Sunday, November 13: Pre-Conference Programs

7:30 AM
Registration Opens
Breakfast on your own.

8:30 AM-5:00 PM
Room 204 AB
Biobanking in an Era of Research Towards Precision Medicine: Approaches to the Ethical, Regulatory, and Practical Challenges

8:30 AM-4:30 PM
Room 204 C
Critical Topics in SBER

8:30 AM-4:30 PM
Room 202 B
Ethical and Practical Issues in Global Human Research

8:30 AM-4:30 PM
Room 203 AB
IRB 101™

8:30 AM-4:30 PM
Room 201 D
IRB 201: An In-Depth Analysis of the Criteria for Review

8:30 AM-4:30 PM
Room 201 B
IRB Chairs Boot Camp: Tools for Successful IRB Leadership

8:30 AM-12:00 PM
Room 201 C
Integrity in Research: Responsible Conduct in Research Concepts and Cases

8:30 AM-4:30 PM
Room 209 AB
Single IRBs Are Here: Are You Ready?

1:00-4:30 PM
Room 201 C
A Systematic Exploration of IRB Review and Oversight of Research On, About, and Including Vulnerable Populations

4:30-6:00 PM
Room 207
Pre-Conference Programs Networking Reception
All those registered to attend a pre-conference program are welcome to attend a networking reception. Light refreshments will be served.

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

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Monday, November 14: 2016 AER Conference

7:00 AM
Registration Opens
Breakfast on your own.

7:00-8:00 AM
Continental Breakfast to Welcome First-Time Attendees – SOLD OUT!
Attending the AER Conference for the first time can be exciting and overwhelming, which is why PRIM&R invites all first-time attendees to participate in this special breakfast. This event is a great opportunity for first-time attendees to ask questions of the PRIM&R staff and seasoned attendees about the conference and PRIM&R in general, and to learn about strategies and resources that can help them make the most of their conference experience. We would love to see you there! Please note this event is now sold out.

7:00-8:00 AM
Peer-to-Peer Networking Continental Breakfast – SOLD OUT!
Join fellow attendees before the conference starts to connect and network! All attendees are welcome. Tables will be divided into the following topics: Career/Leadership/Management, IRB Administrators/Coordinators, Compliance/Federal/Legal/Regulatory, QA/QI/Post Approval Monitoring, IRB Chairs, Global Research, SBER, and Single IRBs. Discussion questions for each group will be available to kick-start conversation. Please note this event is now sold out.

8:00-8:20 AM
Welcome from the Conference Co-Chairs
P. Pearl O’Rourke, MD, Director, Human Research Affairs, Partners HealthCare System, Inc.
Laura Odwazny, JD, MA, Senior Attorney, Office of the General Counsel,
Department of Health and Human Services

8:20-8:35 AM
Welcome from PRIM&R’s Executive Director
Elisa A. Hurley, PhD

8:35-8:50 AM
Presentation of the Research on Medical Practice Study Results
Benjamin S. Wilfond, MD, Director, Treuman Katz Center for Pediatric Bioethics, Seattle Children’s Research Institute; Professor and Chief, Division of Bioethics; Professor, Pulmonary and Sleep Medicine, Department of Pediatrics; Adjunct Professor, Department of Bioethics and Humanities, University of Washington School of Medicine
8:55-9:40 AM
Keynote Address: When Human Subjects, Science, and Consumer Rights Collide
Mary L. Gray, PhD, Senior Researcher, Microsoft Research; Fellow, Harvard University’s Berkman Center for Internet and Society; Associate Professor of the Media School, with affiliations in American Studies, Anthropology, and Gender Studies, Indiana University

9:45-11:00 AM
A New Framework for Human Subjects Research? An Update From the National Academies of Sciences, Engineering, and Medicine
Moderator: Alexander M. Capron
Panelists: Barbara E. Bierer, Heather H. Pierce, Steven Joffe
On June 29, 2016, NAS released the second part of their report, Optimizing the Nation’s Investment in Academic Research: A New Regulatory Framework for the 21st Century. The report examines the impact of regulations and policies governing federally funded academic research in the United States, and makes a number of recommendations for achieving a “more sensible regulatory structure that harmonizes and streamlines, where appropriate, federal regulation and policies.” Among them is a recommendation that Congress create a Research Policy Board (RPB), a “self-funded, government-linked entity serving as the primary policy forum for discussions related to the regulation of federally funded research programs in academic research institutions.” And, a second recommendation of particular relevance to the research protections community is that “Congress authorize, and the President appoint, an independent, free-standing national commission modeled on the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research,” the body that created the Belmont Report in 1978. During this plenary session, speakers will provide background about the impetus for and creation of the report, review the report’s recommendations for a RPB and a “Belmont 2.0,” and discuss the potential implications of the report’s recommendations for the field.

11:00-11:30 AM
Beverage Break
Join us for coffee in the Exhibit Hall. PRIM&R would like to thank iMedRIS for helping to support this break.

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Panel I: 50 Years After Beecher’s Bombshell: Where Are We Now, What Have We Learned?
Moderator: Alexander M. Capron
Panelists: Barbara E. Bierer, Susan E. Lederer, David H. Strauss
Henry K. Beecher’s “Ethics and Clinical Research,” published in the New England Journal of Medicine in 1966, described 22 studies conducted by prominent physicians and medical researchers that reflected serious ethical lapses, including lack of informed consent and apparent disregard for subjects’ rights and welfare. The paper’s extraordinary and enduring influence was a major contributor to the field of human research ethics and the evolution of human subjects regulations. How did Beecher come to examine unethical research and what did he find? How should we understand the complicated historical circumstances that led physician-researchers to embark on projects that seemed so unethical? Can we explain past transgressions without exonerating those involved? Beecher chaired a committee to review research, but did not think highly of committees. Was his skepticism justified? What would he think of today’s research ethics? Both Beecher and medical ethics advocate, Jay Katz, argued strongly for ethical reform, but their views of how it should be accomplished differed in many ways. Whose views were more influential in shaping the system that was adopted? Are contemporary researchers susceptible to the same types of pressures, misguided thinking, and conflicts of interest that sometimes led their predecessors astray? This panel will examine aspects of the continuing legacy of Beecher’s paper, a half century later.

Moderator: Jeremy M. Sugarman
Panelists: Leonard Glantz, Steven Joffe, Kevin P. Weinfurt, Benjamin S. Wilfond
Note: This session will run until 1:00 PM. Activities such as quality improvement and comparative effectiveness research, collectively referred to as ROMP, are becoming more prevalent. This category of research that is conducted in the clinical setting has blurred the distinction between research and clinical care, making regulatory and ethical oversight more challenging. A better understanding of how ROMP is perceived by various stakeholders, particularly patients, might help inform how to appropriately protect the rights and welfare of research subjects. In 2013, the NIH and Patient Centered Outcomes Research Institute awarded five grants to address these questions. This panel will present data on public, patient, and regulator attitudes about randomization in ROMP, and panelists will examine how the data from these studies can be interpreted, and how they might be used in practice. Panelists will also explore the implications of these findings for IRBs.

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Panel III: Research With Children and Adolescents: Who and How Is the Decision Made to Participate?

**Moderator:** Susan Z. Kornetsky

**Panelists:** Janet L. Brody, Celia B. Fisher, Eric Kodish

During the 30 years since its adoption, the Common Rule and Subpart D, Additional Protections for Children Involved as Subjects in Research, has helped investigators and IRBs strive to appropriately balance research risk against benefit to individual children and the pursuit of scientific knowledge to advance children’s welfare. In thinking about research with children and adolescents, there are issues that arise around how decisions to participate are made and by whom. It is important for IRBs and investigators to consider the role of the parent and child in making these decisions, how this relationship plays out in different types of research, and how the decision-making process impacts the research being conducted, who participates, etc. As such, understanding the differences in the decision-making process can provide a context for IRBs when reviewing research dealing with medically vulnerable youth and adolescent populations. Drawing on the experience and scientific expertise of nationally recognized child and adolescent researchers, this panel will review the decision-making process from three different perspectives: (1) Using examples from asthma research, what are the similarities and differences in how parents and adolescents evaluate opportunities for research participation? How is the decision for children and adolescents to participate in research made by the family unit? What factors enhance adolescent autonomy in the family decision-making process?; (2) Looking at children’s participation in Phase I cancer clinical trials, how do parents, adolescents, and older children make decisions about the child participating in research? How do researchers and IRBs gauge parental and child understanding of what they’re agreeing to? What other reasons might the IRB consider for why a parent decides to have their child participate in this type of research?; and (3) Examining the case of HIV prevention research involving lesbian, gay, bisexual, and transgender youth, what family and legal factors might prompt the use of a waiver of guardian permission to protect the rights and welfare of adolescents participating? What additional protections, including an assessment of youths’ ability to self-consent, would be needed if a waiver is approved?

**12:45-2:00 PM**

**Networking Lunch**

Time to connect...over lunch! Meet peers for conversation and networking. All are welcome! PRIM&R would like to thank Kinetiq for helping to support today’s lunch.

**12:45-2:00 PM**


**Moderator:** Barbara E. Bierer

**Author:** Sarah R. Gray

Participate in a vibrant discussion of *A Life Everlasting, The Extraordinary Story of One Boy’s Gift to Medical Science* by author Sarah R. Gray, the director of communications for the American Association of Tissue Banks. After Ms. Gray’s unborn son, Thomas, was diagnosed with anencephaly, a terminal condition, she decided to donate his organs to scientific research. Attendees will have the opportunity to hear from and participate in a discussion with Ms. Gray about her journey and her work with the researchers and scientists who received her son’s donations, and she will be available to sign books during this time. Ms. Gray’s book is available wherever books are sold online, and copies will be available for purchase at the Conference Bookstore. Pre-registration is required for this event. **Note:** Attendees of this event should get their lunch in the Exhibit Hall before going to the session room. The formal presentation will start at 1:05 PM.
Monday, November 14

1:30-1:50 PM  
Demonstration of PRIM&R’s Ethical Research Oversight Course (E-ROC)  
Exhibit Hall  
Join us in the demo theater in the Exhibit Hall for a demonstration of our interactive online course, E-ROC. During this brief overview, you will be introduced to this tool and how it can strengthen your understanding of the core regulations and underlying ethical principles of human subjects protections. If you are unable to join us for this presentation, but would like to learn more about E-ROC while onsite at the conference, stop by the PRIM&R Booth or email Nora Murphy, online learning coordinator, to set-up a one-on-one demonstration.

1:45-2:15 PM  
Meet the AER16 Supporters and Exhibitors  
Exhibit Hall  
Network with this year’s conference Supporters and Exhibitors, and learn about their important services.

1:45-2:15 PM  
FDA Office Hours  
Exhibit Hall  
☑️  
Do you have a specific question for FDA representatives or on a FDA-related topic? Or do you have a follow-up question after attending a session with a FDA representation? If so, stop by FDA Office Hours, and representatives from the FDA will be available to help answer your questions.

1:45-2:15 PM  
OHRP Office Hours  
Exhibit Hall  
☑️  
Do you have a specific question for OHRP representatives? Or, do you have a follow-up question after attending a session with an OHRP representation or on an OHRP-related topic? If so, stop by OHRP Office Hours, and representatives from the OHRP will be available to help answer your questions.

1:55-2:15 PM  
Overview of PRIM&R’s Member Benefits  
Exhibit Hall  
Join us in the demo theater in the Exhibit Hall for a discussion of the many benefits that come with your PRIM&R membership. During this overview, you’ll learn about the ways membership pays for itself during the course of the year. If you are unable to join us, but would like to learn more about your member benefits (or becoming a member) while onsite at the conference, stop by the PRIM&R Booth or email Elise Davis, membership coordinator, to set-up a one-on-one appointment.

Didactic Sessions and Workshops Series A, 2:30-3:45 PM

A1  
A Dialogue with the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) (A Dialogue with the Feds I Track) Kata L. Chillag, Lisa M. Lee, Nicolle K. Strand  
Room 304 C  
☑️ ✔️ CIP  
This session will be led by representatives from the Bioethics Commission. Attendees are encouraged to come with questions of interest to all. During this session, faculty and attendees will:

- Hear about the Bioethics Commission’s body of work
- Review topics relevant to stakeholders, including: (1) the Bioethics Commission’s recent recommendations about using democratic deliberation and ethics education to strengthen decision-making about complex bioethical issues; and (2) the Bioethics Commission’s recent public meetings to reflect upon the role of national bioethics advisory bodies, both in the United States and abroad
- Participate in a question and answer session with Bioethics Commission staff

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A2
A Dialogue With the Secretary’s Advisory Committee on Human Research Protections (SACHRP) (A Dialogue with the Feds II Track) David A. Borasky, Jr., David G. Forster, Julia G. Gorey
This session will be led by representatives from SACHRP. Attendees are encouraged to come with questions of interest to all. During this session, faculty and attendees will:
- Hear from SACHRP representatives about evolving initiatives, issues, and guidance
- Participate in an open discussion about topics relevant to SACHRP stakeholders
- Discuss best practices currently under consideration by SACHRP
- Ask questions of SACHRP representatives

A3
Tips on Involvement of US Army Personnel as Human Subjects (Advanced Forum for IRB Professionals Track) Jessica C. Candia, Molly M. Klot
This session will inform HRPP personnel and researchers on the important considerations applicable to involvement of US Army personnel or assets in human research. Attendees should understand that the Department of Defense and US Army impose additional requirements on research involving Army personnel or assets. During this session, faculty will:
- Discuss issues for consideration before involving US Army personnel or assets in human research proposals
- Identify common requirements applicable to human research supported by the US Army
- Explore strategies to overcome barriers to involvement of the US Army in human research

A4
You’ll Know it When You See it: Defining "Human Subjects Research" Under the DHHS Regulations (Boundaries & Balance Track) Julie Kaneshiro, Cheri M. Pettey, Ada Sue Selwitz
Evaluating whether an investigator is conducting 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,” and “human subjects” can be tricky, thorough consideration is needed to ensure appropriate application of the regulations. During this session, faculty will:
- Define a process and a set of criteria for determining whether an activity is research, according to the current federal regulations
- Explore key decision points for determining whether or not a research study involves human subjects, according to the current federal regulations
- Discuss proposed changes to the Common Rule’s definitions for “research” and “human subjects” (e.g., if not human subjects research, who should review it?)

