programs Track) Maria Arnold, Paul J. Reitemeier

This session will explore ways of identifying and tracking infrequent but significant IRB determinations that affect protocol approving, and is appropriate for individuals from institutions that self-identify as having a small research programs according to any of the criteria laid out in the track descriptor. In this session, faculty will:

- Identify study-related features that significantly affect IRB protocol approval decisions, including external authorizations and oversight, investigator qualifications, study site adequacy, and risk to subjects including data security.
- Explore ways to identify, record, track, and retrieve key information from prior IRB approval decisions using both paper-based and electronic record systems.
- Discuss when IRB approval practices and standards should become formal policies.
### Saturday, November 9 (cont.)

#### Didactic Sessions and Workshops Series D, 9:30-10:45 AM

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<th>Session</th>
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| D25 | Scientific Aspects of Clinical Study Design: A Primer for Non-Scientists | 108 | (Unaffiliated and Non-Scientist IRB Members Track) Susan S. Fish, Lindsay McNair  
In this session, faculty and attendees will:  
- Begin with a review of the scientific process, from observation to hypothesis generation and testing, to peer review/critique of conclusions.  
- Review the basics of clinical study design.  
- Discuss the clinical research process.  
- Describe the norms and expectations of the community regarding scientific design from multiple perspectives, including those of a biomedical scientist and a social-behavioral scientist. |

**10:45-11:00 AM**

**Demonstration of PRIM&R's Online Course**

Join us in the PRIM&R Booth for a demonstration of our interactive online resource—*Ethical Research Oversight Course (E-ROC)*. A 15 minute presentation on E-ROC will provide you with an introduction to utilizing this tool to strengthen your understanding of human subjects protections.

**10:45-11:15 AM**

**Break**

Join us in The Conference Connection for coffee.

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### Didactic Sessions and Workshops Series E, 11:15 AM-12:30 PM

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| E1 | A Dialogue with the Secretary’s Advisory Commission on Human Research Protections (SACHRP) | 311 | (A Dialogue with the Feds I Track) Jeffrey R. Botkin, David G. Forster, Julia Gorey, Daniel K. Nelson  
This session will be led by representatives from SACHRP. Attendees are encouraged to come with questions of interest to all. In this session, attendees will:  
- Hear from SACHRP representatives about evolving initiatives, issues, and guidance, including forthcoming recommendations on Certificates of Confidentiality, engagement, and cluster randomized trials.  
- Participate in an open discussion about topics relevant to SACHRP stakeholders.  
- Discuss best practices currently under consideration by SACHRP.  
- Ask questions of SACHRP representatives. |

| E2 | Considering Incidental Findings (IFs) in HIV Research: A Must in Today’s Environment | 111 | (A Dialogue with the Feds II Track) Linda Ehler, Betto Ortiz  
Determining what constitutes an IF in clinical research and determining whether, and when, it should be returned to the participant has been a topic of discussion in the field of subject protections for the last 10 years. Implementing a comprehensive approach that addresses both the responsibility of researchers to return these findings and the expectation of participants upon receiving this information can be not only logistically challenging, but also costly. In this session, faculty involved in National Institute of Allergy and Infectious Diseases-sponsored HIV research will:  
- Address possible approaches for considering and returning IFs in clinical research, drawing on their experience with IFs in HIV research.  
- Use examples to describe how study teams developing a research plan can better integrate the response to IFs discovered during research participation.  
- Review a new informed consent template being used by a diverse group of HIV researchers worldwide, examine its approach to addressing IFs, and discuss how that approach might apply to clinical research more broadly. |

| E3 | Making Accreditation Happen in Small Research Programs (Accreditation of HRPPs Track) | 101 | Francis DiMario, Scott Lipkin, Elyse I. Summers  
Attendees should come with questions. In this session, faculty and attendees will:  
- Discuss the special challenges faced by small research organizations in building a comprehensive HRPP.  
- Identify strategies for mustering resources and embarking on accreditation.  
- Examine effective strategies used by small research organizations and offer guidance based on their own experience. |

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**CALL FOR SESSION PROPOSALS**

