



Sunday, November 5: Pre-Conference Programs

7:00 AM  
On-Site Check-In Opens  
Breakfast on your own.

Hall 4 West Lobby

Pre-Conference Programs

8:30 AM-4:30 PM  
[IRB 101<sup>sm</sup>](#)

Room 007AB

8:30 AM-4:30 PM  
[Integrity in Research: Responsible Conduct in Research Concepts and Cases](#)

Room 006CD  
 CIP

8:30 AM-5:00 PM  
[Quality Assurance/Quality Improvement in Human Subjects Research](#)

Room 008AB

8:30 AM-4:30 PM  
[Research Ethics in the Biopharmaceutical Industry](#)

Room 006B  
 CIP New

8:30 AM-4:30 PM  
[Single IRBs: From Idea to Implementation](#)

Room 007CD  
 CIP

4:30-6:00 PM  
Pre-Conference Programs Networking Reception

River Level Foyer

All those registered to attend a pre-conference program are welcome to attend a networking reception. Light refreshments will be served.

ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	



**Monday, November 6: 2017 AER Conference**

**7:00 AM**

**On-Site Check-In Opens**

Breakfast on your own.

Hall 4 West Lobby

**7:00-8:00 AM**

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

Attending the AER Conference for the first time can be exciting and overwhelming, which is why PRIM&R invites all first-time attendees to participate in this special breakfast. This event is a great opportunity for first-time attendees to ask questions of the PRIM&R staff and seasoned attendees about the conference and PRIM&R in general, and to learn about strategies and resources that can help them make the most of their conference experience. We would love to see you there!

Hemisfair Ballroom 2



**7:00-8:00 AM**

**A Capella Musical Performance Supported by Huron Consulting**

Join us before the conference starts for a musical performance by a local a capella group. PRIM&R would like to thank Huron Consulting for supporting this performance.

Exhibit Hall 4A

**8:00-8:15 AM**

**Welcome from the Conference Co-Chairs**

P. Pearl O'Rourke, MD, Director, Human Research Affairs, Partners HealthCare System, Inc.; Associate Professor, Pediatrics, Harvard Medical School

Laura Odwazny, JD, MA, Senior Attorney, Office of the General Counsel, HHS

Exhibit Hall 4A



**8:15-8:30 AM**

**Welcome from PRIM&R's Executive Director**

Elisa A. Hurley, PhD

Exhibit Hall 4A



**8:30-9:15 AM**

**Keynote Address: The Ethics Beat: Writing About Ethics for the Front Page and Beyond**

Amy Dockser Marcus, MBE, Staff Reporter, The Wall Street Journal

Exhibit Hall 4A



**9:15-9:25 AM**

**Presentation of the Lifetime Achievement Award for Excellence in Research Ethics Awarded to Ruth Macklin, PhD, Distinguished University Professor Emerita (Bioethics), Albert Einstein College of Medicine**

Presented by Alexander M. Capron, LLB, University Professor; Scott H. Bice Chair in Healthcare Law, Policy and Ethics; Vice Dean, Faculty and Academic Affairs, Gould School of Law; Professor of Medicine and Law, Keck School of Medicine; Co-Director, Pacific Center for Health Policy and Ethics, University of Southern California

Exhibit Hall 4A



**9:25-10:15 AM**

**Lifetime Achievement Award Plenary Address by Ruth Macklin, PhD: Dealing With Controversies in Research Ethics: Four Decades of Experience**

Ruth Macklin, PhD, Distinguished University Professor Emerita (Bioethics), Albert Einstein College of Medicine

Exhibit Hall 4A



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

**Beverage Break Supported by Kinetiq**

Join us for coffee in the Exhibit Hall. PRIM&R would like to thank Kinetiq for helping to support this break.

Exhibit Hall 4B

**ICON KEY**

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	



## Panel I: New Frontiers: The Changing Landscape of Research Regulations

**Moderator:** Michele Russell-Einhorn

**Panelists:** Melissa E. Abraham, John R. Baumann, Emily Chi Fogler

The past year has seen the promulgation of changes in the Federal regulations, as well as new legislative and policy requirements, based on the principles of protection of subjects, streamlining, and efficiency. These include the substantial changes to the Federal Regulations for the Protection of Human Subjects in Research; the 21<sup>st</sup> Century Cures Act; and the NIH Policy on the Use of a Single IRB of Record for Multi-Site Research. Do these initiatives taken together provide better protections for human subjects in research and streamline the review processes? What are the pros and cons of some of the flexibilities introduced by these changes and will implementation of these initiatives create a stronger platform for both the conduct of research and the safe and ethical participation of human subjects? This panel brings together three individuals who will discuss these changes in the context of: (1) social and behavioral research where there has been, for the first time, a significant elimination of types of research subject to IRB review raising both positive and negative questions regarding IRB oversight of research, human subjects participation in research, and investigator responsibilities; (2) institutional responsibilities and the positive and negative implications of shifting research out of IRB oversight, as well as moving IRB review to a single IRB landscape for multi-site research; and (3) the concept of harmonization identified as a legislative mandate, but that may be difficult to implement.

Hemisfair Ballroom 3



## Panel II: Sovereignty in Research

**Moderator:** Sara Chandros Hull

**Panelists:** Heather L. Larsen, Terry J. M. Powell, Bobby R. Saunkeah

The history of research with Indigenous populations in the United States includes important advances with respect to specific topics (e.g., vaccines, diabetes) and research approaches (e.g., community-based participatory research). However, instances of egregious ethics violations tend to dominate the narratives about tribal research both within and outside of tribal communities. For example, the Nutritional Studies in Residential Schools in Canada during the 1940s, the Study of Alcohol Abuse in a Northern Alaska community during the 1980s, and studies of Havasupai biospecimens in Arizona during the early 2000s, are three frequently cited examples of research harms that often drive present-day conversations about tribal research to start from a place of fear. The sovereign status of American Indian and Alaska Native nations, however, provides an opportunity for tribes to steward research in a way that reflects cultural values and that benefits and protects their citizens and communities. In the context of changing federal and institutional research policies, it is increasingly important to move narratives about tribal research beyond fear toward conversations that acknowledge points of tension and possible benefit, respect tribal sovereignty, and identify the practical needs necessary to support tribal research oversight. This session will provide an overview of historical experiences of tribal research, convey the importance of tribal sovereignty in guiding research for the benefit of tribal peoples, and review implementation needs associated with rapidly evolving research technology and interest in research oversight among tribal nations.

Hemisfair Ballroom 1



## Panel III: The Role of Research Ethics Consultation in IRB-Reviewed Research: Opportunities and Challenges

**Moderator:** Steven Joffe

**Panelists:** Susan Z. Kornetsky, Holly A. Taylor, Benjamin S. Wilfond

The principal source of ethical review for human subjects research in recent history has been the IRB. For a variety of reasons, many institutions have developed research ethics consultation services to provide ethics guidance to investigators, study teams or, potentially, IRBs about ethical aspects of particular research studies. The presence of an additional source of ethics input and guidance raises important questions about the nature of ethics expertise and the lines of responsibility and authority between research ethics consultants and IRBs. Are IRBs no longer primarily responsible for ethical review? How do research ethics consultants and IRBs fit together? How do they complement each other and how do they conflict? Panelists will present a series of interesting cases and will discuss the contributions and scope of authority of research ethics consultants and IRBs.

12:00-1:00 PM

Exhibit Hall 4B

## Networking Lunch Supported by CITI Program, a Division of BRANY

Time to connect...over lunch! Meet peers for conversation and networking. All are welcome! PRIM&R would like to thank CITI Program, a division of BRANY, for helping to support today's lunch.

### ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

12:00-1:15 PM

**Research Ethics Book Group Lunch and Book Signing: *The Vaccine Race: Science, Politics, and the Human Costs of Defeating Disease*****Moderator:** Carol Juliet Weil**Author:** Meredith Wadman

Participate in a vibrant discussion of *The Vaccine Race: Science, Politics, and the Human Costs of Defeating Disease* by author Meredith Wadman, a reporter for *Science*. In the *Vaccine Race*, Ms. Wadman discusses the major breakthrough in cell biology that beat back German measles and other devastating diseases. Through her writing, she reviews the science involved in this race, as well as the political roadblocks that nearly stopped scientists. Attendees will have the opportunity to hear from and participate in a discussion with Ms. Wadman about her book, and she will be available to sign books after the lunch. Ms. Wadman's book is available wherever books are sold online, and copies will be sold at the conference. **Note:** Please get your boxed lunch in the Exhibit Hall before going to the session room. The formal presentation will start at 12:15 PM.

Hemisfair Ballroom 2



12:40-1:00 PM

**Overview of PRIM&R's Focus on the Revised Common Rule Educational Resources and Programs**

Join us in the demo theater in the Exhibit Hall to learn more about PRIM&R's Focus on the Revised Common Rule educational resources and programs. PRIM&R offers comprehensive in-person and online education to help you understand the new provisions of the revised Rule and what they mean for your HRPP. If you are unable to join us, visit [primr.org/commonrule](http://primr.org/commonrule) for more information, or [email](mailto:nora.murphy@primr.org) Nora Murphy, online learning coordinator.

Exhibit Hall 4B

1:00-1:30 PM

**Meet the AER17 Supporters and Exhibitors**

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

Exhibit Hall 4B

1:00-1:30 PM

**Federal Agency/Accrediting Body Office Hours**

Do you have specific questions for federal agency or the accrediting body representatives? Or, do you have a follow-up question after attending a session that featured a federal agency or accrediting body representative(s)? If so, representatives from the following federal agencies/accrediting body will be available during this time slot to help answer your questions:

- AAHRPP, Inc.
- CDC
- DOD
- DOE
- FDA
- OHRP

Exhibit Hall 4B



1:05-1:25 PM

**Simplifying Research Compliance With Cayuse IRB**

Join us for a discussion in the demo theater of the many features of Cayuse IRB that help institutions reduce the burdensome process of completing, submitting, and reviewing IRB studies. During this overview, we will look at how Cayuse IRB truly "simplifies" compliance with innovative features like role-based dashboards, configurable electronic applications, automatic messaging and reminders, and centralized meeting management – all in a secure, cloud-based environment. Decrease your turnaround time and risk using the tools provided by Cayuse IRB.

Exhibit Hall 4B

**Didactic Sessions and Workshops Series A, 1:45-3:00 PM**

A1

**A Dialogue With OHRP (A Dialogue With the Feds Track)**

Julie Kaneshiro, Yvonne Lau, 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, speakers and attendees will:

- Hear from OHRP representatives about evolving initiatives, issues, and guidance
- Ask questions of OHRP representatives
- Participate in an open discussion on topics raised at the session

Room 007AB

**ICON KEY**

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

## A2

### A Dialogue With the VA (A Dialogue With the Feds Track)

Annette R. Anderson, Kristina C. Borrer, Charlotte K. Jeans, Cindy G. Paulsen

This session will be led by representatives from the VA. Attendees are encouraged to come with questions about VA research. During this session, speakers and attendees will:

- Hear from representatives of the VA's Office of Research and Development and Office of Research Oversight about issues and activities related to the conduct of VA research
- Participate in an interactive dialogue about topics related to VA research
- Ask questions about the VA's current policies related to human subjects protections and the direction of the VA's future policies

Room 210



## A3

### A Pediatric Case Study: Referral of a FDA-Regulated Clinical Investigation Under 21 CFR 50.54

(Advanced Forum for IRB Professionals Track)

Kip M. Kantelo, Robert M. "Skip" Nelson

Each IRB that reviews studies involving children as subjects covered by the FDA regulations in 21 CFR part 50 Subpart D may approve only those studies that satisfy the criteria described in 50.51, 50.52, or 50.53, and the conditions of all other applicable sections of Subpart D. If the IRB does not believe the study meets the requirements of 50.51, 50.52 or 50.53, the study must be referred and may only proceed if it meets the conditions found in 50.54. On May 18, 2017, FDA held a public advisory committee meeting to discuss a referral by an IRB of a clinical investigation titled, "A Double-Blind, Placebo-Controlled, Multi-Center Study with an Open-Label Extension to Evaluate the Efficacy and Safety of SRP-4045 and SRP-4053 in Patients with Duchenne Muscular Dystrophy." This session will review the study and discuss how and why it was referred to FDA. Attendees should have an understanding of the basic protections in 21 CFR 50 Subpart D, including component analysis, before attending this session. During this session, speakers will:

- Review the IRB referral process under 21 CFR 50.54
- Discuss the protocol and identify issues raised that led to the 50.54 referral
- Summarize the meeting and public comments and provide IRB points-to-consider for review of studies that may require a 50.54 referral

Room 214C



Advanced

## A4

### You'll Know It When You See It, or Will You?: Defining "Human Subjects Research" Under the Revised Common Rule

(Boundaries and Balance Track) Warren Capell, Dean R. Gallant, Julia G. Gorey

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. This session is designed to provide attendees with insights into those things that fall in that grey area, and it will explore slightly more advanced concepts. Attendees are expected to have knowledge of the current and revised Common Rule definitions for "human subject" and "research," as well as knowledge and/or experience in making distinctions between activities that do/do not fall within the ambit of human subjects research oversight. During this session, speakers and attendees will:

- Define a process and a set of criteria for determining whether an activity is research, according to the revised Common Rule
- Explore key decision points for determining whether or not a research study involves human subjects, according to the revised Common Rule
- Discuss implications of the revised Common Rule definitions for "research" and "human subjects" (e.g., if no longer human subjects research, then who should review these activities?)
- Examine the tricky issues related to the definition of human subjects research (e.g., deceased patients, publishing with those who have identifiers or collected tissue, etc.)