A5
Staying on Top of Your Game: Professional Development for Human Subjects Protections Staff (Educating & Training Track) Hila F. Berger, Charlotte H. Coley, Karen M. Hansen
For human subjects protections staff and IRB members, keeping up with the evolving field can be a challenge. Faculty will discuss current options and new trends in professional development, training, education, and will provide tips on networking. During this session, faculty and attendees will:
- Review methods, techniques, and credentialing programs available for staff development, including: Certified IRB Professional, Certified Clinical Research Associate, Certified IRB Manager, etc.
- Share information on available opportunities for training and education
- Discuss the importance of networking as it relates to professional development in this field

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A6
Examine Participant Perspectives on Social and Structural Constraints on Research Involving Vulnerable Populations (Empirical Research Ethics Track) Brandon J. Brown, Celia B. Fisher, Lianne A. Uradz
This session will focus on examining participant perspectives on the social and structural constraints on research involving vulnerable populations, including sex workers and substance use populations. Specifically, aspects of the social, physical, economic, and policy environments (guided by Rhodes’ risk environment framework) will be discussed (e.g., the influence and perspectives of venue managers, police, and other structural barriers and facilitators to conducting research and intervening with vulnerable populations). During this session, faculty will:
• Identify key ethical issues involving vulnerable populations in research and the feasibility and utility of carrying out research specifically on the ethical conduct of research with these populations
• Review how to develop research questions examining the ethical barriers and facilitators to participation in HIV and substance use intervention research
• Discuss best practices in the ethical conduct of research by utilizing community advisory boards and community mobilization building strategies

A7
Introduction to Ethical Principles for Research Involving Human Participants as Study Subjects (Ethical Issues Track) Elizabeth A. Bankert, Robert J. Levine
Various ethical norms, standards, and principles, as well as professional standards, speak to researchers’ and institutions’ responsibilities for the protection of persons who participate as study subjects. This session will provide attendees with an overview of these ethics frameworks. During this session, faculty will:
• Discuss the evolution and development of prevailing ethics norms, standards, and principles for human research protections
• Identify distinctions between ethics frameworks from legal requirements for the protection of human research subjects
• Examine, through case studies, how researchers, institutions, and IRBs may address ethics challenges in studies with human subjects

A8
A Primer in Determining When an Investigational New Drug (IND) Application Is Needed for Studies Involving Drugs or Biologics (FDA Regulations Track) Karen N. Hale, Patrick J. McNeilly
Sponsors and sponsor-investigators are responsible for determining whether an IND is required for a study they are conducting involving an FDA-regulated drug or biologic product. In general, the IND regulations require that human research studies involving drugs or biologics be conducted under an IND if the study is a clinical investigation as defined in the IND regulations at 21 CFR 312, and the clinical investigation is not otherwise exempt from the IND requirements. IRBs should have an understanding of the regulatory platform for review of drug and biologic studies and ask questions of the sponsor and sponsor-investigator about whether or not an IND is needed for a particular study when needed. During this session, faculty will:
• Provide a basic overview of the applicability of the IND regulations that address when an IND is required
• Discuss how to apply these regulations to studies involving investigational and marketed drug and biologic products
• Review case examples to assist IRBs in understanding when an IND might be needed for a clinical investigation of a drug or biologic

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Different models of Review: A Global Comparison (Global Research Track) Feras Alkasab, Eman Sadoun, Delia Y. Wolf, Rachel Zand
Different countries have adopted different types of ethics review systems for research. Such systems might include various combinations of structures that comprise local, regional, and national committees, and may involve different processes. For example: What is the relationship between national and regional committees? Does the national committee perform reviews and, if so, are the reviews restricted to certain types of research? What are the implications of different structures on issues such as the quality of reviews, the turnaround time for reviews when multiple committees review the same protocols, and the implication for human resources? During this session, faculty will:
- Review the different models of national ethics review systems
- Discuss how context and concepts drive the structure and processes of different review structures
- Consider how the structure of ethics review systems can affect functionality

Updated International Guidelines for Stem Cell Research: Implications for IRBs, Stem Cell Research Oversight Committees (SCROs), and Institutions (Hot Topics Track) Geoff Lomax, P. Pearl O’Rourke, Jeremy M. Sugarman
In May 2016, the International Society for Stem Cell Research (ISSCR) released new guidelines for stem cell research. The new guidelines consolidate and update ISSCR’s previous guidelines in light of scientific advances and advances in research ethics and oversight. During this session, faculty will:
- Review the process of revising the guidelines and describe their key features, focusing on the implications for IRBs, SCROs, and institutions
- Discuss the need for updating international guidelines for stem cell research
- Outline the key features of the guidelines

Implementing NIH Single IRB Policy Using the National Center for Advancing Translational Sciences (NCATS) SMART IRB Reliance Platform in the Clinical and Translational Science Award (CTSA) Program (Hot Topics Track) Barbara E. Bierer, Michelle A. Culp, Valery M. Gordon, Ann Johnson, Emily Sheffer
During this session, attendees will learn how NCATS is leading the implementation of the NIH single IRB Policy in the CTSA Program Platform. This session will review the SMART IRB Agreement, how to sign on to the agreement, and describe how the CTSA Trial Innovation Network will support central IRB review of multisite studies in the CTSA Trial Innovation Network. During this session, faculty will:
- Describe the scope and applicability of the NIH Single IRB Policy
- Illustrate how the SMART IRB Agreement is a flexible master reliance agreement for all institutions to use
- Identify the tools that will facilitate single IRB review of multisite studies
A12
How Do We Assess the Quality of an HRPP? (Institutional Officials and HRPP Leadership Track) Wesley G. Byerly, Kip M. Kantelo, James Riddle
This session will look at how to measure quality and the right staffing levels in the HRPP, as well as novel ways to assess quality. During this session, faculty will:
- Review new models and approaches, aside from time to approval, as a metric for evaluating quality
- Discuss approaches to operationalizing efficiency
- Explore how to eliminate unnecessary bureaucracy and institutional requirements that exceed regulatory burden

A13
Pre-IRB Review: IRB Ready or Not? (IRB 101 Track) Elizabeth Bartrum, Sandra Bonifant, Sharon Freitag
Through lecture, interactive discussions, and case studies, this session will provide attendees with the core concepts and fundamental knowledge of pre-IRB review. After attending this session, attendees will be able to: (1) understand the need for pre-IRB review; (2) define the pre-IRB review process; and (3) apply the pre-IRB review process through case studies. This session is ideal for those interested in streamlining the IRB review process, and study investigators and their support staff. During this session, faculty will:
- Review the importance of pre-IRB review and how it enhances the review process by assuring completeness, consistency, and accuracy of submissions, thereby easing administrative burden on the IRB
- Outline the pre-IRB review process
- Use real-world examples to explore approaches to developing a thorough and efficient pre-IRB review process, including dissemination of model pre-IRB review standard operating procedures

A14
IRB Chairs and Members: Recruiting, Developing, Training, and Managing (IRB Chairs Track) Courtney A. Jarboe, Eric C. Mah
During this session, faculty will:
- Discuss best practices in recruiting, developing, training, and managing diverse and skilled board members and chairs
- Describe succession planning strategies for leadership development of IRB chairs
- Explore how to work with institutional leadership to support IRB membership

A15
Institutions and HRPPs have discretion in the interpretation of the regulations, and risk tolerance varies by institution and over time. This interactive session will focus on identifying when adjustments in risk tolerance may be appropriate and how to manage this change within the IRB and the institution. Before attending this session, attendees should have an understanding of the regulations as they relate to where IRBs have flexibility in interpreting their application. During this session, faculty and attendees will:
- Review approaches to assessing risk tolerance in IRB administration and review
- Discuss options for recalibrating risk tolerance and evaluating how to make changes in practice
- Explore ways to introduce flexibility in practice while maintaining regulatory compliance

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A16
Designing and Implementing Expanded Access Programs (Issues Pharma/Biotech Track) Kate Gallin Heffernan, Richard Klein, Beth E. Roxland
This session will discuss how institutions and sponsor companies are approaching expanded access, especially in light of public scrutiny/social media interest in decisions about access, questions about conflict of interest, and equitable selection of individuals for access opportunities. During this session, faculty will:
- Explain the legal frameworks applicable to expanded access, including FDA’s existing regulatory structure
- Review the potential ethical risks raised by access to investigational drugs outside of controlled clinical trials, including therapeutic misconception, distribution of unsafe drugs, and the potential harm from unknown side effects
- Address where the line between autonomy and beneficence should be drawn for terminal patients seeking access to investigational products (i.e., do we, as a society, have an obligation to allow people this choice, or an obligation to help patients accept futility and death?)
- Discuss strategies institutions and sponsor companies are implementing to evaluate access requests

A17
Reserved for Late-Breaking Session

A18
The Inside Scoop: What Every Non-Scientist IRB Member Should Know (Non-Scientist IRB Members Track) Dahron A. Johnson, Greg E. Manship
In this session, non-scientist IRB members will share their perspective about the who, what, where, why, and how of IRB membership. During this session, faculty and attendees will:
- Outline the role of the non-scientist in the IRB and the importance of this role to the review process
- Discuss first-hand knowledge and perspective of how the non-scientist can best contribute to the IRB
- Share strategies for being a non-scientist on the IRB

A19
The ABCs of Genetics, DNA, and Related Research Issues (Out-of-Body Experiences: Research Involving Tissue and Data Track) Marianna J. Bledsoe, Stacey A. Donnelly, Carol Juliet Weil
IRBs are reviewing an increasing number of research proposals involving genetic and genomic research. This session will offer a primer on genetic concepts and terminology, and the state of the science and HRPP in genome-scale research. During this session, faculty will:
- Review the basics of genetics, different types of genetic research, and how genetic research can contribute to improved health and healthcare
- Identify the risks associated with genetic information and ways to protect subjects who participate in genetic research
- Provide an overview of empirical research on patient and public perspectives on genetic research, including views about risk and informed consent

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A20  
**Defining Vulnerability: Regulations and Beyond**  
*Populations Requiring Additional Protections Track*  
Jeremy Block, Bruce G. Gordon, Irene E. Stith-Coleman  
In this session, faculty will give a basic overview of the regulations that cover vulnerable populations, and will provide an expanded view of vulnerability beyond that outlined in the regulations, reframing vulnerability in the context of laws, policies, and processes in other fields. During this session, faculty will:  
- Review the basic regulations when doing research with vulnerable populations  
- Share examples of different types of vulnerabilities and explore how to think about these examples in the context of clinical research  
- Discuss the threshold questions an IRB should address before permitting research with these subjects  
- Go over examples of risks to subjects that may be different in nature or frequency for these subjects  
- Provide examples of how to incorporate additional protections into informed consent

A21  
**Nuts and Bolts of Investigator Site Audits**  
*QA/QI and Post-Approval Monitoring Track*  
Kelly Damin-Koss, Jennifer A. Graf, Sarah A. White  
Investigator site audits are a hallmark of post-approval monitoring and are integrated into many IRB QA/QI programs. This session will introduce participants to the key concepts and practical strategies for developing investigator onsite audit activities. During this session, faculty will:  
- Provide an overview of the investigator site review/audit process  
- Address specific considerations of the investigator audit activity including, but not limited to: triggers for audits, sampling plans, grading/scoring onsite reviews, and who receives the report (the considerations will be compared/contrasted between multiple QA/QI programs)  
- Discuss how audits can be an opportunity for investigator education  
- Review practical and useful tools that sites can modify for their own use

A22  
**IRB Review of Big Data Research**  
*Research Conducted in the Digital World Track*  
Elizabeth A. Buchanan, Laura Odwazny  
This session will introduce participants to big data research and contextualize the rise of big data research in relation to human subjects research. During this session, faculty and attendees will:  
- Define and describe big data  
- Clarify the unique and specific risks and benefits of big data research and how they are sometimes consistent and inconsistent with current regulations  
- Review examples of big data research through the lens of IRB considerations  
- Work through a big data research protocol

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**ICON KEY**

- Didactic session  
- Pre-registration required  
- CME accredited  
- Interactive workshop  
- Call for Session Proposal  
- Double session  
- Recorded session  

**Advanced** – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.

**Basic** – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.
A23

**Does Anyone Here Get What I Do? Educating Your Institution on What the HRPP Is All About**  
*(Small Research Programs Track)*  
*Robert S. Bienkowski, Bonnie Frisard*

HRPPs in institutions with small research programs often work with severe constraints, and some may not even be perceived as “real.” However, many HRPPs at small institutions function at high levels of efficiency and efficacy, and can serve as role models for others. More aggressive education and relationship building can result in better understanding and appreciation of the HRPP and its importance to an institution’s research programs. This session will provide attendees with ideas to educate institutions about HRPPs. During this session, faculty and attendees will:

- Define HRPP (more than just the IRB) and compare and contrast operations of HRPPs in institutions with medical and SBER portfolios
- Describe the roles and responsibilities of the HRPPs (including the various components, i.e., institutional official, IRB, investigator, compliance, legal, subject, sponsor)
- Discuss strategies for building relationships
- Review approaches for providing education throughout the institution

A24

**Best Practices for Assessing Risks and Benefits in SBER**  
*(SBER I Track)*  
*Jeffrey M. Cohen, Dean R. Gallow, Jaime O. Hernandez*

This introductory session will explore the unique characteristics of SBER, and will provide best practices for evaluating risks and benefits that commonly arise in this type of research. During this session, faculty will:

- Define the criteria for evaluating risk and address whether a study is “minimal risk”
- Outline the types of risks that arise in SBER, and how risks in SBER differ from risks typically encountered in biomedical research
- Discuss when an SBER IRB may need to obtain outside expertise to properly evaluate risk
- Explore methods IRBs can recommend to minimize risk to participants
- Provide insight on how risk should be explained to potential participants in the informed consent process

A25

**Mandatory Reporting**  
*(SBER II Track)*  
*Todd Franke, Andrew P. Ruscak, Julie F. Simpson*

This session will discuss the requirements for mandatory reporting, such as federal and state laws, and local/institutional requirements, as well as discuss the intersection of mandatory reporting and Certificates of Confidentiality (CoCs) and National Institute of Justice (NIJ) Privacy Certificates. The session will also cover the impacts of mandatory reporting on study methodology and ethical issues, and address best practices for IRBs and researchers. Attendees should have an understanding of 45 CFR 46, informed consent for research, risk assessment, and confidentiality and privacy before attending this session. During the session, faculty will:

- Identify the legal aspects of mandatory reporting, such as who is/is not required to report, the implications of not reporting (e.g., duty of a citizen), and legal definitions of “reporter”
- Review common federal and state mandatory reporting requirements that researchers face, as well as their intersection with CoCs and NU Privacy Certificates
- Explore how mandatory reporting may affect study design and risk assessment, and mandatory reporting requirement considerations for informed consent
- Discuss best practices for IRBs and researchers when conducting and reviewing research that involves mandatory reporting

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Monday, November 14

3:45-4:00 PM
Beverage Break
Join us for coffee and cold drinks in the Exhibit Hall.

Didactic Sessions and Workshops Series B, 4:00-5:15 PM

B1
A Dialogue With the Office for Human Research Protections (OHRP)  
(A Dialogue with the Feds I Track) Misti Ault Anderson, Kristina C. Borror, Julie Kaneshiro, Jerry Menikoff, Ivor A. Pritchard, Irene Stith-Coleman
This session will be led by representatives from OHRP. Attendees are encouraged to come with questions of interest to all. During this session, faculty and attendees will:
- Hear from OHRP representatives about evolving initiatives, issues, and guidance
- Ask questions of OHRP representatives
- Participate in an open discussion on topics raised at the session

B2
A Dialogue With the Department of Energy (DOE) (A Dialogue with the Feds II Track) Mary L. Fields, John C. Ordaz, Elizabeth P. White
This session will be led by representatives from the DOE. Attendees are encouraged to come with questions of interest to all. During this session, faculty and attendees will:
- Participate in an open discussion of issues relevant to DOE stakeholders, including DOE’s implementation of a new software system for processing IRB applications; how DOE has implemented the Clinton memo requirements; and other/new initiatives
- Ask questions about new and ongoing initiatives at the DOE

B3
Things that Keep an Institutional Official (IO) Up at Night  
(Advanced Forum for IRB Professionals Track) Lois Brako, Suzanne M. Rivera
This session will provide an explanation of the role and responsibilities of the IO, and will stimulate discussion about the kinds of risks and problems IOs face. Participants will engage in a discussion about several highly-publicized cases in which a campus’ HRPP was severely impacted by noncompliance or an unfortunate accident for which an emergency response was required. Participants will be encouraged to share how their HRPPs plan for and respond to research crises. Attendees should have an understanding of human research regulations and procedures for managing regulatory non-compliance before attending this session. During this session, faculty and attendees will:
- Learn about the responsibilities of the IO in an HRPP
- Discuss several high-profile cases of research “disasters” that led to major institutional turmoil
- Share practical skills for thinking about how to respond if a research crisis should happen on their own campus

ICON KEY

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

Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.

