

## Thursday, November 12: Pre-Conference Programs

7:00 AM

[Registration Opens](#)

Breakfast on your own. Coffee only will be available in Boylston Hallway on the second level.

Pre-function Hall C

8:30 AM-4:30 PM

[Contemporary Issues in Biobanking: Forum on Research Involving Tissue and Biobanking – Domestic and International Considerations](#)

Room 203



8:30 AM-4:30 PM

[IRB 101<sup>sm</sup>](#)

Room 210



8:30 AM-5:00 PM

[QA/QI in Human Subjects Research](#)

Room 204



8:30 AM-4:30 PM

[Single IRBs Are Here: Are you Ready?](#)

Room 202



4:30-6:00 PM




[Pre-Conference Programs Networking Reception](#)



All those registered to attend a pre-conference program on November 12 are welcome to attend a networking reception immediately following the conclusion of their program. Light refreshments will be served.




Boylston Hallway,  
second level



### ICON KEY

 Didactic session  
 Pre-registration required  
 CME accredited

 Interactive workshop  
 Call for Session Proposal

 Double session  
 Recorded session  
 CIP eligible

# Friday, November 13: 2015 AER Conference

7:00 AM

## Registration Opens

Breakfast on your own, but enjoy a coffee in The Conference Connection in Exhibit Hall C, compliments of IRBNet

Pre-function Hall C

7:00-8:00 AM

## Continental Breakfast to Welcome First-Time Attendees **SOLD OUT!**

Looking to connect and network with other first-time attendees before the conference starts? If so, please join us at this breakfast where you'll have an opportunity to meet with colleagues, as well as hear answers to the top 10 most frequently asked questions about the conference from the PRIM&R staff. Pre-registration is required for this event. Please [register online](#) or [email us](#).

Room 302



7:00-8:00 AM

## Affinity Group (AG) Peer-to-Peer Networking Continental Breakfast

Join your AG facilitators and fellow members before the conference starts to connect and network! All attendees registered for an AG are welcome, and discussion questions for each group will be available to kick-start conversation. Pre-registration is required for this event. Please [register online](#) or [email us](#).

Ballroom A



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*

Veterans Memorial Auditorium



8:15-8:30 AM

## Welcome from PRIM&R's Executive Director

*Elisa A. Hurley, PhD*

Veterans Memorial Auditorium



8:30-9:15 AM

## Keynote Address: Myth and Reality - An Insider's Perspective on the Ethics of Healthcare Research in Developing Countries.

[Boghuma Kabisen Titanji, MD, MSc, PhD](#), Physician and Clinical Researcher, Ministry of Public Health, Cameroon

Veterans Memorial Auditorium



9:15-9:30 AM

## Break

## Concurrent Plenary Sessions, 9:30-10:45 AM

### Panel I: From Ideal to Real: Post-Trial Access, Expanded Access, and Use of Ancillary Treatments in Global Studies

**Moderator:** Robert J. Levine

**Panelists:** Michael A. Turik, Mark Barnes, Jerome A. Singh

Global clinical trials are studies conducted in two or more countries around the globe, one of which may be the US and, usually, multiple countries are involved across two or more continents. Global research of this type must deal with a number of ethical challenges, three of which this session will explore: expanded access (sometimes referred to as compassionate use), post-trial access, and access to ancillary care. These topics will be discussed by three panelists representing varying perspectives: a physician from the pharmaceutical industry, an expert on multi-regional clinical trials, and an international bioethicist with experience in the developing world.

Ballroom C



Didactic session



Pre-registration required



CME accredited

#### ICON KEY



Interactive workshop



Call for Session Proposal



Double session



Recorded session



CIP eligible

### Panel II: The Challenge of Research on Campus Sexual Violence: Ethical, Scientific, and Political Dimensions

Ballroom B

**Moderator:** *Claude Ann Mellins*

**Panelists:** *Elizabeth A. Armstrong, Shamus Khan, Sharyn J. Potter*

Efforts to understand and address the troubling prevalence of sexual assault on college campuses have brought together college students, administrators, and scientists with varied agendas and diverse methodological backgrounds. This panel will offer data and perspectives on current research on campus sexual violence with reference to the challenges and barriers presented by this ethically complex and politically charged area of inquiry.



### Panel III: Moving Targets: The Challenges of Responsible Mobile Health (mHealth) Research

Veterans Memorial Auditorium

**Moderator:** *Camille Nebeker*

**Panelists:** *Dror Ben-Zeev, Jeremy Block, Stanley Y. Shaw*

Over the past 10 years, mHealth technologies have increased dramatically with the proliferation of the smartphone, numerous apps, and other wearable data devices. The recent introduction of Apple's "ResearchKit" and similar interfaces have made the rapid, widespread collection of personal health data possible on a scale and range unthinkable only a few years ago. This panel will discuss recent developments in mHealth research, highlight challenges for IRBs and researchers, including privacy and regulatory concerns, data reliability, subject perceptions of participation, and risks to subjects, and consider possible approaches to addressing these concerns.



10:45-11:15 AM

Exhibit Hall C

#### Break

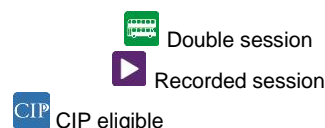
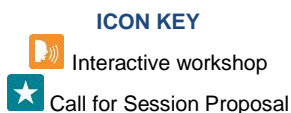
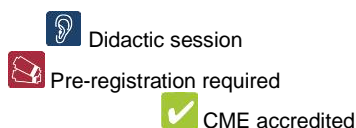
Join us for coffee in The Conference Connection, compliments of iMedRIS.

10:45-11:15 AM

Pre-Function Hall C

#### Book Signing with Authors and Panel II Speakers Elizabeth A. Armstrong and Shamus Khan

Join us at the onsite Bookstore in Pre-Function Hall C for a book signing with authors and Panel II speakers Elizabeth A. Armstrong and Shamus Khan. Copies of Drs. Armstrong and Khan's books are available online, as well as at the onsite Bookstore.



Friday, November 13

Innovations in... Series, 11:15 AM-12:30 PM

Drawn from a rich pool of poster abstract submissions, the Innovations in... panel series features poster authors whose cutting-edge research and practices are advancing the field of human subjects protections. These sessions are loosely grouped around a specific theme, and each session features three posters selected from this year's Poster Presentation Program.

### Innovations A: Innovations in Global Settings

Ballroom C

**Moderator:** Nancy E. Kass

Regardless of where research is conducted, issues may arise that require careful assessment and critical thinking in order to improve research operations and enhance subject protections. This panel will feature speakers from diverse global settings who will discuss their recent work navigating difficult issues and challenges related to the conduct of research, including, specifically, their work on research misconduct, student research, and informed consent in crisis situations. While the work being presented is specific to these countries and projects, the issues studied, data collected, innovations implemented, and lessons learned transcend their setting and will offer something to all those working within the research enterprise. The following posters will be presented during this session:

- [Poster #18: Attitudes Towards and Prevalence of Research Misconduct Among Investigators in Egypt](#)  
*Marwan T. Felaeef, American University in Cairo*
- [Poster #21: Development and Implementation of a Graphic Aid to Consent for an Ebola Vaccine Trial in Liberia](#)  
*Jerome F. Pierson, Office of Clinical Research Policy and Regulatory Operations, Division of Clinical Research, National Institute of Allergy and Infectious Diseases, National Institutes of Health*
- [Poster #27: Establishing a Cancer Research Ethics Committee in Resource Limited Setting: Procedures, Challenges, and Lessons Learned](#)  
*Annet Nakaganda, BSc, MPH, Uganda Cancer Institute*



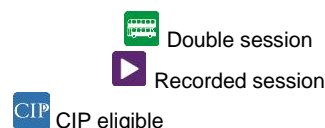
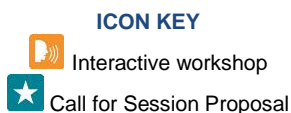
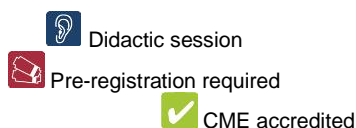
### Innovations B: Innovations in IRB Operations

Veterans Memorial Auditorium

**Moderator:** Elyse I. Summers

As research programs expand, collaborations become more frequent, and committee workloads increase, IRB offices are looking for new ways to facilitate the research review process. In light of this, efforts to streamline processes and procedures in order to create more effective operations, while still maintaining the highest standard for subject protections, are becoming increasingly common. This panel will highlight three initiatives carried out in the US aimed at improving research operations, including an evaluation of single patient exceptions to clinical trials, the creation of a Reliance Services Program to expedite industry-sponsored clinical trials, and the adoption of a flexible IRB model. The following posters will be presented during this session:

- [Poster #46: An Institutional Experience Regarding the Classification and Approval Rates of Single Patient Exceptions to Clinical Trials in the Committee on Human Research](#)  
*Charles J. Ryan, University of California, San Francisco*
- [Poster #44: Innovation in IRB Reliance: A New Model Advances Multi-Site Research](#)  
*Rachael Sak, University of California Biomedical Research Acceleration, Integration, and Development*
- [Poster #45: Transformation to an All-Videoconference Flexible IRB Model: One Institution's Experience](#)  
*Jon Newlin, North Shore-Long Island Jewish Health System*



## Innovations C: Innovations in Subject Perspectives: Risks, Benefits, and Incidental Findings

**Moderator:** Steven Joffe

Ballroom B



The perspectives of research subjects can help to enhance our understanding of human subjects protections. Yet, many questions remain about what subjects think about certain aspects of research, as well as how their views on these topics inform their decision to participate in research. In this panel, three speakers will discuss their work to assess subject perspectives in relation to research protections, incidental findings in neuroimaging research, and the risks and benefits associated with a mobile health study, respectively. The following posters will be presented during this session:

- [Poster #58: "A Real Super Ethical Super Moral Perspective": The Research Ethics of Research Participants](#)  
Justin Snyder, Pennsylvania State University
- [Poster #12: "Ethical Responsibility" or a "Whole Can of Worms": Differences in Opinion on Incidental Finding Review and Disclosure in Neuroimaging Research from Focus Group Discussions With Participants, Parents, IRB Members, Investigators, Physicians, and Community Members](#)  
Jody M. Shoemaker Roberts, University of New Mexico Health Sciences Center
- [Poster #13: Persons Who Inject Drugs' Perspectives on the Risks and Benefits of Participation in a Mobile Health Study of Polydrug Use](#)  
Alexis M. Roth, Drexel University School of Public Health

12:45-1:45 PM

### Common Ground Networking Lunch

Time to connect... over lunch! Meet peers for conversation and networking. The tables will be divided by institution type: University/College (Medical), University/College (Non-Medical), Hospital/Medical Center, Government Agency, Pharma/Biotech Company, and, Small Research Programs. We will also have tables available for those wishing to "just lunch. All are welcome!

Exhibit Hall D

12:45-1:45 PM

### Research Ethics Book Group Lunch and Book Signing: *The Malaria Project: The US Government's Secret Mission to Find a Miracle Cure*

Ballroom A



Participate in a vibrant discussion of *The Malaria Project: The US Government's Secret Mission to Find a Miracle Cure* by Karen M. Masterson, a former political reporter for the Washington Bureau of the *Houston Chronicle* who left newspapers to pursue her interest in microbiology. In 2005, she won a Knight Journalism Fellowship to study malaria at the US Centers for Disease Control and Prevention in Atlanta and in rural Tanzania. Attendees will have the opportunity to hear from and participate in a discussion with Ms. Masterson about her book and her work, and she will be available to sign books during this time. Ms. Masterson's book is available in print and for the Kindle through [Amazon.com](https://www.amazon.com), and copies will be available for purchase onsite at the conference Bookstore. Pre-registration is required for this event. Please [register online](#) or [email us](#).

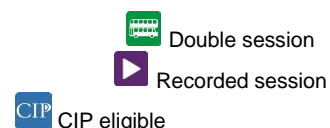
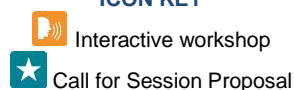
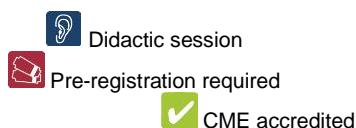
1:15-1:35 PM

### Demonstration of PRIM&R's Ethical Research Oversight Course (E-ROC)

Join us in the PRIM&R Pavilion 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, please stop by the PRIM&R Pavilion or [email](#) Maeve Luthin, professional development manager, to set-up a one-on-one demonstration of this resource.

Exhibit Hall C

#### ICON KEY



1:40-2:00 PM

Exhibit Hall C

### Demonstration of PRIM&R's Knowledge Center

Join us in the PRIM&R Pavilion for a demonstration of our online resource for members, the Knowledge Center, and its new 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, please stop by the PRIM&R Pavilion or [email](#) Maeve Luthin, professional development manager, to set-up a one-on-one demonstration of this resource.

1:45-2:15 PM

Exhibit Hall C

### Meet the 2015 AER Conference Poster Authors

Visit with the authors of the posters featured in the 2015 AER Conference Poster Presentation Program and learn about their innovative and important work on new program initiatives, empirical research, and conceptual analysis. The development and presentation of scientific and programmatic 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.

1:45-2:15 PM

Exhibit Hall C

### Meet the 2015 AER Supporters and Exhibitors

Network with this year's conference Supporters and Exhibitors, and learn about their important services.

1:45-2:15 PM

Exhibit Hall C

### FDA Office Hours

Do you have a specific question for FDA representatives? Do you have a follow-up question after attending a session with a FDA representation or on a FDA-related topic? If so, we encourage you to stop by the FDA Office Hours during this time, and representatives from the FDA will be available to help answer your questions.

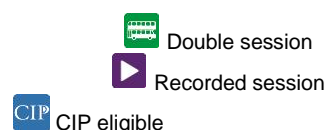
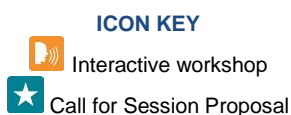
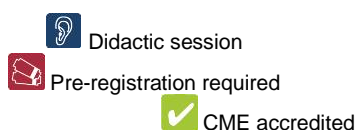


2:05-2:20 PM

Exhibit Hall C

### Overview of PRIM&R's Member Benefits

Join us in the PRIM&R Pavilion 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, please stop by the PRIM&R Pavilion or [email](#) Megan Frame, membership manager, to set-up a one-on-one discussion.



A1

**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 representatives from the NIH. Attendees are encouraged to come with questions of interest to all. During this workshop, attendees will:

- Hear from representatives of the NIH Office of Science Policy about activities that are pertinent to clinical research policy and the protection of human subjects in research
- Participate in an open discussion about topics relevant to NIH stakeholders
- Ask questions about new and ongoing initiatives at the NIH

Room 107



A2

**A Dialogue with the Department of Energy (DOE)** (*A Dialogue with the Feds II Track*) John 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, attendees will:

- Participate in an open discussion of issues relevant to DOE stakeholders
- Ask questions about new and ongoing initiatives at the DOE

Room 301



A3

**Return of Results to Participants: Logistical, Ethical, and Regulatory Considerations** (*Advanced Forum for IRB Professionals Track*) Zachary Hallinan, Rebecca Li, Laurie Myers

During this session, faculty will:

- Review the current mandate for and operational issues attending to return of results to participants with an emphasis on patient centricity
- Outline the principles of health literate communications and numeracy
- Address the ethical challenges of return of results in the national and global context

Room 302



Advanced

A4

**You'll Know it When You See it: Defining "Human Subjects Research" Under the DHHS Regulations** (*Boundaries and Balance Track*) Elizabeth Bankert, Julie Kaneshiro, Ada Sue Selwitz

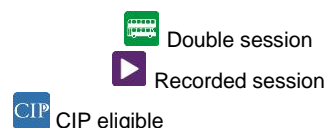
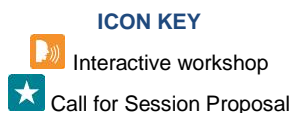
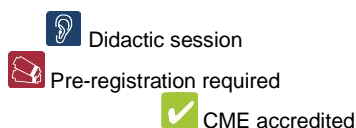
Evaluating whether an investigator is conducting research involving human subjects has many important ramifications for both the institution and the investigator in terms of cost, time, and requirements for the activity. Since interpretation of key definitions in the regulations – including "systematic," "generalizable," and "human subjects" can be tricky, thorough consideration is needed to ensure appropriate application of the regulations. During this session, faculty and attendees 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."