### ICON KEY

- Didactic session
- Pre-registration required
- CME accredited
- Interactive workshop
- Call for Session Proposal
- Double session
- Recorded session
- CIP eligible
E4
Decedent Research: When Is IRB Review Required? (Activities Along the Boundaries Between Research and Practice Track) Chris Asmann-Finch, Paula Bistak
The federal definition of a human subject notes the regulations protect "living" individuals. However, there are areas where decedent research may have an impact on the living including a) tissue and data findings from the deceased that may be relevant to living family members; b) legal status of transplant donors on life support; and c) ethnic communities' views about respect for the dead. In this session, faculty will:
- Discuss the current federal definition of a human subject.
- Identify federal and state regulations, laws, or statutes that deal with decedent research.
- Examine the implications of varied ethnic and religious views of the sanctity of the deceased.

E5
Cautions Against Breaking the Blind at the End of Randomized Controlled Psychopharmacology Studies Involving Minors: Protecting the Patient Versus Protecting the Science (Advanced Forum for IRB Professionals Track) Albert J. Allen, Laurence Greenhill, David H. Strauss
Industry-sponsored psychotropic medication randomized-controlled trials follow strict guidelines about not breaking the blind until all subjects have completed the study and the database is locked. This practice raises challenges for determining the benefit/risk ratio for minors, since it is a benefit if a family can learn the identity of the medication when an individual child completes a protocol. This is particularly true in phase IV studies that involve medications already approved for adults and widely available from physicians. In such cases, a child could be randomly assigned, under double-blind conditions, to a medication she/he could readily receive at a physician's office, but which may give her/him no benefit. In this session, faculty will:
- Review the federal regulations that apply to research in youth under the age of 18 involving minimal risk and minor increment over minimal risk.
- Discuss arguments for maintaining double blind status in phase IV trials until all subjects have been through the trial.
- Address the controversy around suggestions for breaking the blind with a separate treating staff who are advised to keep information about whether a specific subject was treated with placebo or study drug from the investigators.
- Ask attendees to discuss a) the strength of the evidence that breaking the blind at a site corrupts the study data, b) alternative arrangements that might be acceptable to the FDA and industry, and c) what perspective could help an IRB balance the benefits and risks to minors without stopping the research.

E6
What to Do When Things Go Wrong? (Educating Research Teams Track) Lisa Buchanan, Charlotte Coley, Bruce Gordon
In this session, faculty will:
- Present a root cause analysis of noncompliance issues.
- Examine how to identify knowledge gaps that lead to noncompliance issues in research.
- Review one retraining model for filling in knowledge gaps that lead to noncompliance on the part of research staff.
- Present a model to address these deficits through training of investigators and staff.

E7
The Ethics of Paying Research Subjects (Ethical Issues Track) Alan Wertheimer
In this session, faculty will:
- Evaluate concerns and address justifications surrounding the topic of payment to research subjects.
- Demonstrate IRB members' trepidations about payment.
- Offer guidance as to which concerns merit the attention of the IRB.
- Discuss pseudoprotectionism and hyperprotectionism.

E8
In Vitro Diagnostic (IVD) Devices Used as Integral Parts of Therapeutic Clinical Trials: IRB Issues and Significant Risk Determinations (FDA Regulations Track) Ernest D. Litwack
In this session, faculty will:
- Examine the issues IRBs should consider when IVD devices are used as an integral part of therapeutic clinical trials.
- Review guidance on IVD devices related to IRB review and oversight, and discuss the initiatives developed by the National Cancer Institute and FDA to manage the use of investigational tests in clinical investigations of drugs.
- Discuss considerations for distinguishing significant risk from non-significant risk in IVD investigations.
E9
Sea Change in Europe: The Impact of the New EU Clinical Trials and Data Protection Regulations (Global Research Track) Mark Barnes, Edward Bartlett, Rebecca Li
In this session, faculty will:
- Explain the main provisions of the current EU Clinical Trials Directive and the key changes in the proposed Clinical Trials Regulation.
- Outline the key provisions of the current EU Data Protection Directive and the main changes in the proposed Data Protection Regulation.
- Describe how the proposed changes in the European research landscape are likely to affect IRBs based in the United States.
- Review the current requirements around, as well as barriers to, clinical trials data sharing.
- Examine how to formulate potential solutions to clinical trial data sharing.