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B4
Opposing Forces: How to Align Flexibility and Consistency in Reliance Agreements
(Boundaries & Balance Track) Daniel Alderson, Nichelle Cobb, Kathleen Lawry
During this session, faculty will explore the concept of “flexibility” as it applies to IRB reliance arrangements. For example, when ceding IRB review to a variety of sites that differ in their use of the flexibility in the regulations, how do you remain both consistent and flexible when reviewing research (e.g., two-year continuing review, new category of exemption)? Or, as a reviewing IRB or relying institution, when does being flexible regarding processes and expectations promote human subjects protections and compliance, and when can it simply impede the reliance and review process? During this session, faculty will:
- Describe areas where the use of flexibility is/is not appropriate
- Discuss “best practices” for flexibility that will be compliant and that allow for ceding of review to another IRB
- Explore how these “best practices” are developed and by whom, in order to allow for broader participation

B5
Training for Success: Tools and Educational Methods for IRB Staff
(Educating & Training Track) Sarah Fowler-Dixon, Abby Keeley, Jeanne Velders
Regardless of the size and complexity of your office, IRB intensive staff training using formal training manuals can improve the functionality and morale of the work environment by empowering staff to become experts in the field of human subjects protections. These training manuals are important in that they train IRB professional staff in a standardized and documented manner; establish staff expectations early on with a structured plan that contains incremental attainable goals over a period of time; are flexible and individualized based on staff learning styles; experience at entry, and progress through training; establish the level of knowledge needed to work with the IRB; help to professionalize the field of human subjects protections and prepare for the Certified IRB Professional exam; can be used as part of continuous quality improvement; and demonstrate to senior leadership the complexity and breadth of IRB related functions to help provide justification for staff salaries, space, resources, etc. During this session, faculty will:
- Provide an efficient and effective training tool for IRB professionals at all levels of experience
- Describe a training method that is proven successful in support of adult learners who have a need for job-based, continuing education in a highly regulated environment
- Discuss the use of orientation and training manuals as companion tools for an effective QA/QI program for IRB staff

B6
This session will provide an opportunity for attendees of Panel II: Empirical Research About Attitudes on the Ethics of ROMP (or those unable to attend) to engage in further discussion with the panelists on the data presented, how it should be interpreted, what it means for IRBs, and how it impacts policy. During this session, faculty and attendees will:
- Discuss in more detail the particulars of the studies presented in Panel II
- Engage in discussion and questions/answers on what the data means, how it should be interpreted, etc.
- Share about the policy implications for doing empirical research on the ethics of ROMP

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B7
Ethical Issues in Community-Based Participatory Research (CBPR) (Ethical Issues Track)
Myra E. Parker, Steven Wakefield
CBPR theory posits that capacity building and “giving back” are an ethical requirement of research with communities. While communities may see job training, capital goods, or employment as benefits of research, many IRBs prohibit researchers from presenting them as such. During this session, faculty and attendees will:
- Discuss the ethical arguments in support of capacity-building within the CBPR framework
- Review the regulatory requirements regarding the definition of benefit
- Through case studies, explore model approaches for balancing communities’ expressed interests with regulatory requirements surrounding benefits
- Share real-world examples and answer learner questions about CBPR to find concrete recommendations

B8
FDA Oversight and IRB Review of Investigational In Vitro Diagnostics (IVDs) (FDA Regulations Track) George Gasparis, Ernest D. Litwack
IVD products are medical devices intended to diagnose disease or determine a state of health. The FDA oversees studies involving investigational IVDs under the investigational device exemption (IDE) regulation. Under this regulation, study sponsors and IRBs must recognize when a study is using an IVD that is investigational, and determine whether it meets the criteria for an exempt device, a non-significant risk device, or a significant risk device. The rapid growth in studies involving genomics and other molecular tests in the use of IVDs to select patients for drug trials has posed particular challenges for sponsors, investigators, and IRBs. During this session, faculty will:
- Provide an overview of the FDA regulatory framework for investigational IDEs for IVDs
- Explain how to determine if a study uses an investigational IVD
- Describe FDA’s approach to risk determination
- Highlight IRB scenarios and share processes developed by one institution through the use of case studies

B9
Ensuring Research Compliance of Multicenter and International Research (Global Research Track) Edward E. Bartlett, David J. Borasky, Jr., Leslie M. Howes, Lama Jamhawi
During this session, faculty will:
- Introduce the concepts of QA and QI and their functions as part of the larger HRPP
- Share strategies for building and operationalizing effective QA/QI programs for multicenter and international studies
- Discuss how QA/QI programs can utilize remote monitoring to achieve QA/QI reviews for multicenter and international studies
- Review commonly recognized compliance risks identified while monitoring international and multicenter studies

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- CIP eligible
B10
Competence Standardization, Development as a Means to Improving Patient Safety and Clinical Trial Operations
(Hot Topics Track) Terri Hinkley
This session will examine ongoing initiatives to improve human subjects protections and clinical trial operations through workforce development, including standardization and development of core competencies for clinical research professionals. During this session, faculty will:
- Explore current workforce development practices and impact on subject safety and clinical trial conduct/oversight
- Review the importance of incorporating a framework of core competencies into the education/training programs and career development plans for clinical investigators and staff
- Discuss benefits of competence-based workforce development and the impact on patient safety and clinical trial conduct/oversight

B11
Reserved for Late-Breaking Session

B12
The Characteristics of “High Performance” HRPPs
(Institutional Officials and HRPP Leadership Track) Karen Allen, Thomas M. Bechert, Wayne R. Patterson
This session provides HRPP leaders with simplified frameworks to aid in identifying and managing key institutional factors that impact their HRPP’s level of compliance, productivity, and investigator satisfaction. Prior to attending this session, attendees should have a general understanding of the regulatory obligations associated with IRB oversight, challenges impacting their own HRPPs, and the AAHRPP accreditation requirements. During this session, faculty will:
- Explore characteristics of the most efficient and effective HRPPs that are useful in overcoming challenges
- Help attendees gain a greater understanding of an idealized “High Performance” HRPP and its characteristics as a tool to support internal programmatic improvements

B13
Essential Documentation: IRB Membership, Record Keeping, Minutes, and More
(IRB 101 Track) Janet C. Donnelly, Lauren Hartsmith, Ada Sue Selwitz
The federal regulations define the requirements for IRB membership and for documenting discussions, decisions, findings, and communications of IRB decisions. During this session, faculty will:
- Outline the basic federal requirements for IRB documentation
- Discuss the federal requirements for the maintenance of accurate, complete, and timely IRB records
- Identify the components of a complete record of IRB meeting activities as reported in the IRB meeting minutes
B14
Continuous quality improvement is the hallmark of a model IRB, but how does an institution evaluate its IRB members? What are the political/environmental considerations and change management strategies to address in order to evaluate IRB members and chairs? This session will explore these themes. During this session, faculty will:
- Identify methods for evaluating members, chairs, and staff
- Review different types of evaluation processes in IRBs
- Discuss feedback systems that work and ones that don’t

B15
Case Studies in IRB Quality Improvement Initiatives
(IRB Operations Advanced Track) Kristin J. Craun, Eifang Li
Increasingly, it is expected that IRBs have internal processes for assessing quality and implementing improvements in response to these quality evaluations. This session will review examples of quality improvement initiatives undertaken by IRBs and discuss the lessons learned from these initiatives. Attendees should have a basic understanding of IRB operations before attending, as this session will focus on mechanisms through which improvements to operations may be designed, implemented, and evaluated. During this session, faculty will:
- Provide practical tips for developing and implementing quality initiatives
- Discuss specific examples of quality initiatives, their successes and failures, and the lessons learned from these initiatives

B16
Considerations for Effective IRB Review and Management of Protocol Deviations and Violations
(Issues Pharma/ Biotech Track) Albert J. Allen, Michele Russell-Einhorn, Megan Kasimatis Singleton
FDA and the Common Rule regulations require prospective IRB approval of modifications to the research, unless such changes must be implemented immediately by the investigator to remove/minimize potential imminent harm to subjects. Obtaining prospective sponsor and IRB approval for individual subjects poses potential compliance challenges for investigators. This session will discuss effective policy and processing considerations to enhance compliance of protocol deviations. During this session, faculty will:
- Define what types of deviations need prompt reporting and prospective IRB approval
- Categorize the types of deviations/violations that should be submitted promptly versus those that should be submitted for continuing review
- Explore the types of deviations that raise serious noncompliance concerns

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B17
Certificates of Confidentiality (CoCs): When, Why, and So What?
(Legal Track) Petrice Brown-Longenecker, Karen E. Moe, Leslie E. Wolf
CoCs are often an area of confusion and consternation for investigators and IRBs. Determining when a study warrants a certificate and what the process is for obtaining one are only the first steps. Confusion and misinformation also exist as to the scope of protection this document offers. During this session, faculty will:
- Define the scope of legal protection and privilege afforded to researchers under a CoC, including a review of the applicable regulations and federal guidance
- Review considerations around when it would be prudent to obtain a CoC and how to avoid potential pitfalls when implementing one
- Outline how a CoC interfaces with state requirements
- Share strategies for defending a CoC if challenged
- Discuss the implications for informed consent and how a CoC interfaces with other protective laws and possible disclosures

B18
Keys to the Magic Kingdom: Defining Roles, Expectations, and Challenges for the Non-Scientist IRB Member
(Non-Scientist IRB Members Track) Michelle M. Feige, David Heagerty, Nancy A. Olson
When it all sounds like Greek, how does the non-scientist IRB member know when to be concerned? This session will define research and regulatory terminology that commonly occurs during protocol review and describe the background, role, and expectations of the non-scientist IRB member. The faculty will also facilitate discussion and provide tips for reviewing research, and provide suggestions for success. During this session, faculty will:
- Identify problematic areas of protocols
- Define specific issues for methodological consideration in IRB review
- Provide suggestions for the non-scientist IRB member when reviewing challenging protocols

B19
Consenting Subjects for Bio/Data Repositories: Evaluating Approaches and Their Implications for Future Solutions
(Out-of-Body Experiences: Research Involving Tissue and Data Track) Laura M. Beskow, W. Andrew Faucett, Julia G. Gorey
Using case examples from institutions/individuals who have adopted a variety of consenting strategies for bio/data repositories, this session will explore the pitfalls and successes of varied consenting approaches, and evaluate how lessons learned from past efforts can help inform new strategies to operationalize consent for bio/data repositories. During this session, faculty will:
- Describe varied approaches to consent and evaluate the pitfalls/successes of each approach
- Review the practical implications for each consenting approach
- Provide tips for institutions in selecting and implementing their consent approach

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B20
Research With Children: Regulations and Beyond
(Populations Requiring Additional Protections Track) Francis J. DiMario, Jaime O. Hernandez, Robert M. Nelson
When conducting research with minors, researchers and IRBs must be aware of and meet additional regulatory requirements. In addition, it is both the ethical and regulatory responsibility of the IRB to ensure the research does not endanger the children’s safety or well-being. During this session, faculty will:
- Identify the regulatory requirements when conducting research with minors, including the categories of permissible research and research conducted in school settings
- Review assent and parental permission requirements and best practices
- Discuss unique issues that may affect research with minors, including internet research emancipated minors, returning research results, etc.

B21
Nuts and Bolts of Assessing IRB Compliance
(QA/QI and Post-Approval Monitoring Track) Lisa R. Buchanan, Lisa Denney, Keren R. Dunn
This session will introduce attendees to the various activities QA/QI programs can implement to assess IRB compliance with federal, state, and local requirements for research. During this session, faculty will:
- Provide considerations and mechanics for QA/QI review of IRB files, meeting minutes, and membership composition
- Identify triggers that may prompt QA of the IRB
- Discuss approaches to self-auditing HRPP offices, including techniques and timing
- Review training approaches for QA/QI staff conducting QA of the IRB
- Outline corrective and preventive actions that can be used to address IRB noncompliance

B22
Clinical Research in the Age of Digital Health: Best Practices for IRBs
(Research Conducted in the Digital World Track) Jeremy N. Block, Jennifer S. Geetter
Digital health, the intersection of digital tools and digitized data with healthcare paradigms, is driving an intense demand for new solutions and tools related to telemedicine, quality improvement, cost control, big data, and FDA-regulated mobile medical products. This push for innovation presents a number of challenges to traditional definitions of research and the application of research protections. This session will explore digital health as it relates to research involving human subjects, and identify issues that lawyers, senior executives, developers, and IRBs need to consider. Attendees should have an understanding of the basic concepts, challenges, and opportunities that arise with digital and mobile health research and mobile health technology before attending this session. During this session, faculty will:
- Identify specific examples of how digital health priorities challenge traditional research definitions and protections
- Consider practical solutions and tools for providing oversight and direction to research in the digital health area
- Discuss policies, procedures, and practices that can assist with this challenge
B23
Building and Maintaining an HRPP Within a Primarily SBER Institution with a Small Research Portfolio (Small Research Programs Track) Greg E. Manship, Andrea R. McDowell
This session will focus on the challenges of developing and maintaining an effective HRPP at an institution conducting primarily SBER. Topics to be discussed include: managing training for IRB members and researchers, student-led research, informed consent waivers and alterations, research involving college students who are legal minors, and data security. During this session, faculty and attendees will:
- Explore strategies for establishing and maintaining an effective HRPP in a small institution that conducts primarily SBER
- Provide examples and proven strategies used to engage senior leadership, investigators, and IRB members

B24
Scientific Merit, Generalizability, and Risks in Qualitative Research: A Case Study Approach (SBER I Track) Alison S. Orkin, Matthew D. Stafford
Using case studies, this session will provide strategies IRBs can use in assessing scientific merit, generalizability, and risks in SBER. Attendees should have an understanding of qualitative research, including methodology and methods, the challenges related to risk and informed consent that such studies often raise, and a working knowledge of 45 CFR 46 before attending this session. During this session, faculty and attendees will:
- Discuss strategies for assessing scientific merit and generalizability in qualitative research
- Identify risks to subjects and affected populations in qualitative research
- Share IRB training resources

B25
Understanding Qualitative Research and Associated Ethical Issues to Protect Research Participants from Harm (SBER II Track) Julie F. Simpson, Julie Slayton
In qualitative inquiry, researchers study phenomena in their natural settings where the purpose is contextualization, interpretation, and/or understanding the perspectives of others. The role of qualitative researchers in a study is characterized by personal involvement and empathetic understanding. This session will help facilitate the review of qualitative research applications by IRBs by providing IRB members with a better understanding of qualitative research and the challenges faced by researchers using this paradigm, and by providing qualitative researchers with strategies to address the issues that this research paradigm often presents. During this session, faculty will:
- Examine the foundations of research paradigms and qualitative inquiry, and review the basic characteristics, including nomenclature and common data collection methods
- Identify and understand the ethical issues qualitative research may present to study participants, including recruitment, informed consent, privacy and confidentiality, and conducting research online
- Learn about strategies for minimizing harm for participants in qualitative research studies

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5:15-5:35 PM  
**Demonstration of PRIM&R’s Ethical Research Oversight Course (E-ROC)**  
Join us in the demo theater in the Exhibit Hall for a demonstration of our interactive online course, E-ROC. During this brief overview, you will be introduced to this tool and how it can strengthen your understanding of the core regulations and underlying ethical principles of human subjects protections. If you are unable to join us for this presentation, but would like to learn more about E-ROC while onsite at the conference, stop by the PRIM&R Booth or email Nora Murphy, online learning coordinator, to set-up a one-on-one demonstration.

5:15-6:30 PM  
**AER16 Welcome Reception Supported by Schulman IRB**  
Join us in the Exhibit Hall to celebrate the opening of AER16. During this time, you’ll be able to meet our conference Supporters and Exhibitors and view the Poster Presentations. Drinks and hors d’oeuvres will be served, compliments of Schulman IRB, this year’s Diamond Supporter.

5:15-6:30 PM  
**Roundtable Discussions**  
Gather with your colleagues to solve problems and share best practices. Tables will be divided by topics and led by a fellow conference attendee. Groups will include: Career/Leadership/Management, IRB Administrators/Coordinators, Compliance/Federal/Legal/Regulatory, QA/QI/Post Approval Monitoring, IRB Chairs, Global Research, SBER, and Single IRBs. During this activity, participants can present an issue or question they have to the group and group members will respond to the problem or issue presented. Pre-registration is recommended, but attendees may also come onsite to fill any open seats that are still available. Please register online or email us.

5:40-6:00 PM  
**Demonstration of PRIM&R’s Knowledge Center**  
Join us in the demo theater in the Exhibit Hall for a demonstration of the Knowledge Center, our online resource for members, and its annotated regulations feature. During this brief overview, you will see how you can use resources found in the Knowledge Center as continuing education tools at your institution. If you are unable to join us for this presentation, but would like to learn more about the Knowledge Center while onsite at the conference, stop by the PRIM&R Booth or email Maeve Luthin, assistant director for professional development, to set-up a one-on-one demonstration.

7:00-9:00 PM  
**Young Professionals Networking Reception**  
Connect with other young professionals interested in research ethics and relax after a busy day in Anaheim at Bubba Gump Shrimp Co. (Anaheim GardenWalk, 321 W Katella Ave #101, Anaheim, CA 92802). Don’t forget to bring the drink ticket you received with your registration materials! While all attendees are welcome, complimentary drink tickets will be provided for young professional registrants only.
7:00 AM  
Registration Opens  
Breakfast on your own.  