Room 304



Basic



A5

**Recruitment Strategies: Sharing Our Secrets for Success** (*Educating and Training Track*) Albert J. Allen, Karen Christianson, Stavroula Osganian

Room 101



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
- Discuss if and when consent/assent is required during the recruitment process
- Work through cases where recruitment is challenging and ethically complex

A6

**How to Read the Empirical Ethics Literature** (*Empirical Research Ethics Track*) Robert M. "Skip" Nelson

Room 111



During this session, faculty will:

- Discuss key aspects of research methods relevant to assessing empirical studies of ethical issues
- Consider common logical fallacies in drawing conclusions from empirical data
- Review and discuss an empirical study with a critical eye

A7

Open

A8

**Special Topics for IRBs that Review FDA-Regulated Medical Device Investigations** (*FDA Regulations Track*) Dominic Chiarelli, Fabienne Santel

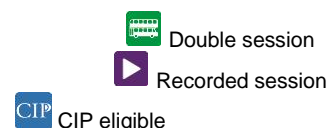
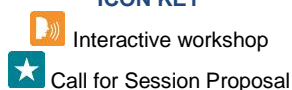
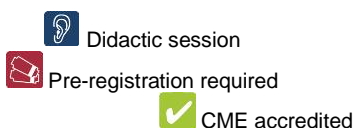
Room 311



There are some specific determinations that must be made by an IRB when they review a clinical investigation involving an FDA-regulated medical device. This session will cover special topics and situations encountered by IRBs when reviewing medical device studies and how best to address them to ensure subject safety, data quality, and regulatory compliance. During this session, faculty will:

- Explore FDA expectations of IRBs for certain device-specific situations, including IDE exempt, significant risk/non-significant risk determinations, Expanded Access, and HUDs.
- Review examples of IRB 483 citations and warning letters where IRBs were not able to successfully address these situations.
- Discuss IRB best practices in meeting FDA's expectations for review of medical device studies.

## ICON KEY



A9

**Different Models of Review: A Global Comparison** (Global Research Track) Lama Jamhawi, Annet Nakaganda, Delia Y. Wolf, Rachel Zand

Room 104



Different countries have adopted different types of ethics review systems for health 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 such reviews, the turnaround time for reviews when multiple committee review the same protocols, and the implication for human resources? During this session, faculty and attendees 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

A10

**Proposed Changes: An In-Depth Discussion on the Notice of Proposed Rulemaking's (NPRM's) Section on Proposed Changes to Informed Consent** (Hot Topics Track) Heather H. Pierce, David H. Strauss

Room 312



A NPRM has been released, and it is important for those involved in research to have an awareness of the proposed changes and their potential implications for the field. This session will focus on the sections of the NPRM related to obtaining, waiving, and documenting informed consent, including provisions designed to ensure that only the most pertinent information is included in consent forms, the use of broad consent for research with biospecimens, additional elements of consent for some types of research, and new criteria for waivers of consent and its documentation. During this session, faculty and attendees will:

- Review, briefly, the current rules on consent
- Discuss what is being proposed in the NPRM and potential implications
- Provide information on how to submit public comments on the NPRM

A11

**Managing Intellectual Property Interests of Researchers and Institutions**

(Institutional Officials and HRPP Leadership Track) Rupinder Grewal, Ross E. McKinney, Jr

Room 203

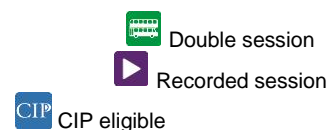
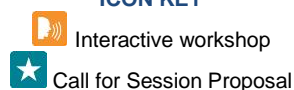
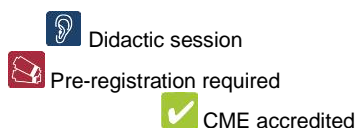


Advanced

During this session, faculty will:

- Discuss the potential challenges that arise for research designed to evaluate an invention/technology for which an investigator and/or the institution have intellectual property interests
- Review when intellectual property interests may represent significant financial interests
- Outline management strategies that may be employed to address and potentially mitigate conflicts of interest in these circumstances

## ICON KEY



A12

**Unanticipated Problems and Adverse Events: A Practical Approach for IRBs** (*IRB Boot Camp Track*)

Kristina C. Borrer, Jeffrey A. Cooper

Room 306



Basic

During this session, faculty and attendees will:

- Define what is an unanticipated problem involving risk to subjects or others, and the overlap between unanticipated problems and adverse events
- Use case examples to determine whether certain events should be considered unanticipated problems or an adverse events
- Review the practical mechanisms for IRB receipt and review of reports of unanticipated problems and adverse events
- Discuss strategies for managing and reporting adverse events, unanticipated problems involving risks to subjects or others, and other deviations from the original protocol
- Share strategies for managing and dealing with adverse events, noncompliance, and expiring/expired protocols

A13

**IRB Chairs and Members: Recruiting, Developing, Training, and Managing Board Members** (*IRB Chairs Track*)

Charlotte H. Coley, Sarah H. Kiskaddon, Eric C. Mah

Room 200



Advanced

IRBs consistently struggle with identifying and retaining quality, committed IRB members, and are often in need of creative mechanisms for attracting new members or ensuring valued members will continue their service. During this session, faculty will:

- Discuss best practices in identifying, recruiting, developing, and training IRB members and chairs
- Describe succession planning strategies for leadership development of IRB chairs
- Demonstrate how to work with institutional leadership to support IRB membership
- Review various strategies to retain IRB members including member incentive programs

A14

**Considerations in the Selection of an Electronic Submission System** (*IRB Operations and Toolkit Track*)

Patricia A. MacCubbin, Nancy A. Olson

Room 206



Have you decided to move towards an electronic submission system, but are not sure where to start?

This session will provide a detailed look at the various steps involved with an electronic system selection process and will provide guidance on what needs to be considered at each stage of the process. During this session, faculty will:

- Discuss methods for strategic planning to ensure the needs of various stakeholders are considered
- Review the logistics of electronic system selection including development of a formal request for proposals from external vendors and mechanisms for product evaluation
- Provide insights on what must be considered when pursuing a packaged product versus a home grown approach



Didactic session



Pre-registration required



CME accredited

## ICON KEY



Interactive workshop



Call for Session Proposal



Double session



Recorded session



CIP eligible

A15

**Investigator-Initiated Research: An Overview of Sponsor-Investigator Responsibilities and Tips for Success at Your Institution** (*Issues Pharma/Biotech Track*) George Gasparis, Cynthia M. Kern

Room 102



A sponsor-investigator is an individual who both initiates and conducts, alone or with others, an investigation that is under whose immediate direction the test article is administered, dispensed, or used. Investigators who become a sponsor-investigator, and institutions where investigator-initiated studies are conducted, must understand the regulatory responsibilities a sponsor-investigator assumes in such research. During this session, faculty will:

- Discuss the specific regulatory responsibilities a sponsor-investigator assumes when conducting investigator-initiated research
- Examine some of the challenges in meeting the regulatory requirements
- Provide tips on processes the investigator and institution can implement to assist in meeting the regulatory requirements

A16

**State Law Issues in Online Research** (*Legal Track*) Elizabeth A. Buchanan, Julie M. Rusczek

Room 309



Advanced

Research conducted through the internet and social media presents a number of unique challenges and questions for institutions, IRBs, researchers, and their legal counsel. Among the challenges is that participants may reside in any jurisdiction within the US, which raises questions about which state laws apply and when, and how to identify and comply with them. This session will focus on the issues in internet research most commonly posed or affected by state laws and variances in state laws. (Although internet research may also involve participants in countries outside the US, and consequently may raise issues under those countries' laws as well, international law issues are not the focus of this session.). During this session, faculty will:

- Identify the most common state law issues that arise in internet research, including: definition of who is a "child" for consent/assent purposes; determination of when electronic signatures may be used in the consent process; assessment of what researcher-participant interactions constitute the "practice of medicine" and in what jurisdiction; and compliance with professional "duty to warn" obligations (such as of harm to self or others) and various obligations under state mandatory reporting rules (such as child and elder abuse reporting)
- Provide a framework for determining which state laws apply to a project and strategies for assuring compliance

A17

**The Inside Scoop: What Every Non-Scientist Should Know** (*Non-Scientist IRB Members Track*)

Greg E. Manship, Veronica Todaro

Room 108



In this session, IRB members considered to be "non-scientists" 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 on 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 tips and tricks for being a non-scientist on the IRB



Didactic session



Pre-registration required



CME accredited

## ICON KEY



Interactive workshop



Call for Session Proposal



Double session



Recorded session



CIP eligible

A18

**The ABCs of Genetics, DNA, and Related Research Issues** (*Out-of-Body Experiences: Research Involving Tissue and Data Track*) Melissa P. Wasserstein, Stacey Donnelly.

Room 310



Basic

IRBs are reviewing an increasing number of research proposals involving genetic and genomic research. If genetic concepts and terminology are unfamiliar to you, or you'd like a primer on the state of the science and HRPP in genome-scale research, please consider attending. 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

A19

**Defining Vulnerability: Regulations and Beyond** (*Populations Requiring Additional Protections Track*) Jeremy Block, Michelle Feige, Bruce G. Gordon, Irene E. Stith-Coleman

Room 204



Basic

In this session, faculty will give a basic overview of the regulations that cover vulnerable populations, and then discuss 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.

A20

**The Intersection of Research Subjects Protections and Grants Management** (*Potpourri Track*) Debra Schaller-Demers

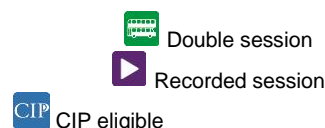
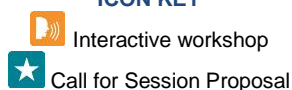
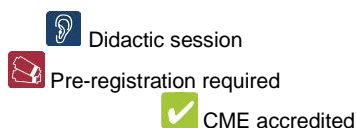
Room 110



Why do grants managers need to understand IRB policies and procedures? Why do IRB administrators need to understand grant submission and award acceptance policies and procedures? Often, the IRB and the Sponsored Program Office work in silos and neither may truly appreciate the processes, deadlines, and responsibilities of the other. In order to ensure timely communication with sponsors, compliant grant applications and progress reports, and audit-ready grants management records, it is best when both sides are in sync and can ensure grant congruency. During this session, faculty and attendees will:

- Explore best practices for maintaining quality assurance in grants management with regard to research subjects protections information
- Share strategies for communicating more effectively with colleagues in order to achieve grant congruency and accurate records for both offices

## ICON KEY



A21

**Nuts and Bolts of Investigator Site Audits** (QA/QI and Post-Approval Monitoring Track) Kelly Dornin-Koss, Jennifer A. Graf, Sarah A. White

Room 308



Basic

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/scaling onsite reviews, and who receives the report (the considerations will be compared/contrasted between multiple QA/QI programs)
- Address how audits can be an opportunity for investigator education
- Review practical and useful tools that sites can modify for their own use

A22

**Ethical Issues in Research with Big Data** (Research Involving the Internet and Social Networking Track)

Liza Dawson, Miguel Hernan, Rachel Sachs

Room 210



Increasing amounts and types of data are collected on individuals through electronic means such as commercial databases, social media, GPS, and other sources of data. These large datasets have great potential for health-related research, but questions of public trust, privacy, identifiability of individuals or groups, and protection of public interest have yet to be fully explored. This session will summarize some key ethical issues and areas for further empirical and philosophical work related to big data. During this session, faculty will:

- Review the kinds of data sources that can be used in big data research and what questions about identifiability might emerge in using, combining, and analyzing datasets
- Discuss current legal frameworks for privacy in data collection and use
- Describe the key ethical challenges for researchers, policy makers, and IRBs in establishing standards and guidelines for big data research
- Highlight proposed solutions for participant protections, governance, and oversight

A23

**Building and Maintaining an HRPP Within a Primarily SBER Institution With a Small Research Portfolio** (Small Research Programs Track) Eric Allen, Shannon L. Harr

Room 109

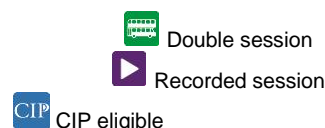
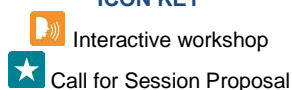
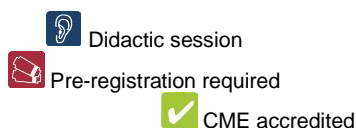


Basic

This session will focus on the challenges of developing and maintaining an effective HRPP at an institution doing limited and primarily SBER. Topics will include: managing individualized and web-based training for IRB members and investigators, student-led research, informed consent waivers and alterations, research involving college students who are legal minors, and data security without encryption, and more. During this session, faculty and attendees will:

- Explore and outline how to establish and maintain an effective HRPP in an institution with a small SBER program
- Identify proven strategies for engaging senior leadership, investigators, IRB members, and HRPP staff

## ICON KEY



A24

**Best Practices for Assessing Risks and Benefits in SBER** (*SBER I – Basic Track*) Moira A. Keane, Yvonne Lau, Katherine Lerner

Room 103



Basic

This session will explore the unique characteristics of SBER and best practices for evaluating the types of risks and benefits that most commonly arise. During this session, faculty will:

- Define the criteria for evaluating risk (both magnitude and probability of harm – assessing the level of risk involves taking both into account), and address whether a study is “minimal risk”
- Outline the types of risks that arise in SBER (including physical, psychological, social and economic harms), and how risks in SBER differ from the risks typically encountered in biomedical research (e.g., social and psychological risks are time and situation-specific and very subjective)
- Discuss when a SBER IRB may need to obtain outside expertise to properly evaluate risk (e.g., input on appropriate data security procedures, and SBER studies that involve the use of MRIs and other techniques more commonly associated with biomedical research)
- Review 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

**Scientific Merit, Generalizability, and Risks in Qualitative Research: A Case Study Approach** (*SBER II – Advanced Track*) Julie F. Simpson, Matthew D. Stafford

Room 202



Advanced

Using case studies, this session will provide strategies IRBs can use in assessing scientific merit, generalizability, and risk in SBER. During this session, faculty and attendees will:

- Review a quick study guide with regard to the types of qualitative research methods
- 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

3:45-4:00 PM

**Break**

Join us for coffee and cold drinks in The Conference Connection.