E10
The Ethics and Practice of Proxy Decision Makers in Informed Consent Procedures (Informed Consent Track) Ilene F. Wilets
Many research protocols investigate procedures and products that may contribute primarily or secondarily to changes in mental status or cognition. Changes in cognition may result in incapacity and/or incompetence to continue to give voluntary informed consent to participate in ongoing research. The use of proxy decision makers may alleviate the ethics and human research protections questions this issue raises. In this session, faculty and attendees will:
- Reinforce the importance of obtaining ongoing informed consent throughout the duration of study participation.
- Discuss the relationship between medical consent statutes and informed consent procedures for research.
- Develop strategies for ensuring and obtaining ongoing informed consent when subjects become incapacitated and/or incompetent.

E11
Understanding the Elements of a Strong Compliance Program (Institutional Officials Track) Wesley Byerly, F. Lisa Murtha
In this session, faculty will:
- Identify the key components and characteristics of a strong compliance program.
- Discuss the challenges of day-to-day operations.
- Outline compliance program performance metrics.

E12
What Happens After the Protocol Is Approved? (IRB Bootcamp Track) Kaarkuzhali Babu Krishnamurthy, Samantha Smith
In this session, faculty will:
- Describe the responsibilities and obligations of researchers and IRBs in the post-approval phase of research.
- Discuss how modifications are made through protocol amendments.
- Review expectations for managing and reporting adverse events, unanticipated problems involving risks to subjects or others, and other deviations from the original protocol.
- Outline the steps in the approval process of FDA investigational applications.

E13
How to Develop Effective IRB Forms to Ensure Compliance and Keep Investigators Happy (IRB Operations and Toolkit Track) Kelley O’Donoghue, James Riddle
In this session, faculty will:
- Review practical strategies for using IRB forms to help ensure IRB compliance, auditability, and ease of IRB member review, including options for adjusting form layout or question sequences.
- Describe how researchers view IRB forms and how to use that perspective to the greatest advantage.
- Identify practical and accessible techniques for helping researchers select the right form, complete their forms accurately, and ensure they attach all the right supporting materials.
- Discuss strategies for transitioning from a paper-based form to an online submission system and for improving the use of an online system once implemented.
- Share case studies from two institutions to show how they improved the effectiveness of their forms and facilitate the sharing of ideas about best practices.

E14
Ethical and Regulatory Issues in Clinical Trials Websites and Social Media (Issues for Pharma/Biotech Track) Lindsay McNair, James Warner
In this session, faculty will:
- Discuss the use of clinical trial websites and/or social media in recruiting and/or managing the participation of subjects in research studies.
- Explore how online platforms like Research Match, TrialX, and Patients Like Me work, and the regulatory and ethical issues that arise with their use.
- Provide an overview of Pfizer’s online clinical trial experience.

ICON KEY
- Didactic session
- Pre-registration required
- Call for Session Proposal
- CME accredited
- Double session
- Recorded session
- CIP eligible

Recordation: Not required
Name: Lisa Murtha
Affiliation: Pfizer Inc.
Title: Global Medical Affairs - Rare Diseases
Email: Lisa.Murtha@pfizer.com
Phone: 646-253-0327
The Rules of Engagement: Analyzing Challenging Scenarios Under the Existing OHRP Engagement Framework (Legal Track) Kate Gallin Hefferman, Emily Wood

Even beyond the challenges presented by multi-site research and large-scale banking and repository research, the varied and complex ways investigators and other physicians are contributing to the design, management, technical advancement, statistical analysis, and oversight of research they are not necessarily directly conducting raise new questions under the existing rules of engagement. How should IRBs presented with such research respond, and what oversight role should an institution play, even when there is no formal “engagement”? In this session, faculty and attendees will:

- Review the framework under the current OHRP Guidance on Engagement of Institutions in Human Subjects Research (2008), as well as the more recent correspondence on “Non-Engaged” Scenarios (2011).
- Discuss several challenging case studies (that will be made available to workshop participants in advance).
- Think through the role of the IRB and institutional officials in managing risks presented when their physicians and investigators contribute significantly to research in which they are not technically “engaged,” and which is not under their direct oversight and control.