7:00-8:00 AM  
Certified IRB Professional (CIP) Continental Breakfast – SOLD OUT!  
Interested in earning your CIP credential? Want to connect with other CIPs? Attend this breakfast to learn more about the credential, meet representatives of the Council for CIPs, network with fellow CIPs, and ask questions of those already certified. Please note this event is now sold out. If you would like to be added to the wait list, please email us.  

8:00-8:15 AM  
Welcome from the Conference Co-Chairs  
P. Pearl O’Rourke, MD Director, Human Research Affairs, Partners HealthCare System, Inc.  
Laura Odwazny, JD, MA Senior Attorney, Office of the General Counsel, Department of Health and Human Services  

8:15-8:25 AM  
Presentation of PRIM&R’s Applied Research Ethics National Association Legacy Award to Patricia A. MacCubbin, MS, President and CEO, Research Ethics Group  
Presented by Susan Z. Kornetsky, MPH, Director, Clinical Research Compliance, Boston Children’s Hospital; Board Chair, PRIM&R  

8:30-9:15 AM  
Keynote Address: “SUBJECTS” Matter: Burden of Participation for Children in Clinical Trials  
Patricia Furlong, Founding President and CEO, Parent Project Muscular Dystrophy  

9:15-9:45 AM  
Beverage Break  
Join us for coffee in the Exhibit Hall.
Innovations A: Innovations in Public Perceptions of Research and Risks
Moderator: Warren Capell
Understanding public perceptions of research and its risks can serve to enhance our knowledge on how best to protect human subjects. Many questions remain about what human subjects think about certain aspects of research, as well as how these views inform their decision to participate. In this panel, three poster authors will discuss their work related to human subjects’ perspectives of research and risks, including the return of incidental findings in a way that is accessible to human subjects why human subjects enroll in multiple studies and how that affects both their health and the research as a whole; and perspectives on the use of personal data by the public versus private sector.

- **Poster #20**: Health Literacy Challenges of Returning Neuroimaging Incidental Finding Radiology Reports in Research
  Linda Petree, BA, CIP, The University of New Mexico
- **Poster #19**: Simultaneous and Sequential Study Enrollment Among 34,237 Clinical Trial Patients and Patients’ Motivation for Duplicate Enrollment
  Jonathan Rabinowitz, PhD, Bar Ilan University
- **Poster #2**: Public Perspectives on Use of De-Identified Health Information for Private Sector or Commercial Uses
  Donald J. Willison, ScD, University of Toronto

Innovations B: Innovations in Respecting Persons
Moderator: Emily E. Anderson
The Belmont Report notes that voluntary informed consent is a requirement for the ethical conduct of human subjects research. However, even in the most straightforward research setting, difficulties arise in informing human subjects adequately and appropriately. In this panel, three poster authors will present their work on obtaining informed consent in deception studies and studies involving pediatric subjects; how human subjects understand the consent process; and best practices for training research staff on obtaining informed consent.

- **Poster #29**: Consent Consultation
  Michele Antisdal, MBA, CIP, Yale University
- **Poster #17**: Attitudes and Perceptions in an Authorized Deception Placebo Analgesia Research Study
  Susan J. Goo, MSN, RN, Clinical Center
- **Poster #1**: What Children and Adolescents Value in Research and the Assent Process: A Pediatric Hospital’s Experience
  Jessica Macha, BA, CIP, Stanley Manne Children’s Research Institute, Ann & Robert H. Lurie Children’s Hospital of Chicago
Innovations C: Innovations in Building Global Infrastructure for Ethical Research

Moderator: Delia Y. Wolf

Regardless of where research is conducted, issues may arise that require careful assessment and critical thinking in order to improve research operations and enhance human subjects protections. This panel will feature three poster authors from diverse global settings who will discuss their recent work navigating difficult issues and challenges that, while specific to their countries, reflect greater problems related to the conduct of research. These issues and challenges include rebuilding trust and recruiting human subjects for the Ebola vaccine research in Liberia, barriers in the research ethics committee system in the country of Georgia, and ensuring sustainable and measurable contributions for ethics review in global research partnerships.

- **Poster #26:** Building Global Ethics Review Capacity: An Innovative Model for IRB Administrator Training
  Megan Kasimatis Singleton, JD, MBE, CIP, Johns Hopkins University School of Medicine

- **Poster #3:** Social Mobilization and Communication: An Essential Component of Success of the Partnership for Research on Ebola Virus in Liberia (PREVAIL) I Ebola Vaccine Study Conducted During the Ebola Outbreak
  Bartholomew Wilson, PREVAIL

- **Poster #58:** Challenges and Barriers in the Research Ethics Committee System and Regulations in the Country of Georgia
  Marina Topuridze, MD, MS, National Center for Disease Control and Public Health, country of Georgia

11:00-11:15 AM
Break

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

C1
A Dialogue With the Food and Drug Administration (FDA)
(A Dialogue with the Feds I Track) Jan L. Hewett, Soma Kalb, Richard Klein, Joanne R. Less, Diane M. Maloney, Patrick J. McNeily, Kevin A. Prohaszka

This session will be led by representatives from the FDA. Attendees are encouraged to come with questions of interest to all. During this session, faculty and 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 and initiatives at the FDA

C2
A Dialogue With the Office for Research Integrity (ORI)
(A Dialogue with the Feds II Track) Kathryn M. Partin

This session will be led by the new director of ORI. Attendees are encouraged to come with questions of interest to all. During this session, faculty and attendees will:

- Participate in an open discussion of issues relevant to ORI stakeholders
- Ask questions about new and ongoing initiatives at ORI's new director

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**Advanced** - assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.

**Basic** - for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.
C3
Risky Business: Exposing Children to Potential Harm Without Compensating Clinical Benefit
Research interventions and procedures that present more than minimal risk, but offer no prospect of
direct benefit to children provoke controversy about their acceptability. Two members of The National
Commission voted against this recommendation in 1977, and many jurisdictions around the world limit
“research only” procedures in children to minimal risk. This session will review critically the development
of this category by The National Commission, and the ethical concerns it raises. A facilitated discussion
of the application of this category to pediatric research will examine selected (and likely controversial)
cases, including the use of procedural sedation and the performance of tissue biopsies (e.g., brain,
kidney) to explore potential drug targets. Attendees should have an understanding of the basic
protections in Subpart D for children in research (21 CFR 50, 45 CFR 46) before attending this session.
During this session, faculty and attendees will:
• Review the reasons for the development of this category of pediatric research by The National
  Commission
• Identify the ethical concerns raised by this category of pediatric research and how they might be
  addressed
• Apply this category of pediatric research to the analysis of the ethical acceptability of selected
  case examples
This is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please select the
session during registration. Please get your boxed lunch in the Exhibit Hall before going to the session room.

C4
Crossing the Line: When Does Innovative Care Become Research? (Boundaries & Balance Track)
George Gasparis, Lindsay McNair
The federal regulations allow for activities involving human subjects to be labeled “innovative care.”
However, there remains some confusion and, at times, ambiguity on when innovative care crosses the
line to become research. During this session, faculty will:
• Discuss when innovative care may or may not be considered research
• Describe circumstances under which innovative care activities should implicate applicability of
  human research regulations
• Explore variability among institutions and IRBs in providing review and oversight activities that
  may constitute non-standard or innovative care
• Identify strategies and processes for managing the review of clinical activities that may occur in
  the grey zone of human research protections

ICON KEY
Didactic session
Pre-registration required
CME accredited
Interactive workshop
Call for Session Proposal
Double session
Recorded session
Advanced – assumes mastery of ethical concepts and principles, the
regulations, and research oversight processes. Attendees should have
sufficient experience and understanding in order to actively contribute to
discussion and solutions. These sessions will not review basic concepts.
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for a refresher. The focus is on introducing, explaining, and illustrating basic
concepts, principles, regulations, policies, or best practices relevant to the topic.
C5  
Recruiting, Educating, and Retaining Non-Scientist/Community IRB Members (Educating & Training Track) Charlotte H. Coley, Michelle M. Feige, Gianna McMillan  
IRBs are responsible for protecting the safety, rights, and welfare of human subjects in clinical research. The regulations dictate that experience, expertise, and diversity of the members are important attributes of an effective IRB. Research institutions can draw on a large pool of physicians and other scientists to fill most of the Board seats, but what about non-scientist IRB members? The non-scientist IRB member is usually the one member at the IRB table with perspectives unfettered by an institutional affiliation, and therefore adds enormous value to the IRB and its deliberations and discussions. During this session, faculty will:  
- Review the definition of a non-scientific IRB member  
- Go over the responsibilities of the non-scientist IRB member  
- Address where non-scientist IRB members can be found and how they should be trained  
- Explore how to retain non-scientist IRB members once they’ve been recruited

C6  
Preventive Misconception in HIV Prevention: What it Is and How to (Try to) Measure it (Empirical Research Ethics Track) Jeremy Sugarman, Kevin P. Weinfurt  
The preventive misconception involves an overestimate of the probability or level of personal protection afforded by participating in a preventive research trial. A preventive misconception raises ethical concerns if participants in an HIV prevention trial change their risk behaviors as a result of it. This session will review the concept of a preventive misconception, challenges in developing a way to measure it, and the results obtained from fielding the measure in two major international HIV prevention trials. Attendees should have an understanding of HIV prevention research and/or survey development before attending this session. During this session, faculty will:  
- Describe a conceptual model of preventive misconception  
- Relate the challenges of developing a measure of the preventive misconception  
- Discuss how a measure behaves in the context of actual HIV prevention trials

C7  
Ethical and Regulatory Review of Research: Case Studies (Ethical Issues Track) Bruce G. Gordon, Ernest D. Prentice  
In this session, faculty will present case studies for discussion by a beginner/novice audience. The cases are intended to explore primarily ethics aspects of the regulatory criteria for approval, as well as provide a framework for IRB members and administrators to approach reviewing a protocol. During this session, faculty and attendees will:  
- Review the regulatory requirements for approval of research  
- Explore the meaning of risk and the ways IRBs should consider whether research adequately minimizes risk using reasonable standards  
- Address practical ethics beyond specific regulatory language (e.g. "ethical access" to potential subjects, and compensation for participation)  
- Discuss the interplay between ethics and regulations when reviewing biomedical or social science research
This is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please select the session during registration. Please get your boxed lunch in the Exhibit Hall before going to the session room.
C8
What Are Dietary Supplements and How Are They Regulated by the FDA?
(FDA Regulations Track) Paul M. Coates, Cynthia V. Rider, Steven Tave
FDA regulates both finished dietary supplement products and dietary ingredients under a different set of regulations than those covering “conventional” foods and drug products. Under the Dietary Supplement Health and Education Act of 1994 (DSHEA), manufacturers and distributors of dietary supplements and dietary ingredients are prohibited from marketing products that are adulterated or misbranded. This means these firms are responsible for evaluating the safety and labeling of their products before marketing to ensure they meet all the requirements of the DSHEA and FDA regulations. FDA is responsible for taking action against any adulterated or misbranded dietary supplement product after it reaches the market. During this session, faculty will:

- Examine the definition of a dietary supplement and explore what a dietary supplement is and what it is not
- Provide a basic overview of how dietary supplements are regulated at FDA
- Discuss FDA guidance addressing when a clinical investigation of a dietary supplement may need an investigational new drug application

C9
Determining Vulnerable Populations and Associated Risks in Low and Middle-Income Country (LMIC) Settings: Additional Ethical Considerations
(Global Research Track) Wesley G. Byerly, Wayne R. Patterson
Innovations for Poverty Action’s (IPA) IRB navigates a uniquely challenging landscape in managing academically and geographically diverse projects. Not only must IPA’s IRB grapple with the nuances of monitoring research in academic fields where fewer guidelines apply, it must do so in contexts that differ widely in terms of cultural sensitivities, literacy rates, and institutional research ethics support. As such, the IPA’s IRB has found many instances where they face additional risks and ethical considerations that are not comprehensively addressed by either OHRP or nascent local regulatory agencies. During this session, faculty will:

- Review additional vulnerable populations that are not conventionally recognized as high risk when conducting SBER in LMICs
- Explore how to balance benefits and risks where other populations would be vulnerable to a degree not found in developed country settings (i.e., research staff)
- Promote a robust debate on establishing guidelines for research organizations operating in developing countries

C10
The Certified IRB Professional (CIP®) Credential: What Is it About?
(Hot Topics Track) Gregorio Lim, Kelley O’Donoghue, Lori Roesch
During this session, faculty and attendees will:

- Review the CIP council’s role in the development of exam content, as well as oversight and management of the certification program
- Discuss the CIP credential and the steps involved in pursuing it
- Go over the CIP Handbook eligibility and recertification requirements
- Explore the Body of Knowledge and outline the types of questions on the CIP exam
- Share general tips and resources for study preparation

Please note this session will not review specific exam questions, nor provide exam preparation.
C11
Reserved for Late-Breaking Session

C12
Ethical and Operational Issues Related to Clinical Trial Billing: What HRPPs and IRBs Should Consider (Institutional Officials and HRPP Leadership Track) Keren R. Dunn, Scott J. Lipkin, F. Lisa Murtha, Ann Rodavitch
In an increasingly complex clinical research environment, HRPPs must recognize the importance of clinical trial billing both in the context of proper regulatory billing, as well as minimizing financial harm to participants. During this session, faculty and attendees will:
  • Provide a comprehensive review of the Centers for Medicare and Medicaid Services (CMS) Clinical Trial Billing Requirements
  • Examine the implications of the CMS requirements as they apply to the ethical review of research
  • Discuss governmental enforcement activity
  • Illustrate best practices to integrate Medicare Coverage Analysis with IRB review of research
This is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please select the session during registration. Please get your boxed lunch in the Exhibit Hall before going to the session room.

C13
This interactive session aims to assist IRB staff, chairs, and members with the initial review of projects submitted for review, including the determination as to whether IRB review is required, whether a protocol may qualify for exemption, and, if expedited or convened IRB review is required, what specific considerations need to be addressed during the review process. During this session, faculty and attendees will:
  • Review the definitions of human research as found in the HHS and FDA regulations
  • Discuss how these regulations are applied and how determinations on exempt human subjects research are made, using case examples for illustration
  • Use case examples to walk through the regulatory considerations required for protocol review by either the expedited mechanism or via convened full IRB review
This is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please select the session during registration. Please get your boxed lunch in the Exhibit Hall before going to the session room.

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C14
IRB Chairs Forum: A Structured Discussion for IRB Chairs (IRB Chairs Track) Robert W. French, Jr., R. Peter Iafrate, Charles J. Ryan, Julie Slayton
Given it can be difficult to find venues where IRB chairs can convene to discuss and wrestle with tough questions, this session will provide IRB chairs a forum to share ideas and best practices. In advance of the conference, attendees will be surveyed on topics of interest to them. The final list of topics will be sent to attendees before the meeting, and faculty members will provide a summary of each issue during the session. The discussions on each topic will be facilitated by the faculty ensuring no one dominates the conversation. Any off-topic issues that arise during discussion will be placed in a “parking lot” for later discussion if time permits. Participants are encouraged to bring relevant policies, forms, etc., with them to share with the group. During this session, faculty and attendees will:

- Review and discuss contemporary issues related to human subjects protections that are commonly faced by IRB chairs, and that may not have clear guidance in the federal regulations
- Share best practices, policies and procedures, forms, and methods that aid in resolving difficult issues presented by investigators and research study staff
- Develop a list of contacts so attendees can share ideas or benchmark issues that arise once they return to their institutions
- Discuss real-world situations and problems attendees face with a focus on coming up with a few possible concrete solutions

This is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please select the session during registration. Please get your boxed lunch in the Exhibit Hall before going to the session room.