Hynes Hall C

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

B1

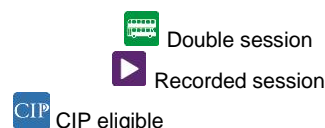
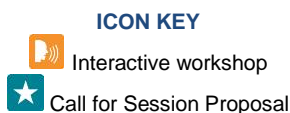
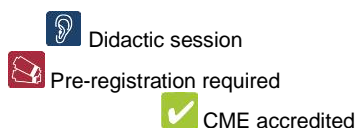
**A Dialogue with the FDA** (*A Dialogue with the Feds I Track*) Richard Klein, Joanne R. Less, Diane M. Maloney, Catherine Parker, Kevin A. Prohaska, James F. Saviola

Room 200



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



B2

**A Dialogue with SACHRP** (*A Dialogue with the Feds II*)

Jeffrey R. Botkin, David G. Forster, Julia Gayle Gorey, Michele Russell-Einhorn

This session will be led by representatives from SACHRP. Attendees are encouraged to come with questions of interest to all. During this session, 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

Room 104



B3

**Reliance Agreements** (*Advanced Forum for IRB Professionals Track*)

Jeremy J. Corsmo, Susan Z. Kornetsky

During this session, faculty will:

- Review different types of reliance agreements, including what to consider when drafting an agreement
- Discuss the responsibilities of review when relying on different sites
- Provide insight on how to educate investigators about their responsibilities when reliance agreements are used
- Address considerations of IRB infrastructure in accommodating agreements

Room 310



Advanced

B4

**Electronic Consent: A Discussion of the eConsent Experience, Ethical and Regulatory****Considerations, and IRB Review** (*Boundaries and Balance Track*) J. Andrew Bertolatus, Donna A. Messner

During this session, faculty will:

- Review the use of electronic consent using computer-based, interactive approaches, including examples of eConsent processes
- Discuss the use of “remote” consent
- Outline the regulatory requirements of IRB review and consent documentation in the context of an electronic informed consent process and the regulatory acceptability of eConsent
- Explore the potential ethical challenges of using electronic technology in streamlining the informed consent process

Room 311



B5

**Strategies for Using Empirical Research Articles for IRB Member Education**(*Educating and Training Track*) Emily E. Anderson, Joan E. Sieber

In this session, strategies will be presented 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-making. Participants will be introduced to “research on research ethics,” and shown 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). Resources available to PRIM&R members via the PRIM&R website and through a partnership with the *Journal of Empirical Research on Human Research Ethics* will be highlighted, and sample articles will be provided along with talking points and potential discussion questions. During this session, faculty and attendees will:

- Identify research articles relevant to issues commonly debated by IRBs that can be informed by empirical data
- Develop summaries of empirical research articles for IRB member educational purposes
- Develop discussion questions about empirical research articles for IRB member educational purposes

Room 110



Advanced

## ICON KEY



Didactic session



Pre-registration required



CME accredited



Interactive workshop



Call for Session Proposal



Double session



Recorded session



CIP eligible

B6

**Enhancing the Responsible Conduct of Adolescent and Young Adult Health Research through Empirical Studies on Research Ethics** (*Empirical Research Ethics Track*) Erin E. Bonar, Celia B. Fisher, Faith E. Fletcher

This session will feature presentations describing empirical studies on research ethics issues that can help IRBs evaluate human subjects protections for health research involving adolescents and young adults. The research described draws on the perspectives of adolescents and parents to illuminate opportunities and barriers to the responsible conduct of HIV, drug use, and mental health research. During this session, faculty will:

- Review how mixed-method research (surveys and interviews) can illuminate best practices for assessing risks and benefits and protecting confidentiality in mobile health-based research on drug use and sexual risk among emerging adults
- Describe how empirical data on African American mothers' and daughters' attitudes toward adolescent participation in HIV biomedical prevention trials can inform IRB evaluations of research vulnerability.
- Outline how to evaluate ethical justifications for requests to waive guardian permission using data from an innovative, web-based, asynchronous focus group methodology that examined ethical barriers and facilitators to Lesbian, gay, bisexual and transgender youth participation in HIV prevention medication adherence trials

Room 204



B7

**Ethical and Regulatory Issues in Controlled Exposure Studies** (*Ethical Issues Track*) Daniel K. Nelson, Toby L. Schonfeld

Controlled exposure studies, in which human volunteers are intentionally exposed to pollutants under controlled condition, are critically important for protecting public health, but present unique challenges for ethical review and oversight. The goal of these studies is to establish air quality standards, rather than clinical interventions, when there is no prospect of benefit to study participants. During this session, faculty will:

- Describe issues related to risk-benefit analysis of controlled exposure studies
- Detail a variety of related ethical issues, including informed consent, regulatory oversight, and compensation

Room 301



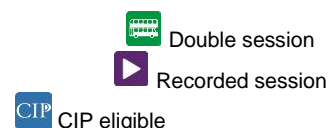
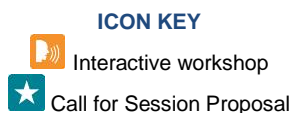
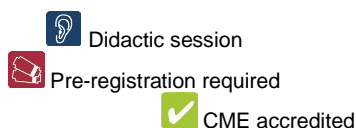
B8

**What Are Combination Products and How Are they Regulated by the FDA?** (*FDA Regulations Track*) Thinh X. Nguyen

Combination products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products. Because combination products involve components that would normally be regulated under different types of regulatory authorities, and frequently by different FDA Centers, they raise challenging regulatory, policy, and review management challenges. During this session, faculty will:

- Provide a general overview of how combination products are defined and regulated by the FDA
- Present examples of combination products and test the knowledge of what attendees learned
- Share resources for IRBs that oversee studies involving combination products

Room 202



B9

**Recruiting Marginalized, Vulnerable Populations into Health Research: Issues in International Research** (*Global Research Track*) Latifa Adarmouch, A. Cornelius Baker, Henry Silverman, Jerome A. Singh,

To ensure that marginalized, vulnerable populations have equitable access to health services, they need to be included in important health services research. Such groups include refugees, internally displaced persons, orphans, lesbians, gays, bisexuals, transgender people, sex workers, individuals with drug addiction, and others who suffer from social exclusion. Key questions include: What are the ethics of doing research with these populations when identifying them could lead to stigma or legal and political repercussions, but not doing the research can leave such populations at greater risk of health disparities? What are the risks to these populations and to investigators when a country has a poor record involving human rights? During this session, faculty and attendees will:

- Discuss the ethical issues when performing research on marginalized, vulnerable populations
- Describe how risks can be minimized
- Review the process of obtaining ethics approval

Room 313



Advanced

B10

**Clinical Research During the Ebola Epidemic: Recommendations from the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission)** (*Hot Topics Track*)

Kata L. Chillag, Elizabeth Fenton, Christine Grady

The suffering and mortality brought about by the recent Ebola epidemic in western Africa created a demand for accelerated clinical research to test experimental preventative, diagnostic, and therapeutic interventions. Conducting clinical research in the midst of an ongoing public health emergency, and in a context of poverty and limited health infrastructure, raises numerous ethical challenges. This session will present the Bioethics Commission's findings and recommendations on these complex ethical challenges from its Brief, *Ethics and Ebola: Public Health Planning and Response*, focusing on the use of placebo controls in clinical trials for experimental Ebola vaccines and treatments, and the collection, storage, and international sharing of biospecimens for future research. During this session, faculty will:

- Describe the ethical complexities of conducting research during a public health emergency
- Discuss the Bioethics Commission's recommendations on clinical research during the recent Ebola epidemic and their broader relevance for those involved in conducting or reviewing clinical research in advance of or during a public health emergency
- Address the importance of ethics preparedness for public health emergency response, including conducting clinical research

Room 309



B11

**Ethical and Operational Issues Related to Clinical Trial Billing: What Do HRPPs and IRBs Need to Consider** (*Institutional Officials and HRPP Leadership Track*) Keren R. Dunn, Scott J. Lipkin, Sujatha Sridhar

During this session, faculty will:

- Review 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

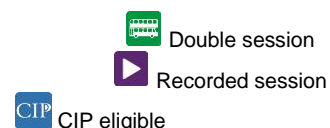
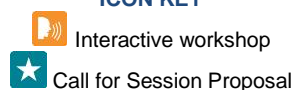
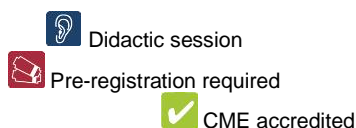
Illustrate best practices to integrate Medicare Coverage Analysis with IRB review of research

Room 101



Basic

## ICON KEY



B12

**Tools, Templates, and Checklists: Resources to Improve IRB Operations** (IRB Boot Camp Track)

Lois Brako, Sharon Freitag, Megan Kasimatis Singleton

Institutions and IRBs are often in need of new resources to help streamline the IRB application and review process and ensure all requirements for human subjects protections are appropriately addressed.

During this session faculty and attendees will:

- Go over the resources compiled in PRIM&R's Knowledge Center
- Review various types of checklists and how they can be used in the IRB review process and by investigators
- Discuss the use of templates for IRB applications, consent, and other processes
- Describe other tools, including guidance, policy documents, and standard operating procedures
- Share how IRB personnel can identify, access, and customize existing resources for use by their own IRB
- Address the shortcomings of these resources and mechanisms for avoiding over-reliance on them during implementation

Room 210



Basic

B13

**Evaluating Members, Chairs, and Staff: What Works, What Doesn't?** (IRB Chairs Track) Robert W.

Frenck, Yvonne K. Higgins

One critical aspect of managing IRB membership is the IRB member performance review process. 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 consider when evaluating IRB members and chairs? During this session, faculty will:

- Identify methods for evaluating members, chairs, and staff
- Review different types of evaluation processes in IRBs
- Provide insight on feedback systems that work and ones that don't, including strategies for using the IRB member performance appraisal process as a method for identifying member needs and increasing retention

Room 306



Advanced

B14

**Managing Subject Complaints** (IRB Operations and Toolkit Track) Stephanie Collins Reed, Ilene Frances

Wilets

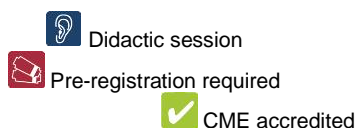
During this session, faculty and attendees will:

- Review a step-by-step process for addressing subject complaints, allegations, or questions
- Explore how to apply and adapt a standard operating procedure for managing subject complaints using case studies from biomedical and behavioral research
- Share guidance for determining the legitimacy of a complaint or allegation
- Discuss the special considerations for complaints from at-risk and marginalized study subjects

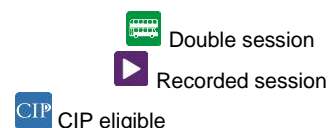
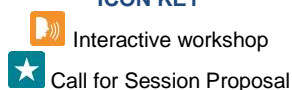
Room 109



Basic



## ICON KEY



B15

**Is Facebook Hurting Your Study? Ethical and Study Integrity Concerns When Participants Use Social Media** (*Issues Pharma/Biotech Track*) Elizabeth A. Buchanan, Lindsay McNair

With the ever-increasing use of social media, study participants are just one of many groups becoming increasingly connected online. The proliferation of interactions and opportunities for inter-subject discussions have raised concerns with researchers and research sponsors that discussion about adverse events and the perceived efficacy of investigational drugs could introduce bias in the conduct of clinical studies. Comparison of trial experiences and personal information can even lead to inadvertent or intentional unblinding during studies. During this session, faculty will:

- Discuss the benefits and challenges of study participant communication through social media platforms
- Explore implications to the study conduct and data validity when participants share study experiences
- Review specific tools and techniques for participant education, including the Center For Information and Study on Clinical Research Participation's "Speak Out, but Speak Smart" website and videos

Room 111



B16

**Certificates of Confidentiality (CoCs): When, Why, and So What?** (*Legal Track*) Ann Hardy, Julia Hesse, Leslie E. Wolf

CoCs are often an area of confusion and consternation for investigators and IRBs. Determining when a study warrants one and what the process is for obtaining one are only the first steps. Confusion and misinformation also exist as to the scope of protection offered by this document. 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 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
- Address issues and differences specific to CoCs and Privacy Certificates issued by FDA and the Department of Justice (from CoCs issued by NIH)

Room 103



Basic

B17

**Identifying Red Flags: Research Review for the Non-Scientist IRB Member** (*Non-Scientist IRB Members Track*) Michelle Feige, Nancy A. Olson, Veronica Todaro

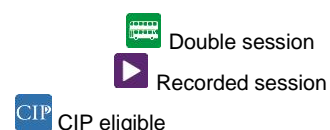
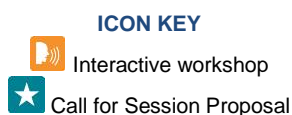
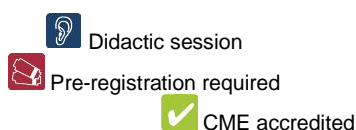
When it all sounds like Greek, how does the non-scientist IRB member know when to be concerned? This session will address the potential red flags to be aware of when reviewing a study protocol. During this session, faculty will:

- 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

Room 203



Basic



B18

**Tissue Research Now and in a Potential Post-Notice of Proposed Rulemaking (NPRM) World** (*Out-of-Body Experiences: Research Involving Tissue and Data Track*) Stacey A. Donnelly, Julie Kaneshiro, P. Pearl O'Rourke

The ability to de-identify tissue (and to some degree data) is being challenged; contributors include the explosion of genetic data, as well as the increased use of big data and the power of data aggregation. The NPRM, in fact, proposes that all biospecimens should be treated as human subjects research. What are the implications of the proposed changes for consent and waivers of consent? During this session, faculty will:

- Address the difficulty of defining identifiability
- Review the implications of considering all tissue identifiable
- Outline the various options for consent/permission
- Explore possible conditions for waiving consent
- Discuss the proposed changes in the NPRM on biospecimens in research and consent, and implications for the field

Room 302



B19

**Research With and About Gender and Sexual Diversity (GSD)** (*Populations Requiring Additional Protections Track*) Sean Cahill, John A. Guidry

This session will explore a variety of considerations and challenges when conducting research with and/or about GSD. During this session, faculty will:

- Examine the special considerations study teams should address when designing a study involving individuals across the spectrum of GSD
- Discuss complex issues such as how to assure confidentiality, balancing concerns about stigma, and avoiding pathologizing
- Outline additional risks such as violence, discrimination, depression, and suicide
- Explore unique considerations particular to recruiting and maintaining contact with subjects from these populations

Room 206



B20

**It's Here! A Review of the Notice of Proposed Rulemaking (NPRM)** (*Hot Topics Track*) John R. Baumann, Katherine Gallin Heffernan, Andrew Ruscsek,

A NPRM has been released, and it is important for researchers, institutions, IRBs, and other stakeholders involved in research to have an awareness of the proposed changes and their potential implications for the field. During this session, faculty will:

- Review the history of human subjects protections regulations in the US leading up to the NPRM
- Outline key proposals from the NPRM
- Provide commentary on the implications of those proposals if adopted
- Address how to review and submit comments on the NPRM

Room 312



B21

**Nuts and Bolts of Assessing IRB Compliance** (*QA/QI and Post-Approval Monitoring Track*) Lisa Buchanan, Susan A. Corl, Lisa Denney

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:

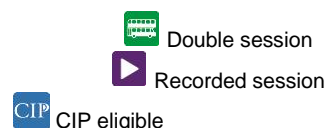
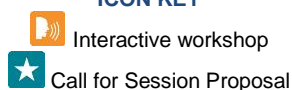
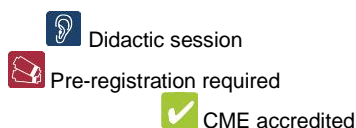
- Provide considerations and mechanics for QA/QI review of IRB files, meeting minutes, and membership composition
- Identify triggers that may prompt QA of the IRB
- Discuss approaches to self-auditing HRPP offices, including techniques and timing
- Review training approaches for QA/QI staff conducting QA of the IRB
- Outline corrective and preventive actions that can be used to address IRB noncompliance

Room 308



Basic

## ICON KEY



B22

**The Internet and the IRB: A Review of Human Subjects Issues in Technology-Based Research***(Research Involving the Internet and Social Networking Track) Brenda Curtis, Abby E. Rudolph*

Human subjects research that uses technology-based interventions (TBIs) have been increasing steadily. TBIs constitute research delivered via computer, internet, or mobile devices, and many of these interventions involve social networking sites either at the recruitment or intervention delivery phase of research. In addition, researchers are developing their own smartphone apps that include location-based technologies. This session will update participants on recent forms of TBI research and the attitudes and perspectives of research participants with regard to technology. Discussion will focus on IRB review of three major areas of ethics concern: privacy and confidentiality, informed consent, and validity of data collected in general and in research on socially and legally sensitive areas. Participants will discuss specific case examples of TBIs. During this session, faculty and attendees will:

- Review human subjects research that uses TBIs and the specific challenges this presents for privacy and confidentiality, informed consent, and validity of data collected
- Share guidelines and strategies for protecting privacy and confidentiality, providing adequate consent information, and validating the nature of data collected
- Explore how to develop IRB decisional strategies for reviewing research utilizing TBIs