Tissue Issues: Ethical and Regulatory Issues in Banking Biological Specimens for Research (Out of Body Experiences: Research Involving Tissue and Data Track) Marianna J. Bledsoe, Julie Kaneshiro, Ada Sue Selwitz

The content presented during this breakout session will provide attendees with a basic introduction to the ethical and regulatory issues in banking specimens for research. In this session, faculty will:

- Provide an overview of specimen banking.
- Discuss the ethical and regulatory principles that guide biobanking for research purposes.
- Review informed consent and waivers for use of tissue for research purposes.

Community-Based Participatory Research (CBPR) as a Corrective Lens for Research: Case Studies in Psychiatric Research (Populations Requiring Additional Protections Track) Celia Brown, Kathleen O'Hara

Despite regulatory safeguards, traditional research approaches often stigmatize marginalized and vulnerable communities. CBPR emerges as an effective paradigm that aims to make research more inclusive and democratic by fostering partnerships between communities and scientists to address disparities and community-relevant priorities. This workshop fosters capacity building in the practice and ethics of CBPR through case studies in psychiatric research. In this session, faculty will:

- Consider, identify, and problem solve ethical conflicts in CBPR that might affect community subjects, researchers, institutions, and research outcomes.
- Examine best practices for weighing risks to individuals and the community.
- Discuss how to anticipate ethical concerns and recognize boundary issues within the practice and situated ethics of a CBPR collective, including the practice of “process consent,” transparency for an authentic CBPR research agenda, inside-outside tensions, and more.
- Explore social validity and the value of hybrid knowledge as benefits of research.
- Provide tools for ethics in practice through two lenses: the “community of interest” and the research enterprise.


The amount of empirical research on research ethics is growing exponentially, and it should be read and integrated by IRBs to improve the protection of research subjects. This session will suggest ways of gathering evidence and applying it to particular “sticky” problems that frequently arise during IRB deliberations, e.g., whether or not incentive payment amounts are acceptable; whether subjects should be required to pass a knowledge test for informed consent and, if so, the best measures to use; what are the actual risks of certain diagnostic procedures used for research purposes or sensitive survey questions; and how these risks should be communicated to subjects. In this session, faculty and attendees will:

- Discuss where (e.g., key journals) and how (e.g., common Medline subject headings) to identify appropriate empirical evidence that can inform research ethics/IRB review.
- Describe the steps of an evidence-based research ethics/IRB review.
- Review how to apply empirical evidence to a common dilemma that arises during IRB review in light of ethical principles and regulatory requirements.
Assessing the Quality of a HRPP: Quality Indicators (QIs) for HRPP Assessment (QA/QI and Post-Approval Monitoring Track) Min-Fu Tsan

While human subjects protection cannot be directly measured, it is possible to assess the quality of a HRPP. The Department of Veterans Affairs (VA) has recently developed a set of HRPP QIs to do so. In this session, faculty will:

- Explore what the VA’s data show about the effects of using different IRBs (i.e., VA IRBs versus affiliated university IRBs) on VA facility’s HRPP QI data, and the effects of program size on VA facility HRPP QI data.
- Discuss how to develop QIs for your institution’s HRPP.
- Examine how to use QIs to assess the quality of your institution’s HRPP.
- Discuss how to use QIs to improve your institution’s HRPP.


In this session, faculty will:

- Review the use of electronic consent using iPad and computer-based interactive approaches.
- Discuss experience using “remote” consent, using an iPad-based consent in a pilot study and the work that was done to develop the consent, and (if available) provide preliminary data from a comparison of iPad consent and traditional paper consent.
- Examine the regulatory requirements of IRB review and consent documentation in the context of an electronic informed consent process.
- Discuss the potential ethical challenges of using electronic technology in streamlining the informed consent process.