Room 217D



Advanced

## ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	



## A5

### Facilitating Informed Consent in Light of the Revised Common Rule (Educating and Training Track)

Susie R. Hoffman, Angela Hvitved, Jerry A. Menikoff

Room 008AB



The revised Common Rule includes new requirements for informed consent to better ensure potential human subjects are receiving the information they need to make informed decisions about their participation in research. In addition, an array of tools and technologies are now available to help human subjects better understand the nature and complexities of research. This session will review how the revised Common Rule strengthens informed consent.

During this session, speakers and attendees will:

- Discuss requirements for communication with research subjects in view of the “reasonable person” standard
- Examine the requirements for putting “key information” first, including how this affects other elements required for informed consent
- Share their experience in using different presentation techniques, tools, or technologies to improve human subjects’ understanding of research
- Review OHRP’s new public outreach website, About Research Participation, and highlight how this resource can be used to facilitate the informed consent process

## A6

### Using Empirical Data to Inform Ethical Analyses of Novel HIV+ Organ Transplants

(Empirical Research Ethics Track) Macey L. Henderson, Sarah Van Pilsum Rasmussen, Jeremy Sugarman

Room 218



The HIV Organ Policy Equity (HOPE) Act now makes it possible to use HIV+ organs for transplantation into HIV+ recipients in the research setting. It is hypothesized that HIV+/HIV+ transplants will prove to be safe and effective, thereby providing a novel source of organs for people living with HIV who face high mortality on organ waitlists, as well as alleviating the organ shortage more generally. However, the novel practice of HIV+/HIV+ transplantation raises substantial ethical issues that must be addressed for both recipients and donors related to access to organs and risk and consent. Furthermore, while there are published federal research requirements for HIV+/HIV+ transplants being conducted under the HOPE Act, and standard clinical and research practices at individual institutions offer basic ethical protections, such as IRB review and oversight, they are necessarily limited by lack of substantial experience with these novel transplants. Without empirical data, it is unclear how well such approaches protect and respect those offering and receiving HIV+ organ transplants. During this session, speakers will:

- Explain briefly what is scientifically known about novel HIV+/HIV+ organ transplants and the research provisions of the HOPE Act
- Describe emerging empirical ethics data regarding HIV+/HIV+ transplants, including: in-depth qualitative information from the early recipients of HIV+/HIV+ transplants, as well as those patients living with HIV who are offered an HIV+ organ and refuse; interviews with independent recipient advocates; surveys from patients living with HIV who are on an organ waitlist about their attitudes and beliefs about HIV+ transplants; and efforts to develop patient reported ethical outcome measures regarding these transplants
- Explore how IRBs and policy makers may use these data to help ensure HIV+/HIV+ transplantation is responsibly and appropriately translated into clinical practice

## A7

### Introduction to Ethical Principles for Research Involving Humans as Study Subjects

(Ethical Issues Track) Charlotte H. Coley, Robert J. Levine

Room 006B



Basic

Various ethical norms, standards, and principles, as well as professional standards, speak to researchers' and institutions' responsibilities for the protection of persons who participate as study subjects. This session will provide attendees with an overview of these ethics frameworks. During this session, speakers will:

- Discuss the evolution and development of prevailing ethics norms, standards, and principles for human research protections
- Identify distinctions between ethics frameworks from legal requirements for the protection of human research subjects
- Examine, through case studies, how researchers, institutions, and IRBs may address ethics challenges in studies with human subjects

#### ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

## A8

### The Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

(FDA Regulations Track) Owen Faris, Karen L. Ullisney

To protect and promote public health, FDA needs to understand and evaluate the available evidence related to regulated products. For medical devices, available evidence is traditionally comprised of non-clinical and, in some cases, clinical studies conducted and provided to FDA by the device manufacturer or sponsor. However, FDA recognizes that a wealth of data covering medical device experience exists and is routinely collected in the course of treatment and management of patients. In July of 2016, FDA's Center for Device Evaluation and Radiological Health issued draft guidance for public comment on the use of real-world data to determine whether it may be sufficiently relevant and reliable to generate the types of real-world evidence that can be used in FDA regulatory decision-making for medical devices. During this session, speakers will:

- Discuss general considerations for the use of real-world evidence
- Examine whether the collection of real-world data may be subject to the application of the FDA regulatory requirements
- Explore the relevance and reliability of real-world data sources
- Provide examples of where real-world evidence may be useful for regulatory decision-making
- Outline the IRBs role in the oversight of real-world evidence studies

Room 217C



## A9

### Different Models of Review: A Global Comparison (Global Research Track)

Byung-in Choe, Sujatha Sridhar, Delia Y. Wolf, Rachel Zand

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. 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 related to the quality of such reviews, the turnaround time for reviews when multiple committees review the same protocols, and the implication for human resources? During this session, speakers 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

Room 209



## A10

### Exploring and Enhancing Diversity Within Our Compliance Committees (Hot Topics Track)

Eric Allen, Owen Garrick

Diversity is one of PRIM&R's core values. During this session, speakers and attendees will discuss ways to promote regulatory affairs/regulatory compliance through the lens of diversity, and will:

- Define diversity, inclusion, and implicit bias
- Explore the benefits and challenges of working within diverse groups
- Examine mechanisms to increase diversity competencies of regulatory personnel and committee members who communicate with researchers from diverse backgrounds
- Discuss how to manage conflict while embracing diverse perspectives

Room 216B



#### ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

## A11

### Let's Walk the Line Together: Examining the Work of Human Subjects Research Compliance Programs

(Institutional Officials and HRPP Leadership Track) Jeri R. Barney, Scott J. Lipkin, Jessica A. Randall

Even though the HHS Office of Inspector General developed draft guidance in 2005 on the essential elements of a compliance program, there is little agreement in the field regarding the structure of the compliance program, or what should be the process for detecting, determining, and managing noncompliance. During this session, speakers and attendees will:

- Review the various structures, staffing patterns, and functions of compliance programs
- Explore the types of changes that should be made to compliance programs in light of the revised Common Rule
- Discuss the variation in programs in relation to serious and continuing noncompliance determinations
- Share best practices and models that promote collaboration between the compliance program and HRPP
- Solicit collaborative sharing across programs in order to define next steps required for better understanding of compliance programs

Room 214D



## A12

### To IRB or Not to IRB, That Is the Question (IRB 101 Track)

Paula Bistak, Donna Hoagland, Cheryl A. Savini

This session is for novice IRB administrators or researchers seeking to better understand the IRB. This session will also offer alternatives to IRB review for research that is non-human subjects or exempt. This session will provide a systematic presentation explaining when an institution is "engaged" in human subjects research and needs IRB review, and what human subjects activities need to be reviewed by an IRB. During this session, speakers and attendees will:

- Identify when an institution is "engaged" in human subjects research
- Clarify what research activities need to be reviewed by an IRB
- Discuss alternatives to IRB review

Room 217B



Basic

## A13

### Meeting Management for IRB Chairs (IRB Chairs Track) Barbara Engel, R. Peter Iafraite

This session will cover key topics in the management of an IRB meeting from the IRB chair's perspective. During this session, speakers will:

- Discuss the fundamentals of meeting management and member interactions from a leadership perspective
- Explore how to increase engagement of members and interaction with staff/consultants
- Focus on tips, strategies, and approaches to becoming an IRB chair or building on current skills and training

Room 214A



## A14

### Considerations When Transitioning to the Revised Common Rule

(IRB Operations Advanced Track)

Lauren Hartsmith, P. Pearl O'Rourke, Heather H. Pierce

Transitioning to the revised Common Rule poses complex questions on many levels. OHRP staff and experienced institutional representatives will discuss these complexities and how to manage them. Attendees should have reviewed the proposed revisions to the Common Rule before attending the session. During this session, speakers will:

- Provide information on the compliance dates and transition provisions, the complexities involved with implementation of the revised Common Rule, and considerations institutions might wish to undertake in preparing for implementation
- Share their concerns and experience regarding the implementation of the revised Common Rule

Room 217A



Advanced

## ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	



A15

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

(Issues Pharma/Biotech Track) Albert J. Allen, David G. Forster, Megan Kasimatis Singleton

Room 211



FDA regulations and the Common Rule 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. In many cases protocol deviations may be avoided by careful consideration regarding protocol design and/or by prospectively seeking IRB/sponsor approval. This session will discuss effective policy and processing considerations to enhance compliance with protocols. During this session, speakers will:

- Present the perspective of industry, academia and independent IRB about the review and management of deviations and violations
- Discuss varied definitions of deviations and violations and how differences in these definitions may impact reporting requirements
- Provide recommendations for best practices in managing review of deviations and violations, with specific consideration of new challenges in managing deviations/violations in the era of single IRB review

A16

### The Evolving Clinical Research Enterprise: What Recent Legal and Regulatory Changes Mean to You

(Legal Track) Barbara E. Bierer, Dominic Chiarelli, Emily M. Levine

Room 214B



This year has ushered in a tide of statutory and regulatory revisions and other policy innovations (e.g., Common Rule requirements, 21st Century Cures Act, NIH Grants Policy, etc.) intended to modernize clinical research and human subject protections. While most agree tweaks were needed, the sudden and dramatic influx of change has created uncertainty for research administrators, IRBs, and principal investigators. This session will help orient attendees to the recent changes, and highlight aspects that may require deeper consideration. During this sessions, speakers will:

- Introduce recently proposed and adopted changes affecting clinical research
- Outline key consideration related to the changes and possible implementation hurdles
- Provide a road map to other conference sessions where a more in-depth review of each may be presented

A17

### Defining Roles, Expectations, and Challenges for the Non-Scientist IRB Member

(Non-Scientist IRB Members Track) Michelle M. Feige, Dahrn A. Johnson, Nancy A. Olson

Room 212



This session will describe the background, role, and expectations of the non-scientist IRB member and define research and regulatory terminology that commonly occurs during protocol review. A non-scientist IRB member will share his perspective about the "who, what, where, why, and how" of IRB membership. Speakers will also facilitate discussion, provide tips for reviewing research, and suggestions for success. "During this session, speakers and attendees will:

- Outline the role of the non-scientist IRB member on the IRB and the importance of this role to the review process
- Discuss first-hand knowledge and perspective of how the non-scientist IRB member can best contribute to the IRB
- Identify the problematic areas of protocols
- Define specific issues for methodological consideration in IRB review
- Provide suggestions for the non-scientist IRB member when reviewing challenging protocol

A18

### Obtaining Consent from Subjects for Bio/Data Repositories: Evaluating Approaches and Their Implications for Future Solutions

(Out-of-Body Experiences: Research Involving Tissue and Data Track)

Mildred Cho, Christine Grady, Sarah Marie Huban

Room 205



Using case examples from institutions/individuals who have adopted a variety of consenting strategies for bio/data repositories, this session will explore the pitfalls and successes of varied consenting approaches, and evaluate how lessons learned from past efforts can help inform new strategies to operationalize consent for bio/data repositories. During this session, speakers will:

- Describe varied approaches to consent and evaluate the pitfalls/successes of each approach
- Review the practical implications for each consenting approach
- Provide tips for institutions in selecting and implementing their consent approach

#### ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

A19

**Vulnerability: Concepts and Applications** (*Populations Requiring Additional Protections Track*)

Bruce G. Gordon, Robert E. Nobles

Speakers will discuss an expanded view of vulnerability beyond what is outlined in the regulations, including: diminished capacity, cultural sensitivities, and power differentials (e.g., students as subjects). Attendees should have a basic understanding of the regulations that cover vulnerable populations before attending this session. During this session, speakers will:

- Share examples of different types of vulnerabilities and explore how to consider and deal with them in the context of clinical research
- Discuss the threshold questions an IRB should address before permitting research with these subjects
- Review examples of risks particular to these subjects that may differ from those usually considered
- Show how to incorporate appropriate additional protections into informed consent