Room 304



Advanced

B23

**Tactical and Strategic Planning for Small IRBs***(Small Research Programs Track) Parker Nolen, Dale E. Theobald*

Using concepts grounded in strategic management theory, and real-life examples of IRB transformations, this session will provide small IRBs with tips and tools on how to make the local IRB a legitimate option to sponsors. This topic is intended not only for hospital- or clinic-based IRBs, but also academic centers who still struggle with meeting or exceeding performance metrics of commercial IRBs. During this session, faculty and attendees will:

- Identify key elements that impact IRB efficiency
- Review cost and revenue curves and ways to maximize revenue while minimizing cost (i.e., measure the economic cost/benefit of the IRB to the organization)
- Share potential strategic opportunities for positioning your local IRB as economically viable and competitively advantageous

Room 107



B24

**Data Streams, Behavioral Research, and Public Health***(SBER I – Basic Track) Camille Nebeker, Matthew D. Stafford*

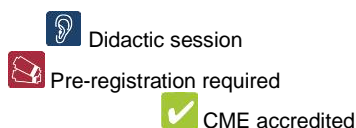
This session will provide an overview of emerging public health research and the ways in which social media, mobile applications, and big data technologies are being employed. During this session, faculty will:

- Discuss the different types social media, mobile applications, surveillance tools, and big data technologies, how they're being used in public health research, and the challenges they pose to the IRB
- Describe different approaches to intervention research via ambulatory assessment methodologies
- Review the ethical concerns around privacy and risks as it relates to public health research and the use of new technologies

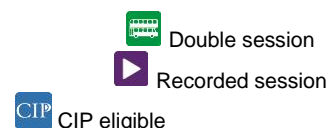
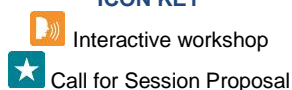
Room 108



Basic



## ICON KEY



B25

**IRB Revolt: Navigating and Negotiating Undergraduate Human Subjects Research Projects**

(SBER II – Advanced Track) Rebecca D. Armstrong, Leah A. Carroll

At many institutions, undergraduate students learn how to conduct research, and their first forays into the field often involve going back to their home communities and experiences in life. In areas where students come from underrepresented or marginalized groups, some very risky research projects are proposed. During this session, faculty will:

- Describe the process in terms of players involved – individuals and their offices – in negotiating a resolution to the IRB/undergraduate researcher crisis
- Identify and share strategies developed by an IRB, IRB staff, and an undergraduate research office (URO) to facilitate undergraduate human subjects research projects to better ensure the protection of research subjects
- Share lessons learned by an IRB and an URO
- Review a university's continuous improvement of interaction in support of undergraduate investigators conducting human subjects research

Room 102

    
Advanced

B26

**A Dialogue with the Department of Commerce (DOC) Human Subjects Protection Office: The National Institute of Standards and Technology (NIST) Is Leading the Effort**

(A Dialogue with the Feds II Track) Anne M. Andrews, Laura A. Baxter, Linda Beth Schilling

NIST is the primary agency within the DOC conducting human subjects research. NIST continues to develop intramural, extramural, and collaborative research efforts in the area of human subjects research. During this session, attendees will:

- Learn about evolving initiatives, issues, and guidance from NIST regarding their new Human Subjects Protection Office
- Review specific requirements involved in conducting DOC/NIST sponsored research
- Discuss best practices for collaborating with DOC/NIST

Room 305

5:15-6:30 PM

**2015 AER Welcome Reception with the Supporters and Exhibitors**

Join us in The Conference Connection to celebrate the opening of the 2015 AER Conference. During this time, you'll be able to meet our conference Supporters and Exhibitors, view the Poster Presentations, and receive a complimentary mini-massage. Light refreshments will be served.

Exhibit Hall C




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 Boston at the Back Bay Social Club, located on Boylston Street across the street from The Hynes Convention Center. Don't forget to bring the drink ticket you received with your registration materials! While all attendees are welcome, complimentary drink tickets are reserved for young professional registrants.

Back Bay Social Club

**ICON KEY**

 Didactic session  
 Pre-registration required  
 CME accredited

 Interactive workshop  
 Call for Session Proposal

 Double session  
 Recorded session  
 CIP eligible

# Saturday, November 14: 2015 AER Conference

7:00 AM

## Registration Opens

Breakfast on your own. Coffee only will be served in The Conference Connection in Exhibit Hall C.

Pre-function Hall C

7:00-8:00 AM

## Certified IRB Professional (CIP®) Continental Breakfast

Interested in earning your [CIP credential](#)? Want to connect with other CIPs? Attend this continental breakfast to learn more about the credential, meet representatives of the Council for Certification of IRB Professionals, network with fellow CIPs, and ask questions of those already certified. Pre-registration is required for this event. Please [register online](#) or [email us](#).

Ballroom A



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*

Veterans Memorial  
Auditorium



8:15-8:30 AM

## Presentation of PRIM&R's ARENA Legacy Award to Karen N. Hale, RPh, MPH, CIP, Director, Office of Responsible Research Practices, The Ohio State University

*Presented by Elisa A. Hurley, PhD, Executive Director, PRIM&R*

Veterans Memorial  
Auditorium



8:15-8:30 AM

## Presentation of the Pillars of PRIM&R Award to Francis Kombe, MPH, Senior Community Facilitator, Kenya Medical Research Institute (KEMRI), Kenya

*Presented by Elisa A. Hurley, PhD, Executive Director, PRIM&R*

Veterans Memorial  
Auditorium



8:30-9:15 AM

## Keynote Address: Big Data and Human Subjects

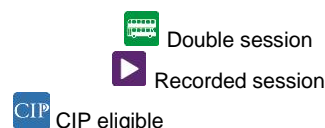
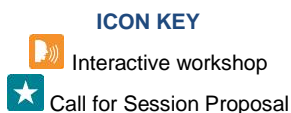
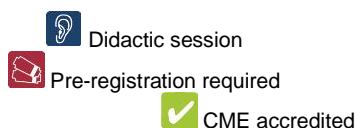
[Sendhil Mullainathan, PhD](#), Professor of Economics, Harvard University

Veterans Memorial  
Auditorium



9:15-9:30 AM

## Break



# Saturday, November 14: 2015 AER Conference

Concurrent Plenary Sessions, 9:30-10:45 AM

## Panel IV: Picked Out of a Crowd: Privacy and Re-Identification Research

Veterans Memorial Auditorium



**Moderator:** *Laura Odwazny*

**Panelists:** *Jim Adler, Madeleine Price Ball, Michelle N. Meyer*

Some research protocols are designed to explore the limits of existing privacy and confidentiality protections; in particular, research attempting to re-identify supposedly de-identified data sets. These "proof of concept" projects involve re-identification risks to living individuals. What kinds of research are being conducted, and what are the ethical and regulatory issues presented by such research proposals? How should the IRB consider the risk-benefit calculus for research designed to identify an individual who may have no reason to believe that such re-identification is possible? Should subjects' expectations of privacy be managed to acknowledge this possibility? If significant vulnerabilities that might be very difficult to correct are discovered, how should they be publicized, if at all? What obligations should be placed on the researchers conducting such research, and who should be responsible for any resulting harms to subjects? The panelists will examine the ethical tensions raised by re-identification research and share their perspectives as to how researchers and IRBs should address the relevant concerns.

## Panel V: Editing the Human Germline: The Promise and the Peril

**Moderator:** *Carol Juliet Weil*

**Panelists:** *Misha Angrist, Joanna Smolenski*

The human genome harbors the building blocks for all human inherited traits, as well as the formulas for creating life. However, what if something goes wrong? Can it be fixed? Scientists have developed gene editing technology with the goal of changing mutated genetic segments to prevent or treat disease. A remarkable new technology for gene editing, called CRISPR/Cas9, is so simple and cost-effective that researchers say human trials to fix genetic conditions could be just a few years away. However, editing the genome, particularly germline editing, would have profound implications for the future of humanity and the planet. Given the ethical concerns gene editing techniques raise, in March 2015, scientists called for a moratorium on germline editing in *Nature* saying, "scientists should agree not to modify the DNA of human reproductive cells" because it "could have unpredictable effects on future generations." This session will explore the ethical challenges associated with research involving germline editing, including public engagement versus self-regulation in setting scientific priorities, and distributive justice between generations (benefits to current persons versus unknown risks to future populations). This session will also consider the relative risks and benefits of proceeding with research involving modification of the human germline, including clinical and therapeutic applications of gene editing technologies.

Ballroom C



## Panel VI: Presenting Risks and Potential Benefits to Prospective Human Subjects

**Moderator:** *Ivor A. Pritchard*

**Panelists:** *Scott Y. H. Kim, Lynn A. Jansen, Alan R. Tait*

Enormous attention is paid to what will be disclosed to prospective subjects as the risks of participating in research studies, while what is disclosed as the potential benefits of research generally receives less attention. The concern is about how these disclosures may influence prospective subjects' decisions about whether to participate in research. At the same time, some researchers and others in the field worry these disclosures may serve to exaggerate the risks of research and impede enrollment. This session will consider how the risks and potential benefits of research are identified (e.g., What counts as risks or potential benefits of research? How should we decide, for example, whether compensation or feelings of altruism due to participation should be included?), and explore how people understand information about risks and potential benefits of research.

Ballroom B



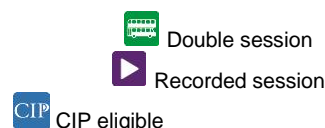
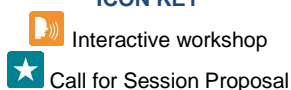
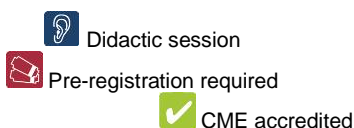
11:00 -11:15 AM

### Break

Join us for coffee in The Conference Connection.

Exhibit Hall C

### ICON KEY



C1

### A Dialogue with Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) (A Dialogue with the Feds I Track) Elizabeth Fenton, Nicolle Strand

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

- Hear about the Bioethics Commission's latest work
- Review topics relevant to Bioethics Commission stakeholders, including: the Bioethics Commission's recent recommendations concerning (i) ethical challenges of the public health response to the Ebola epidemic (including research ethics challenges) and ethics preparedness for future public health emergencies, and (ii) topics at the intersection of neuroscience, ethics, and society, including research with participants with diminished consent capacity; the Bioethics Commission's current project on deliberation and bioethics education; and new Bioethics Commission educational materials
- Participate in a question and answer session with Bioethics Commission staff

Room 200



C2

### A Dialogue with the Office for Research Integrity (ORI) (A Dialogue with the Feds II Track) Kristen Grace, Loc Nguyen-Khoa

This session will be led by representatives from ORI. Attendees are encouraged to come with questions of interest to all. During this session, attendees will:

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

Please note this is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please [register online](#) or [email us](#). Please use the ticket included on your name badge to get your boxed lunch in Exhibit Hall D before the session.

Room 107



C3

### Conflicted About Conflicts of Interest (COIs): When IRBs Don't Know About or Disagree with Investigator COI Management Plans (Advanced Forum for IRB Professionals Track) Raed A. Dweik, Katherine Gallin Heffernan, Lynn E. Smith

During this session, faculty will:

- Review several models of communication channels between the IRB and the COI committee from academic institutions
- Discuss the timing of COI determinations and IRB reviews
- Address what an institution can do when the committee actions are not timed or structured to facilitate timely communication
- Using case studies, explore methods of resolving disagreements between determinations of the COI office and concerns about potential conflicts raised by IRBs

Room 104



C4

### The Flexible IRB: Finding and Applying Flexibility in the Federal Regulations and Beyond

(Boundaries and Balance Track) Rebecca Dahl, Martha F. Jones, Irene E. Stith-Coleman

This session will explore various procedures that incorporate flexibilities within the regulations while providing equivalent protections to research subjects in both biomedical and behavior/social science research. During this session, faculty and attendees will:

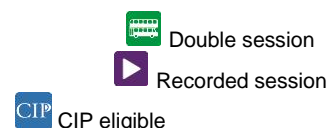
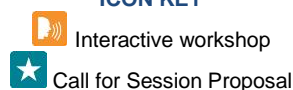
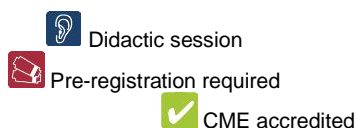
- Review the flexibilities in the regulations related to exemptions and expedited review
- Examine the issues related to consent, as well as issues around assent, parental permission, and documentation of assent/permission
- Describe what a flexible IRB model is
- List the pros and cons of the flexible IRB model compared to the more traditional IRB models
- Provide implementation considerations for the flex IRB model

Please note this is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please [register online](#) or [email us](#). Please use the ticket included on your name badge to get your boxed lunch in Exhibit Hall D before the session.

Room 312



#### ICON KEY



C5

**Evidence-Based Ethical Problem Solving** (Educating and Training Track) Emily E. Anderson, Amy Corneli, Toby L. Schonfeld, Joan E. Sieber

Evidence-based ethical problem solving is increasingly recognized as a means for enhancing the ethical design of human research. However, determining whether the answer to a research question would be helpful to a broader audience can be difficult. What conversations should you have to identify the usefulness of answering a research question? Who should you talk to? During the first part of this session, associate editors of the *Journal of Empirical Research on Human Research Ethics*, will use case examples to provide an overview of empirical ethics research methods and approaches. During the second part of the session, attendees will have an opportunity to share their own ideas for research questions or projects in various stages of implementation. During this session, faculty and attendees will:

- Outline a process for identifying and developing an empirical research study on research ethics
- Identify methods and designs for conducting empirical research on research ethics
- Describe how findings from such studies can be used to inform evidenced-based decisions on ethical issues
- Discuss ideas for research questions and projects and ways to move these projects forward

Please note this is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please [register online](#) or [email us](#). Please use the ticket included on your name badge to get your boxed lunch in Exhibit Hall D before the session.

Room 308



C6

**How to Be an Informed Consumer of Data on Research Subjects' Understanding**

(Empirical Research Ethics Track) Scott Y. H. Kim, Rebecca D. Pentz, Kevin P. Weinfurt

Data from interviews and surveys are often cited as evidence of the ubiquity of the therapeutic misconception and, therefore, of the poor quality of informed consent. However, there are several conceptual and methodological complexities that make it difficult to conclude that a research participant labors under a therapeutic misconception. This session will provide attendees with important tools for dissecting the empirical literature (or designing studies) on how well research participants understand the various elements of informed consent. During this session, faculty will:

- Discuss main points from the literature on how well research participants understand elements of informed consent
- Address the strengths and limitations of research on "therapeutic misconception"
- Review the main validity issues to consider when reading research (or designing studies) on research subjects' understanding

Room 110



C7

**Pulling the Plug on Psych Student Pools: Should they be Abolished?** (Ethical Issues Track)

Andrew Hedrick, Ivor A. Pritchard

Many colleges and universities have established research pools of introductory-level psychology students to participate in research studies. This session will consider the pros and cons of such pools, and ask the question of whether such pools should be abolished. During this session, faculty and attendees will:

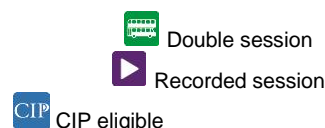
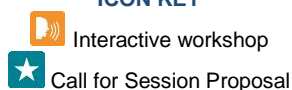
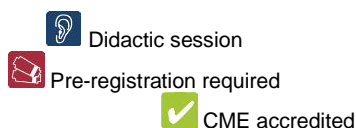
- Briefly review the regulatory requirements that must be met by student research pools
- Discuss what features make some research pools better than others
- Debate whether research pools should be abolished in favor of alternative recruitment strategies

Room 101



Advanced

### ICON KEY



C8

### 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 particular study. 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, and if 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 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
- Share resources and guidance to assist IRBs who struggle with understanding when an IND might be needed

Room 302



Basic

C9

### Determining the Effectiveness of Community Engagement in Global Health Research

(Global Research Track) Edward E. Bartlett, David A. Borasky, Regina Kamene Owino, Steven Wakefield

Community engagement has been recognized as an important ethical requirement for global health research. Various models have been used by researchers to engage with communities. However, challenges remain with determining the effectiveness of various models/strategies for engaging communities. During this session, faculty and attendees will:

- Examine the value and science of community engagement in global health research
- Share practical examples of community engagement models based on experience, including what works, best practices, and challenges
- Elicit information about models and best practices in community engagement in research sites from session participants
- Review the various ways of evaluating the effectiveness of community engagement including, what works and the way forward

Please note this is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please [register online](#) or [email us](#). Please use the ticket included on your name badge to get your boxed lunch in Exhibit Hall D before the session.