C15
Operationalizing Collaborative IRB Review (IRB Operations Advanced Track) Nichelle Cobb, Michael Linke, Amy C. Waltz
In light of the Final National Institutes of Health (NIH) Policy on the Use of a Single IRB for Multi-Site Research, which requires the use of a single IRB of record for multi-site NIH funded research, many institutions are engaging in reliance agreements. However, little guidance exists to help institutions consider the resources required to operationalize these agreements, either as an IRB of record or relying IRB. Attendees should have a basic understanding of reliance agreements and what it means for one IRB to rely on another IRB for its review before attending this session. During this session, faculty and attendees will:

- Discuss strategies for operationalizing various types of collaborative IRB agreements within an existing review structure, including document sharing and protocol tracking
- Share work-aids and tools for successfully and efficiently serving as the reviewing IRB for a multi-site study or choosing to serve as a relying IRB
- Review challenging issues that may arise in the context of reliance agreements such as investigator noncompliance and strategies for managing these issues across IRBs
- Explore strategies for training IRB members, staff, and the research community on processes related to reliance agreements

This is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please select the session during registration. Please get your boxed lunch in the Exhibit Hall before going to the session room.
C16
Patient-Centric Trial Design and Conduct
(Issues Pharma/Biotech Track) Selena Daniels, Dawn M. Furey, Mary A. Short
Researchers and regulators are recognizing that patients are the experts in their disease and its impact. Across the research enterprise, stakeholders are working to identify how to best leverage this expertise to enhance trial design, conduct, and overall relevance to patients. During this session, faculty will:
- Review FDA guidance and regulatory encouragement for patient-centered trials
- Discuss how the patient perspective can enhance trial design (e.g., by inclusion of endpoints that are meaningful to patients)
- Provide the patient perspective on how patients could be better engaged in trial design and recruitment
- Share examples of ways in which sponsors are employing innovative methods to better engage patients while addressing regulatory, privacy, ethical, and other concerns
- Explore practical tools for integrating patient-centric approaches into the design and review of clinical trials

C17
When it Happens to You: Preparing for Phase II Health Insurance Portability and Accountability Act (HIPAA) Audits and Identifying and Managing Privacy Breaches in Research
(Legal Track) Emily Chi Fogler, Susie R. Hoffman, Deven McGraw, Megan Kasimatis Singleton
Earlier this year, the HHS Office for Civil Rights (OCR) announced that it has begun Phase II of its HIPAA Audit Program. OCR’s publicly available audit protocol contains a number of items related to HIPAA requirements applicable to research, and in the view of recent breaches in the research context, covered entities can expect that audits may include review of their research-related HIPAA compliance. The first part of this session will focus on OCR’s plans for its Phase II program and, based on the audit protocol, what research-related HIPAA requirements entities should be attending to in preparation for the possibility of an audit. Even with robust policies and procedures, breaches of Protected Health Information do occur. The second part of this session will focus on how covered entities and IRBs can best prepare to respond to breaches in the research context. When a privacy or data security incident occurs in research, it may trigger reporting obligations under the HIPAA regulations, as well as under federal human subjects regulations and specific state laws. Each of these laws/regulations has a different definition of a reportable incident and different requirements for who must receive notification. In addition, within an institution, different offices or groups, including the Privacy Office and the IRB, are responsible for analyzing and reporting incidents and determining appropriate corrective actions in response. The existence of different reporting standards and requirements, and of multiple institutional “owners,” can cause confusion and create risks and challenges for institutions and investigators in identifying, reporting, and managing these incidents. Attendees should have a basic knowledge and understanding of how HIPAA applies in the conduct of research before attending this session. During this session, faculty and attendees will:
- Discuss OCR’s Phase II HIPAA Audit Program and audit protocol and how those might impact covered entities using and disclosing Protected Health Information for research
- Review the various legal and regulatory requirements applicable to privacy/security incidents
- Go over case examples of breach analyses and possible resolutions
- Share practical strategies for improved coordination of multiple processes, communication among institutional stakeholders, and investigator compliance with reporting requirements

This is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please select the session during registration. Please get your boxed lunch in the Exhibit Hall before going to the session room.

**ICON KEY**

- Didactic session
- Pre-registration required
- CME accredited
- Interactive workshop
- Call for Session Proposal
- Double session
- Recorded session

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**CIP eligible**
C18
Statistics Without Tears
(Non-Scientist IRB Members Track) Susan S. Fish, H. Lester Kirchner
This session will explain the intimidating statistical terms that make your eyes glaze over! Attendees will start by reviewing the statistical basics and then, half-way through the session, the group will divide 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. During this session, faculty and attendees will:
- Outline the basic concepts of testing and learn how to apply statistical vocabulary
- Discuss different ways to be right and wrong (e.g., type I and type II 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
This is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please select the session during registration. Please get your boxed lunch in the Exhibit Hall before going to the session room.

C19
Return of Individual Research Results - Complex Considerations for a Not So Simple Request: Perspectives from Scientists, Subjects, and Regulators
(Out-of-Body Experiences: Research Involving Tissue and Data Track) Michelle Grienauer, Michele Russell-Einhorn, Mark E. Sobel
The return of individual research results seems like a simple enough expectation that respects a subject’s rights to information about themselves. In practice, though, the highly complex considerations, finding the right balance for protecting autonomy, and promoting beneficence is not easy. Attendees should have a basic understanding of the ethical and regulatory challenges related to the return of individual research results before attending this session. During this session, faculty and attendees will:
- Describe the spectrum of research results and their meaningfulness
- Explore the complexities related to differences in Centers for Medicare and Medicaid Services, Health Insurance Portability and Accountability Act, and Clinical Laboratory Improvement Amendments requirements related to sharing of results
- Discuss the ethical considerations of sharing results
This is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please select the session during registration. Please get your boxed lunch in the Exhibit Hall before going to the session room.

C20
Populations on the Edge: The Homeless, Substance Abusers, the Lesbian, Gay, Bisexual, and Transgender (LGBT) Community, and More
(Populations Requiring Additional Protections Track) Cynthia A. Gómez, John A. Guidry, Amy Ahrens Terpstra
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. During 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, LGBT identified individuals, undocumented residency, or other issues
- Examine the special considerations study teams should address when designing a study involving these populations and that IRBs should be aware of when reviewing these studies (e.g., payment and undue influence, recruitment, maintaining contact with subjects, confidentiality, etc.)
- Outline additional risks such as violence, discrimination, depression, and suicide

ICON KEY
- Didactic session
- Pre-registration required
- CME accredited
- Interactive workshop
- Call for Session Proposal
- Double session
- Recorded session
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C21  
**Novel Methods, Approaches, and Tools for QA/QI, Including Electronic Systems and Technology (QA/QI and Post-Approval Monitoring Track)**  
Jeffrey A. Cooper, Stephanie deRijke, Elizabeth Tioupine  
Despite improved technology, to err is still human. IRB offices, whether fundamentally paper-based or using electronic systems, may not be fully realizing the tools and techniques available to identify errors, improve compliance, and support QA/QI activities. QA/QI programs conducting investigator onsite reviews collect a tremendous amount of data that is critical to driving quality improvement across the HRPP. This session will address novel methods and approaches to ensuring quality improvement across HRPP operations and regulatory compliance. During this session, faculty and attendees will:

- Learn how to create reports and perform analyses (even simply using Excel) to better target concerning areas, identify data entry errors or omissions, and implement process improvement strategies
- Explore how to use reports for quality assurance IRB submission processing, for identifying staff errors, and as a guide for additional office-wide training needs
- Address techniques to identify outliers as possible noncompliance concerns or process-improvement opportunities, including Process Control for IRB Quality Improvement Review, and demonstrate what programs can do with aggregate information
- Review the advantages of a QA/QI database
- Discuss considerations for developing a QA/QI database, including selecting a model and translating user needs into design
- Share novel and innovative ways that quality improvement programs can store, track, and analyze investigator and IRB compliance using technology tools

This is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please select the session during registration. Please get your boxed lunch in the Exhibit Hall before going to the session room.

C22  
**The Intersections of Data Security, Privacy, Confidentiality, and Compliance in Digital Health and Mobile Health (mHealth) Research (Research Conducted in the Digital World Track)**  
Jeremy N. Block, Brenda Curtis  
This session will provide a basic introduction to the concepts, challenges, and opportunities with digital and mHealth research. Speakers will review real and perceived constraints, questions to consider when designing research incorporating mHealth, and general best practices in conducting and reviewing digital/mHealth. During this session, faculty and attendees will:

- Provide participants with insights into the range of digital and mHealth technologies and their potential application in both SBER and biomedical research
- Discuss privacy, security, and compliance issues in mHealth and digital health research
- Explore strategies for conducting and reviewing mHealth and research protocols

This is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please select the session during registration. Please get your boxed lunch in the Exhibit Hall before going to the session room.
C23
Flying Solo: A Moderated Discussion on Challenges Encountered by Single Staff IRB Offices
(Small Research Programs Track) April V. Baker, Kim R. Diccianni
This interactive session will explore the organizational, professional, and procedural circumstances that challenge HRPPs with only one staff person. Participants will create networks for ongoing professional development and support. During this session, faculty and attendees will:
• Discuss implementation of solutions for recognized challenges unique to single staff offices
• Learn specific strategies and share resources and potential solutions via shared experiences and ideas
• Network with others from similar programs
This is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please select the session during registration. Please get your boxed lunch in the Exhibit Hall before going to the session room.

C24
College Students and Research: Challenges and Issues for IRBs
(SBER I Track) Andrea R. McDowell, Julie F. Simpson
A considerable amount of research takes place on college/university campuses involving college students as subjects. This includes departmental pools of introductory-level students to participate in research studies and other projects for credit (subject pools). This session will review regulatory and legal standards, as well as specific ethical issues, that arise when reviewing research in which college students on campus are subjects, and when they may serve as investigators or study staff. During this session, faculty and attendees will:
• Identify different types of issues that frequently arise when conducting research on a university/college campus, including best practices for addressing ethical issues (e.g., use of incentives and compensation; students who are minors; recruitment)
• Discuss the issues that arise when college students conduct research on campus, either as principal investigators and/or as research personnel
• Review the issues that arise with the operation of university/college subject pools, including best practices
This is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please select the session during registration. Please get your boxed lunch in the Exhibit Hall before going to the session room.

C25
FDA Oversight, SBER, and the IRB
(SBER II Track) Cami Gearheart, Robin S. Tyndall
There is a growing trend for historically SBER institutions to step into the foray of research involving devices, applications, supplements, food, and possibly drugs. This session provides a primer on FDA oversight, including guidance on whether a study requires an investigational new drug or investigational device exemption. During this session, faculty and attendees will:
• Discuss when an IRB should consider whether FDA oversight may be required
• Review the basic regulatory requirements that FDA-covered research applies in addition to the Common Rule
• Describe the nuances between such concepts as “food,” “drug,” “dietary supplement,” “medical device,” and “app”

12:45-1:45 PM
Networking Lunch
Time to connect...over lunch! Meet peers for conversation and networking. A boxed lunch will be served.
PRIM&R would like to thank Huron Consulting Group for helping to support today’s lunch.
Panel IV: Echoes of Tuskegee in 2016? African Americans and Participation in Research  
**Moderator:** Owen Garrick  
**Panelists:** Jonca C. Bull, Vickie M. Mays, Coleman K. Obasaju  
It has been over 40 years since public disclosure of the US Public Health Service study of syphilis in a group of African-American males in Tuskegee, Alabama resulted in outrage that helped trigger the revolution that resulted in today’s human research protections system. Although the Tuskegee study ended long ago, and the research oversight system has since been reformed, some types of research studies still struggle to recruit a diverse population, with African Americans generally under-represented in clinical trials. Why is this? Is trust still damaged by Tuskegee and other events? Are there other barriers to African Americans participating in trials? This panel will look at what we know about African-American participation in research, the National Institutes of Health’s expectations and efforts to increase inclusion of African Americans in federally-funded research, and how research partners in industry are addressing this concern.

Panel V: Precision Medicine Initiative (PMI): What Are the Promises and What Are the Ethical Challenges?  
**Moderator:** P. Pearl O’Rourke  
**Panelists:** Ysabel Duron, Nancy E. Kass  
The success of the PMI relies on individuals’ sustained engagement in the research by sharing their personal data over a long period of time. In return, participants are promised not only access to information, but a partnership role in the research itself. What does this mean to individuals, as well as to the public? This panel will explore issues regarding this partnership; for example: (1) What partnership role will respectfully engage individuals as well as communities, both at the initiation of the PMI and over time?; (2) In an environment of mistrust towards research, is there enough public trust to recruit such partners?; (3) How will “individuals as partners” promote not only individual benefits, but community and national benefits as well?; and (4) How does the variable research literacy of the public affect these partnerships?

Panel VI: Re-Framing Informed Consent: Respecting Participants When Barriers to Regulatory Consent Exist  
**Moderator:** Christine Grady  
**Panelists:** Michelle H. Biros, Neal Dickert, Jr., Robert Silbergliet  
This panel will explore a proposal to re-frame informed consent in a manner that promotes underlying ethical mandates. The research enrollment process serves several morally meaningful roles, including: (1) demonstrating respect for participant autonomy; (2) enhancing communication; (3) promoting engagement in the research; and (4) providing transparency about research aims. These functions are particularly important for research in situations where barriers to traditional consent exist, such as research with semi-conscious or deeply stressed individuals, research involving participants with diminished decision-making capacity, or comparative effectiveness research. Considering the underlying ethical foundations of informed consent is especially timely given the Notice of Proposed Rule-Making’s focus on revising the enrollment process. During this session, speakers will describe a function-based approach to informed consent derived from ethical principles; discuss the application of this framework to specific research contexts, with particular emphasis on the acute care setting; and explore how this approach addresses human subjects regulatory requirements.

**ICON KEY**  
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- Interactive workshop  
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- Double session  
- Recorded session  
- CME accredited  
- CIP eligible  

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**Basic** – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.
3:15-3:30 PM
Beverage Break
Join us for coffee and cold drinks in the Exhibit Hall.

Didactic Sessions and Workshops Series D, 3:30-4:45 PM

D1
A Dialogue With the Department of Defense (DOD): Updates for DOD and DOD-Sponsored Research Protections Personnel
(A Dialogue with the Feds I Track) Imelda Catalasan, William Deniston, Molly M. Kote, Patrice D. Robinson-Haley
This session will be led by senior leaders from DOD Human Research Protections Programs. Attendees are encouraged to come with questions of interest to all. During this session, faculty and attendees will:
- Explore changing policies that affect the conduct of DOD-funded research with DOD personnel
- Discuss questions about current issues and initiatives
- Participate in an open discussion about DOD-related topics relevant to the research protections community

D2
Exploring and Enhancing Diversity Within Our Compliance Committees
(Hot Topics Track) John A. Guidry
Diversity is one of PRIM&R’s core values. During this session, faculty and attendees will discuss ways to promote regulatory affairs/regulatory compliance through the lens of diversity and will:
- Define diversity, inclusion, and implicit bias
- Explore the benefits and challenges of working within diverse groups
- Examine mechanisms to increase diversity competencies of regulatory personnel and committee members who communicate with researchers from diverse backgrounds
- Discuss how to manage conflict while embracing diverse perspectives

D3
Moving From Fossils to Young Blood for the HRPP/IRB Engine
(Advanced Forum for IRB Professionals Track) Karen M. Hansen, Kelley O’Donoghue
This session will involve case studies/examples from different presenters who will share personal experiences, practical strategies, and best practices about succession planning in the HRPP/IRB and the use of techniques, such as on the job training, support for self-training and skill-set improvement (e.g., Certified IRB Professional credential, etc.), and mentoring. Attendees should have an understanding of human resources activities and basic management principles before attending this session. During this session, faculty and attendees will:
- Review the definition of “Succession Planning” (i.e., a process for identifying and developing internal people who have the potential to fill key leadership positions in the organization)
- Discuss the benefits of succession planning, including increasing the availability of experienced and capable employees that are prepared to assume these roles as they open through retirement, resignation, or expansion
- Share challenges in succession planning for the HRPP/IRB function (e.g., size of the organization: some HRPP/IRB offices have so few positions that they may not have the ability to offer opportunities for advancement; employees with the potential and the desire to advance their careers may move to larger organizations as a result; senior leaders staying in their positions so promotion cannot be guaranteed; inadequate communication resulting in confusion and turmoil within the organization due to staff speculation about the content or meaning of a succession plan

ICON KEY
- Didactic session
- Pre-registration required
- CME accredited
- Interactive workshop
- Call for Session Proposal
- Double session
- Recorded session
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D4
The Seven Habits of Highly Effective and Flexible IRBs
(Boundaries & Balance Track) Jeffrey A. Cooper, Martha F. Jones, Ernest D. Prentice
Attendees will learn how to identify ways that the IRB can become more effective at protecting subjects, while also becoming more efficient. Experts will explore best practices on how to reduce time-consuming activities that can be eliminated in order to focus more effectively on the critical requirements of the IRB. During this session, faculty will:
- Differentiate between what the IRB must do and what it can delegate
- Discuss ways to limit the back and forth with the IRB
- Suggest ways to streamline submissions
- Create mechanisms to identify issues before they go to the IRB for review