Room 206A



Advanced

A20

**Impact of the Revised Common Rule on QA/QI Programs** (*QA/QI and Post-Approval Monitoring Track*)

Edward E. Bartlett (OHRP resource person), David A. Borasky, Jr., Sarah A. White

The changes in the revised Common Rule decrease upfront review of human subjects research. Based on their role of being onsite with the investigator and study teams, QA/QI programs could play an important role as the revised Common Rule is implemented at institutions. Could additional post-approval monitoring of the investigator site ensure investigators are in compliance? During this session, speakers and attendees will:

- Discuss whether audits/on-site reviews aid in institutional control/oversight in exempt, non-research, and limited research projects
- Explore what happens to minimal risk/expedited research, and whether, after the research has started, quality improvement audits/on-site reviews could improve protocol adherence and reporting adverse events/deviations
- Outline whether in studies under a single IRB investigator, audits/on-site reviews could help inform reviewing and relying IRBs of what's going on at the site

Room 006CD



A21

**IRB Review of Big Data Research** (*Research Conducted in the Digital World Track*)

Jacob Metcalf, Laura Odwazny, Ivor A. Pritchard, Stephen J. Rosenfeld

This session will explore the evolution of the field of big data health research, discuss the Secretary's Advisory Committee on Human Research Protections (SACHRP) recommendations on big data research and how provisions of the revised Common Rule apply in the context of big data research, and review some of the real-life cases that exemplify considerations of risk assessment with regard to big data research. Data scientists have expressed concern that IRBs create delays, over-regulation and road-blocks due to misapplied or un-empirical risk and privacy assessments. Some of those concerns may be ameliorated by new exemption categories in the revised Common Rule, which could operate to exclude a significant portion of big data health research from IRB review. Further, increased IRB expertise as to risk assessment and risk management in the context of big data health research can serve to dismiss 'hype' regarding the actual risks and benefits to research participants and facilitate ethical research with these valuable data sets. At the same time, we will discuss how big data research techniques pose new forms of risk that are largely invisible to the Common Rule and outside of the regulatory purview of IRBs. Attendees should be experienced with IRB review of research involving different types and sources of health datasets, and familiar with the regulatory criteria for levels of IRB review required. During this session, speakers will:

- Identify big data health research, including the overlap with social and behavioral research
- Discuss the real and perceived risks and benefits of big data research, SACHRP recommendations pertinent to big data research, and the implications for applying the Common Rule requirements
- Identify changes to the Common Rule that may be especially significant for some types of this research
- Share options for increasing protection of subject privacy and confidentiality through appropriate safeguards for information in health data sets

Room 007CD



Advanced

ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

A22

International Case Studies in Research Misconduct - **CANCELLED**

A23

Understanding and Negotiating Your Way Around a Small Research Program: The Basics

(Small Research Programs Track) Bonnie Frisard, Delilah Ofosu-Barko

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

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

Room 215



Basic

A24

Rules, Glorious Rules (SBER Track)

Le'Quan Jackson, Andrew P. Rusczyk, Julie F. Simpson

This session will provide an overview of the major types of rules IRBs and researchers need to consider when designing, reviewing, and conducting research studies in the United States beyond 45 CFR 46 and the FDA regulations. These rules include: federal laws and regulations, sponsoring agency requirements, state laws, institutional policies, and journal requirements. During this session, speakers will:

- Review the federal laws and regulations that impact human subjects research (e.g., Family Educational Rights and Privacy Act, Protection of Pupil Rights Amendment, Health Insurance Portability and Accountability Act, Title IX)
- Examine federal funding agency requirements for studies involving human subjects (e.g., NIH's ClinicalTrials.gov requirement, Department of Justice Privacy Certificates)
- Discuss types of state mandatory reporting laws and the implications for confidentiality and risk assessments
- Explore types of institutional policies and journal requirements that may impact human subjects research (e.g., Title IX reporting, open data requirements)

Room 206B



Basic

A25

Assessing and Mitigating Risk in SBER Research: A Case Study Approach (SBER Track)

Amy Ben-Arieh, Jennifer A. Graf

Unlike the sometimes easily quantifiable risks of biomedical research, SBER risks are often time- and situation-specific, variable, very subjective, less predictable than many biomedical risks, and often unknown (there is little or no empirical data on the likelihood of risk in behavioral or social research). During this session, speakers will present SBER case studies created by the SBER Subcommittee of the Harvard Catalyst Regulatory Foundations, Ethics, and Law Program that were designed to help assess risks of various kinds of SBER studies. During this session, speakers and attendees will:

- Review the nature of the risks, harms, and impacts associated with SBER
- Explore factors likely to contribute to increased risk in otherwise relatively low-risk research
- Go over how to design research with sufficient protections in place to minimize the risk of negative impacts
- Discuss how risks may change as the nature of the research changes or moves forward in a different direction

Room 213



3:00-3:30 PM

Beverage Break Supported by Quorum Review IRB

Join us for coffee and cold drinks in the Exhibit Hall. PRIM&R would like to thank Quorum Review IRB for helping to support this break.

Exhibit Hall 4B

ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

B1

**A Dialogue With the Office for Research Integrity (ORI)** (*A Dialogue with the Feds Track*)

Kathy M. Partin

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

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

Room 218



B2

**A Dialogue With Patient-Centered Outcomes Research Institute (PCORI)** (*A Dialogue With the Feds Track*)

Neal W. Dickert, Jr., Jason Gerson, Joe V. Selby

This interactive session will be led by representatives from PCORI, a funder of clinical comparative effectiveness research (CER). Critical human subjects protections challenges arise in the conduct of the "real-world" studies funded by PCORI, such as big data studies requiring data linkages between two or more data sets (e.g., claims data, electronic health record data, and registry data) held by different entities raise privacy and informed consent issues for the data owners, funders, researchers, and IRBs. For cluster randomized clinical trials where individual informed consent is not usually feasible, alternative ways of involving and informing patient communities that a study is underway would be extremely valuable. PCORI staff will discuss some of these challenges, and one awardee will present relevant work from PCORI-funded study on the ethics of CER. Attendees are encouraged to come with questions of interest to all. During this session, speakers and attendees will:

- Hear from representatives of PCORI about their experience with HSP issues, such as informed consent, privacy, data and safety monitoring
- Discuss PCORI-funded empirical bioethics projects with a PCORI awardee
- Ask questions about key human subjects protections challenges in conducting CER

Room 206A



B3

**Defining and Measuring IRB Quality** (*Advanced Forum for IRB Professionals Track*)

Holly Fernandez Lynch, Holly A. Taylor

The burdens imposed by IRB review are often lamented by investigators and have been the subject of substantial empirical research. Even after stripping away burdens related to inefficiency, inconsistency, and bureaucracy, how can we tell whether the intentional burdens imposed by the IRB system are worth it? Beyond regulatory compliance and procedural measures, what are IRBs supposed to do? How can we assess whether they are achieving those goals? And, what improvements can be made to the system? With implementation of the NIH Policy on the Use of a Single IRB for Multi-Site Research (and recent changes to the Common Rule), how can local IRBs monitor reviewing IRBs to ensure both regulatory and ethical standards are satisfied? Overall, how can we identify "quality IRBs" and, ultimately, how can we answer the question "is a world with IRBs better than one without it?" Attendees should have a strong familiarity with the revised Common Rule and a basic understanding of the history of the regulatory and ethical requirements for IRB review prior to attending this session. During this session, speakers and attendees will:

- Identify key concerns regarding the burdens of IRB review
- Discuss goals of the IRB system beyond regulatory compliance, and consider potential mechanisms for measuring whether those goals are being met
- Consider policies and approaches to improving and measuring IRB quality at an institution, and at reviewing IRBs in multi-site studies

Room 006CD



Advanced

B4

**The Seven Habits of Highly Effective and Flexible IRBs** (*Boundaries and Balance Track*)

Jeffrey A. Cooper, Jonathan M. Green, Ernest D. Prentice

Attendees will learn how to identify ways the IRB can be more effective at protecting subjects, while also becoming more efficient. Experts will explore ways to reduce time-consuming activities that can be eliminated in order to focus more effectively on the critical requirements of the IRB, including the implications of best practices in the revised Common Rule requirements that pertain to continuing review, limited IRB review, and broad consent. During this session, speakers will:

- Differentiate between what the IRB must do and what it can delegate
- Discuss ways to limit the back and forth with the IRB
- Suggest ways to streamline submissions
- Create mechanisms to identify issues before they go to the IRB for review

Room 007AB



ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

B5

**Navigating IRB Review and the Determination Process in the Era of the Revised Common Rule: What Investigators Need to Pay Attention to and the Role of Decision Tools** (*Educating and Training Track*)

Gretchen L. J. Anding, Shawn L. Axe, Julia G. Gorey

This session will explore the role of decision tools in determining the necessity and level of IRB review. It will examine the types of IRB review listed under the revised Common Rule, and will offer perspectives from HRPP staff from research institutions with different levels of resources on how they handle the IRB review and the determination process. During this session, speakers and attendees will:

- Examine the role of decision tools in helping investigators understand the necessity and level of IRB review
- Explore the IRB's role in limited, expedited, and continuing reviews insofar as is useful for investigators to know
- Describe investigators' responsibilities in the era of the revised Common Rule
- Discuss shared experiences from the perspectives of research institutions with different levels of resources

Room 214A



B6

**Stakeholder Perceptions on Early Informed Consent for Clinical Trials** (*Empirical Research Ethics Track*)

Amy Corneli, Thomas L. Holland

In an era of increasing antibiotic resistance, new antibiotics for treating Hospital-Acquired Bacterial Pneumonia (HABP) and Ventilator-Associated Bacterial Pneumonia (VABP) are critically needed. Yet, implementing HABP/VABP therapeutic clinical trials is challenging because of clinical care standards and FDA requirements. One way to address these challenges is to use an early enrollment strategy, whereby, patients at high risk for developing HABP or VABP (or their legally authorized representatives (LARs)) are asked to give their informed consent to enroll in a clinical trial in advance of developing pneumonia. Patients agree to study staff monitoring their condition and, if pneumonia develops, to being randomized to receive one of the study antibiotics. Formative research was conducted to assess the acceptability of this early enrollment approach and to identify essential information that should be explained about an early enrollment strategy among key stakeholders: patients at risk for HABP/VABP, LARs, study coordinators, investigators, and members of IRBs. The formative research was followed by a Delphi process among all study human subjects to build consensus on language to use in the future informed consent process about how to explain topics that were identified as essential. During this session, speakers will:

- Describe human subjects' acceptance of an early enrollment strategy, including perceptions on consenting to enroll in the study before developing the condition under investigation
- Discuss the type of information human subjects believed to be essential to include in the informed consent form
- Provide findings from the Delphi process on building consensus on key consent language

Room 216B



B7

**The Ethics of Genome Editing** (*Ethical Issues Track*)

Stacey A. Donnelly, Carol Juliet Weil

CRISPR-Cas9 promises to be the most efficient method of gene editing available today, and the watershed biological discovery of this century. The medical promises of this technology are endless, as are the ways for potential abuse. This session will review the basics of how the technology works, and introduce the fundamental terms and myriad ethical issues this technology raises. Speakers will debate the ethical decisions society will be forced to struggle with as we review the recent report by the National Academies of Science, Engineering, and Medicine titled, *Human Genome Editing: Science, Ethics, and Governance*. During this session, speakers will:

- Review how genome editing works, and introduce basic terminology related to genome editing (e.g., somatic vs. germline, CRISPR-Cas9, etc.)
- Discuss the ethical questions and concerns raised by this technology
- Explore the various positions on genome editing/engineering and how these positions support their stance on what policies should be put into place to govern this powerful tool
- Examine the points made in *Human Genome Editing: Science, Ethics, and Governance*, and assess its recommendations

Room 205



ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	



B8

### FDA's Office of Regulatory Affairs (ORA) Realignment and What it Means for Your Next FDA Inspection

(FDA Regulations Track) Chrissy J. Cochran

FDA's ORA, which conducts Bioresearch Monitoring (BIMO) inspections, has reorganized and moved away from a geographic regional management model to align with a commodity-based program structure. During this session, FDA's BIMO Program Director will:

- Explain the functional and organizational changes in the ORA reorganization
- Discuss what's new for the BIMO inspection program
- Answer BIMO inspection questions

Room 212



B9

### Human Subjects Protections Across Borders (Global Research Track)

Edward E. Bartlett, John R. Baumann, Byung-in Choe

While there are challenges to human subjects oversight of intra-national research collaborations, they pale in comparison to those faced when participating in international research collaborations including, but not limited to, those arising from different cultural, regulatory, and institutional contexts. But, then, so do the opportunities. This session will explore the various challenges that HRPPs face when conducting collaborative international research. Speakers will discuss how they would address a variety of issues that may arise regarding protections of human subjects in international research. During this session, speakers and attendees will:

- Identify the various challenges in human subjects protections international research collaborations
- Discuss various approaches for the elimination or mitigation of challenges to human subjects oversight of international research collaborations
- Examine policy and process best practices for IRB/ethics committees in the review of inter/trans-national human subjects research

Note: this session is also on the SBER17 agenda (session C6)

Room 210



B10

### IRB Review of Research With Participants at Increased Risk for Suicide (Hot Topics Track)

David H. Strauss

In the last year for which data is available, nearly 45,000 people died as a result of suicide in the United States. The vast majority of these suffered from mental illness and nearly half committed suicide with a firearm. More startlingly, the rate of suicide in the United States population has increased steadily and consistently since 1999. Research on the causes and prevention of suicide is essential and good research demands careful attention to the safe and appropriate inclusion of individuals at risk for suicide. This session will emphasize the importance of research on suicide, review conceptual and practical considerations in the identification and minimization of risk in research with suicidal patients, and use case discussion to apply principles and engage workshop participants. During this session, speakers will:

- Describe the National Institute of Mental Health (NIMH) guidance on suicide research
- Explore the challenges in doing this type of research and what IRBs and researchers should know
- Address if and how changes to the Common Rule will affect this type of research

Room 215



B11

### Structure and Organization of HRPPs: Leadership Observations and Perspectives, and Lessons Learned

(Institutional Officials and HRPP Leadership Track) Lois Brako, Cheryl L. Byers, Kristin J. Craun

HRPPs may vary considerably across institutions, including with regard to organizational placement, staffing, and resources. This session will bring together institutional officials and HRPP leadership to describe their HRPP structures (e.g., centralized or independent, including challenges, successes, and lessons learned). During this session, speakers and attendees will:

- Describe models of HRPP organization, including leadership, staffing, workload, and IRBs
- Discuss challenges and successes of different HRPP models with regard to post-approval compliance monitoring
- Examine the prospect of organizational change or restructuring in response to new Common Rule revisions, particularly reduced regulatory burdens upon institutional HRPPs and IRBs

Room 006B



Basic

#### ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	



B12

### Back to Basics: Does My Project Fall Within the Scope of the Revised Common Rule, or Is it Exempt?

(IRB 101 Track) Angela Hvitved

This interactive session aims to assist investigators and IRBs with the initial assessment and determination as to whether a study project falls within the scope of the revised Common Rule, especially concentrating on the new exemption categories. During this session, speakers and attendees will:

- Review the definitions of research, human subjects, and exemptions under the revised Common Rule
- Identify how the revised Common Rule differs from the original rule
- Discuss the flexibilities provided by the revised Common Rule and use case examples to assist the audience with understanding and applying the revised Common Rule

Room 008AB



Basic

B13

### IRB Chair Responsibilities and Roles: Beyond the IRB Meeting (IRB Chairs Track)

J. Andy Bertolatus, Geeta K. Swamy

The work of the IRB chair is primarily conducted outside of IRB meetings, and this session will review the broad spectrum of other duties assigned to an IRB chair. During this session, speakers and attendees will:

- Discuss how IRB chairs, especially in small institutions, have added responsibilities and challenges, often without significant administrative support
- Review best practices for pre-review and preparation for an IRB meeting, and the regulatory expertise required of the chair or designee
- Describe techniques used in resolving disputed issues between IRBs and researchers
- Share practices for communicating with the research integrity office, legal counsel, risk management, sponsored programs, and others

Room 214C



B14

### Tips and Tools for Implementing Single IRB Review

(IRB Operations Advanced Track) Carol Pech, Kimberly K. Summers

This session will focus on providing practical guidance for implementing single IRB review. Although general guidance exists, access to specific tools and practices successfully employed by institutions to implement single IRB review is much harder to come by. This interactive session will show how tools and practices are used by IRBs at different institutions to implement single IRB review and, through a discussion with attendees, provide tips on how to adapt these tools for use at other institutions. Attendees should be familiar with the proposed revisions to the Common Rule related to cooperative research and the NIH Policy on the Use of a Single IRB of Record for Multi-Site Research. During this session, speakers and attendees will:

- Discuss, in practical terms, how single IRB review can be successfully implemented at a range of institutions
- Share tools (e.g., tracking sheets, workflows, etc.) that can be adapted by other institutions seeking to implement efficient single IRB review processes
- Provide tips for handling the more challenging aspects of single IRB review, whether relying on another IRB or serving as the reviewing IRB

Room 007CD



Advanced

B15

### Designing and Implementing Expanded Access Programs

(Issues Pharma/Biotech Track) Marjorie A. Speers, Walter Straus

This session will discuss how institutions and sponsor companies are approaching expanded access, especially in light of public scrutiny/social media interest in decisions about access, questions about conflicts of interest, and equitable selection of individuals for access opportunities. During this session, speakers will:

- Explain the legal frameworks applicable to expanded access, including FDA's existing regulatory structure
- Review the potential ethical risks raised by access to investigational drugs outside of controlled clinical trials, including therapeutic misconception, distribution of unsafe drugs, and the potential harm from unknown side effects
- Address where the line between autonomy and beneficence should be drawn for terminal patients seeking access to investigational products (i.e., do we, as a society, have an obligation to allow people this choice, or an obligation to help patients accept futility and death?)
- Discuss strategies institutions and sponsor companies are implementing to evaluate access requests

Room 206B



Advanced

#### ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

B16

**Mastering Master Agreements: When Are Broad-Based Standardized Agreements Beneficial to Research Collaborations?** (*Legal Track*) Nichelle Cobb, Libby D. Salberg

This session will explore the research community's shift to master research agreements in various contexts, including clinical trial agreements (e.g., Accelerated Clinical Trial Agreement), IRB reliance agreements (e.g., SMART IRB), federal sub-award agreements (e.g., The Federal Demonstration Partnership), etc. What goals drive this "master" approach to standardizing research contracting? If efficiencies are gained, at what cost? What should institutions be aware of when asked to sign-on to such agreements? Are there specific terms institutions should include in order to avoid potential pitfalls of such agreements? This session will provide practical experiences from institutions that have used these agreements to educate attendees on the pros and cons of master agreements, with a particular eye towards the way in which such reliance agreements may be used to meet the new single IRB mandate. During this session, speakers will:

- Review common types of master agreements in the research context
- Discuss the benefits of entering into such agreements
- Outline the challenges institutions can expect to encounter when using master agreements
- Explore potential pitfalls of such agreements, and the terms institutions should be aware of when entering such arrangements

Room 217C



Basic

B17

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

H. Lester Kirchner, Sharon Shriver

This session will focus on the intimidating statistical terms that make your eyes glaze over! Attendees will start by reviewing the statistical basics and then move on to a discussion of more advanced topics. During this session, speakers will:

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

Room 208



B18

**"Let it Go": What Should Be Exempt and How to Limit IRB Review of These Studies (Including Those With Sensitive Data)** (*Out-of-Body Experiences: Research Involving Tissue and Data Track*)

Teresa Doksum, Lauren Hartsmith, Daniel K. Nelson, Sean Owen, Katie B. Speanburg

This session will focus on how to interpret and apply the revisions to the Common Rule on exemption categories related to the new type of review, limited IRB review. Using case studies, speakers will share their experiences and provide suggestions for development of review processes that may meet the expectations of limited IRB review. Any additional guidance issued by the HHS and the Office of Management and Budget after January 10, 2017, about limited IRB review will be incorporated and discussed. During this session, speakers will:

- Describe how IRBs can implement a limited IRB review for studies that qualify for such a review
- Outline how to develop review processes that incorporate appropriate institutional partners
- Use case studies to highlight key components of limited IRB review required for research with data and biospecimens, and outline how the requirements for limited IRB review differ for each according to the new exemption criteria

Note: this session is also on the SBER17 agenda (session C4)

Room 217A



ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

B19

**Research With Children: Complexities in Practice** (*Populations Requiring Additional Protections Track*)

Bruce G. Gordon, Susan Z. Kornetsky, Robert M. "Skip" Nelson

In this session, speakers will dive deeper into the ethical complexities of conducting research with children and adolescents. Attendees of this session should have a strong foundation in the regulations that govern research with children and adolescents before attending the session. During this session, speakers will:

- Discuss complex issues related to conducting research with minors, including research conducted in school settings
- Review the ethical and practical issues related to assent and parental permission requirements, and share best practices
- Explore unique issues that may affect research with minors, including: internet research, emancipated minors, returning research results, etc.

Room 214D



Advanced

B20

**Nuts and Bolts of Investigator Site Audits** (*QA/QI and Post-Approval Monitoring Track*)

Kelly Dornin-Koss, Jennifer A. Graf, Jessica A. Randall

Investigator site audits are the hallmark of post-approval monitoring and are integrated into many IRB QA/QI programs. This session will introduce attendees to the key concepts and practical strategies for developing investigator on-site audit activities. During this session, speakers will:

- Provide an overview of the investigator site review/audit process
- Address specific considerations of the investigator audit activity, including: triggers for audits, sampling plans, grading/scaling on-site reviews, and who receives the report (the considerations will be compared/contrasted between multiple QA/QI programs)
- Discuss how audits can be an opportunity for investigator education
- Review practical and useful tools sites can modify for their own use

Room 217B



Basic

B21

**Crawling in the Dark: The Ethics of Research Use of Data From the Dark Web**

(*Research Conducted in the Digital World Track*) Jeremy N. Block, Elizabeth A. Buchanan, Brenda Curtis

This session will review a case study involving research use of breached data from the dark web, and the subsequent ethical dilemmas the IRB and institution grappled with (e.g., can researchers use data released by such groups as Anonymous?). In addition, the session will explore other types of data that exist from the dark web, and provide an opportunity for those in attendance to share their experiences with research use of data from this realm. During this session, speakers and attendees will:

- Define and describe the dark web and dark web research, and provide insights into review of this research
- Review identified and unidentified actors in the dark web (e.g., Anonymous)
- Discuss the potential ethical issues that may occur from research use of dark web data
- Share potential solutions and strategies to assist researchers in conducting dark web secondary data studies while protecting human subjects in research
- Learn about the resources and stakeholders available that can help institutions make decisions on research use of data from the dark web
- Bring to light ethical issues that can potentially appear from researchers using data from the dark web, and provide insights into review of this research based on a case study from a prominent research institution

Room 214B



Basic

ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

B22

## An Interdisciplinary Approach to Implementing Institutional Responsible Conduct of Research (RCR) Education

(Responsible Conduct of Research Track)

Carolyn J. Broccardo, Bradley R. Woods

This session will focus on implementing an inclusive RCR educational model that allows for incorporation of all disciplines, and it will provide a strategic set of approaches that have been successfully implemented at two major land-grant universities. Attendees will learn from interactive discussions, case study activities, and presentation of current institutional examples. During this session, speakers and attendees will:

- Review the evolution of RCR education from its roots in the biomedical sciences to current requirements, which now extend to the basic and applied sciences, as well as the humanities
- Discuss strategic models for establishing interdisciplinary RCR education programs at the institutional level
- Share best practices for oversight professionals in leveraging disciplinary expertise to engage institutional stakeholders in supporting RCR education

Room 211



B23

## How to Increase the Efficacy of the Underfunded IRB Office (Small Research Programs Track)

Sarah H. Kiskaddon, Greg E. Manship

Many smaller HRPPs are still working with limited support and funding. This session will provide processes that can be immediately applied to increase IRB efficiency, compliance, and effectiveness, as well as assist the beginning/intermediate IRB manager/administrator who needs additional strategies to manage the IRB process with restricted resources. During this session, speakers and attendees will:

- Outline an efficient process for the identification and review of incoming materials
- Discuss effective work flows and forms to support and document the process and review
- Review strategies to obtain additional support/resources

Room 209



B24

## SBER in the Era of the Revised Common Rule: An Overview of the Most Relevant Regulatory Changes

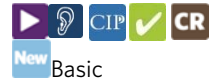
(SBER Track) Yvonne Lau

This presentation will provide a birds-eye-view summary of the changes to the Common Rule that are likely to have the most impact on SBER. During this session, the speaker will:

- Describe activities that are now excluded from the definition of research
- Review changes to exemptions, expedited review, and informed consent

Note: this session is also on the SBER17 agenda (session B4)

Room 217D



Basic

B25

## Mental Health and Safety Plans (SBER Track)

Julie Slayton, Matthew D. Stafford

Many studies involve assessments (e.g., quality of life questionnaires, behavioral assessments, mental health screens). In assessing risks and benefits, it's the IRBs responsibility to consider whether and how: (1) results of assessments are communicated back to the subject, or if the researcher has an obligation to follow up and/or offer resources to the subject; and (2) the researcher should be expected to communicate with healthcare providers under certain circumstances. There is often an expectation that appropriate information learned about a subject during the course of research will be utilized to maximize the potential for direct benefit to the human subject. However, specific immediate safety plans may only be required when a subject may be at risk for immediate harm to oneself or others. In some situations, information may be expected based on the characteristics of the eligible research population or the information may be learned incidentally. Speakers will provide helpful anecdotes and sample plans will be available for discussion. During this session, speakers and attendees will:

- Go over what triggers the need for a safety plan, and best practices for the procedures that researchers should be expected to use
- Review what type of questionnaires or assessments would require an immediate safety action plan
- Discuss the responsibility of the researcher when assessments are administered online, and/or when there is a planned time delay between the administration of the assessment and the review of the data captured by that assessment
- Explore when quality of life assessments or questionnaires should require a safety action plan
- Share examples of immediate safety plans

Room 213



Advanced

### ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

4:45-5:05 PM

Exhibit Hall 4B

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

Join us in the demo theater in the Exhibit Hall to learn about the many benefits that PRIM&R membership has to offer. During this overview, you'll learn about the ways membership pays for itself during the course of the year, provides invaluable networking resources, and more. If you are unable to join us at this time, but would like to learn more about your current member benefits (or becoming a member) while onsite at the conference, stop by the PRIM&R Booth or [email](#) Shana Sonbolian, membership coordinator, for more information.