Room 301



C10

### The Certified IRB Professional (CIP®) Credential: What's it About? (Potpourri 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 or provide exam preparation

Room 109



Saturday, November 14

#### ICON KEY



Didactic session



Pre-registration required



CME accredited



Interactive workshop



Call for Session Proposal



Double session



Recorded session



CIP eligible

C11

**Understanding the Elements of a Strong Compliance Program** (*Institutional Officials and HRP Leadership Track*) Wesley G. Byerly, F. Lisa Murtha

During this session, faculty will:

- Identify the key components and characteristics of a strong compliance program
- Discuss the challenges of day-to-day operations of such a compliance program
- Outline compliance program performance metrics

Room 210



C12

**Let's Review a Protocol: Regulatory Considerations in the IRB Review Process** (*IRB Boot Camp Track*) Yvonne Lau, Judy Matuk, Cheryl A. Savini

This interactive session aims to assist IRB members, chairs, and staff 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 must be addressed during the review process. During this session, faculty and attendees will:

- Review the definitions of human subjects research found in the DHHS and FDA regulations to determine if IRB review is required
- Discuss the federally mandated exemption categories and understand how to apply them
- Use case examples to walk through the regulatory considerations required for protocols reviewed using the expedited mechanism or via convened IRB review

Room 306



Basic

C13

**IRB Chairs Forum: A Structured Discussion for Experienced IRB Chairs** (*IRB Chairs Track*) Robert W. French, Elizabeth L. Hohmann, R. Peter Iafrate, C. Eglar Rabinovich

Given that it can be difficult to find venues where experienced 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
- Participate in topic development for future IRB chairs offerings

Please note this is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please [register online](#) or [email us](#). Please use the ticket included on your name badge to get your boxed lunch in Exhibit Hall D before the session.

Room 304



Advanced

## Saturday, November 14

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

### ICON KEY



Didactic session



Pre-registration required



CME accredited



Interactive workshop



Call for Session Proposal



Double session



Recorded session



CIP eligible

C14

### Operationalizing Collaborative IRB Review (IRB Operations and Toolkit Track) Jeanette Bailey, Paula Bistak, Tracy A. Ziolek

In light of the recent draft NIH policy, which would require use of a single IRB of record for multi-site NIH funded research, many institutions are proactively 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. During this session, faculty 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

Room 313



Advanced

C15

### Assessing Phase I/First-in-Human Pediatric Studies Under Subpart D (Issues Pharma/Biotech Track) Hal Landy, Michelle Roth-Cline, David A. Williams

Pediatric studies must be approved under the Additional Safeguards for Children, 45 CFR 46 and 21 CFR 50 Subpart D of the DHHS/FDA regulations. According to these regulations, interventions presenting more than minimal risk must hold out a prospect of direct benefit to pediatric subjects. This session will discuss approaches to IRB review of early phase I/first-in-human pediatric research. During this session, faculty and attendees will:

- Examine the issue of assessing prospect of direct benefit if adult human studies are absent or limited
- Discuss the circumstances under which data from animal models may contribute to determinations regarding prospect of direct benefit and risk assessment
- Outline frequently encountered concerns in first-in-pediatric study design, including dose selection, endpoint development, and nontherapeutic interventions and procedures

Please note this is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please [register online](#) or [email us](#). Please use the ticket included on your name badge to get your boxed lunch in Exhibit Hall D before the session.

Room 103



Advanced

C16

### When it Happens to You: Identifying and Managing Privacy Breaches in Research (Legal Track) Lisa A. Griffin, Christina Heide, Susie R. Hoffman, Susan Stayn

When a privacy or data security incident occurs in research, it may trigger reporting obligations under the Health Insurance Portability and Accountability Act (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. During this session, faculty and attendees will:

- Review how HIPAA applies in the conduct of research
- Discuss the various legal and regulatory requirements applicable to privacy/security incidents
- Work through 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
- Explore data security risks and best practices

Please note this is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please [register online](#) or [email us](#). Please use the ticket included on your name badge to get your boxed lunch in Exhibit Hall D before the session.

Room 102



Basic

## Saturday, November 14

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

#### ICON KEY



Didactic session



Pre-registration required



CME accredited



Interactive workshop



Call for Session Proposal



Double session



Recorded session



CIP eligible

C17

**Statistics Without Tears** (Non-Scientist IRB Members Track) Susan S. Fish, Janice Weinberg

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:

- Review the basic concepts of testing
- Discuss different ways to be right and wrong (e.g., type 1 and type 2 errors)
- Review the concept of "power," the types of statistical tests, and when to bring in a statistician
- Explore the relationship between statistics and ethics
- Learn how to apply statistical vocabulary

Please note this is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please [register online](#) or [email us](#). Please use the ticket included on your name badge to get your boxed lunch in Exhibit Hall D before the session.

Room 202



C18

**Ethical, Regulatory, and Practical Challenges in the Use of Legacy Collections** (Out-of-Body Experiences: Research Involving Tissue and Data Track) Ty Hoover, Megan C. Morash, William E. Grizzle, Carol Juliet Weil, TBD

Specimens that have been collected for specific research projects or clinical trials in the past may be useful for additional research projects not originally envisioned at the time the specimens were collected. When is it acceptable to permit the use of specimens that were originally not described in the initial informed consent? How does one decide when the initial consent is adequate or when a new consent is required? During this session, faculty and will:

- Explore the ethical, regulatory, and practical challenges in the use of legacy collections for additional research purposes
- Discuss strategies for addressing these challenges
- Share examples of how researchers and institutions are addressing these challenges

Please note this is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please [register online](#) or [email us](#). Please use the ticket included on your name badge to get your boxed lunch in Exhibit Hall D before the session.

Room 203



C19

**Resilience and Reciprocity: What Mindful Research Looks Like** (Populations Requiring Additional Protections Track) John A. Guidry, Cynthia R. Pearson, Amy Terpstra

The intent of research is to help, not harm; yet, research has the ability to covertly harm already stigmatized groups or groups with low social standing. IRBs are trained to minimize the physical, emotional, and social risks to individual subjects involved in research studies and so, IRBs, in reviewing research, must also weigh studies' potential pathologizing effects for entire social groups. During this session, faculty and attendees will:

- Identify examples of bodies of research that have served to pathologize specific groups of people
- Review the ethical principles that guide concern for how research shapes or reinforces stereotypes
- Explore how researchers and IRBs can be mindful of how each phase of a study, from question formulation to dissemination of findings, represents an opportunity to ensure that consideration is also given to the resiliency and strengths of stigmatized groups

Please note this is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please [register online](#) or [email us](#). Please use the ticket included on your name badge to get your boxed lunch in Exhibit Hall D before the session.

Room 204

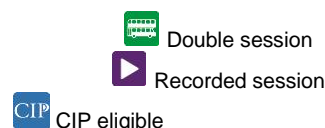
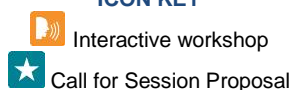
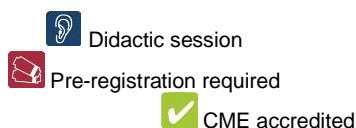


Advanced

Saturday, November 14

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

## ICON KEY



C20

**The Uncomfortable Conversation: Talking About Diversity** (Potpourri Track) Eric Allen, Donna H. Eaton, Dorothea Love Hall

Room 108



The issue of diversity is not directly addressed in the federal regulations governing human subjects research, although it is referenced in the Belmont Report. Nevertheless, IRB professionals have opportunities to consider issues of diversity during the protocol review process, development of policies and procedures, investigator training, and the like. During this session, faculty and attendees will:

- Discuss how IRB professionals can ensure the issue of diversity is adequately addressed during protocol review
- Review how to develop policies and procedures that support diversity when there are no clearly defined federal regulations
- Share strategies on how to encourage investigators to recruit diverse subject populations when resources are short

Please note this is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please [register online](#) or [email us](#). Please use the ticket included on your name badge to get your boxed lunch in Exhibit Hall D before the session.

C21

**Novel Methods, Approaches, and Tools for QA/QI, Including Electronic Systems and Technology** (QA/QI and Post-Approval Monitoring Track) Jeffrey A. Cooper, Michele Gomez, Elizabeth Tioupine

Room 309



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 site 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:

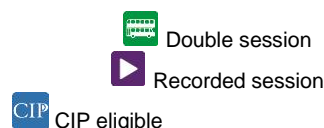
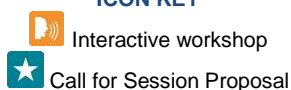
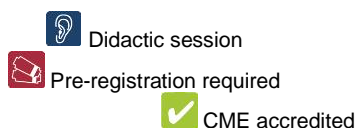
- Learn how to create reports and perform analyses (even simply using Excel) to better target concerning areas, identify data entry errors or omissions, and implement process improvement strategies
- Explore how to use reports for quality assurance IRB submission processing, for identifying staff errors, 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

Please note this is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please [register online](#) or [email us](#). Please use the ticket included on your name badge to get your boxed lunch in Exhibit Hall D before the session.

## Saturday, November 14

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

#### ICON KEY



C22

**Mobile Health (mHealth) Applications: Best Practices for IRBs** (Research Involving the Internet and Social Networking Track) *Jeremy Block, Linda Rogers*

In the past year, an uptick in mHealth applications are in use throughout the US, with many more to come. This session will discuss the challenges these applications pose IRBs who review them, as well as best practices that will allow IRBs to be forward-leaning to meet these new challenges. During this session, faculty will:

- Describe problems that can now be solved through emergent properties of mobile technology used in research
- Review some of the unique issues surrounding security, confidentiality, and privacy, and the risks central to research tasks using a mobile device
- Identify best practices for IRB review of mHealth applications submitted to the IRB, including what to ask for and what to tell researchers to provide

Room 310



Basic

C23

**Flying Solo: A Moderated Discussion on Challenges Encountered by Single Staff IRB Offices**

(Small Research Programs Track) *Ann Morrison, Amy Nolan*

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 resources to support staff in single staff offices
- Network with others from similar programs

Please note this is a double session and will end at 1:45 PM. Pre-registration for this session is required. Please [register online](#) or [email us](#). Please use the ticket included on your name badge to get your boxed lunch in Exhibit Hall D before the session.

Room 111



C24

**Speed it Up: Exempt, Expedite, Relax!** (SBER I – Basic Track) *Kristina C. Borrer, Jeffrey M. Cohen, Dean R. Gallant*

During this session, faculty and attendees will:

- Discuss the procedural sequence process for review of SBER
- Use case vignettes to test the review process and classification system
- Identify flexibility in the regulations consistent with ethical research
- Share strategies for how to make the decision between exempt and expedited

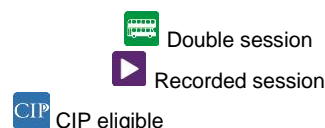
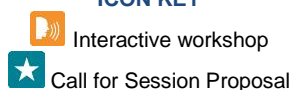
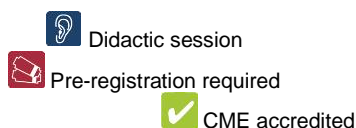
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Room 206



Basic

#### ICON KEY



C25

### Is That Illegal? Developing Best Practices for IRB Review of Research Investigating Illegal Behaviors (SBER II – Advanced Track) Celia B. Fisher, Leonard Glantz

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, institutions—to risks and harms to personal well-being, social standing, and legal culpability. Inasmuch as human research protections professionals have the obligation to ensure minimization of risks in human subjects research, such professionals should develop and implement best practices for reviewing scientifically valid research involving illegal/illicit behaviors. During this session, faculty will:

- Review the definitions of “illegal” and “illicit” as they apply to human research protections within particular jurisdictions
- Identify the nature, severity, and probability of risks inherent to research of illegal/illicit behaviors
- Share best practices for meliorating risks in study design and conducting IRB review of study protocols

Room 311



Advanced

C26

### A Dialogue with the OIG (A Dialogue with the Feds II Track)

Chris Galvin, Elizabeth M. Havener, Kimberly A. Ruppert

This session will be led by representatives from OIG. Attendees are encouraged to come with questions of interest to all. During this session, attendees will:

- Receive an overview of OIG’s structure and initiatives
- Learn about OIG’s evaluation work related to oversight of human subjects protections
- Ask questions of OIG representatives

Room 305



12:45-1:45 PM

Lunch

Exhibit Hall D

## Didactic Sessions and Workshops Series D, 2:00-3:15 PM

D1

### A Dialogue with OHRP (A Dialogue with the Feds I Track) Lisa Buchanan, Julie Kaneshiro, Yvonne Lau, Jerry Menikoff, Irene E. 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, 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

Room 313



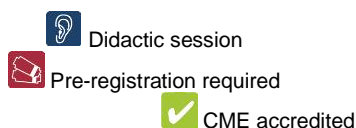
D2

### A Dialogue with the National Science Foundation (NSF) (A Dialogue with the Feds II Track) Jeffrey W. Mantz

This session will be led by a representative from NSF. Attendees are encouraged to come with questions of interest to all. During this session, attendees will:

- Hear from a NSF representative about evolving issues, initiatives, and guidance
- Participate in an open discussion of topics relevant to NSF stakeholders
- Ask questions of a NSF representative

Room 109

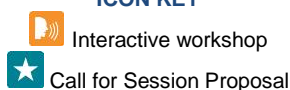


Didactic session

Pre-registration required

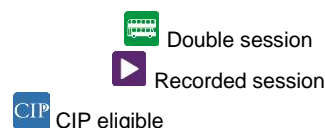
CME accredited

#### ICON KEY



Interactive workshop

Call for Session Proposal



Double session

Recorded session

CIP eligible

D3

**Research With the Seriously Mentally Ill: Optimizing Benefit and Minimizing Risk** (Advanced Forum for IRB Professionals Track) David H. Strauss

The review of research with psychiatric patients with serious mental illness, those with and without impaired consent capacity, requires an IRB to identify risks and susceptibilities to risk uniquely associated with these disorders and the settings in which these subjects are recruited. As some populations may demonstrate multiple vulnerabilities (socio-economic, cognitive, etc.), careful review of recruitment strategies, research design, inclusion and inclusion criteria, monitoring plans, exit criteria, etc., is necessary to safeguard subject rights and welfare. This case-based workshop will describe conceptual strategies and practical tools for IRB review of research with serious mentally ill. During this session, faculty and attendees will:

- Review the characteristics of psychiatric disorders that confer susceptibility to risk in the research setting
- Identify opportunities to minimize risk during protocol review, using monitoring and by enhancing consent
- Consider the broader justification for protectionism in IRB review

Room 308



Advanced

D4

**IRB Oversight and the Boundaries Between Evidence-Based Practice (EBP), Performance Improvement, and Research** (Boundaries and Balance Track) Judy E. Davidson, Hugh H. Tilson

Clinical practice may be advanced through EBP change, performance improvement, or novel research. IRB review is indicated for novel research, but at times project leaders seek IRB approval solely for the purpose of potential publication, and this increases the workload of IRB staff and members. 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

Room 312



Advanced

D5

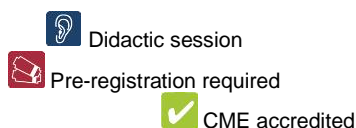
**Training for Success: Tools and Educational Methods for IRB Staff** (Educating and Training Track)