D5
Recruitment Strategies: Sharing Our Secrets for Success
(Educating & Training Track) Jonca C. Bull, Karen Christianson, Grant D. Huang
Recruitment for research is often difficult and poses many ethical and concrete challenges. In this session, faculty will share tips for successful subject recruitment, offer case examples of ethically complex recruitment situations, and discuss potential outcomes. Faculty will also discuss recruitment of populations that may require special considerations, such as non-English speaking subjects, prisoners, and high-risk populations. During this session, faculty and attendees will:
- Share tips on successful recruitment strategies for both biomedical and SBER
- Discuss if and when consent/assent is required during the recruitment process
- Work through cases where recruitment is challenging and ethically complex

D6
Strategies for Incorporating Empirical Research into IRB Member Education
(Empirical Research Ethics Track) Emily E. Anderson, Joan E. Sieber
In this interactive session, faculty will present strategies for developing and delivering IRB member education that highlights empirical research on key research ethics topics and that encourages incorporation of evidence into IRB decision and policy-making. Participants will be asked about key areas where education is needed by their IRB members and researchers, and what they perceive to be the barriers to understanding or learning to apply that new knowledge. Presenters will discuss how to find articles that relate to issues commonly debated by IRBs that can be informed by empirical data (e.g., the potential for participants to experience emotional distress from participating in research on traumatic experiences), and resources provided through a partnership with the Journal of Empirical Research on Research Ethics, available in PRIM&R’s Knowledge Center, will be highlighted. Participants will be encouraged to generate content to share in the Knowledge Center, and discussion will inform development of future educational materials related to this topic. During this session, faculty and attendees will:
- Identify research articles relevant to issues commonly debated by IRBs that can be informed by empirical data
- Explore strategies to generate summaries of empirical research articles for IRB member educational purposes
- Review approaches to developing discussion questions about empirical research articles for IRB member educational purposes

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**D7**
**The International Conference for Harmonization (ICH) E6 Integrated Addendum: What Do the Proposed Changes to the Good Clinical Practice (GCP) Guidelines Mean for the Clinical Research Community?**
(Hot Topics Track) Gary Chadwick, Linda M. Coleman, Christina Erickson
At the end of July 2015, ICH released a proposed integrated addendum to ICH E6 (R2) for comments by January 31, 2016 (EU and USA) and September 30, 2015 (Japan). This is the first update to this GCP guideline since its release in 1996. The additions are intended “to encourage implementation of improved and more efficient approaches to clinical trial design, conduct, oversight, recording, and reporting while continuing to ensure human subject protection and data integrity.” Among the changes are a new section on investigator responsibilities, including oversight; a substantial new sponsor section on Quality Management, including risk assessment; definitions, monitoring plans, and requirements for implementation; and new recommendations on computer validation and electronic records. During this session, faculty will:
- Review key changes proposed to the ICH E6 guidance and the ICH process and timelines
- Discuss benefits and challenges of the proposed integrated addendum and the implications for sponsors and clinical investigators
- Explore practical examples of how these new responsibilities might be translated into practice

**D8**
**Expanded Access and Off-Label Use of Medical Devices**
(FDA Regulations Track) Soma Kalb
An unapproved medical device may normally only be used on human subjects through an approved clinical study in which the subjects meet certain criteria and the device is only used in accordance with the approved protocol by a clinical investigator participating in the clinical trial. However, there may be circumstances under which a healthcare provider may wish to use an unapproved device to save the life of a patient or to help a patient suffering from a serious disease or condition for which no other alternative therapy exists. But, what if a healthcare provider wants to use a legally marketed device in the practice of medicine versus as part of a research study collecting safety and effectiveness data. During this session, faculty will:
- Provide an overview of the various mechanisms by which FDA may make an unapproved device available through expanded access
- Discuss the criteria and requirements for each mechanism of expanded access for an unapproved device
- Explain the nuances in the submission and review requirements for off-label use of a legally marketed device in the practice of medicine versus as part of a research study collecting safety and effectiveness data
D9
(Global Research Track) Liza Dawson, Robert Klitzman, Jeremy Sugarman
The HPTN conducts a wide array of research on HIV prevention, including pre-exposure prophylaxis (PreP), antiretroviral treatment as prevention, and behavioral interventions. These studies are usually multi-site clinical trials conducted both in the US and overseas, and often raise critical ethical issues, which the HPTN EWG helps to address. The EWG has a unique model of working side-by-side with researchers on clinical trial issues during design and study implementation. The EWG has also consulted on ethical challenges that HIV researchers have confronted, and initiated scholarship on cutting edge ethical issues concerning HIV prevention research in resource limited settings. In this session, members of the EWG will present an overview of this novel approach to addressing the ethical issues in research, and provide a description of some specific projects recently undertaken, including an empirical study of the roles of IRBs in research in sub-Saharan Africa, and a conceptual project addressing research with people who inject drugs in settings where policy makers have not adopted evidence-based treatment of substance use and HIV prevention. During this session, faculty will:
- Examine recent, cutting-edge ethical challenges that are emerging with HIV prevention research in resource limited settings
- Explore how these challenges can be addressed through close consultation with researchers, empirical research, and conceptual scholarship
- Probe how the EWG of HPTN might serve as a model for grappling with ethical issues in other research settings

D10
IRB Considerations When Conducting Research During Public Health Emergencies: Ebola, Influenza, Zika and Whatever Is Next...
(Hot Topics Track) Wendy Carr, Bruce G. Gordon
How do you deal with a critical and immediate healthcare crisis, and what are the best practices for review? This session will focus on the balance between speed of approval and the necessary ethical and scientific considerations that should be in place. During this session, faculty will:
- Discuss the ethical challenges arising with conducting human subject research during a public health emergency
- Consider novel ways to address need for rapid IRB review of human subject research during a public health emergency
- Explore study design considerations when conducting research during a public health emergency in international settings and/or with vulnerable populations

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D11
Building a Better Clinical Trial: Enhancing Stewardship at NIH (Hot Topics Track)
Michelle A. Culp, Valery M. Gordon, Carrie D. Wolinetz
This session will describe a series of recent policy changes announced by the NIH to improve our stewardship of clinical trials, including changes in solicitation, personnel training, and data sharing. This session will include information on the recently finalized Rule on registering and reporting results via ClinicalTrials.gov and the parallel NIH policy. During this session, faculty will:
- Outline changes to the clinical trials applications for NIH funding
- Discuss new requirements for Good Clinical Practice training
- Review the enhancements of clinical trial registration and summary results reporting

D12
This session is a presentation of important case studies that may impact an institution or HRPP. Attendees should have an understanding of the basic concepts underlying legal actions and the regulatory enforcement authority that may be implicated by clinical research activities, including IRB review and oversight, before attending this session. During this session, faculty will:
- Review and analyze recent claims and enforcement actions brought against IRB members and institutions supporting IRBs related to human subjects protections
- Discuss approaches for minimizing risk of litigation
- Use hypothetical cases to illustrate institutional risk minimization
- Explore potential litigation and enforcement actions under the highly anticipated revised common rule

D13
The ABCs of Writing Standard Operating Procedures (SOPs) (IRB 101 Track) Elizabeth A. Bankert, Kristina C. Borror, Michelle M. Feige
During this session, faculty will:
- Discuss the components of comprehensive and effective HRPP/IRB SOPs
- Focus on the practicalities of developing an effective SOP, including the art of formatting and writing SOPs
- Explore the difference between a "policy" and a "procedure"
- Review the resources, input, and/or approvals required to develop specific SOPs

D14
Meeting Management for IRB Chairs (IRB Chairs Track) R. Peter Iafrate, Charles J. Ryan
This session will cover key topics in the management of an IRB meeting from the IRB chairs’ perspective. During this session, faculty will:
- Discuss the fundamentals of meeting management and member interactions from a leadership perspective
- Explore how to increase engagement of members and interaction with staff/consultants
- Focus on tips, strategies, and approaches to becoming an IRB chair or building on current skills and training
D15
True Stories from the IRB and their Impact on IRB Operations (IRB Operations Advanced Track) Elizabeth L. Hohmann, James Riddle, Susan L. Rose, Elyse I. Summers
The goal for this session is to have a fun and honest conversation with attendees about the wild side (yes, there is one!) of running an IRB office on a university/medical center campus. This session will focus on the experiences that led to an operational change and descriptions of those changes. Attendees should have a basic understanding of common challenges in IRB operations before attending this session. During this session, faculty and attendees will:
- Share funny, anonymous, and true stories about the jaw-dropping and head-scratching questions, comments, and requests heard in the IRB office that led to an operational change
- Describe the operational changes that occurred as a result of the incident
- Discuss approaches for dealing with challenging situations that may involve colleagues and/or higher ups

D16
Making Risk-Based Quality “Fit for Purpose” for Your Organization (Issues Pharma/ Biotech Track) Marta Fields, Katherine Tygum Goldstein
Global regulators are strongly encouraging trial sponsors to develop a more systematic, prioritized, risk-based approach to quality management of clinical trials to support the principles of Good Clinical Practice. Specifically, regulators recommend that protocol design and trial planning include appropriate attention to making the study feasible and incorporate methods that help avoid important errors (i.e., Quality by Design (QbD)). Recent guidance from the FDA and European Medicines Agency suggests that quality oversight can also be enhanced by focusing on data and activities that are critical to trial participants’ safety and the reliability of trial results, rather than on monitoring the accuracy of each individual data point (i.e., Risk-Based Monitoring (RBM)). While there is general agreement that these risk-informed approaches could enhance the quality and efficiency in clinical development, many organizations have struggled to move from principles to practice. Adopting clinical QbD and RBM can seem particularly daunting to small and medium-sized companies, as well as to academic organizations. During this session, faculty will:
- Briefly review key tenets of RBM and QbD
- Provide practical examples of how organizations can integrate RBM and QbD into their operations
- Evaluate how understanding RBM and QbD plans can facilitate and/or support ethics review
D17  
You’ve Heard the Noise, Now What Are the Facts? The Legal Underpinnings of Fetal Tissue Research (Legal Track) Mark Barnes, Lynn Borgatta, Heather H. Pierce
Since the release last year of controversial materials regarding the Planned Parenthood Federation of America’s role in supplying fetal tissue to medical researchers, fetal tissue research has once again been front and center in the national conversation. In particular, public attention has focused on how tissue is obtained for such research from elective abortions. Last fall saw the initiation of a Congressional investigation of fetal tissue procurement and research practices led by a special House panel titled, The Select Investigative Panel on Infant Lives. This panel has requested documents and information pertaining to such practices from numerous organizations, including universities, companies, and IRBs. Putting aside the various political, ethical, and scientific debates surrounding fetal tissue research, this session will examine current federal laws, regulations, and policies governing the procurement of fetal tissue for research, the funding and conduct of such research in the US, and how it has evolved over the past several decades. Because many of the current requirements derive from state law, the session will review selected state laws as well. The goal of the session is to inform attendees of the legal background underlying fetal tissue research to better equip them to evaluate the current controversy. During this session, faculty will:
- Briefly review the Planned Parenthood matter and the events giving rise to the Congressional investigation
- Describe current federal and state sources of requirements pertaining to the procurement of fetal tissue and the conduct of fetal research, including requirements regarding informed consent, restrictions on sale or profit from distribution of such material, and protections surrounding its procurement in the context of elective abortions
- Discuss the current status of the Congressional investigation and the potential impact of the controversy on the availability of fetal tissue for research and the conduct and oversight of such research going forward

D18  
It Takes a Village: Community Members as Research Partners in Community-Based Participatory Research (CBPR) (Non-Scientist IRB Members Track) Robert Hood, Steven Wakefield
With its unique orientation to research that involves all stakeholders in the entire research process, from conceptualization to dissemination, CBPR blurs the line between researcher and subject. How can IRBs understand and assess risk and weigh human subject considerations in these types of studies? During this session, faculty will:
- Review the core concepts of CBPR with a special emphasis on the multiple roles of the subjects
- Identify common risks for stakeholders inherent in this research approach
- Discuss potential tensions between CBPR and human subjects protections principles, and explore ways for how to minimize them

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D19
In the ERA of Big Data: Data Sharing
(Out-of-Body Experiences: Research Involving Tissue and Data Track) Laura Lyman Rodriguez, Christine Suver, Vivian Ota Wang
This session will review major challenges and emerging issues for research with big data related to data sharing including consent, process, and scalability. Implications for researchers and IRBs will be discussed. Attendees should have a basic understanding of how the availability of big data and data sharing have changed our concept of “identifiability” and privacy (or potential lack thereof) with research subjects, and what level risk that may impose, before attending this session. During this session, faculty will:
• Define and describe big data
• Discuss the implications of the SACHRP recommendations on big data
• Review emerging issues related to data sharing, including consent, process, and scalability
• Provide practical models for data sharing
• Explore recommendations for IRB review of research with big data that includes a plan for data sharing

D20
Meeting of the Minds: Research and Consent With Subjects With Impaired Decisional Capacity
(Populations Requiring Additional Protections Track) Katherine Gallin Hefferman, David H. Strauss
There is agreement that participants signing consent forms must have adequate decision-making capacity to do so. However, the process and procedures for determining and ensuring capacity remain unclear. This session will provide guidance and best practices that will assist institutions, IRBs, researchers, and surrogate decision-makers in the ethical conduct of research involving adults who currently or may eventually lack the capacity to consent. During this session, faculty will:
• Define decisional capacity and provide tools for screening and evaluating capacity
• Present guidelines for both primary and secondary conditions that include or lead to permanent or transitory cognitive impairment (e.g., mental illnesses, terminally ill, illnesses that lead to cognitive deficits)
• Explain how the risk/benefit ratio may be different when conducting research with subjects with decisional impairment
• Discuss the use of research advanced directives

D21
Beyond Auditing and Monitoring and Towards Quality Improvement
(QA/QI and Post-Approval Monitoring Track) John R. Baumann, Cheryl L. Byers, Mariette Marsh
Every HRPP engages in audits and not for cause monitoring activities. However, are we making full use of the information, resources, and opportunities that auditing and monitoring offer an HRPP? Are we integrating individual audit/monitoring findings into a broader analysis of institutional strengths, weaknesses, or gaps of quality improvement? In this session, speakers from various HRPPs will discuss how they integrate auditing and monitoring into a coherent quality improvement program through their review and analysis of audit/monitoring findings as a collective whole. During this session, faculty will:
• Review how audit and monitoring findings can be integrated into a quality improvement program
• Discuss how institutions are developing quality improvement programs based in part on the analysis of auditing and monitoring findings
• Explore how to develop quality improvement programs based on audit and monitoring findings

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D22
Ethical Issues in Patient-Led and Crowdsourced Clinical Research (Research Conducted in the Digital World Track) Emil J. Chiauzzi, Lindsay McNair
Emerging models of research, such as studies led by patients and studies conducted through “crowdsourcing,” have changed the nature of the traditional relationship between researcher and participant. The researcher may be a patient themselves, or the researcher and participant may even be the same person. Much of crowdsourced research is internet-based, which brings additional challenges in roles, identification, and anonymity. All of these issues challenge traditional notions of informed consent, research ethics, and even the ethical codes on which the current system of human subjects protections is based. During this session, faculty will:
• Explore key differences in the nature of the researcher and participant roles between traditional, patient-led, and crowdsourced studies
• Identify differing perspectives and roles of IRBs, data-sharing platforms, researchers, and participants from the viewpoint of the patient
• Discuss the application of traditional codes of research ethics (e.g., The Belmont Report, the Declaration of Helsinki), as they apply to research in which the roles of researcher and participant are combined

D23
All By Myself: Where Can You Go for Mentorship When You Are the Only Person in the IRB Office? (Small Research Programs Track) Elise Davis, Stephanie Henkel, Greg E. Manship
This interactive session will examine how the mentor/mentee relationship supports and promotes ongoing personal and professional development for those who work in single-staff IRB offices. During this session, faculty and attendees will:
• Define the mentor/mentee relationship and describe its various expressions
• Discuss the pros and cons of mentoring
• Develop strategies for establishing and maintaining a mentoring relationship