4:45-6:00 PM

Exhibit Hall 4B

**AER17 Welcome Reception**

Join us in the Exhibit Hall to celebrate the opening of AER17. During this time, you'll be able to meet our conference Supporters and Exhibitors and view the Poster Presentations. Drinks and light refreshments will be served.

4:45-6:00 PM

Exhibit Hall 4B

**Federal Agency/Accrediting Body Office Hours**

Do you have specific questions for federal agency or the accrediting body representatives? Or, do you have a follow-up question after attending a session that featured a federal agency or accrediting body representative(s)? If so, representatives from the following federal agencies/accrediting body will be available during this time slot to help answer your questions:

- AAHRPP, Inc.
- DOE
- FDA
- OHRP
- ORI
- VA

5:35-5:55 PM

Exhibit Hall 4B

**PRIM&R's Research Ethics Snapshots in Action**

PRIM&R has launched a new educational resource, Research Ethics Snapshots, to provide quick, on-demand, interactive, and engaging learning opportunities. Snapshots can be used for a 15-minute discussion at an IRB meeting, for an informal discussion or icebreaker at an office gathering, or for individual use. Join us in the demo theater in the Exhibit Hall to participate in a discussion about Research Ethics Snapshot, and find out first-hand how these fun mini-case studies work in action. If you are unable to join us, but would like to learn more about Research Ethics Snapshots while onsite at the conference, stop by the PRIM&R Booth or [email](#) Nora Murphy, online learning coordinator, for more information.

6:30-8:30 PM

Offsite:  
Guadalajara Grill**Young Professionals Networking Reception**

Connect with other young professionals interested in research ethics and relax after a busy day in San Antonio at Guadalajara Grill (301 South Alamo Street, San Antonio, TX, 78205, on the second floor). Don't forget to bring the drink ticket you will receive when you check in onsite! While all attendees are welcome, complimentary drink tickets will be provided for young professional registrants only.

**ICON KEY**

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

7:00 AM

**On-Site Check-In Opens**

Breakfast on your own.

Hall 4 West Lobby

7:15-8:00 AM

**A Capella Musical Performance Supported by Tech Software**

Join us before the conference starts for a musical performance by a local a capella group. PRIM&R would like to thank Tech Software for supporting this performance.

Exhibit Hall 4A

8:00-8:15 AM

**Welcome from the Conference Co-Chairs**

P. Pearl O'Rourke, MD, Director, Human Research Affairs, Partners HealthCare System, Inc.; Associate Professor, Pediatrics, Harvard Medical School

Laura Odwazny, JD, MA, Senior Attorney, Office of the General Counsel, HHS

Exhibit Hall 4A



8:15-8:30 AM

**Presentation of PRIM&R's Applied Research Ethics National Association Legacy Award to Ada Sue Selwitz, MA, Executive Integrity/Compliance Advisor; Adjunct Associate Professor, Department of Behavioral Sciences, College of Medicine; Co-Director, Center for Clinical and Translational Science Regulatory Support, University of Kentucky**

Presented by Susan Z. Kornetsky, MPH, Senior Director, Clinical Research Compliance, Boston Children's Hospital; Board Chair, PRIM&R

Exhibit Hall 4A



8:30-9:15 AM

**Keynote Address: The Continuum from Truth and Knowledge Generation to Opinion to False Information: Do We Have the Right Balance?**

Robert M. Califf, MD, MACC, Donald F. Fortin, MD, Professor of Cardiology; Professor of Medicine, Division of Cardiology, Duke University School of Medicine; Adjunct Professor of Medicine, Stanford University; Advisor, Verily

Exhibit Hall 4A



9:15-9:45 AM

**Beverage Break Supported by HRP Consulting Group**

Join us for coffee in the Exhibit Hall. PRIM&R would like to thank HRP Consulting Group for helping to support this break.

Exhibit Hall 4B

**Innovations in... Series, 9:45-10:45 AM**

The Innovations in... panel series features poster authors from this year's Poster Presentation Program 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.

**Innovations A: Innovations in Emergency and Disaster Research Settings**

Exhibit Hall 4A

**Moderator:** Emily E. Anderson

Research during health emergencies and disasters is vital; however, ethical concerns with a stressed population and constraints inherent in the regulations make it difficult to initiate studies in a timely fashion. During this panel, three poster authors will discuss their work related to research done in public health emergency and/or disaster settings, including the Zika vaccine for pregnant women, prehospital informed consent processes following traumatic injuries, and the National Institute of Environmental Health Sciences Best Practices Working Group for Special IRB Considerations in the Review of Disaster Related Research, which the NIH formed to enhance research oversight capacity after crises such as these.

- **Poster #20: [Women's Views About Rules Governing Reproductive Issues in the Context of Biomedical Clinical Trials](#)**  
Kristen Sullivan
- **Poster #27: [FDA and IRB Approval of a Novel Prehospital Consent Process for Emergency Research](#)**  
Michael Linke
- **Poster #62: [Conducting Science in Disasters: Recommendations from the National Institutes of Health/National Institute of Environmental Health Sciences Working Group for Special IRB Considerations in the Review of Disaster Related Research](#)**  
Joan Patrice Packenham

**ICON KEY**

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	



**Innovations B: Innovations in IRB Function****Moderator:** Cheryl A. Savini

As research programs flourish, institutions invest more in undergraduate education, and research collaborations happen more frequently, it's important for IRBs to recognize the steps needed to streamline processes for more effective operations. From a learning management system that includes resources for putting together protocols, to joint ethics reviews to address capacity needs for research ethics review in Sudan, to the formation of a Central IRB (cIRB) Liaison Team to streamline cIRB-related processes, this panel will feature three poster authors who will discuss how they improved their IRB functions, while maintaining human subjects protections standards.

- **Poster #34: [Joint Ethics Review of a Clinical Trial in Sudan: Experiences and a Way Forward](#)**  
Serah W. Gitome
- **Poster #49: [Clinical Coordination Center and Academic Central IRB \(cIRB\): The cIRB Liaison Team—The Tie That Binds Them](#)**  
Melissa J. Ricker
- **Poster #11: [Improving IRB Application Success Through a Learning Management System](#)**  
Megan Williams

Hemisfair Ballroom 3

**Innovations C: Innovations in Research With Overlooked Ethical Perspectives****Moderator:** Warren Capell

In order to maintain strong and meaningful standards of human subjects protections, research must be done to gauge participant perceptions of common practices. This panel will feature three poster authors who surveyed research participants to get their thoughts on common practices that are often perceived as potentially problematic. These authors conducted qualitative studies with, respectively, surgical cancer patients on their understanding of their broad consent for future biobanking research; persons who inject drugs (PWIDs) regarding their privacy concerns with photographic data; and US military service members on their research experiences to provide insight into various potential ethical concerns.

- **Poster #14: [Agency in Photovoice Research: Exploring the Lived Experience of Persons Who Inject Drugs](#)**  
Suzanne Carlberg-Racich
- **Poster #67: [Insider Experiences: United States Military Service Members as Participants in Health Research](#)**  
Wendy A. Cook
- **Poster #2: [Multi-Site Survey of Cancer Patients Who Donated Excess Surgical Tissue for Broad Future Research Uses](#)**  
Carol Juliet Weil

Hemisfair Ballroom 1

**Didactic Sessions and Workshops Series C, 11:00 AM-12:15 PM****C1****A Dialogue With the Secretary's Advisory Committee on Human Research Protections (SACHP)***(A Dialogue With the Feds Track)*

Mark Barnes, David A. Borasky, David G. Forster, Julia G. Gorey, Stephen J. Rosenfeld

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

- Hear from SACHP representatives about evolving initiatives, issues, and guidance
- Participate in an open discussion about topics relevant to SACHP stakeholders
- Discuss best practices currently under consideration by SACHP
- Ask questions of SACHP representatives

Room 205

**C2****A Dialogue With the FDA (A Dialogue With the Feds Track)**

Owen Faris, Jan L. Hewett, Joanne R. Less, Diane M. Maloney, Patrick J. McNeilly, Kevin A. Prohaska

This interactive session will be led by representatives from the FDA who will provide brief updates on FDA activities within their center/office, and then open up the session for questions. Attendees are encouraged to come with questions of interest to all. During this session, speakers and attendees will:

- Hear from representatives of the FDA about new and evolving issues, initiatives, regulations, and guidance
- Participate in an open discussion about topics relevant to FDA stakeholders
- Ask questions about evolving issues and initiatives at the FDA

Room 213

**ICON KEY**

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

C3

### Human Subjects Protections in Patient-Centered Outcomes Research (PCOR): Challenges and Opportunities

(Hot Topics Track) Luke Gelinas, Emily Largent, Joel Weissman

This session will focus on research and discuss perspectives on IRB oversight of PCOR, defined as investigations that engage patients in non-traditional roles such as advisors, recruiters, or investigators. The Patient-Centered Outcomes Research Oversight Study is a Patient-Centered Outcomes Research Institute (PCORI)-funded study tasked with investigating these issues using mixed methods, including focus groups, case studies of major research institutions, stakeholder interviews, and a national survey of IRB chairs. During this session, speakers will:

- Present results and implications from a report of stakeholder views by exploring their knowledge of PCOR, identifying where issues may arise, and identifying strategies for addressing these issues
- Discuss the results from the national survey of IRB chairs describing IRB policies and practices for PCOR, challenges with the incorporation of digital health into research protocols, and the need for guidance
- Go over draft recommendations that will eventually form the basis of a white paper

Room 218



C4

### Distinguishing Public Health Surveillance from Public Health Research at the Centers for Disease Control and Prevention (CDC) (Boundaries and Balance Track)

Micah H. Bass, Ivor A. Pritchard, Laura Youngblood

As the nation's health protection agency, the CDC conducts critical science, provides health information that protects the nation against health threats, and responds when health threats arise. The CDC has a vital role in ensuring the highest quality of scientific products originating from the agency are used as a foundation for putting public health research into much needed practice. As noted in the revised Common Rule, some public health activities involve research and others do not; this presents many grey areas. Statutory authority of state and local health departments to conduct public health activities using methods similar to those used by researchers may add to the complexity (although the revised Common Rule now defines public health authority). Appropriate protections applicable for activities occurring at the boundary between public health surveillance and public health research are not readily interpretable from the regulations. Attendees should be knowledgeable about public health practice activities and the current Common Rule definition for "research," as well as have familiarity with the revised Common Rule definitions for "human subject," "public health authority," and "research" before attending this session. During this session, speakers and attendees will:

- Describe the CDC's process and criteria for determining whether an activity is research, according to the revised Common Rule
- Discuss key considerations and decision points unique to public health practice activities (e.g., surveillance, public health response investigations, program evaluation)
- Review real-world examples to demonstrate the decision-making process

Room 212



C5

### Building Bridges Through IRB Education Outreach (Educating and Training Track)

Colleen P. Gilrane, Joy Jurnack

This session will explore the importance of interaction between the IRB and research staff, and how developing this relationship through educational offerings enhances communication and improves the quality of submissions. Speakers will share practical examples on how to engage research staff and work with them in a collaborative manner to ensure human subjects protections in research. The session will cover perspectives from both biomedical research and SBER. During this session, speakers will:

- Show how using approaches common in medical education can foster the medical staff's understanding of human subjects research
- Discuss the methods used at an academic medical center and a comprehensive land grant university
- Explore how varying educational sessions increases success to investigators
- Share a multifaceted approach to human subjects education that incorporates SBER and biomedical research methods, as well as a "catch-them-young" approach

Room 007CD



#### ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

C6

**Disasters, Deception, and Decision-Making Capacity: Empirical Research to Guide SBER IRBs**

(Empirical Research Ethics Track) Emily E. Anderson, Holly A. Taylor

Room 211



This session will begin with a brief introduction to the empirical research literature relevant to research ethics and IRB decision-making. Speakers will present best evidence-based practices on three specific topics: engaging individuals with limited decision-making capacity in research; using deception and debriefing human subjects involved with research; and conducting research during disasters. The session will end with a discussion on how individuals can encourage evidence-based decisions and policies at their own IRBs. During this session, speakers and attendees will:

- Review the difference between IRB decisions and policies that are evidence-based and those that are not
- Discuss findings from recent empirical research on participant decision-making capacity, deception/debriefing, and research during disasters
- Explore how to apply findings from empirical research studies to IRB decisions and policies

C7

**Ethical and Regulatory Review of Research: Case Studies** (Ethical Issues Track)

Bruce G. Gordon, Ernest D. Prentice

Room 214A



Basic

Speakers will present case studies intended to explore primarily ethics aspects of the regulatory criteria for approval, as well as provide a framework for IRB members and administrators to use in reviewing a protocol. During this session, speakers and attendees will:

- Review the regulatory requirements for approval of research
- Explore the meaning of risk and the ways IRBs should consider whether research adequately minimizes risk using reasonable standards
- Address practical ethics beyond specific regulatory language (e.g., "ethical access" to potential subjects, and compensation for participation)
- Discuss the interplay between ethics and regulations when reviewing biomedical or social science research
- Consider how the revised Common Rule impacts review
- Review the new 8<sup>th</sup> criteria for IRB approval of research (e.g., limited IRB review and broad consent, and discretion regarding IRB approval criteria 1-7)

This session will end at 1:15 PM. Please get your boxed lunch in the Exhibit Hall before going to the session room.