“I Agreed to What?” Terms of Service Versus Consent (Research Involving the Internet & Social Networking Track) Elizabeth Buchanan, Tomas A. Lipinski, Laura O'dwazny

This session will discuss the emerging importance of terms of service (TOS) and end user license agreements (EULAs), and the ways they may influence IRB review. From Facebook to mTurk, term agreements may complicate the dual roles of being a user of an internet tool or venue and being a subject of research with that tool or venue. In this session, faculty will:

- Define TOS/EULAs, and address their potential influence on IRB review.
- Review the legal standing of TOS/EULAs.
- Describe common internet tools and venues.
- Provide guidance for IRBs and researchers on what to look for in TOS/EULAs that can aid in effective IRB review.

Special Problems in Reviewing Student-Led Research (SBER I – Basic Track) Eric Allen, Suzanne Stone

This session will focus on assessing research subject risk and scientific merit in student-conducted research. In the session, faculty will:

- Discuss how to effectively respond to poorly prepared student research proposals due to substandard faculty oversight and mentorship.
- Review the data security issues that can arise when student investigators or faculty advisors separate from the institution and IRB oversight.
- Review the issues that can arise from multi-year research requiring “protocol passing” from graduating student investigators to other student investigators, including data integrity, ownership, security, etc.

Ethically Valid Consent and Assent in Persons with Diminished Cognitive Capacity (SBER II – Advanced Track) Rebecca Davis, Paul J. Reitemeier

IRB members are aware of studies showing that many research subjects are unable to accurately describe or explain the research in which they have enrolled. This suggests that neither the enrolled subjects nor the researchers are part of an ethically valid consent process. Many researchers describe the consent process as an administrative paperwork burden rather than a dialogical process that seeks to establish, secure, and perpetuate ethically valid consent. This session will explore selected challenges and tensions in the consent process that originate from study subjects, researchers, and IRB members. In this session, faculty will:

- Review the obstacles to ethically valid informed consent arising from subjects, researchers, and IRBs.
- Examine innovative methods of engaging in the consent process.
- Provide a reference tool for assessing research-related risks to persons with diminished cognitive capacity.
- Use complex case studies from social and behavioral research to stimulate audience discussion about how researchers and their IRBs can protect human subjects from harm without unnecessarily restricting scientific inquiry.
Individuals who are the ostensible subjects of the study. At the regulatory and ethical levels, what obligations are owed to these “secondary subjects”?

Mobile device research frequently involves fundamentally different oversight approaches. Is mobile device research genuinely so different from “conventional” research that it requires a different approach, or is it not so different after all?

Third parties and “secondary subjects.”

When designing mobile device studies and when explaining them to potential subjects, how do mobile device interventions influence subjects’ sense of autonomy, privacy, and agency? When subjects receive communications and interventions delivered to devices that are constantly with them, how does this influence their ability to decide what to do? What about their sense of what is private? And, do people ill enough to merit an intervention have the capacity to consent? Apprehension about new technologies. Some express the concern that these technological developments are so revolutionary that conventional approaches to the protection of human subjects in research are wholly inadequate. This is of course not the first time society has reacted to technological innovation with alarm. Is mobile device research genuinely so different from “conventional” research that it requires a fundamentally different oversight approach, or is it not so different after all?

Third parties and “secondary subjects.”

When it all sounds like Greek, how does the non-scientist IRB member know when to be concerned? This session will address the potential red flags that non-scientist reviewers should be aware of when reviewing a study protocol. In this session, faculty will:

- Identify problematic areas of protocols.
- Define specific issues for methodological consideration in IRB review.
- Provide suggestions for the unaffiliated/non-scientist IRB member when reviewing challenging protocols.

Substance use disorders are highly prevalent in the U.S. Substance use and treatments that work are ongoing. Research on substance abuse poses unique ethical questions that challenge fundamental attitudes about voluntariness, autonomy, and privacy. Is it reasonable to administer drugs of abuse to drug abusers? When is subject capacity to consent compromised by addiction, the availability of drugs in the research, and compensation? Under what circumstances are researchers obligated to treat substance users or report illegal activities? The panel will address these questions in both practical and theoretical terms.
Panel XII: Is Meaningful Regulatory Change Possible?