D24
School Rules! Conducting Research in Elementary and Secondary Public Schools (SBER I Track) Julie Slayton
This session will cover the regulatory requirements for protecting confidentiality of students’ academic records and identify areas of flexibility to enable research on students’ records, especially in challenging populations, venues, and districts with historically low parental involvement. During this session, faculty will:
• Review the Family Educational Rights and Privacy Act and the Protection of Pupil Rights Amendments, including what is required, permitted, prohibited, and waivable
• Discuss who has “school authority” to release information
• Explore how to determine whether an education project qualifies either as not human subjects research (quality improvement), exempt human subjects research, or non-exempt human subjects research
• Outline requirements for parental permission and identify “opt-out” or “passive” parental permission as an alteration of the consent process in non-exempt research
• Analyze how opt-out parental permission may or may not meet the four criteria for waiver/alteration of the consent process
• Share strategies for developing relationships with local school districts for ongoing research activity presence

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D25
Yours, Mine, and Ours: IRB Arrangements for Multiple Institutions Involving Research With Vulnerable Populations and Sensitive Topics
(SBER II Track) Kip K. Kantelo, Matthew D. Stafford, Sharon L. Zack
Using three case studies from different HRPPs (a university, a hospital, and a private sector survey firm), this session will highlight the IRB review, approval, and partnership collaborations necessary to conduct research involving sensitive topics and vulnerable populations. The decision to collaborate on research with another institution, or numerous institutions, may slow down the process and add additional layers of frustration. Not only must investigators negotiate through the application for review and approval by their own institution's review process, but they must also consider the involvements of numerous other stakeholders from partnering institutions such as institutional officials, HRPPs, IRBs, and their legal departments, to name a few. It is also crucial to speak the same language, whether it refers to reliance or IRB authorization agreements, IRB of record, or what it means to be "engaged" in the research. During this session, faculty will:
- Examine three research protocols to determine how to meet the regulatory requirements and oversight responsibilities for all stakeholders involved
- Explore challenges faced to secure IRB approval and execute numerous institutional agreements
- Share lessons learned and discuss best practices for improving this process

4:45-5:05 PM
Demonstration of PRIM&R’s Ethical Research Oversight Course (E-ROC)
Join us in the demo theater in the Exhibit Hall for a demonstration of our interactive online course, E-ROC. During this brief overview, you will be introduced to this tool and how it can strengthen your understanding of the core regulations and underlying ethical principles of human subjects protections. If you are unable to join us for this presentation, but would like to learn more about E-ROC while onsite at the conference, stop by the PRIM&R Booth or email Nora Murphy, online learning coordinator, to set-up a one-on-one demonstration.

4:45-6:00 PM
Networking Reception with the Supporters and Exhibitors
Join us in The Exhibit Hall to meet and greet the Supporters and Exhibitors. Light refreshments will be served.

4:45-6:00 PM
Meet the AER16 Poster Authors
Visit with the authors of the posters featured in the AER16 Poster Presentation Program and learn more about their innovative and important work on new program initiatives, empirical research, and conceptual analysis. The presentation of the posters promotes interdisciplinary sharing and collaboration, and facilitates the exchange of ideas, information, and practical strategies for managing the many challenges faced by research professionals. Light refreshments will be served.

4:45-6:00 PM
FDA Office Hours
Do you have a specific question for FDA representatives or on a FDA-related topic? Or do you have a follow-up question after attending a session with a FDA representative? If so, stop by FDA Office Hours, and representatives from the FDA will be available to help answer your questions.
Tuesday, November 15

4:45-6:00 PM  
OHRP Office Hours  
Do you have a specific question for OHRP representatives or on an OHRP-related topic? Do you have a follow-up question after attending a session with an OHRP representation? If so, stop by OHRP Office Hours, and representatives from the OHRP will be available to help answer your questions.

4:45-6:00 PM  
VA Office Hours  
Do you have a specific question for VA representatives? Are you interested in learning more about the VA’s human subjects protections policy or their compliance oversight activities? If so, stop by VA Office Hours, and representatives from the VA will be available to help answer your questions.

5:35-5:55 PM  
Overview of PRIM&R’s Member Benefits  
Join us in the demo theater in the Exhibit Hall for a discussion of the many benefits that come with your PRIM&R membership. During this brief overview, you’ll learn about the ways membership pays for itself during the course of the year. If you are unable to join us, but would like to learn more about your member benefits (or becoming a member) while onsite at the conference, stop by the PRIM&R Booth or email Elise Davis, membership coordinator, to set-up a one-on-one appointment.

Wednesday, November 16: 2016 AER Conference

7:00 AM  
Registration Opens  
Breakfast on your own.

8:00-8:15 AM  
Welcome from the Conference Co-Chairs  
P. Pearl O’Rourke, MD Director, Human Research Affairs, Partners HealthCare System, Inc.  
Laura Odwazny, JD, MA Senior Attorney, Office of the General Counsel, Department of Health and Human Services

8:15-8:25 AM  
PRIM&R Membership Update  
Kelly O’Keefe, MPH Research Ethics Board Manager, Population Services International; Member, PRIM&R’s Membership Committee

8:30-9:15 AM  
Low Hanging Fruit in the Reproducibility and Translatability Crisis: How IRBs Can Critically Assess Animal Data Before Approving First-In-Human-Studies  
Joseph Garner, DPhil, Associate Professor, Department of Comparative Medicine; Courtesy Associate Professor, Department of Psychiatry and Behavioral Sciences; Member, Child Health Research Institute, Stanford University

9:15-9:45 AM  
Beverage Break  
Join us for coffee in the Exhibit Hall.

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9:35-9:40 AM
**Treasure Hunt Prize Drawing**
Join us for a treasure hunt with our supporters and exhibitors in the Exhibit Hall! Included in each conference attendee bag is a Treasure Hunt form with fun facts about the supporting and exhibiting companies. Complete this sheet and turn it in at the PRIM&R Booth by November 16 at 9:30 AM, then join us in the demo theater during this time slot for a chance to win several prizes! Attendees must be present to win.

### Concurrent Plenary Sessions, 9:45-11:00 AM

Panel VII: Amplifying the Challenges: Return of Results in Pediatric Research

**Moderator:** Albert I. Allen  
**Panelists:** Celia B. Fisher, David G. Forster, Jill McNair

Surveys indicate that adult research participants desire to learn the results of a study when it is completed—both the overall findings of the study (group results) and their individual results. However, even though patients must be allowed access to labs and other medical records as part of their ongoing care, they are often not provided with study results when they are a subject in a clinical trial. There is some reason to believe that older pediatric research participants share the desire to have results returned to them. In response, a number of pharmaceutical companies are beginning to return group results to study participants, including pediatric study participants. In addition, some companies are exploring ways to make individual research results available to adult and pediatric research subjects.

A number of questions have been raised about this practice: Should return of results be limited to biomedical research, or may it be appropriate in some social and behavioral research as well? For example, genetic testing is increasingly used to study correlates of behavior disorders in children and adolescents raising questions of whether parents of youth should be informed if research indicates a participant’s genetic profile places them at risk for mental health or other behavioral disorders. Do IRBs have a role in returning results, especially since study sites have often been “closed out” by the time return of results occurs? What are the best practices for returning results? This panel will consider these and other issues, using pediatric research cases to illustrate various situations.
Panel VIII: Beyond Vulnerability, Toward Inclusion: Comparable Access for Women Across the Lifespan

Moderator: Laura Odwazny
Panelists: Christine Grady, Anne Drapkin Lyerly, Robert M. Nelson

Women across the lifespan—women of childbearing potential, pregnant women, and lactating women—historically have been excluded to a greater or lesser extent from research participation. There is a tension between the Belmont Report, which advises the community to be cognizant of principles involving equitable selection of subjects, autonomy, and inclusion in research, and the federal human subjects research regulations that categorize pregnant women as a vulnerable subject population. These additional protections that the federal regulations provide to pregnant women may lead to the under-representation of women in research, and the subsequent scarcity of scientific data on conditions that impact pregnant women, lactating women, and fetuses. These “protections” are more reminiscent of “paternalism,” since they may work against two overarching ethical principles: equal inclusion in research and recognition that the informed consent process provides capable individuals with sufficient information to make voluntary decisions about participation in research. Furthermore, lactating women, pregnant women, and fetuses have unique biological considerations and react differently to medical treatments and vaccines than the general population. The intended protective effect of considering pregnant and lactating women as “vulnerable” is negated if insufficient research is conducted on preventive care or medical treatment best suited to their particular condition, thus placing these populations at additional risk in their daily lives. This panel will explore the idea that, based on the above considerations and a focus on the “forgotten” Belmont principle of justice, there is an ethical imperative to include fertile, pregnant, and lactating women in research.

Panel IX: Can’t Buy Me Love, but Maybe a Clinical Trial Spot? How IRBs Wrestle With Participant Funding and Influence

Moderator: Melissa E. Abraham
Panelists: Elizabeth L. Hohmann, Glenn O’Neil, Govind Persad

This panel will focus on the role of money, wealth, and patient funding in biomedical research. Topics will include the impact of wealth or money on individuals’ involvement in clinical research activities. During this panel, speakers will provide commentary on how IRBs and institutions might consider these issues when they arise, as well as some of the ethical issues for which IRB members need further guidance. Examples will include consideration of how donors influence the line of investigation and their impact on ownership of research; how someone might purchase a spot in a clinical trial that requests payment; and the patient who is a subject in his or her own research or approaches researchers to fund and participate in research on his or her own condition.

11:00-11:15 AM
Break
E1
A Dialogue With the National Institutes of Health (NIH) (A Dialogue with the Feds I Track) Carrie D. Wolinetz
This session will be led by a representative from the NIH. Attendees are encouraged to come with questions of interest to all. During this workshop, faculty and attendees will:
- Hear from a representative of the NIH Office of Science Policy about activities that are pertinent to clinical research policy and the protection of human participants in research
- Participate in an open discussion about topics relevant to NIH stakeholders
- Ask questions about new and ongoing initiatives at the NIH

E2
A Dialogue With the Association for the Accreditation of Human Research Protection Programs (AAHRPP, Inc.) (A Dialogue with the Feds II Track) Michelle M. Feige, Robert Hood, Elyse I. Summers, Rob Withrow
AAHRPP, Inc., founded by PRIM&R and six other research-focused organizations in 2001, is an international nonprofit organization that accredits high quality HRPPs. It provides peer-based, collaborative, collegial evaluations of HRPPs, based on applicable standards and elements. This interactive session is designed to answer questions about accreditation for organizations that are already AAHRPP-accredited and those considering AAHRPP accreditation. During this session, faculty and attendees will:
- Review the process of achieving or maintaining AAHRPP accreditation
- Discuss AAHRPP’s approach to cutting edge issues in the human research enterprise
- Become familiar with AAHRPP staff and web resources available to all wishing to maintain or achieve a robust system of human research protections

E3
When Exception Does Not Apply: Practical Strategies for Ethical Enrollment of Situationally Impaired Subjects in Clinical Trials in the Emergency Setting (Advanced Forum for IRB Professionals Track) Michelle H. Bisos, Neal Dickert, Jr., Ronald F. Maio, Robert Silbergleit
Investigators and IRBs frequently struggle with how to handle the informed consent process for clinical trials in emergency setting situations, where patients are awake and communicative, but situationally impaired. Situational impairment frequently results from enrollment decisions having to be made very quickly, from the patient being in pain or otherwise distracted by fear, anxiety, or grief. These are situations where exception from informed consent or minimal risk waivers may be unlikely to apply. The goal of this session is to make IRB professionals familiar with consent strategies, such as staged consent, and the effective use of short forms. Attendees should have a working knowledge of the Common Rule, including some familiarity with regulations related to short form consent and minimal risk waivers of informed consent, before attending this session. During this session, faculty and attendees will:
- Review a range of situational impairments and constraints on interventions that create challenges for informed consent to participate in clinical trials
- Share strategies, including condensed forms, short forms, staged consent, and minimal risk exemptions, which may be most appropriate in different emergency trials enrolling patients that are situationally impaired
- Practice application of different strategies to specific examples of prior or current clinical trials involving situationally impaired subjects in the emergency setting

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**ICON KEY**

- **Advanced** – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.
- **Basic** – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.

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**E4**
IRB Oversight and the Boundaries Between Evidence-Based Practice (EBP), Performance Improvement, and Research (Boundaries & Balance Track) Judy E. Davidson, Anthony Magit

Clinical practice may be advanced through EBP change, performance improvement, or novel research. IRB review is indicated for novel research and other projects that may incur risk. At times, project leaders seek IRB approval solely for the purpose of potential publication, and this increases the workload of IRB staff and members. Attendees should have an understanding of the definitions of EBP change and performance improvement, as well as experience with IRB review of activities intended to advance clinical practice, before attending this session. During this session, faculty and attendees will:

- Identify the boundaries between performance improvement, EBP change, and research
- Define a process for ensuring appropriate oversight of low risk performance improvement and EBP change projects, while maintaining the quality assurance standards required for publication
- Analyze three project plans to determine whether IRB oversight is required according to regulatory standards

**E5**
Exploring Strategies on How to Effectively Provide Education on Human Research Protections to Investigators (Educating & Training Track) Alison L. Antes, Mina P. Busch

This session will provide attendees with ideas and strategies on how to effectively provide education on human research protections to investigators. Attendees should have a working knowledge of the regulations on human research protections, in particular the expectations on investigators, and some experience with conducting education and training targeted to investigators before attending this session. During this session, faculty will:

- Go over intentional/unintentional noncompliances and discuss strategies for resolving and educating investigators on the best ways to manage
- Describe the characteristics of adult learners and review the strategies that can be used to engage investigators in learning about human research protections
- Review a variety of activities, job aids, and tools that could be used to facilitate education for researchers, from mentorship support to remediation training for researchers with issues of persistent noncompliance
- Share experience and strategies used in developing a comprehensive training curriculum on human research protections for investigators

**ICON KEY**
- Didactic session
- Pre-registration required
- CME accredited
- Interactive workshop
- Call for Session Proposal
- Double session
- Recorded session
- Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.
- Basic – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.
- CIP eligible
E6
Ethical Risks and Remedies for Recruiting and Obtaining Consent in Adolescent Risk Research Involving Sexual and Gender Minority Youth (SGMY)  
(Empirical Research Ethics Track) Celia B. Fisher
There is an urgent need for effective, evidence-based prevention tools for SGMY at risk for HIV, substance use, and depression. However, prevention research continues to suffer from disproportionately low representation of SGMY between the ages of 14 and 17. Barriers to such research include: youth’s fear of being “outed” by research recruitment and guardian permission requirements; lack of information on the part of investigators and IRBs regarding how to avoid over or under-estimation of research risks; and how to develop participant affirming recruitment approaches and ethical procedures. This session will introduce members to empirical data that can help reduce barriers to participation while ensuring participant protections. During this session, faculty will:

- Discuss how to distinguish social vulnerability from research vulnerability in ways that minimize over or under-estimation of harm in adolescent risk research involving SGMY
- Review studies examining SGMY’s perspectives that can inform the responsible design and implementation of recruitment strategies for online adolescent health risk research
- Present how empirical data on SGMY’s attitudes toward the risks of being “outed” and their ability to give self consent can inform IRB decisions regarding waiver of guardian permission for adolescent risk

E7
Research Ethics Through the Eyes of a Subject (Ethical Issues Track) Meredith Elkins, Lisa Hofheimer, Greg E. Manship, Glenn O’Neill
This session will explore the research enterprise through the eyes of a research subject: a perspective that may be less familiar than that of your typical PRIM&R colleague. During this session, faculty and attendees will:

- Provide a glimpse of the research process through a different lens
- Share what is important to research participants
- Be available so attendees can ask questions of research participants and gain their perspectives

E8
An Overview of FDA’s Program Alignment and What it Means for Your Next Inspection (FDA Regulations Track) David K. Glasgow
In September 2013, FDA brought together leaders from its Office of Regulatory Affairs and Product Centers and charged them with identifying changes to Agency functions and processes that would improve collaboration, communication, and provide clarity on roles and responsibilities. This Program Alignment recognizes that the combined efforts and commitment of the offices and programs across the Agency are needed for FDA to meet its evolving responsibilities. This session will review the history of FDA’s Program Alignment Group (PAG) and review upcoming functional and organizational changes for FDA’s onsite inspection programs. During this session, faculty will:

- Review the rationale for and recommendations of FDA’s PAG
- Discuss the actions taken and planned to fully implement the PAG recommendations
- Describe specific implications for inspections of sponsors, clinical researchers, and IRBs
E9
Data Access Versus Patient Privacy in the European Union (EU): Ethical Mandates in the Crucible of Public Debate

(Global Research Track) Albert J. Allen, Mark Barnes, Edward E. Bartlett
Competing societal interests of patient privacy versus data access have become the focus of a heated ethical and legal debate in Europe. On one hand, Europeans have become increasingly wary about governmental and commercial intrusions into their private lives. On the other hand, groups are pressing to gain access to subject-level data from clinical trials in order to assure the integrity of research efforts and quality of research data. This conflict has played out in ongoing debates surrounding two public policies: (1) The EU’s recently approved General Data Protection Regulation, regarded as one of the most stringent data protection laws in the world, and (2) the European Medicines Agency’s Data Sharing Policy, which to date, has not been fully implemented. This session will feature leading experts who will review key policy developments, explain their relevance to IRB members and researchers in the United States, and highlight the broader implications of this debate for the ethical conduct of research. During this session, faculty will:

- Explain the two data protection laws enacted in the EU: Data Protection Directive and General Data Protection Regulation
- Summarize the controversies surrounding the European Medicines Agency Data Sharing Policy
- Review the implications of these developments for ongoing ethical and regulatory debates in the United States

E10
Study Review Using Single IRBs (sIRBs)

(Hot Topics Track) Susan Z. Kornetsky, P. Pearl O’Rourke
On June 21, 2016, the National Institutes of Health (NIH) released its final policy on the use of an sIRB for multi-site research to establish the expectation that an sIRB of record will be used in the ethical review of non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the United States. This policy will go into effect in May 2017. Limited exceptions to the rule are provided, primarily to accommodate prohibitions established by federal, tribal, or state laws, regulations, or policies. With this new mandate, research protections professionals must be educated about the technicalities of working with an sIRB and the implications of centralizing review. Attendees should have an understanding of centralized review models (e.g., share and non-share models, etc.), the respective institutional and IRB responsibilities for each model, and the new policy before attending this session. During this session, faculty will:

- Outline the logistics of using an sIRB and the potential benefits, costs, challenges, and implications for an institution
- Review what principal investigators need to think about and consider in terms of their involvement with a protocol or consortium that relies on an sIRB, and what they need to be aware of as they embark on this endeavor
- Explore how sIRBs might employ strategies to properly review local context
- Discuss the potential ways to meet the requirement for considering local context during centralized review by considering current commercial and academic central IRB practices

E11
Reserved for Late-Breaking Session
E12
Top Considerations for Leadership When Accepting Department of Defense (DOD)-Supported Research
(Institutional Officials and HRPP Leadership Track) Jean Barone, Laura R. Brosch, T. Howard Stone
The DOD imposes many and unique human research protection requirements and responsibilities upon institutional officials (IOs) and HRPP leadership when research is supported by the DOD, challenging IOs and HRPP leaders to develop and exert robust and compliant oversight programs and mechanisms across a wide range of institutions, studies, and related activities. This session will provide attendees with special insight into how IOs and HRPP leaders can meet and overcome these challenges. Attendees are expected to have experience with and/or knowledge about research that is conducted or supported by the DOD before attending this session. During this session, faculty will:
- Review the unique human research protections requirements when research is supported by the DOD
- Discuss key challenges and common pitfalls faced by IOs and HRPP leaders in complying with DOD requirements
- Share IO and HRPP leaders’ lessons learned, best practices, and management strategies

E13
Unanticipated Problems (UPs) and Adverse Events (AEs): A Practical Approach for IRBs
(IRB 101 Track) Lisa R. Buchanan, Jeffrey A. Cooper, Sarah Marie Huban
During this session, faculty and attendees will:
- Define UPs involving risk to subjects and others, and the overlap between UPs and AEs
- Use case examples to illustrate the determination process
- Review the practical mechanisms associated with IRB receipt and review of UPs and AEs
- Describe the best practices, policies, procedures, forms, and methods that aid in streamlining IRB submission and review of reportable events
- Discuss the strategies for managing and reporting UPs, AEs, and other deviations from the approved protocol
- Explore OHRP’s process for handling incident reports and making determinations on noncompliance

E14
IRB Chair Responsibilities and Roles: Beyond the IRB Meeting
(IRB Chairs Track) J. Andrew Bertolatus, Elizabeth S. Moore, Patience B. Stevens
The work of the IRB chair is primarily conducted outside of IRB meetings. This session will cover the broad spectrum of other duties that come with being an IRB chair. During this session, faculty and attendees will:
- Explore how chairs, especially in small institutions, have added responsibilities and challenges often without significant administrative support
- Review a 360 evaluation of the HRPP process and IRB chair leadership
- Share best practices for pre-review and preparation for an IRB meeting, and the regulatory expertise required of the chair or designee
- Describe techniques used in resolving disputed issues between IRBs and researchers
- Discuss the age old question of checking the boxes on the Federalwide Assurance
- Expand on ways of recognizing service by members and staff
- Go over practices for communicating with the research integrity office, legal counsel, risk management, sponsored programs, and others
E15
Enhancing Effective Communications Between IRBs and Investigators
(IRB Operations Advanced Track) John R. Baumann, Moira A. Keane
This interactive session will use case studies and concrete examples to enhance communication between IRBs and investigators. Attendees should have a basic understanding of the common challenges in investigator/IRB communications before attending this session. During this session, faculty and attendees will:
• Review techniques for delivering information (good or bad) to investigators in clear, concise, and tactful ways
• Provide feedback and strategies to IRBs from investigators regarding helpful, respectful interactions with the research community
• 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

E16
(Issues Pharma/Biotech Track) Rubén D. Flores-Saaib, Mary A. Short
Partnerships between the pharma/biotech industry and academia have expanded beyond the traditional clinical trial agreement. New models in industry/academic partnerships may create innovative pathways for drug/device development, but may also introduce new challenges for both parties. Attendees should have an understanding of common models for academic/industry partnerships (the Clinical Trial Agreement) before attending this session. During this session, faculty will:
• Review the evolving landscape of academic/industry partnerships, providing case examples of specific partnerships from the academic and industry perspective
• Discuss strategies for effective partnering
• Share best practices and lessons learned related to complex legal and compliance considerations surrounding topics such as data ownership, data sharing, and trial oversight

Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.

Basic – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.
E17
O...R...I Have No Idea What You’re Talking About!
(Legal Track) Kristina C. Borror, Yvette M. Carter, Keri Godin, Katherine Gallin Heffernan
IRBs are often adept at responding to allegations of serious or continuing noncompliance with the human subjects protections regulations and the requirements imposed on human subjects research by the IRB in their efforts to protect human participants. However, these noncompliance matters may also involve parallel allegations of “research misconduct” in the form of fabrication, falsification, or plagiarism, which are governed by a separate regulatory framework aimed at preserving research integrity and is overseen by the Office of Research Integrity (ORI). The goal of this session is to educate IRB chairs, members, administrators, directors of HRPPs, institutional officials, and investigators on the general legal framework that applies to allegations of research misconduct, the institutional individuals usually charged with facilitating such processes, and the enforcement path such matters tend to track, to ensure that IRBs are best positioned to coordinate any IRB investigation with a parallel research misconduct inquiry or investigation. Careful coordination can help ensure that potentially competing obligations are coordinated appropriately without adversely impacting either process, and ensuring comprehensive compliance. Effective cooperation between the processes, within the confines of regulatory obligations related to confidentiality, will also be explored. During this session, faculty will:

- Review the legal framework for responding to allegations of research misconduct pursuant to 42 CFR Part 93 as compared to the requirements on IRBs to respond to allegations of serious or continuing noncompliance
- Explain the different jurisdictions and agendas between OHRP, FDA, and ORI
- Describe how IRB chairs, members, administrators, directors of HRPPs, and others involved in the oversight of human research protections may become involved in research misconduct proceedings
- Highlight potential areas of conflict between the two regulatory frameworks and effective approaches to coordination and cooperation

E18
Scientific Aspects of Study Design: A Primer for Non-Scientist IRB Members
(Non-Scientist IRB Members Track) Susan S. Fish, Lindsay McNair
This session will serve as a primer on the scientific process, clinical study designs, and the structure of research programs for the non-scientist IRB member. During this session, faculty and attendees will:

- Discuss the essential components of a study question and how the question can be addressed in a clinical study
- Review the basics of both observational and interventional clinical study designs, and the strengths, weaknesses, and application of each design
- Explain the essential considerations (e.g., bias, confounding) that can impact the validity of a clinical study and the analysis of study data

Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.

Basic – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.
E19
This session will discuss the ethical, legal, and practical considerations related to research using certain types of biospecimens that may involve additional considerations for IRBs and investigators: those from pediatric biobanking, newborn blood spots held by state agencies or public health authorities, and specimens including or derived from fetal tissue. During this session, faculty will:
- Review the federal and state regulatory landscape related to consent for future research with certain types of biospecimens
- Discuss the unique considerations related to consent for biospecimens acquired through newborn screening programs, collected from pediatric patients, or donated by women who have miscarriages or abortions
- Provide suggestions for IRBs and investigators to consider when contemplating research that involves these types of biospecimens

E20
Representing Prisoners: Insights from an IRB Member Who Has Been Incarcerated (Populations Requiring Additional Protections Track) Fanny K. Ennever, Julia G. Gorey, David N. Tavares
In 2013, the Committee on the Use of Human Subjects (the IRB) for Harvard University-area research recruited David N. Tavares, a former prisoner, as a member. During this session, faculty will use the seven additional approval criteria from Subpart C of 45 CFR 46 as a framework to present important insights provided by a member who has “been there, done that,” as well as discuss the experience of recruiting a former prisoner and integrating him into the IRB. Case studies will be used to illustrate how David provided a perspective not available from someone who has only worked with prisoners, and how he has improved the ability of the IRB to protect prisoners as research subjects. During this session, faculty will:
- Interpret the federal requirements for membership in IRBs that review research on prisoners
- Analyze the criteria for approval for prisoner research incorporating the perspective of an IRB member who was a prisoner
- Review how an academic IRB was able to incorporate a former prisoner as a valued member

E21
Development of an Effective QA/QI Program at Your Institution (QA/QI and Post-Approval Monitoring Track) Leslie M. Howes, Eunice Yim Newbert, Jessica A. Randall
This session will provide strategies and tools for developing an effective QA/QI program within an organization, regardless of whether it conducts SBER or biomedical/clinical research. This session will provide an opportunity for faculty and attendees to share techniques and ideas that can help improve QA/QI programs. During this session, faculty will:
- Review different models of QA/QI (e.g., stand-alone department versus integrated into IRB), and their advantages and disadvantages
- Explore the various activities a program can take on and how to prioritize activities
- Discuss how to identify, establish, and evaluate benchmarks to assess the quality of an HRPP
- Outline QA/QI specialist qualifications
- Share strategies for developing effective education and training opportunities for investigators

Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.

Basic – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.
E22
Crawling in the Dark: The Ethics of Research Use of Data from the Dark Web
(Research Conducted in the Digital World Track) Elizabeth A. Buchanan, Brenda Curtis, Tani L. Prestage
This session will explore case scenarios of research involving the dark web, and the subsequent ethical dilemmas that IRBs may face (e.g., can researchers use data that is released by groups such as Anonymous?). Speakers will interact with the audience in order to share their experience with the research use of data from this realm. During this session, faculty and attendees will:
- Define and describe the dark web and dark web research
- Go over various actors in the dark web, identified and unidentified (e.g., Anonymous)
- Review potential ethical issues that may occur from research use of the dark web data
- Bring to light ethical issues that can potentially appear from researchers using data from the dark web and provide insights into review of research based on case scenarios
- Identify potential solutions and strategies to assist researchers in conducting dark web secondary data studies, while protecting human subjects in research
- Discover ways to find resources and stakeholders to make decisions for your institution on research use of data from the dark web

E23
Building and Maintaining HRPP in a Large Health System With a Small Research Portfolio
(Small Research Programs Track) Scott J. Lipkin, Lori Roesch
This session will focus on the challenges of developing and maintaining an effective HRPP in a large health system with a small biomedical research program. Topics to be covered include: noncompliance and conflict of interest management, effective interactions with organizational leadership, adherence to FDA requirements when reviewing drug and device research, and more. Attendees should have an understanding of the FDA and OHRP regulations for human research protections and conflicts of interest, and the organizational structure of their home institution before attending this session. During this session, faculty and attendees will:
- Review how to support an effective HRPP in a large health system with a small research portfolio
- Discuss how to create action and priority lists for succeeding in this environment
- Share strategies for engaging senior leadership, investigators, and IRB members

E24
Social Media and Participant Recruitment in SBER
(SBER I Track) Jeffrey M. Cohen, Laura Owadany
This session will provide an overview of social media tools and sites that are frequently used for participant recruitment in SBER. During this session, faculty will:
- Review various social media sites and tools that are used for participant recruitment in SBER
- Describe recent cases of behavioral research and the roles social media played in participant recruitment
- Discuss strategies for effective and compliant strategies for participant recruitment and ways in which an IRB can appropriately review social media recruitment plans
E25
(SBER II Track) Dean R. Gallant, Alison S. Orkin, Andrew P. Rusczek
Insofar as human subjects research involves the study of human behaviors, social values, and public policy, such research studies may involve the investigation of illegal/illicit behaviors. Collecting data about illegal/illicit behaviors exposes all stakeholders—individual participants, investigators, and institutions—to risks and harms to personal well-being, social standing, and legal culpability. This session will use a case-study approach to identify practical, ethical, and legal complexities in order to discuss and develop best practices for reviewing research investigating illegal/illicit behaviors. Topics to be discussed will include informed consent for research, risk assessment and the risk/benefit ratio assessment, and issues related to mandatory reporting, confidentiality, and privacy. During this session, faculty and attendees will:

- Discuss the nature, severity, and probability of risks inherent to research of illegal/illicit behaviors
- Develop best practices for: mitigating risks in study design and conducting IRB review of study protocols

12:45-1:45 PM
Networking Lunch
Time to connect... over lunch! Meet peers for conversation and networking. A boxed lunch will be served.
PRIM&R would like to thank PEER Consulting Group for helping to support today’s lunch.

Closing Plenary Session, 2:00-3:15 PM
Closing General Session: Errors of Enthusiasm: Responsible Communication of Research Findings
Moderator: David H. Strauss
Panelists: Karen Kaplan, Lisa M. Lee, Vinay K. Prasad, Gary Schwitzer
A critical part of conducting research is the responsible and accurate communication of results. Given that research is meant to add to generalizable knowledge, communication is the tool by which that is accomplished. While the scientific community usually thinks of “communication” as the publication of results in peer-reviewed journals, there are numerous other channels of communication. One such important form is media coverage of “exciting” research which, at times, is invited by researchers themselves. Even if a peer-reviewed journal reported on research in an accurate and unbiased way (which is not always the case), downstream communication, such as press releases to the media, can exaggerate the findings so the true results are misrepresented (usually by overstating positive outcomes or potential benefits). This, in turn, has the potential to mislead the general public, political decision-makers, potential funders, and others. This panel will present examples of research results hyperbole and its impact, and discuss ways to address this problem and encourage the honest and accurate communication of results.
This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of Boston University School of Medicine and PRIM&R. Boston University School of Medicine is accredited by the ACCME to provide continuing medical education for physicians.

Boston University School of Medicine designates this live activity for a maximum of 20.5 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This program includes 20.5 credits which meet the criteria of the Massachusetts Board of Registration in Medicine for risk management study.

**Course director:** Susan S. Fish, PharmD, MPH Professor, Biostatistics, Boston University School of Public Health, Boston University School of Medicine

**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.

**Faculty disclosure statement:** Boston University School of Medicine asks all individuals involved in the development and presentation of CME activities to disclose all relationships with commercial interests. This information is disclosed to CME activity participants. Boston University School of Medicine has procedures to resolve any apparent conflicts of interest. In addition, faculty members are asked to disclose when any unapproved use of pharmaceuticals and devices is being discussed.

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