C8

**IRB Risk Assessment in Studies Using In Vitro Diagnostics (IVDs)** (FDA Regulations Track)

Martha F. Jones, Ernest D. Litwack, Michele Russell-Einhorn

Room 006B



Advanced

This session will focus on FDA oversight of IVDs and the analytical framework for IRBs, the use of IVDs in research through a presentation of case studies and an evaluation of how IVDs can be analyzed in the context of investigational device exemption (IDE) exempt criteria, and the non-significant risk and significant risk (NSR/SR) criteria. Attendees should have working knowledge of the device regulations in 21 CFR part 812 (exempt criteria and NSR/SR determinations) before attending this session. During this session, speakers and attendees will:

- Identify when clinical or research-specific genetic or other testing may be considered use of an IVD in the context of clinical research
- Apply key concepts to assessing the risks of an IVD, and gain understanding of the FDA approach to risk assessment for IVDs
- Use the knowledge gained to evaluate the regulatory status of an IVD as either IDE exempt, NSR, or a SR device

This session will end at 1:15 PM. Please get your boxed lunch in the Exhibit Hall before going to the session room.

ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

C9

**Cutting-Edge Challenges in HIV Research Ethics in Resource Limited Settings: Lessons from the Ethics Working Group (EWG) of the HIV Prevention Trials Network (HPTN)** (*Global Research Track*)

Robert Klitzman, Jeremy Sugarman

The HPTN conducts an array of research on the prevention of HIV/AIDS, including pre-exposure prophylaxis, treatment as prevention, and behavioral interventions. These studies raise critical ethical issues, which the HPTN EWG helps to address. The EWG has had a representative engaged with each of its studies being conducted at any time, has consulted on the ethical challenges that researchers have confronted, and has initiated scholarship on cutting-edge ethical issues concerning HIV prevention research in the developing world. In this session, members of the EWG will present an overview of this novel approach to addressing the ethical issues in research, and a description of several specific projects recently undertaken. These projects include: studies of the roles of IRBs in the developing world, problems with cross-cultural linguistic and conceptual translations between multiple countries, dilemmas posed by cash transfers to uninfected individuals, and other questions. During this session, speakers will:

- Examine recent, cutting-edge ethical challenges that are emerging with HIV prevention research in the developing world
- Explore how these challenges can be addressed through close consultation with researchers, conceptual scholarship, and empirical research
- Probe how the EWG of the HPTN might serve as a model for grappling with ethical issues in other research settings

Room 216B



C10

**The Certified IRB Professional (CIP®) Credential: What Is it About?** (*Hot Topics Track*)

Gregorio Lim, Lori Roesch

During this session, speakers and attendees will:

- Review the CIP Council's role in the development of exam content
- Discuss the CIP credential and the steps involved in pursuing it
- Go over the CIP eligibility and recertification requirements
- Explore the Body of Knowledge and outline the types of questions on the CIP exam
- Share general tips and resources for study preparation

Please note this session will not review specific exam questions, nor provide exam preparation.

Room 206A



C11

**Ethical and Operational Issues Related to Clinical Trial Billing: What HRPPs and IRBs Should Consider**

(*Institutional Officials and HRPP Leadership Track*) Keren R. Dunn, Scott J. Lipkin, Ann Rodavitch

In an increasingly complex clinical research environment, HRPPs must recognize the importance of accurate and appropriate clinical trial billing both in the context of minimizing financial harm to human subjects involved in research, as well as promoting and maintaining institutional regulatory compliance. During this session, speakers and attendees will:

- Provide a brief overview of the Centers for Medicare and Medicaid Services (CMS) clinical trial billing requirements
- Examine the implications of the CMS requirements as they apply to the ethical review of research, particularly the review of revised informed consent requirements
- Discuss the most recent governmental enforcement activity
- Illustrate best practices to integrate Medicare Coverage Analysis with IRB review of research

Room 210



ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

C12

**Let's Review a Protocol: Identifying and Applying Federal Regulations to the Review of Research That Requires Expedited or Full Board Review** (IRB 101 Track)

Warren Capell, Ada Sue Selwitz, Amy C. Waltz

This interactive session aims to assist IRB staff, chairs, and members with the initial review of non-exempt human subjects research, including the determination as to whether a study qualifies for expedited or full board review, identifying whether the Common Rule and/or FDA regulations might apply, and what determinations should be documented, in what way, and where (e.g., minutes versus checklist). During this session, speakers and attendees will:

- Discuss key ethical considerations underpinning research regulations and the review process
- Identify and discuss Common Rule and FDA regulations that can affect IRB review
- Explore the criteria for expedited review and models for documenting reviews, and when referral to a convened IRB may be warranted
- Consider how to apply the 111 criteria using case examples
- Outline key methods of documenting regulatory and other requirements as part of the review

*This session will end at 1:15 PM. Please get your boxed lunch in the Exhibit Hall before going to the session room.*

Room 008AB



Basic

C13

**IRB Chairs Forum: A Structured Discussion for IRB Chairs** (IRB Chairs Track)

Barbara C. Engel, Robert W. Frenck, Jr., R. Peter Iafate, Geeta K. Swamy

Given it can be difficult to find venues where IRB chairs can convene to discuss and wrestle with tough questions, this session will provide IRB chairs a forum to share ideas and best practices. Attendees will be surveyed on topics of interest to them, and speakers will provide a summary of each issue during the session. Any off-topic issues that arise during discussion will be placed in a "parking lot" for later discussion, if time permits. During this session, speakers 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
- Discuss real-world situations and problems attendees face with a focus on coming up with a few possible concrete solutions

*This session will end at 1:15 PM. Please get your boxed lunch in the Exhibit Hall before going to the session room.*

Room 214D



C14

**True Stories from the IRB and Their Impact on IRB Operations** (IRB Operations Advanced Track)

Elizabeth L. Hohmann, James Riddle, Susan L. Rose, Elyse I. Summers

The goal for this session is to have a fun and honest conversation with attendees about the wild side of running an IRB office on a university/medical center campus. This session will focus on the experiences that led to an operational change and descriptions of those changes. Attendees should have a basic understanding of common challenges in IRB operations before attending this session. During this session, speakers and attendees will:

- Share funny, anonymous, and true stories about the jaw-dropping and head-scratching questions, comments, and requests heard in the IRB office that led to an operational change
- Describe the operational changes that occurred as a result of the incident
- Discuss the general strategies for dealing with situations where IRB staff may not speak up to their colleagues or higher-ups about situations that have occurred for fear of retribution

Room 007AB



ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

C15

**Final Rule for ClinicalTrials.gov: Requirements and Implementation** (Issues Pharma/Biotech Track)

Sherry Mills, Sarah A. White, Rebecca J. Williams

Room 217A



This session will review the key requirements of the final rule on registry and results reporting. Through a discussion of the practical application of the registration and reporting requirements, this session will review organizational challenges in implementing and adhering to the requirements, as well as review strategies for meeting the rule's obligations. During this session, speakers will:

- Describe the legal requirements and policies for the submission of registration and results information by trial sponsors to ClinicalTrials.gov., including which types of clinical trials will now be expected to be reported under the NIH policy
- Discuss systems, processes, and tools a research institution or hospital can develop and implement to promote compliance with registration and results submission requirements
- Explain how the information on ClinicalTrials.gov can be used by IRBs, researchers, and others involved in ethics oversight of clinical trials

C16

**When It Happens to You: Identifying and Managing Privacy Breaches in Research; Lessons from Health Insurance Portability and Accountability Act (HIPAA) Investigations and Phase II Audits** (Legal Track)

Emily Chi Fogler, Susie R. Hoffman, Marissa Gordon-Nguyen

Room 214C



The HHS Office for Civil Rights (OCR) continues to robustly enforce the HIPAA regulations, including investigations of all breaches involving records of 500 or more individuals, and is wrapping up Phase II of the HIPAA Audit Program. This session will focus on lessons learned from OCR's HIPAA enforcement activities and the Phase II program, to help entities identify common areas of HIPAA noncompliance and improve the compliance posture within their organizations. In addition, it will review how covered entities and IRBs can best prepare for breaches in the research context, including when a privacy or data security incident occurs thus triggering reporting obligations under the HIPAA regulations, federal human subjects regulations, and specific state laws. Each of these laws/regulations has different definitions of a reportable incident and different requirements for whom must receive notification. Also, 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. These differences, as well as multiple institutional "owners," can cause confusion and create risks and challenges for institutions and investigators in identifying, reporting, and managing these incidents. Attendees should have a basic understanding of HIPAA and of how HIPAA applies in the conduct of research before attending this session. During this session, speakers and attendees will:

- Learn from OCR what are common areas of noncompliance with HIPAA regulations and how research entities can use lessons learned from OCR's enforcement activities and Phase II Audit Program to improve HIPAA compliance in their organizations
- Review the various legal and regulatory requirements applicable to privacy/security incidents
- Go over case examples of breach analyses and possible resolutions
- Share practical strategies for improved coordination of multiple processes, communication among institutional stakeholders, and investigator compliance with reporting requirements

This session will end at 1:15 PM. Please get your boxed lunch in the Exhibit Hall before going to the session room.

C17

**Scientific Aspects of Study Design: A Primer for Non-Scientist IRB Members** (Non-Scientist IRB Members Track)

Susan S. Fish, Lindsay McNair

Room 215



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, speakers 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 that can impact the validity of a clinical study and the analysis of study data

This session will end at 1:15 PM. Please get your boxed lunch in the Exhibit Hall before going to the session room.

ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	



C18

**Return of Individual Research Results: Complex Considerations for a Not So Simple Request – Perspectives from Scientists, Subjects, and Regulators** (*Out-of-Body Experiences: Research Involving Tissue and Data Track*)

Michelle Grienauer, Jerry A. Menikoff, Sally Okun, Mark E. Sobel

The return of individual research results seems like a simple enough expectation that respects a subject's rights to information about themselves. In practice, though, highly complex considerations, finding the right balance for protecting autonomy, and promoting beneficence is not easy. Attendees should have a basic understanding of the ethical and regulatory challenges related to the return of individual research results before attending this session. During this session, speakers and attendees will:

- Explore the complexities related to differences in Centers for Medicare and Medicaid Services, Health Insurance Portability and Accountability Act, and Clinical Laboratory Amendments requirements related to the sharing of results
- Discuss the ethical considerations of sharing results

This session will end at 1:15 PM. Please get your boxed lunch in the Exhibit Hall before going to the session room.

Room 006CD



Advanced

C19

**Situational Vulnerability: Considerations and Safeguards When Exploring Gender Identity, Social/Economic Challenges, and At-Risk Behavior** (*Populations Requiring Additional Protections Track*)

Sean Cahill, John A. Guidry

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, speakers and attendees will:

- Identify vulnerabilities, beyond those addressed by federal regulations, resulting from homelessness, substance abuse, lesbian, gay, bisexual, and transgender status, and undocumented residency
- Examine the special considerations that should be taken into account by investigators and IRBs in designing and reviewing studies involving these populations (e.g., payment and undue influence, recruitment, maintaining contact with subjects, confidentiality, stigmatization of research subjects, etc.)
- Discuss the additional risks that may affect these marginalized populations (e.g., violence, discrimination, depression, suicide)

This session will end at 1:15 PM. Please get your boxed lunch in the Exhibit Hall before going to the session room.