 Moderator: Michele Russell-Einhorn

 Panelists: Jeffrey R. Botkin, John D. Lantos, Tom Puglisi

 The scientific literature, the lay press, and the research community frequently call for change to the current requirements for IRB review and research informed consent. Many national committees and commissions have been convened over the years to author thorough and well-informed reports on significant issues involving the protection of human subjects in research and the need for regulatory change to address them. Nevertheless, no change in the federal regulations governing research with human subjects has occurred since the publication of the “Federal Policy for the Protection of Human Subjects” in 1991, despite the publication of the ANPRM two years ago. Why is this? What are the constraints in the regulatory process that surround the current regulations and hinder change? Can we think outside the box and find any flexibility in the existing regulations that do not depend upon a regulatory fix? This panel will describe the barriers to meaningful regulatory change by examining the existing system, and will explore how HRPPs can address the changing needs despite regulatory stagnation by reviewing where flexibility currently exists, but is not used.

 3:15-3:30 PM  
 Break  
 Join us for coffee.

 Grand Finale Sessions, 3:30-4:45 PM

 GF1  
 People and Perspectives (P&P): Bring Your Story!  
 Gianna McMillan, Joan Rachlin

 In honor of its 40th anniversary in 2014, PRIM&R has launched a new online initiative, P&P, a multimedia library that captures and catalogues stories from members of our community. We welcome contributions from anyone working in or around the field of research ethics and research protections. If you’d like to know more about P&P, please join us at this session where the site will be unveiled. Attendees will learn about the tradition of oral history and will receive tips on how to create compelling content and submit it to P&P. The last half of the session will be “open mic,” during which audience members can share a real time snapshot of their work in the research field. We thus ask those of you who would like to “go live” during the session to come with a three to five-minute story about some aspect of your professional life. This casual, fun, and friendly session will be videotaped for inclusion in P&P. Be one of the first to contribute to this archive of our community’s stories and become an early member of PRIM&R’s multimedia, digital, story-telling collection. Content may also be submitted in a variety of formats through the website after the session.

 GF2  
 Affinity Group (AG) Wrap-Up Meetings  
 You’ve spent three days getting to know your colleagues. So where do you go from here? Come to this wrap-up session to connect with your fellow AG members. Participate in a facilitated brainstorming session with your group leaders to determine how you would like to stay in touch after the conference, what topics you would like to see at the next conference, and what other activities your AG might want to undertake. Each AG will have its own wrap-up meeting.

 GF3  
 Human Subjects Protections Jeopardy!  
 Elise I. Summers

 You’ve learned so much at the conference, let’s put it to use! Take part in this fun and interactive Jeopardy! game to test what you’ve learned, show off for your friends, and enjoy your last hours at the PRIM&R conference! Answer: Human Subjects Protections Jeopardy. Question: What is a guaranteed good time for all!?
GF4

The Uncomfortable Conversation: Talking about Diversity
Dorotha Love Hall
The issue of diversity is not directly addressed in the federal regulations governing human subjects research, although it is referenced in The Belmont Report. Nevertheless, IRB professionals have opportunities to consider issues of diversity during the protocol review process, development of policies and procedures, investigator training, and the like. In this session, a member of PRIM&R’s Diversity Advisory Group will pose and address questions such as: How can you, as IRB professionals, ensure the issue of diversity is adequately addressed during protocol review? How can you develop policies and procedures that support diversity when there are no clearly defined federal regulations? How do you encourage investigators to recruit diverse subject populations when resources are short? What arguments should you use, and how are those arguments based in ethics, regulations, science, and research history? Come be part of this important conversation.

GF5

Ask the Experts! Everything You Wanted to Know, But Were Afraid to Ask
Janet Donnelly, Yvonne Higgins, Patrick McNeilly, Irene Stith-Coleman
Are you new to the field of research ethics? Do you still have a nagging question regarding HRPPs and IRBs? Join us for this session where experienced veterans of the field will be available to answer all the questions you’ve been afraid to ask! Come with ideas, questions, and concerns to share with the group and be prepared to participate in an open, interactive, and lively discussion with faculty and your peers.