Sarah Fowler-Dixon, Martha F. Jones, Jeanne Velders

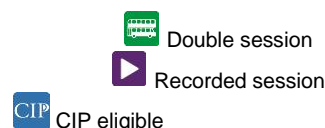
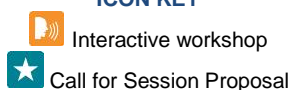
Regardless of the size and complexity of your office, IRB intensive staff training using formal training manuals can improve the functionality and morale of the work environment by empowering staff to become experts in the field of human subjects protections. These training manuals are important in that 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

Room 306



### ICON KEY



D6

### Using Empirical Evidence to Reduce Consent Form Length (Empirical Research Ethics Track)

Amy Corneli

Research has repeatedly demonstrated that study participants often do not fully understand the research in which they are enrolled. The length of informed consent forms is a contributing factor. Long consent forms remain commonplace in clinical research, yet they can negatively affect potential participant's understanding of research, as well as contribute to a time-consuming enrollment process. The Effective Delivery of Informed Consent study is partnering with the HIV Prevention Trials Network to conduct multi-phased, consensus-building research with key stakeholders to identify barriers to and strategies for reducing the length of informed consent forms. At the 2014 AER Conference, preliminary data from the initial key stakeholder interviews on the barriers to reducing the length of consent forms was presented. Data from the follow-up interviews with key stakeholders on the strategies for reducing consent form length will now be provided. During this session, faculty will:

- Describe specific strategies for reducing consent form length that were identified by key stakeholders in the initial interviews
- Review strategies that were supported and non-supported by key stakeholders through the consensus-building follow-up interviews
- Examine shortened consent form language

Room 200



D7

### Ethical Issues in Community-Based Participatory Research (CBPR) (Ethical Issues Track) Regina

Kamene Owino, Terry J.M. Powell, Steven Wakefield

CBPR proposes an engaged, respectful approach to research that envisions study participants as co-researchers, rather than subjects. This session will explore the ethical issues that arise in the design and conduct of CBPR in a variety of settings. During this session, faculty will:

- Present an overview of the ethical principles and practices on which CBPR is based
- Highlight real-life ethical conflicts and their resolution in the context of CBPR

Room 107



D8

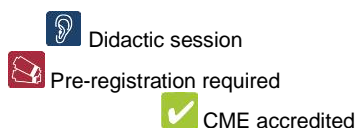
### FDA Inspections of Radioactive Drug Research Committees (RDRCs) (FDA Regulations Track)

Catherine Parker, Kevin A. Prohaska

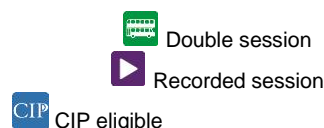
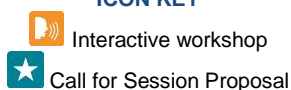
The FDA has regulations explaining when radioactive drugs for basic science and medical research in humans is generally recognized as safe and effective, and is therefore not subject to the same requirements for investigational use as other new drugs. Under these regulations, human research using a radioactive drug or biologic product may be conducted without an Investigational New Drug application under an FDA approved RDRC, but only when that research is basic science research and not research that is intended for immediate therapeutic, diagnostic, or similar purposes, or to determine the safety and effectiveness of the radioactive product for such purposes. FDA conducts periodic reviews of approved RDRCs by looking at committees' annual reports, minutes, and full protocols for certain studies, and through onsite inspections. During this session, faculty will:

- Present a general overview of RDRC responsibilities
- Review the FDA Bioresearch Monitoring RDRC onsite inspection program, including information about what to expect during an inspection
- Share information about where you can find FDA resources on RDRCs
- Provide general tips to help promote a smooth RDRC-IRB working relationship

Room 301



#### ICON KEY



D9

**The Ethics of Genomic Research in International Settings** (*Global Research Track*) Marianna J. Bledsoe, Mark A. Rothstein, Aminu A. Yakubu

Room 310



Advanced

Genomic research presents a range of regulatory and ethical issues related to the collection, export, storage, and reuse of human biological samples, the establishment of biorepositories, and the consent requirements for each of these. This session will focus on the regulatory and ethical issues arising in the conduct of genomic research in an international research setting, using the Human Heredity and Health in Africa initiative (H3Africa) as an example. During this session, faculty will:

- Discuss key regulatory and ethical issues arising in the conduct of international genomic research, sharing experiences from the H3Africa project, including broad consent and re-consent for future uses of samples and feedback of findings (including what to do with incidental findings)
- Examine the rationale and guidelines for storage of biospecimens and data gathering/sharing practices; how access is controlled among multiple sites spread internationally; policies for the sharing of specimens across institutions and countries; and guidelines for biobanks in different countries
- Outline examples/models of data and sample access committees, including the committee's roles and responsibilities and who is able to analyze the data
- Review the role of IRBs and research ethics committees in international collaborative genomic research

D10

**Addressing Ethical Challenges for Enrolling At-Risk Adolescents in Research** (*Hot Topics Track*)

Tamara E. Baer, Leslie Meltzer Henry, Frances E. Jensen, Seema Shah

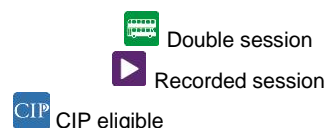
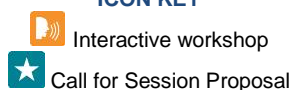
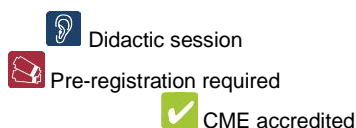
Room 110



In research involving adolescents engaged in risky behaviors, such as HIV prevention research and research on drug addiction, obtaining consent/permission for research participation is challenging for at least two reasons: (1) adolescents may not be developmentally capable of making sound decisions regarding research participation, and (2) whether existing regulations permit adolescents to consent for themselves is unclear. Department of Health and Human Services regulations governing research allow for waiver of parental permission in some cases (though FDA regulations do not), and both sets of regulations do defer to state laws to determine when an individual can consent on her own behalf. Although the standard age of majority is 18, some states have mature minor laws that permit adolescents to consent to treatment when parental permission might serve as a deterrent to seeking treatment (such as abortion, drug abuse treatment, and treatment for sexually transmitted infections). This session will explore whether and how existing laws permit adolescents to participate in research without parental permission, as well as when it would be ethically appropriate for IRBs and investigators to use this legal flexibility given the latest science about the capabilities of the adolescent brain. During this session, faculty will:

- Review the capacity of adolescents to provide consent for their own participation in research based on current developments in neuroscience
- Discuss what existing regulations require for consent to pediatric research
- Provide insight on how IRBs apply mature minor and related laws to consent to pediatric research

### ICON KEY



D11

### Institutional Considerations When Accepting IRB Review from an Independent IRB or Academic Partner (Institutional Officials and HRPP Leadership Track) Robin C. Ginn, Eric C. Mah

Is the use of a central IRB or an external IRB right for your organization and, if so, what must be considered as part of the implementation process? Increasingly institutions are relying on other IRBs or entering into collaborative review agreements for multicenter clinical trial research and cooperative group studies. In light of the recent NIH draft guidance, which proposes mandating use of a single IRB of record for NIH-funded multicenter research, all HRPP leaders need to consider the implications of such reliance agreements. During this session, faculty will:

- Describe institutional responsibilities when outsourcing or ceding IRB review responsibility for multicenter trials
- Discuss implementation of business and operational strategies

Room 304



D12

### Essential Documentation: IRB Membership, Recordkeeping, Meeting Minutes, and More (IRB Boot Camp Track) Janet C. Donnelly, Michelle Feige, Julia Gayle Gorey, Ada Sue Selwitz

The federal regulations define the requirements for IRB membership and for documenting IRB discussions, decisions, findings, and communication of IRB decisions. This session will focus on the basic regulatory requirements for documenting IRB activities. During this session, faculty will:

- Outline the basic federal requirements for IRB documentation
- Discuss the federal requirements for maintenance of accurate, complete, and timely IRB records
- Identify the components of a complete record of IRB meeting activities as reported in IRB meeting minutes
- Hear how the proposed changes in the NPRM could possibly affect IRB membership, recordkeeping and documentation requirements

Room 102



Basic

D13

### Meeting Management for IRB Chairs (IRB Chairs Track) Jeremy Block, Bruce G. Gordon, C. Eglia Rabinovich

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 style perspective
- Review how to increase engagement of members and how to interact with staff/consultants
- Share tips, strategies, and approaches to becoming an IRB chair or how to build on current skills and training

Room 202



Advanced

D14

### IRB Performance: Tools to Evaluate and Improve IRB Operations (IRB Operations and Toolkit Track) Nichelle Cobb, Elizabeth Tioupine

This session is designed to provide IRB administrators with tools and practical tips in assessing the performance of IRB operations. During this session, faculty will:

- Present ideas and techniques that can be used to streamline IRB processes and optimize IRB operations
- Discuss key indicators and performance benchmarks that can be used to assess efficiencies/bottlenecks in the IRB process
- Present ideas for maximizing staff and IRB member efficiency

Room 311



Basic

#### ICON KEY



Didactic session



Pre-registration required



CME accredited



Interactive workshop



Call for Session Proposal



Double session



Recorded session



CIP eligible

D15

**TransCelerate's Risk-Based Monitoring Initiative** (*Issues Pharma/Biotech Track*) Brett Wilson, Kathryn Owen.

The Risk-Based Monitoring Initiative was established in 2012 as one of the five initial goals created by TransCelerate to drive efficient and effective solutions into the research and development industry. By developing a model approach for risk-based monitoring of clinical trials, TransCelerate's objective is to both enhance patient safety and ensure the quality of clinical data. During this session, faculty will:

- Provide an overview of the Risk-Based Monitoring Initiative
- Discuss risk-based monitoring/remote monitoring processes
- Share project milestones, resource solutions, and the latest information on the status of this and similar initiatives

Room 111



D16

**Compassionate Access or Risky Hope? The Legal and Ethical Complexities of "Right to Try" Laws** (*Legal Track*) Katherine Gallin Heffernan, Richard Klein, Greg E. Manship, Beth E. Roxland, Walter L. Straus

Recently enacted and proposed Right to Try legislation in various states has grabbed national public and media attention. This legislation, which gives certain terminally ill patients possible access to experimental medicines for use in last resort treatment, raises important legal, ethical, medical, and financial implications for all stakeholders in medicine and clinical research. During this session, faculty will:

- Explain the legal frameworks applicable to expanded access, including FDA's existing regulatory structure and the shift sought through recent Right to Try bills
- 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, via a representative from industry, the perspective of drug manufacturers and the efforts they are making to respond to these issues
- Provide an overview of the potential economic issues related to who pays for the drugs and the cost of treating any harms, in addition to the possible impact Right to Try laws may have on coverage determinations for new drug therapies

Room 302



D17

**Scientific Aspects of Study Design: A Primer for Non-Scientists** (*Non-Scientist IRB Members Track*) Susan S. Fish, Lindsay McNair

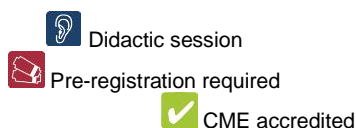
This session will serve as a primer on the scientific process, clinical study designs, and the structure of research programs for the non-scientist IRB member. During this session, faculty and attendees will:

- 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

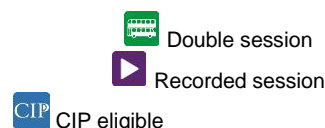
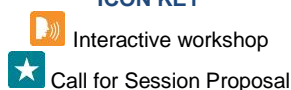
Room 204



Basic



### ICON KEY



D18

**Overview of the New Law on Newborn Blood Spots and Implications for Future Research***(Out-of-Body Experiences: Research Involving Tissue and Data Track)* Mark Barnes, Jeffrey R. Botkin

All states collect newborn dried blood spots in order to conduct mandatory screening for serious medical conditions. Many state newborn screening programs retain residual blood spots after the completion of screening. In recent years, legitimate legal and ethical concerns have been raised about the practice of states to retain residual dried blood spots and use them for purposes unrelated to newborn screening programs. On December 18, 2014, the Newborn Screening Saves Lives Reauthorization Act of 2014 (Public Law No: 113-240) was signed into law. The law requires that all research funded pursuant to the Public Health Service Act using newborn dried spots be considered human subjects research regardless of whether the specimens are identifiable, and eliminates the ability of the IRB to approve alterations or waivers of informed consent under 45 CFR 46.116(c) and 116(d) for research involving newborn dried blood spots. During this session, faculty will:

- Review newborn blood spot screening and research on blood spots
- Discuss the Newborn Screening Saves Lives Reauthorization Act of 2014, which dictates that all research involving newborn blood spots must be considered human subjects research and must require informed consent
- Examine the implications for research and IRB review of research involving newborn blood spots
- Describe possible consent content for such research use

Room 309



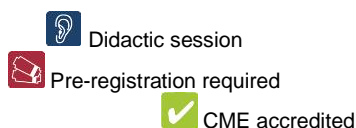
D19

**Populations on the Edge: The Homeless, Substance Abusers, and More** *(Populations Requiring**Additional Protections Track)* Teresa Doksum, Cynthia A. Gómez, Amy Terpstra

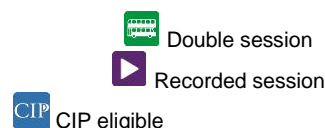
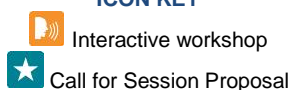
There are many populations that have vulnerabilities related to their marginalized status. Thus, it is important for IRBs to understand the expertise needed to review studies with these populations and some of the special or heightened concerns related to these groups. During this session, faculty and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

- Identify vulnerable populations beyond those addressed by the federal regulations who are nonetheless vulnerable because of homelessness, substance abuse, 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)
- Review the threshold questions an IRB should address before permitting research with these subjects.
- Discuss complex issues such as how to assure confidentiality, balancing concerns about criminal liability with the need to protect subjects and conduct valuable research, the need for assistance to avoid individual harm, and whether Certificates of Confidentiality should be a prerequisite for these studies
- Explore how to recruit and maintain contact with subjects from these populations

Room 203



## ICON KEY



# Saturday, November 14

Didactic Sessions and Workshops Series D, 2:00-3:15 PM

D20

## When Noncompliance Processes Collide: How to Manage Multiple Different Internal Investigations of an Event (Potpourri Track) Kristina C. Borrer, Megan Kasimatis Singleton, Ernest D. Prentice, Andrew Rusczek

One allegation or problem in a clinical study, such as a concern that a researcher has falsified research data, can spiral or uncover additional noncompliance and thereby trigger multiple requirements and policies for investigation and resolution. This session will present a root cause analysis of noncompliance issues, and offer strategies and training models for dealing with these events. During this session, faculty will:

- Briefly review (using a case example) the various legal issues and institutional policies and processes that may be triggered by a noncompliance event, including IRB serious/continuing noncompliance investigations, research misconduct proceedings, and medical staff/peer review processes
- Learn how to identify regulatory disconnects and knowledge gaps that lead to noncompliance issues in research, and recognize the ways in which the substantive and procedural requirements and standards applicable to different processes may overlap or be in tension
- Share practical strategies for coordinating and conducting multiple investigations and stakeholders in a way that maximizes efficiency, but also maintains the integrity of the various processes

Room 101



Advanced

D21

## 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 social and behavioral research 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 and attendees 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 a HRPP
- Outline QA/QI Specialist qualifications
- Share strategies for developing effective education and training opportunities for investigators

Room 103



D22

## Recruitment and Consent Challenges and Opportunities in Internet Research (Research Involving the Internet and Social Networking Track) Brenda Curtis, Laura Odwazny

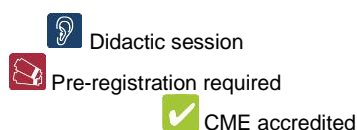
This session will address ethical, regulatory, and methodological issues associated with recruitment and consent in online research. A basic understanding of internet venues and tools is assumed. During this session, faculty will:

- Outline current guidelines and strategies for protecting privacy and confidentiality
- Discuss what constitutes adequate consent with regard to the type of data collected
- Provide IRB decisional strategies for reviewing legally and socially sensitive research that utilizes social media for recruitment using case studies

Room 206



Basic

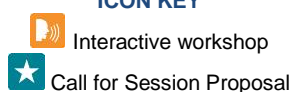


Didactic session

Pre-registration required

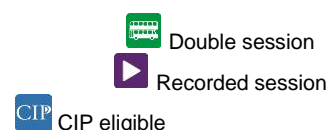
CME accredited

### ICON KEY



Interactive workshop

Call for Session Proposal



Double session

Recorded session

CIP eligible

# Saturday, November 14

## Didactic Sessions and Workshops Series D, 2:00-3:15 PM

D23

### Building and Maintaining an HRPP in a Large Health System with a Small Research Portfolio

(Small Research Programs Track) Scott J. Lipkin, Tina Noonan, 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 will include: noncompliance and conflict of interest management, effective interactions with organizational leadership, adherence to FDA requirements when overseeing drug and device research, emergency use of test articles, and more.