Room 217C



C20

**Beyond Auditing and Monitoring of the IRB and Towards Quality Improvement**

(*QA/QI and Post-Approval Monitoring Track*) John R. Baumann, Cheryl L. Byers, Mariette Marsh

Every HRPP engages in audits and not for cause monitoring activities. But, are they making full use of the information, resources, and opportunities that auditing and monitoring offer an HRPP? Are they integrating individual audit/monitoring findings into a broader analysis of institutional strengths, weaknesses, or gaps of quality improvement? In this session, speakers from various HRPPs will discuss how they integrate auditing and monitoring into a coherent program of quality improvement through their review and analysis of audit/monitoring findings as a collective whole. During this session, speakers and attendees will:

- Review how audit and monitoring findings can be integrated into a program of quality improvement
- Discuss how institutions are developing quality improvement programs based in part on the analysis of auditing and monitoring findings
- Explore how to develop quality improvement programs based on audit and monitoring findings

Room 214B



ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

C21

**The Intersections of Data Security, Privacy, Confidentiality, and Compliance in Digital Health and Mobile Health (mHealth) Research** (Research Conducted in the Digital World Track)

Jeremy N. Block, Brenda L. Curtis

The session will provide a basic introduction to the concepts, challenges, and opportunities with digital and mHealth research. Relevant technologies include: text messages, mobile apps, and wearable devices. Speakers will review real and perceived constraints, questions to consider when designing research incorporating mHealth, and general best practices in conducting and reviewing digital/mHealth. During this session, speakers and attendees will:

- Provide insights into the range of digital and mHealth technologies, and their potential application in both SBIR and biomedical research
- Discuss privacy, security, and compliance issues in mobile/digital health research
- Consider strategies for conducting and reviewing mobile/digital research studies

This session will end at 1:15 PM. Please get your boxed lunch in the Exhibit Hall before going to the session room.

Room 217D



Basic

C22

**Preparing Research Misconduct Committees to Succeed** (Responsible Conduct of Research Track)

Barbara E. Bierer, Mark A. Borrelli, Kate Gallin Heffernan

This session will focus on best practices for orienting committees convened to inquire into and investigate allegations of research misconduct and explore specific challenges raised when such committees investigate allegations arising in multi-site research. Often, individuals on the front lines of the investigation lack practical familiarity with the regulations or have little experience conducting fact-finding investigations. This session will address how institutional officials, research integrity officers, and institutional legal counsel can prepare investigation-naïve committees to conduct research misconduct proceedings in a manner that (1) fulfills the institution's obligations under the federal regulations; (2) focuses the committee on its appropriate jurisdictional scope and charge; (3) frees the institution to manage other challenging aspects of misconduct investigations; (4) minimizes institutional and personal legal exposure; and (5) promotes efficient and fair dispositions. This session will offer practical advice and suggestions for how institutions can maximize their compliance and meet their regulatory obligations through the individuals who are called to serve on investigative committees. During this session, speakers will:

- Discuss how investigation-naïve committees convened to address research misconduct allegations can be adequately prepared to undertake their charge, including consideration of elements of a mini-curriculum or training that can be provided to faculty members to assist them
- Address how certain challenges are magnified when allegations arise in the context of multi-site research, and the impact on investigative committees
- Explore the primary traps that can interfere with research misconduct committees' effectiveness, and potential preventative solutions

Room 208



C23

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

(Small Research Programs Track) April V. Baker, Kim R. Dicciani, Rachel Zand

This interactive session will explore the organizational, professional, and procedural circumstances that challenge HRPPs with only one staff person. Attendees will create networks for ongoing professional development and support, and discuss how developing a mentor/mentee relationship can support and promote ongoing personal and professional development for those working in single-staff IRB offices. During this session, speakers and attendees will:











- Review the organizational, professional, and procedural circumstances that challenge HRPPs with only one staff person
- Discuss how to implement solutions for challenges unique to single staff offices
- Learn specific strategies and potential solutions via shared experiences and ideas
- Develop strategies for establishing and maintaining a mentoring relationship that can assist with managing a single-staff IRB office

This session will end at 1:15 PM. Please get your boxed lunch in the Exhibit Hall before going to the session room.

Room 209



ICON KEY

 Didactic session	 Interactive workshop	 Double session	 Call for Session Proposal
 Pre-registration required	 Recorded session	 Sessions new for 2017	
 Reviews changes to the Common Rule	 CIP eligible	 CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

C24

**Research in K-12 Settings** (SBER Track)

Shannon Sowards, Julie Slayton

Room 206B



Basic

Research conducted with students in elementary and secondary school settings presents specific considerations for IRBs and researchers. Through interactive case studies, speakers will examine various topics as they relate to research conducted in K-12 schools. During this session, speakers will:

- Review considerations, including an overview of the Common Rule revisions, that affects research in K-12 settings
- Discuss consent considerations, including assent, parental permission, and possible alternatives
- Go over the Family Education Rights and Protections Act, the Protection of Pupil Rights Amendment, and common misconceptions about the IRB's role in ensuring investigator compliance with these laws
- Share scenarios that may be encountered in the classroom, including undue influence as a result of teachers as investigators, incidental subjects, and how to respect the rights of students who do not wish to participate
- Explore the potential benefits of "flex policies" for institutions
- Address other IRB considerations, including privacy and protection of data

C25

**You Want to Do What? Developing Best Practices for IRB Review of Research Investigating Illegal/Illicit Behaviors** (SBER Track) Dean R. Gallant, Kathleen E. Murphy, Andrew P. Rusczek

Room 217B



Advanced

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 human subjects, investigators, and institutions—to risks and harms to personal well-being, social standing, and legal culpability. This session will use a case study approach to identify practical, ethical, and legal complexities in order to discuss and develop best practices for reviewing research investigating illegal/illicit behaviors. Topics to be discussed include: informed consent for research, risk assessment and the risk/benefit ratio assessment, and issues related to mandatory reporting, confidentiality, and privacy. During this session, speakers and attendees will:

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

12:15-1:15 PM

**Networking Lunch**

Time to connect...over lunch! Meet peers for conversation and networking.

Exhibit Hall 4B

12:55-1:15 PM

**Overview of PRIM&R's Focus on the Revised Common Rule Educational Resources and Programs**

Join us in the demo theater in the Exhibit Hall to learn more about PRIM&R's Focus on the Revised Common Rule educational resources and programs. PRIM&R offers comprehensive in-person and online education to help you understand the new provisions of the revised Rule and what they mean for your HRPP. If you are unable to join us, visit [primr.org/commonrule](http://primr.org/commonrule) for more information, or [email](mailto:nora.murphy@primr.org) Nora Murphy, online learning coordinator.

Exhibit Hall 4B

ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	



## Panel IV: What Is Comparative Effectiveness Research (CER) and Does it Raise Any Unique Ethical Issues?

**Moderator:** Ruth Macklin

**Panelists:** Scott Y. H. Kim, John D. Lantos, Jerry A. Menikoff, Charles Natanson

There is no standard definition for CER; rather, it generally describes studies comparing two treatments that are in widespread use. It has also been referred to as research evaluating standard of care or research on medical practices. IRBs may be called upon to review protocols for CER and decide whether such studies are riskier than the use of the two treatments according to physicians' clinical judgment. If studies are deemed minimal risk, then researchers request a modification of consent requirements. During this panel, speakers will discuss the ways in which the risks of CER studies might be identified and quantified, and the implications for informed consent. In addition, panelists will examine the implications of the fact that, in CER, all of the therapies being studied are also available outside the study. Thus, patients may choose one therapy or the other, or they may choose whether or not to participate in the study. If the obligation to obtain consent is waived, or the type of consent process is modified, then patients may not be fully informed of reasonably foreseeable risks. Finally, speakers will discuss the ways in which research protocols may modify the treatments to which patients would otherwise receive how those modifications might increase or decrease the risks compared to treatment outside of the study, and the ways in which uncertainty about the efficacy of treatments that are in widespread use might also shape the ethical requirements for consent among patients who choose not to enroll in clinical trials.

Hemisfair Ballroom 1



## Panel V: Social, Behavioral, and Biomedical Transgender Research: Needs and Challenges

**Moderator:** Jeremy Sugarman

**Panelists:** Sean Cahill, Rimah Jaber

Many medical professionals have only recently become aware of the special issues that people who do not identify with their birth-assigned sex or gender confront in healthcare institutions, schools, the workplace, and in their personal relationships. Some of these problems arise from gaps in medical knowledge regarding safe and effective means of helping them to transition to their sexual phenotype, while others arise from health providers' failure to respond appropriately to the needs of these patients. For example, in a 2011 report, the Institute of Medicine underscored the urgency of conducting research on the nature, extent, and consequences of health disparities among transgender persons. Yet, studies on the direct and indirect effects of stigma and discrimination against transgender patients, as well as research regarding medical interventions for transitioning, bring up special challenges for investigators and IRBs. Among these are the difficulties in assessing benefits and risks of social, behavioral, and biomedical research in this field—including the nonphysical risks that can arise from being a research participant—and issues of consent and assent to novel interventions with children and youth. This panel will provide information on the various groups that identify as transgender and examine the ethical issues that arise for these populations in social, behavioral and biomedical research. This session aims to provide practical information for IRBs that want to enhance participant protections in research on the medical, mental health, and sexual health challenges facing transgender children, youth, and adults.

Hemisfair Ballroom 3



## Panel VI: When Citizens Do Science: The Democratization of Research

**Moderator:** Pearl O'Rourke

**Panelists:** Jamie Holloway, Sally Okun, Alicia Zhou

This panel will take a closer look at the increasing role of public participation in science. From the social media collaborative, PatientsLikeMe, to DIYGenomics, from federally funded crowdsourcing projects to inspiring personal innovations, citizen science is best understood as a communal and inclusive experiment in technoscientific practices. This panel will review different types of citizen science, the true democratization of research, and ethical considerations for citizen science, and will discuss how these projects take research participation to a new level, thereby, enriching and enhancing the notion of what it means to develop and contribute to generalizable knowledge.

2:45-3:15 PM

Exhibit Hall 4B

### Beverage Break Supported by IRBNet

Join us in the Exhibit Hall for coffee and cold drinks. PRIM&R would like to thank IRBNet for helping to support this break.

#### ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

D1

**A Dialogue With the Department of Defense (DOD): Updates for DOD and DOD-Sponsored Research Protections Personnel** (*A Dialogue With the Feds Track*)

Stephanie Bruce, Molly M. Klote, Derek J. Larbie, John Lee Melton, Patrice Danielle Robinson-Haley, T. Howard Stone

This session will be led by senior leaders from DOD's HRPPs. Attendees are encouraged to come with questions of interest to all. During this session, speakers and attendees will:

- Explore changing policies that affect the conduct of DOD-funded research with DOD personnel
- Discuss questions about current issues and initiatives
- Participate in an open discussion about DOD-related topics relevant to the research protections community

Room 211



D2

**Developments Regarding Expanded Access and Right to Try (RTT) Laws: Implications for IRBs**

(*Hot Topics Track*) David Forster, Marjorie A. Speers

RTT laws, which purport to give terminally ill patients better access to experimental medicines, have been enacted in 37 states over the past several years; an effort to pass federal RTT legislation is also underway. In a sign of possible things to come, RTT legislation in Texas regarding the provision of investigational stem cell treatments to patients with certain severe chronic diseases or terminal illnesses (TX H.B. 810) explicitly requires IRB oversight. In addition, at the federal level, the recently passed FDA Reauthorization Act of 2017 requires FDA to issue guidance or regulations "to streamline the IRB review of individual patient expanded access protocols." These legislative developments have important implications for IRBs. IRBs are formally part of the FDA's Expanded Access Program, but many IRBs do not know how to approach expanded access protocols. Furthermore, given that access to experimental drugs through RTT laws operates outside any regulatory framework, IRBs are likely not prepared for encountering RTT requests. During this session, speakers will:

- Provide an overview of recent RTT legislation and federal changes to the Expanding Access Program and issues that arise in interpreting these laws
- Explain what various Right to Try legislative moves mean for FDA's jurisdiction and long-standing Expanded Access Program
- Discuss the implications of these new federal and state laws for IRBs, including examining the tension between the push to lessen IRB oversight of expanded access for individuals, and recent RTT legislation's emphasis on IRB approval as a mechanism for safeguarding patients
- Share information about and guidance on how to approach expanded access protocols and compassionate use requests