GF6

Film Screening: Finding Dr. Schatz: The Discovery of Streptomycin and a Life It Saved
Inge Auerbacher, Elisa Hurley
Join us for a screening of the riveting documentary Finding Dr. Schatz: The Discovery of Streptomycin and a Life It Saved based on the book of the same name written by Inge Auerbacher and Albert Schatz. The documentary depicts the relationship formed by Dr. Auerbacher, a child survivor of the Holocaust stricken with tuberculosis, and Dr. Schatz, the co-discoverer of Streptomycin, the drug that saved her life, 50 years after Dr. Schatz discovered the drug. The story is one of hardship, intrigue, and lack of recognition for Dr. Schatz’s contribution to one of the most important medical discoveries of modern times. The film includes testimony of principal witnesses, including Senator Bob Dole, who was saved by Streptomycin after contracting tuberculosis from an injury inflicted in World War II. Please join us for this film, as well as for commentary and a question and answer session with Dr. Auerbacher. During the session, Dr. Auerbacher will also be selling and signing copies of her companion book, Finding Dr. Schatz.

GF7

Connect with PRIM&R: Resources to Network, Volunteer, and Advance Your Career
Megan Frame, Kimberly Hensle Lowrance
Join the PRIM&R staff for a session that will help you learn more about PRIM&R and how our resources can benefit you after the conference. During this session, staff will review PRIM&R’s online course, E-ROC, and explain its benefits as they relate to continuing education. In addition, the PRIM&R staff will explore the Knowledge Center, an online educational resource for members that features PRIM&R program archives; workplace tools, templates and SOPs; Workload Salary Survey Reports; and more. Finally, the PRIM&R staff will highlight ways to connect with other members and the community at large through our website, social media channels, and the IRB Forum, as well as discuss many other networking opportunities, including our Mentoring Program, volunteer opportunities, and the Regional Connections program. Hope to see you there!

4:45-5:45 PM

Closing Reception
Boylston Hallway
Join us to wish each other a fond farewell and to make plans for the 2014 AER Conference! Light refreshments will be served.
Boston University School of Medicine
Continuing Medical Education (CME) Accreditation Statement

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

Boston University School of Medicine designates this live activity for a maximum of 17.5 AMA PRA Category 1 Credits™.

This program meets the criteria of the Massachusetts Board of Registration in Medicine for 17.5 hours of risk management study. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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

Target audience: The target audience of this activity includes Human Research Protection Program/Institutional Review Board (HRPP/IRB) chairs, members, and administrators; researchers and research staff; institutional officials; regulatory officials; compliance officers; those charged with overseeing responsible conduct of research programs; hospital/university attorneys; patient advocates; representatives of voluntary health organizations; industry and biotechnology representatives; and those involved with science policy.

Educational objectives: Upon completion of this activity, participants should be able to: (1) Explain the principles listed in the various research ethics reports (Belmont Report, Nuremberg Report, Declaration of Helsinki) and apply them in their day to day work; (2) Identify the core federal regulations governing human subjects research and recognize which aspects of their work put those regulations into practice; (3) Develop strategies for managing successful HRPPs/IRBs; (4) Assess how their HRPP/IRB policies and procedures compare with the best practices in the field; (5) Communicate effectively with those involved in various aspects of the research enterprise to ensure adherence to federal regulations and that human subjects are properly protected before, during, and after a research study; and (6) Define a vulnerable population and demonstrate how ethical principles and federal regulations apply to these groups during research.

Needs addressed statement: In order to successfully implement HRPPs, professionals involved with IRBs need access to current and accurate information on the laws, regulations, policies, and guidance documents governing human subject research ethics and compliance. How this information and policies are implemented varies. Past participants have rated highly the opportunity to discuss these principles with experts in the field and their peers. This conference enables participants to exchange best practices and other creative strategies that institutions around the country are employing to maximize protection of research participants, while at the same time streamlining administrative procedures influence the implementation of policies.

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