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 challenging structural and operational aspects common in small HRPPs and identify effective solutions
- Share strategies for engaging senior leadership, investigators, IRB members, and those who work in other components of the HRPP
- Outline how to create action priority lists and timelines
- Identify effective institutional change agents, offices, mechanisms, etc.

Room 108



Advanced

D24

### School Rules! Conducting Research in Elementary and Secondary Public Schools (SBER I – Basic Track)

Eric Allen, Fanny K. Ennever, Jeffery Rodamar, Shannon Sowards

This session will cover the regulatory requirements relevant to obtaining parental permission and protecting confidentiality of students' academic records and will identify areas of flexibility to enable research on students and records, especially in challenging populations, venues, and districts with historically low parental involvement. During this session, faculty and attendees will:

- Review the Family Educational Rights and Privacy Act and the Protection of Pupil Rights Amendment, including what is required, permitted, prohibited, and waivable
- Learn about who has "school authority" to release information
- Outline consideration as to when an education project qualifies either as not human subjects research (quality improvement), as exempt human subjects research, or as non-exempt human subjects research
- Explore 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

Room 104



Basic

D25

### Changing Concepts of Anonymity, Confidentiality, and Privacy in SBER (SBER II – Advanced Track)

Scott Bradner, Dean R. Gallant

Can we still promise our research participants anonymity? What are the limits of confidentiality? Is privacy still a fundamental concept for human subjects research? Do individuals have an accurate perception of where their privacy rights end and begin, and does the public have an accurate perception of what privacy is for them? This session will explore the rapidly evolving landscape around these concepts. During this session, faculty and attendees will:

- Discuss the definitions of anonymity, confidentiality, and privacy from the regulatory, philosophical, and research perspectives
- Share examples of de- and re-identification
- Clarify the distinct and overlapping roles that information technology, the IRB, and the researchers share in the common enterprise of data security

Room 210



Advanced



Didactic session



Pre-registration required



CME accredited



Interactive workshop



Call for Session Proposal



Double session



Recorded session



CIP eligible

#### ICON KEY

- Review strategies for SBE researchers and IRBs

## Saturday, November 14

3:30-4:45 PM

### Town Hall Meeting: The Notice of Proposed Rulemaking (NPRM) and the Future of Human Subjects Protections

**Moderator:** David H. Strauss

**Panelists:** Mark Barnes, Diana T. Chingos, Kathy L. Hudson, Jerry Menikoff, Leonard Glantz, TBD

Join PRIM&R for this town hall meeting during which representatives of PRIM&R's Public Policy Committee and other stakeholders will share their perspectives on areas of the NPRM that merit attention, as well as invite audience members to participate in a wide-ranging discussion about the proposed revisions and the ethical considerations underlying the stated goals of the NPRM. This session aims to foster collective critical thinking about the implications for human subjects protections of the proposed changes to the Common Rule and help all stakeholders formulate their comments on the NPRM.

Veterans Memorial Auditorium



5:00-6:00 PM

### Networking Reception with the Supporters, Exhibitors, and Poster Presentation

Join us in The Conference Connection to meet and greet the Supporters and Exhibitors and view this year's Poster Presentations. Light refreshments will be served.

Exhibit Hall C

5:00-6:00 PM

### AER Conference Group Mentoring

Gather with your colleagues for a new group mentoring activity where you can connect with your peers to get answers, solve problems, and improve practices. Tables will be divided by general topics and led by an expert facilitator. Groups will include: Career/Leadership/Management (*group is currently full*), Compliance/Federal/Legal/Regulatory (*group is currently full*), Diversity, Global Research, IRB Chairs (*group is currently full*), IRB Administrators/Coordinators (*group is currently full*), Non-Scientist IRB Members, QA/QI/ Post IRB Approval Monitoring (*group is currently full*), Small Research Programs, and SBER (five seats per table, a maximum of 10 seats per topic). During this activity, participants can present an issue or question they have to the group, and members of the group will respond to the problem or issue presented. The facilitator will manage the time so that all who want to share have time to do so. Participants can also just come for the discussion. Pre-registration is required for this event so we can manage seats onsite, but attendees may also come onsite to fill any open seats that might be available. Please [register online](#) or [email us](#).

Exhibit Hall D



5:00-6:00 PM

### FDA Office Hours

Do you have a specific question for FDA representatives? Do you have a follow-up question after attending a session with a FDA representation or on a FDA-related topic? If so, we encourage you to stop by the FDA Office Hours during this time, and representatives from the FDA will be available to help answer your questions.

Exhibit Hall C

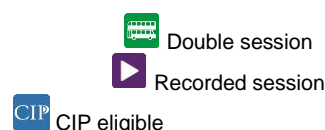
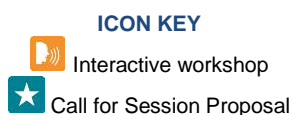
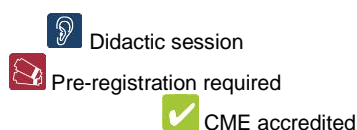


5:00-5:15 PM

### Demonstration of PRIM&R's Ethical Research Oversight Course (E-ROC)

Join us in the PRIM&R Pavilion 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, please stop by the PRIM&R Pavilion or [email](#) Maeve Luthin, professional development manager, to set-up a one-on-one demonstration of this resource.

Exhibit Hall C



## Saturday, November 14

5:15-5:30 PM

Exhibit Hall C

### Demonstration of PRIM&R's Knowledge Center

Join us in the PRIM&R Pavilion for a demonstration of our online resource for members, the Knowledge Center, and its new 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, please stop by the PRIM&R Pavilion or [email](#) Maeve Luthin, professional development manager, to set-up a one-on-one demonstration of this resource.

5:30-5:45 PM

Exhibit Hall C

### Overview of PRIM&R's Member Benefits

Join us in the PRIM&R Pavilion 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, please stop by the PRIM&R Pavilion or [email](#) Megan Frame, membership manager, to set-up a one-on-one discussion.

5:45-6:05 PM

Exhibit Hall C

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6:05-6:25 PM

Exhibit Hall C

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6:00-7:00 PM

Ballroom B

### DNA in Play: The ABC's of Assent, Blurred Boundaries, Capacity, Disclosure, Ethics, Families...

**Moderators:** Lynn W. Bush, Karen H. Rothenberg

**Actors:** Mark Barnes, Jeffrey R. Botkin, Christine Grady, Robert "Skip" Nelson, Pearl O'Rourke, Susan Z. Kornetsky

This interactive new play by Lynn Bush and Karen Rothenberg, and performed by distinguished colleagues, will bring to life the complexity of bioethical challenges in the context of the informed consent and decision-making processes surrounding genome sequencing in pediatric clinical research and medicine. Familial and professional relationships influencing, and influenced by, the ethical landscape of genomics will provide the drama with a way to critically explore and debate thorny issues, including the power of information generated and developmental factors. What, when, how, to whom, and whether findings should be discovered and disclosed is controversial, particularly in determining whose voice matters if children are involved or capacity is diminished. The audience will have the opportunity to weigh in as the mock ethics committee after each act, and a lively discussion between the actor-panelists and audience will follow the play. Pre-registration is required to attend this event. Please



Didactic session



Pre-registration required



CME accredited

#### ICON KEY



Interactive workshop



Call for Session Proposal



Double session



Recorded session



CIP eligible

## Sunday, November 15: 2015 AER Conference

7:00 AM

### Registration Opens

Breakfast on your own. Coffee only will be served in The Conference Connection in Exhibit Hall C.

Pre-function Hall C

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*

Veterans Memorial  
Auditorium

8:15-8:30 AM

### PRIM&R Membership Update

Susan S. Fish, PharmD, MPH, Professor, Biostatistics and Epidemiology, Boston University School of Public Health; Co-Chair, Membership Committee, PRIM&R

Veterans Memorial  
Auditorium

8:30-9:30 AM

### Keynote Address: A Song in the Night: Lessons from a Life of Resilience

[Robert K. Massie, IV, MDiv, DBA](#) Author, A Song in the Night: A Memoir of Resilience

Veterans Memorial  
Auditorium



9:30-9:45 AM

### Book Signing with Author and Keynote Speaker Robert K. Massie, IV, MDiv, DBA

Join us at the onsite Bookstore in Pre-Function Hall C for a book signing with author and keynote speaker Robert K. Massie, IV, MDiv, DBA. Copies of Dr. Massie's books are available online, as well as at the onsite Bookstore.

Pre-function Hall C

9:30-9:45 AM

### Break

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

### Panel VII: The Precision Medicine Initiative: What Is it and What Issues Does it Raise?

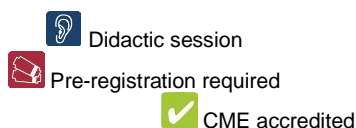
Veterans Memorial  
Auditorium



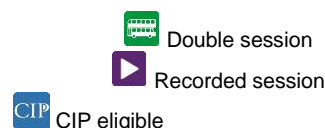
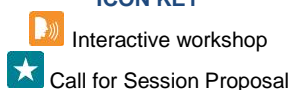
**Moderator:** *P. Pearl O'Rourke*

**Panelists:** *Sandro Galea, Gary H. Gibbons*

Precision medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person involved. The NIH's Precision Medicine Initiative plans to create a one million person cohort to support precision medicine research and, ultimately, to improve treatment of cancer for the present time and other diseases in the future. This session will provide a description of the Precision Medicine Initiative, including the challenges of logistically coordinating and overseeing huge genomic and clinical databases, will review the ethical issues associated with such an initiative, and will address whether such an individualistic, and expensive, approach will enhance or distract from other methods currently available to enhance the health of the population.



#### ICON KEY



# Sunday, November 15

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

## Panel VIII: When the Lines are Blurred Between SBIR and Biomedical Research: Challenges for SBIR IRBs

Ballroom B

**Moderator:** Celia B. Fisher



**Panelists:** Melissa E. Abraham, Michele Kuchera, Elena Leonidovna Grigorenko

This session will examine the wide array of medical devices, such as fMRIs and genetic technologies, that are being employed with greater frequency in social science research and the impact this has on the IRB's review process. Issues to be discussed include: How can social science IRBs determine the investigator expertise necessary to evaluate medical risk and identify and provide appropriate participant referrals for incidental findings for this array of new devices and technologies? Given the increasing incorporation of genetic susceptibility models in social, behavioral, educational, and mental health research, as well as the probabilistic nature of gene-environment influences, what competencies should social scientists have in order to make decisions regarding disclosure to participants of their research-derived, personal genetic information, to ensure adequate privacy protections during analysis and storage, and to provide appropriate informed consent?

## Panel IX: Patients With Lethal Diseases: Experiments in Research Design

Ballroom C

**Moderator:** Alexander M. Capron



**Panelists:** : Jeffrey W. Clark, Richard T. Penson

Recruiting patients with lethal conditions into studies of novel medical interventions raises difficult questions about how to assess the ratio of potential benefits to risks. Moreover, the lack of attractive therapeutic alternatives, which can lead patients to overcome their reluctance to enter a randomized control trial where they may be assigned a relatively ineffective treatment, creates concerns for IRBs about subjects' voluntariness. Recently, FDA officials have indicated possible receptivity to allowing data from "basket trials," a novel study design in which, regardless of the histology of their tumor, patients with particular mutations affecting tumor development are matched to a drug expected to work on that mutation. By essentially eliminating the control arm in the usual trial, this would represent a major change in what counts as supporting evidence for approving new drugs. Is such a change dependent on the lethal nature of some cancers, or could it signal a broader change in methodology, with implications for the current "gold standard" that IRBs usually expect? How would basket trials impact the recruitment of patients with lethal conditions into trials?

11:00-11:15 AM

Exhibit Hall C

Break

Join us for coffee in the Conference Connection.

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

E1

Room 210

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

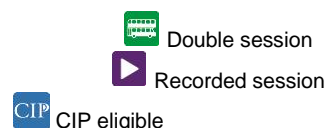
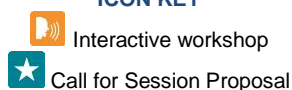
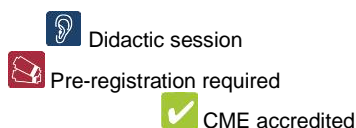


(A Dialogue with the Feds I Track) Cmdr. Joseph V. Cohn, Terrence Clemmons, LtCol Imelda Catalasan, Capt. William Deniston, Col. Molly Klote, Lisa Mattocks, Patrice Robinson-Haley, Leah Watson

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

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

### ICON KEY



# Sunday, November 15

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

E2

## **A Dialogue with the Environmental Protection Agency (EPA)** (*A Dialogue with the Feds II Track*) Daniel

K. Nelson, Toby L. Schonfeld

While the US EPA has adopted the Common Rule, EPA-supported research presents special challenges, and there are some unique regulatory restrictions and requirements. This session will feature two representatives who will give an update on EPA structure and initiatives. During this session, faculty and attendees will:

- Review the regulatory restrictions and requirements that are unique to EPA-sponsored research
- Address some of the special challenges with the types of research conducted or supported by EPA
- Discuss initiatives and organizational developments within the EPA

Room 308



E3

## **Inching Towards Harmonization: Electronic Consent and the FDA/OHRP Guidance** (*Advanced*

*Forum for IRB Professionals Track*) Mark Barnes, Heather H. Pierce

On May 7, 2015, comments were due to FDA and OHRP on two simultaneous requests published in the federal register: one on a draft FDA guidance document on electronic consent, and another from OHRP asking whether the FDA guidance would equally apply to other DHHS funded research and whether it should be issued as a draft guidance from both FDA and OHRP. In addition to providing new guidance, this approach signals a relatively novel approach to harmonization and could lead to similar FDA/OHRP alignment efforts. During this session, faculty will:

- Review the proposed FDA guidance, the practical implications for implementing the draft as is, and the nature of the public comments received (if available)
- Discuss how the draft guidance should or should not apply to research under the Common Rule and what challenges IRBs might face if this were finalized from FDA and OHRP without change

Identify remaining (or next) areas to harmonize FDA and OHRP guidance, using facilitated discussion and the work the SACHRP Subcommittee on Harmonization has been doing over the past several years

Room 302



Advanced

E4

## **QA/QI/Program Evaluation: Is it or Is it Not "Research"?** (*Boundaries and Balance Track*)

George Gasparis, Sean Philpott

This session will use case studies to highlight distinctions between QA/QI, program evaluation, and research. During this session, faculty and attendees will:

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

Room 312



Advanced

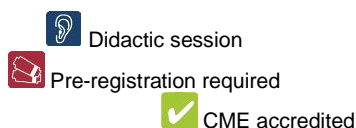
E5

## **Staying on Top of Your Game: Professional Development for Human Subjects Protections Staff and IRB Members** (*Educating and Training Track*) Hila F. Berger, Charlotte H. Coley, Karen M. Hansen

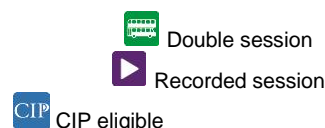
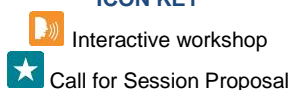
For human subjects protections staff and IRB members, keeping up with the evolving field can be a challenge. Faculty will discuss current options and new trends in professional development, training, and education, and will provide tips on networking. During this session, faculty will:

- Review methods, techniques, and credentialing programs available for staff development, including Certified IRB Professional, Certified Clinical Research Associate, Certified IRB Manager, etc.
- Provide information on available opportunities for training and education

Room 304



### ICON KEY



- Discuss the importance of networking as it relates to professional development in the field

## Sunday, November 15

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

E6

**Questions about Central IRBs: How Can We Use Empirical Research to Find Answers?** (*Empirical Research Ethics Track*) Ann-Margret Ervin, Holly A. Taylor

OHRP, NIH, and the House of Representatives recently issued draft guidance on mandatory use of a single IRB of record (central IRB) for multicenter research. This session will highlight the findings of an NIH-funded project to collect empirical data on the practices of central IRBs in the US to inform future guidance on implementation in the academic setting. This session will present the results of a systematic review and preliminary results from stakeholder focus groups to identify priorities for the formation and conduct of central IRBs. During this session, faculty and attendees will:

- Review how empirical research can inform contemporary policy debates in the conduct of human subjects research
- Solicit feedback from the audience on the faculty's initial and future empirical efforts

Room 103



E7

**Assessing the Prospect of Direct Benefit in Pediatric Studies** (*Ethical Issues Track*) Susan Z. Kornetsky, Robert M. "Skip" Nelson

Under Section 405, Subpart D of the DHHS regulations, pediatric research that presents more than minimal risk, but holds out the prospect of direct benefit for the individual participant may be approvable. This session will discuss approaches to IRB review of such studies. During this session, faculty will:

- Examine the process for reviewing research interventions that offer the prospect of direct benefit to a pediatric population
- Discuss the application of component analysis in the IRB's review of pediatric studies
- Outline the expectations for documenting the prospect of direct benefit and use of component analysis during the review of pediatric studies

Room 204



E8

**Humanitarian Use Device (HUD) Designation and Humanitarian Device Exemptions (HDEs): The Role of the IRB** (*FDA Regulations Track*) David G. Forster, Nicole L. Wolanski

As defined by the regulations, a HUD is a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the US per year. IRBs should be able to distinguish between the "use" of a HUD (i.e., in accordance with its approved labeling and indication) versus the "investigational use"/"clinical investigation" of a HUD (i.e., collection of safety and effectiveness data), whether for its HDE-approved indication or for a different indication. During this session, faculty will:

- Present a general overview of the HUD designation and HDE application process
- Discuss the difference between the use of a HUD in accordance with its approved labeling and indication versus the investigational use of a HUD in a clinical investigation
- Describe the role of the IRB in the review of these various uses of an HUD

Room 203



E9

**QA/QI Activities to Ensure Research Compliance of Multicenter and International Research** (*Global Research Track*) Leslie M. Howes, Lama Jamhawi, Walter L. Straus

During this session, faculty and attendees will:

- 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

Room 109



#### ICON KEY



Didactic session



Pre-registration required



CME accredited



Interactive workshop



Call for Session Proposal



Double session



Recorded session



CIP eligible

- Review commonly recognized compliance risks identified while monitoring international and multicenter studies.

## Sunday, November 15

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

E10

#### **Proposed Changes: An In-Depth Discussion on the Notice of Proposed Rulemaking's (NPRM's) Sections on Exclusions and Exemptions** (*Hot Topics Track*) Dean R. Gallant, Ada Sue Selwitz

A NPRM has been released, and it is important for those involved in research to have an awareness of the proposed changes and their potential implications for the field. This session will focus on the sections of the NPRM related to the new category of activities called "exclusions" and on the proposed revisions to the exemption categories. During this session, faculty and attendees will:

- Review, briefly, the current scope of the Common Rule and exemptions
- Examine what is being proposed in the NPRM and potential implications for IRBs and for human subject protections
- Provide information on how to submit public comments on the NPRM

Room 310



E11

#### **Litigation and Enforcement Actions in Clinical Research: Implications for IRB Members and Institutions** (*Institutional Officials and HRPP Leadership Track*) Lisa Rooney, Robyn S. Shapiro

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
- Utilize hypothetical cases to illustrate institutional risk minimization

Room 102



Advanced

E12

#### **Writing Stellar Standard Operating Procedures (SOPs)** (*IRB Boot Camp Track*) Elizabeth Bankert, Michelle Feige

During this session, faculty will:

- Discuss the components of comprehensive and effective HRPP/IRB SOPs
- Review the resources, input, and/or approvals needed to develop specific SOPs

Room 305



Basic

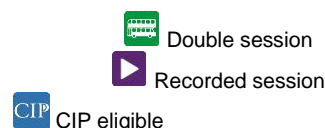
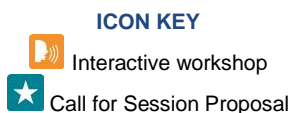
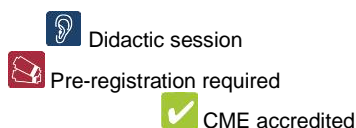
E13

#### **The Work of the IRB Chair: Beyond the IRB Meeting** (*IRB Chairs Track*) J. Andrew Bertolatus, Bruce G. Gordon, Patience B. Stevens

The IRB chair's work 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:

- Discuss how chairs have added responsibilities and challenges often without (or regardless of) significant administrative support
- Best practices for pre-review and preparation for an IRB meeting
- Explore techniques for resolving disputed issues between IRB and researchers
- Learn about the regulatory and other expertise required of the chair or designee
- Share strategies for communicating with Research Integrity Officer, legal counsel, risk management, sponsored programs, and other Committees necessary for appropriate review and follow-up
- Review how to do a 360 evaluation of the HRPP process and IRB chair leadership

Room 200



# Sunday, November 15

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

E14

### Enhancing Effective Communications Between IRBs and Investigators (*IRB Operations and Toolkit Track*) John R. Baumann, Moira A. Keane

This interactive session will use case studies and concrete examples to enhance communication between IRBs and investigators. During this session, faculty and attendees will:

- Review techniques for delivering information (good or bad) to investigators in clear, concise, and tactful ways
- Share feedback and strategies for 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

Room 206



E15

### Considerations for Effective IRB Review and Management of Protocol Deviations and Violations

(*Issues Pharma/Biotech Track*) Albert J. Allen, Megan Kasimatis Singleton, Michele Russell-Einhorn

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
- Discuss effective processing by the IRB for prompt review

Room 202



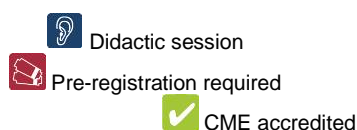
E16

### The Error of Our Ways: IRB and Legal Considerations in Research on Medical Errors and Clinician Behavior (*Legal Track*) Melissa E. Abraham, Emily Chi Fogler, Elizabeth L. Hohmann

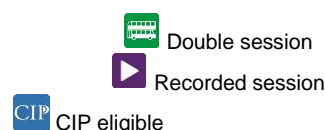
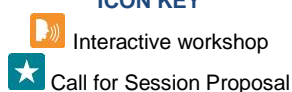
Proposals for research on medical errors and clinician behaviors are increasingly common and complex, and present unique challenges for IRBs and institutions. Investigators may submit such proposals with the assumption or hope that their analyses will benefit from peer review protection and may not appreciate the potential risks to individual clinicians or to their institution from this work. However, most peer review laws will not likely provide protection for such research analyses and indeed are inconsistent with the concept of research and publication. Depending on the circumstances, some of this work may be best conducted as QA/QI under the purview of institutional peer review committees, rather than as research. When it is conducted as research, questions regarding the status of the clinicians as human subjects and the protection of their confidentiality must be considered. This session will explore the risks, as well as the IRB/human subject and legal issues and considerations involved with undertaking these important projects. During this session, faculty and attendees will:




- Review research in medical errors, clinician behavior, and related areas
- Analyze case examples and provide suggestions for structuring these projects, as well as possible strategies for addressing some of the issues
- Identify legal issues that require consideration in medical errors/clinician behavior research
- Clarify risk determinations, identify when consent is required, and share best practices for recruitment and consent methods and minimizing risk for survey, intervention, and record review studies in this area



Room 101






#### ICON KEY



 Didactic session  
 Pre-registration required  
 CME accredited

**ICON KEY**  
 Interactive workshop  
 Call for Session Proposal

 Double session  
 Recorded session  
 CIP eligible

E17

**It Takes a Village: Community Members as Research Partners in Community Based Participatory Research (CBPR)**

(Non-Scientist IRB Members Track) Cynthia R. Pearson, Amy Terpstra

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 principles and human subjects protections principles, and explore ways for how to minimize them

Room 108



E18

**Informed Consent for Genome-Scale Sequencing** (Out-of-Body Experiences: Research Involving Tissue and Data Track) Sandra Soo-Jin Lee, Amelia Wall Warner

As the research use of comprehensive (e.g., whole-exome and whole-genome) sequencing approaches continues to grow, new questions arise with respect to informed consent. This session will explore pragmatic and ethical issues from the perspectives of ethics experts, study participants, and pharmaceutical industry researchers. During this session, faculty will:

- Highlight key issues in informed consent for genome-scale sequencing, including data-sharing, future undefined uses, and re-consent
- Offer recommendations on best practices for informed consent

Room 309



E19

**Representing Prisoners: Insights from an IRB Member Who Has Been Incarcerated**

(Populations Requiring Additional Protections Track) Fanny K. Ennever, Shannon Sowards, David Neil Tavares

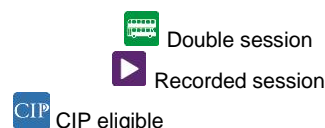
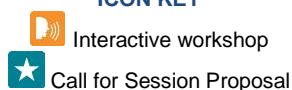
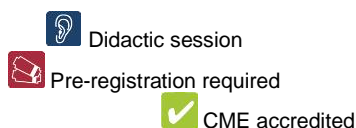
In 2013, the Committee on the Use of Human Subjects (the IRB) for Harvard University-Area research recruited David Tavares, a former prisoner, as a member. During this session, faculty will use the seven additional approval criteria from Subpart C of 45 CFR 46 as a framework to present important insights 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

Room 313



ICON KEY



E20

### Ask the Experts! Everything You Wanted to Know, but Were Afraid to Ask (Potpourri Track)

Rebecca D. Armstrong, Edward E. Bartlett, Jeffrey M. Cohen, Sharon Freitag, Susie R. Hoffman, Kevin A. Prohaska, Elyse I. Summers, Lisa Buchanan

Are you new to the field of research ethics? Do you still have nagging questions regarding HRPPs and IRBs? Join us for this session where experts in the field will be available to answer all the questions you've been afraid to ask. Come with your questions and concerns, and be prepared to participate in an open, interactive, and lively discussion with experienced faculty and peers. During this session, faculty and attendees will:

- Participate in an open and interactive discussion about a broad range of issues in human research protections
- Share ideas and strategies for addressing issues about protocol review, HRPP/IRB operations, and the regulations
- Have a final opportunity to have questions addressed by the experts

Room 111



E21

### "Lean" Thinking for IRB Process Improvement (QA/QI and Post-Approval Monitoring Track)

Ross A. Hickey, Elizabeth Tioupine

This session will emphasize hands-on application of commonly used Lean tools and techniques, and attendees will learn how Lean concepts can enhance their continuous improvement efforts. During this session, faculty will:

- Review basic techniques
- Discuss approaches to simplifying the IRB review process within the HRPP office
- Provide tips and techniques to reduce inefficiencies and minimize hand-offs
- Explore metrics for evaluating efficiency

Room 311



Advanced

E22

### Innovative Approaches to Assent (Research Involving the Internet and Social Networking Track) Rebecca Dahl, Moore Rhys

This session will focus on the development and use of "Consent Quest," a game app developed to educate children ages eight through 12 about participating in a research study by: (1) Giving them examples of what they might be asked to do in a study, and (2) Asking questions throughout the game and providing educational information along with the answers. By thinking about the game cards and giving thoughtful answers to the questions asked, players can eventually gain skills and decide whether or not to participate in a research study. During this session, faculty and attendees will:

- Learn how this application was developed and how it has been used with children
- Demonstrate how "Consent Quest" is used and review the possible outcomes of using an electronic game
- Review the education and learning results from the use of "Consent Quest"

Room 107



E23

### Outsourcing IRB Review While Maintaining a Robust HRPP at an Institution with a Small Research Program (Small Research Programs Track) Shannon L. Harr, Scott J. Lipkin

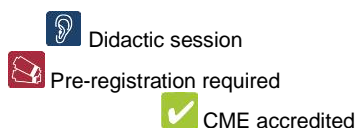
This session will describe how an institution with a self-described small research program maintains an effective HRPP while outsourcing some or all of its IRB review. During this session, faculty will:

- Explore the ethical tensions involved in outsourcing IRB review
- Identify shared and single-sourced responsibilities, accountabilities, and liabilities between the home institution and the outsourced IRB
- Discuss how to measure and maintain an effective HRPP when some or all protocol review is outsourced

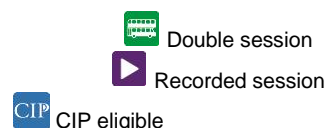
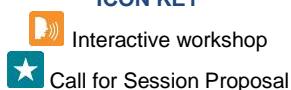
Room 110



Basic



#### ICON KEY



E24

**Ethical and Regulatory Issues in Social and Behavioral Research** (SBER I – Basic Track) Julie Kaneshiro, Ivor A. Pritchard

This session will use dramatic presentations of case studies of social and behavioral research studies to raise questions about IRB review and approval. The ethical principles of the Belmont Report, (respect for persons, beneficence, and justice), as well as the regulatory provisions which apply those principles, will be called into play. A discussion on the application of the principles of the Belmont Report, and tensions between those principles, will be included. During this session, faculty and attendees will:

- Discuss at least two ethical challenges in SBER
- Discuss at least two issues involving the application of the regulations in SBER

E25

**The Use of Deception in SBER** (SBER II – Advanced Track) Andrew Hedrick, Alison Orkin

The use of deception in research is not uncommon, including in psychology, and marketing studies. While most of this research poses few risks to participants and is justifiable for methodological reasons (e.g., avoiding recruitment and response bias), informed consent is the touchstone of the ethical conduct of human subjects research. However, critics argue that any level of deception violates The Belmont Report's principle of respect for persons. This session will explore the ethics of different types and degrees of deception and an IRB's role and responsibility in reviewing such research. During this session, faculty and attendees will:

- Use case studies to discuss IRB considerations and responsibilities when reviewing research involving deception

12:45-1:45 PM

Lunch

2:00-3:15 PM

**Closing General Session: Could this Happen to You? Lessons Learned from the University of Minnesota Reports**

**Moderator:** Elisa A. Hurley

**Panelists:** Brian Herman, Steven Joffe, Martha F. Jones

Recent reports from the University of Minnesota, as well as past situations at other institutions, force HRPPs to carefully review their own research systems and structures. After all, we learn not only from our own mistakes, but also from the mistakes of others. This panel will feature individuals representing various roles in the research enterprise who will discuss their thoughts on how to handle difficult situations that arise within institutions, and the lessons learned for moving forward to ensure effective operations and adequate protections of those involved in research.

Room 104



Basic

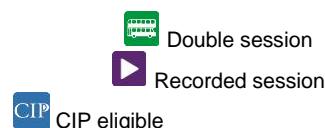
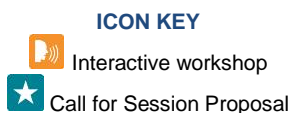
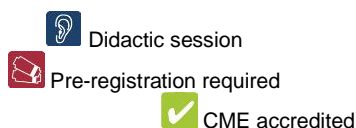
Room 306



Advanced

Exhibit Hall D

Veterans Memorial Auditorium



## Boston University School of Medicine Continuing Medical Education (CME) Accreditation Statement



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 designates this live activity for 18.5 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This program includes for 18.5 hours 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 and Epidemiology, Boston University School of Public Health

**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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### ICON KEY