Room 216B



D3

**Utilizing Technology and Advanced Metrics to Support the HRPP/IRB and Meet Institutional Goals at a Large Academic Cancer Center** (*Advanced Forum for IRB Professionals Track*)

Roy Cambria, Collette M. Houston

This session will focus on how an IRB and an institution's HRPP can leverage current technology to manage the responsibilities of the IRB, improve participant protections in clinical research, support required documentation, enhance regulatory compliance, achieve human subjects protections and Good Clinical Practice standards, while producing data and analytics to meet institutional goals and objectives, and improve upon operational efficiencies. Topics to be discussed include: electronic submissions, eRegulatory binder, eConsent, IRB of record, tableau dashboards, and more. Attendees should have a comprehensive understanding of human research regulations and procedures for managing regulatory compliance before attending this session. During this session, speakers will:

- Demonstrate how using data analytics can drive performance, IRB quality, and operational efficiencies, including time to activation
- Share experiences, both positive and negative, regarding home-grown protocol management systems

Room 206A



ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

D4

**Tissue Repositories and Data Banks in the Era of the Revised Common Rule** (*Boundaries and Balance Track*)

Mark Barnes, Julie Kaneshiro, Susan Stayn

Room 217A



The revised Common Rule introduced the option of broad consent and limited IRB review for secondary research, as well as two new exemptions (exemptions 7 and 8) for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens when broad consent is used. These options, and the new definitions of "human subject," offer new opportunities and challenges for the research enterprise and IRB professionals, but also raise questions about how and whether they can be effectively utilized to facilitate research. During this session, speakers and attendees will:

- Describe the new options of broad consent and exemptions 7 and 8 in the revised Common Rule, and review requirements for their use, restrictions to waiver and alteration of broad consent, and other problems that may be caused by these requirements
- Explore potential challenges in operationalizing the use of these options, including issues with tracking, IRB reviews, etc.
- Discuss how operational problems might or might not be overcome

D5

**"Stories Matter": Use of Narrative in IRB Member Education** (*Educating and Training Track*)

Michael Leary, Gianna McMillan

Room 205



This session will provide information on the current literature about the role of narrative in ethics education, and will provide practical examples and tools for integrating these concepts into IRB member education. Research and experience suggests that the use of narrative in education increases IRB member comprehension of new information, as well as engagement in the review process. This session will present concepts, share experiences, and offer examples, practices, and resources. During this session, speakers and attendees will:

- Discuss the scope of current literature on the role of narrative in research ethics education
- Identify different types of narrative resources
- Explore how to integrate these resources appropriately into IRB member education

D6

**Testing Methods to Modify the Consent Process** (*Empirical Research Ethics Track*)

Christine Grady, Stephanie Morain, Holly A. Taylor

Room 214D



This session will review three approaches to modifying the informed consent process. The first is an effort to enhance understanding by exposing a potential subject to either a fact sheet meant to highlight key points in the consent form, or a video presentation of an investigator sharing identical information in a conversational style. The interventions are piggy-backed onto a variety of actual trials conducted at an academic medical center. The second is an effort to enhance understanding of comparative effectiveness, as well as patient preferences, randomizing patients to seven different versions of a cartoon graphic style video depicting a physician explaining one of two trials to a potential subject. The human subjects involved with the research are asked to consider their hypothetical interest in enrolling in the study. The third is an attempt to simplify consent documents and make them more concise. How the length and complexity of the consent form influenced human subjects' understanding has been tested in a series of studies piggy-backed onto actual clinical trials in which human subjects were randomized to either a standard or a concise consent form. During this session, speakers will:

- Discuss different approaches to modifying the informed consent process
- Consider how investigators study informed consent
- Explore how alternative strategies compare in certain studies

ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	



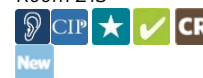
D7

**Ethics in the Grey Zone: A Novel, Risk-Proportionate Review Approach for All Evidence-Generating Projects**  
(Ethical Issues Track) Judith Friedland, George Gasparis, Nancy Ondrusek

This session will describe a novel approach to ethics review, that which uses a risk-based model and offers multiple levels of ethical scrutiny to provide an efficient, proportionate review of research, and other evidence-generating initiatives. Speakers will describe a suite of tools developed to screen out exempt activities, determine the review requirements for remaining projects, and enable fast track review of low risk projects, as well as their experience in implementing this approach, and the resulting benefits and challenges. Using a facilitated discussion with the audience, speakers will show how this approach and tools might inform solutions to challenges identified in the revised Common Rule regarding exemptions and partial review requirements for activities such as QA/QI and program improvement. During this session, speakers will:

- Describe an approach for ethics review of research and other activities and the tools that support its implementation
- Consider the benefits and challenges of implementing this model from the perspective of the institution, investigators, and the ethics review board
- Explore how this approach and tools might support application of the revised Common Rule and inform future developments

Room 213



D8

**Regulations Versus Guidance Versus Local Policy: How Do They Differ?** (FDA Regulations Track)  
Patrick J. McNeilly, Jan L. Hewett

This session will provide an overview of the basics of how government regulations and guidance are established. Speakers will discuss the process of regulation development from statutory requirements, as well as how guidance documents are established based on regulation; the differences between guidance and regulation; the process for public input in regulation and guidance development; and the intersection of regulation and guidance with local institutional policy. During this session, speakers and attendees will:

- Identify the basic distinctions between statute, regulation, and guidance
- Explain the process the government goes through to establish a new regulation or guidance document
- Discuss how the public can provide input into the regulatory development process
- Distinguish how local institutional policy may differ from regulatory requirements

Room 217B



D9

**International Non-Governmental Organization (NGO) Ethical Review Boards: Challenges and Opportunities**  
(Global Research Track) Leslie D. Cannold, Renee J. Holt, Kathryn Reitz

Many NGOs are service-delivery organizations, tasked with providing healthcare and humanitarian assistance to the most vulnerable populations on the globe. However, the growing requirement for evidence-based policies and programs has also driven some into the research space. While the sector once relied on national, commercial, or university review boards to oversee their collection activities, some institutions chose to establish their own ethics committees. This session will explore the specific and often-complex opportunities and challenges that confront NGOs with ethics review boards, and those who lead and serve on such boards. During this session, speakers will:

- Discuss how NGOs decide whether to enter the research space and establish their own ethics review board
- Explore the challenges to the institutional culture of action and service-oriented organizations required for NGOs to make a long-term commitment to staffing, supporting an IRB, and paying for it
- Examine how NGOs navigate challenges to its effective operation posed by time pressures, operational exigencies, and cultural conflicts between a NGO's ethics review board and a local ethics committee that result in contradictory decisions
- Review the practical problems and decisions these research organizations face while doing ethics in the development and humanitarian space

Room 218



**ICON KEY**

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

D10

**NIH-FDA Clinical Trial Protocol Template: Making Protocol Writing Easier for the Investigator, While Enhancing Quality** (*Hot Topics Track*)

Melissa W. Riddle, Carrie D. Wolinetz

The NIH released a protocol template and Electronic Protocol Writing tool that will help investigators prepare clinical trial protocol documents. The template meets the International Council for Harmonisation E6 (R2) Good Clinical Practice Guidance, and contains all the information necessary to enable efficient and timely review by IRBs, as well as comply with FDA regulations. NIH also developed an Electronic Protocol Writing Tool that allows for a collaborative approach to writing and reviewing protocols. The template document and Electronic Protocol Writing Tool are made available for the community at large. Using the Electronic Protocol Writing tool, investigators will be able to form a "protocol writing team" and assign different individuals with writing and reviewing roles who can contribute comments and edit the protocol. The Tool also makes it easy for the investigator to track the progress of the protocol, share comments between team members, and stay in control of the most accurate version. During this session, speakers will:

- Discuss how to recognize where to find NIH protocol template tools and identify the content of the clinical trial protocol template(s)
- Consider the uses of the NIH protocol template tools
- Describe how to launch the Electronic Protocol Writing Tool and use it to write a protocol

Room 217C



D11

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

(*Institutional Officials and HRPP Leadership Track*) Nichelle Cobb, Lori Roesch

This session will explore how a small research program maintains an effective HRPP while outsourcing some or all of its IRB review. During this session, speakers will:

- Discuss the ethical tensions involved in outsourcing IRB review
- Identify shared and single-sourced institutional official and HRPP leadership responsibilities, accountability, and liabilities between the outsourcing institution and the reviewing IRB, especially in light of the revised Common Rule and NIH Policy on the Use of a Single IRB of Record for Multi-Site Research requirements for collaborative research
- Explore strategies to measure and maintain an effective HRPP in this environment

Room 210



D12

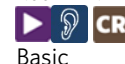
**Essential Documentation: IRB Membership, Record Keeping, Minutes, and More**

(*IRB 101 Track*) Janet C. Donnelly, Ada Sue Selwitz, Irene E. Stith-Coleman

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

- Outline the basic federal requirements for IRB documentation, highlighting specific changes in the revised Common Rule
- Discuss the federal policies and requirements for maintenance of accurate, complete, and timely IRB records, including the joint OHRP/FDA guidance on minutes of IRB meetings
- Test the audience's knowledge through an interactive discussion

Room 217D



D13

**Revisions to the Common Rule: A Primer for IRB Chairs** (*IRB Chairs Track*)

Jeremy J. Corsmo, Patience B. Stevens

This session is designed for IRB chairs and will provide a detailed overview of the revisions to the Common Rule. Operational considerations will be included as part of the discussion. During this session, speakers will:

- Provide a detailed overview of the revisions to the Common Rule
- Discuss operational considerations and implementations including updating policies, procedures, etc.

Room 006CD



ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

D14

**Precision Medicine, Precision IRB** (IRB Operations Advanced Track)

Stacey A. Donnelly, Brenda L. Ruotolo

Room 214A



Advanced

Research protocols that include genomics (e.g., whole exome or whole genome sequencing) are being proposed with increasing frequency as the genomics field that forms the basis for Precision Medicine rapidly evolves. This also includes genetic studies in which patients interact directly, providing great opportunities for engagement, along with challenges of new paradigms. As such, IRBs need to have specific expertise, as well as consider the issues that do not apply to other types of studies. An institution that conducts such research must ensure that IRB review is appropriate, and it must assess the best option for meeting review requirements. This session will identify the pertinent issues related to this topic, present options for review, and describe the reasons to establish a genomics IRB. Case studies that illustrate issues for IRBs and researchers to consider will be presented. Attendees should be familiar with IRB review criteria at 21 CFR 56.111 and 45 CFR 46.111, Investigational Device Exemption (IDE) requirements at 21 CFR 312, and general concepts of genomic research before attending this session. During this session, speakers will:

- Review the unique issues that IRBs face when reviewing genomic research (e.g., IDE considerations, options for and implications of return of results, etc.)
- Identify the qualities an IRB that reviews genomic research should possess
- Share lessons learned from establishing a genomics IRB and reviewing protocols with a focus on whole exome and whole genome sequencing

D15

**Understanding the Implications of Adopting International Conference for Harmonization (ICH) Good Clinical Practice (GCP) as a Standard** (Issues Pharma/Biotech Track)

Ann Meeker-O'Connell

Room 215



Significant changes made to ICH E6 R2 place additional obligations on trial sponsors (e.g., risk-based quality management, Corrective and Preventive Actions). To assist institutions with understanding the implications of attesting that they adhere to ICH E6 (particularly where studies fall outside of regulated areas), this session will review the ICH E6 requirements, summarize the new changes, and provide practical suggestions for understanding the requirements and ensuring adherence to them, when applicable. During this session, speakers will:

- Review the obligations imposed when an organizations attests (e.g., in a protocol) that it "follows ICH E6"
- Describe best practices for applying ICH flexibly for non-regulated research (e.g., cosmetics, health interventions)
- Explain how to conduct a gap analysis to understand the organizational impacts of recent ICH E6 revisions
- Discuss additional changes anticipated for ICH E6 under ICH's proposed "GCP Renovations"

ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

D16

**IRB Noncompliance and Liability in the Single IRB Era** (Legal Track)

Kate Gallin Heffernan, Megan Kasimatis Singleton

Room 008AB



This session will review challenging issues related to IRB and institutional liability under a single IRB model, with a specific focus on management of potential noncompliance. Under both the NIH Policy on the Use of a Single IRB of Record for Multi-Site Research and the Common Rule single IRB mandate, research institutions will unavoidably be in the role of relying on external IRBs and, possibly, providing IRB review for external institutions. Furthermore, the Common Rule expands the application of the regulations to reviewing IRBs, with direct enforcement authority against the IRB (whether or not associated with a Federalwide Assurance-holding institution and/or internal to a site performing the research). What will this shift mean for institutional and IRB liability and how should institutions (whether relying or reviewing) approach risk mitigation in standard operating procedures and the terms of reliance agreements? This session will discuss how this shift creates a need for clearer policies related to the investigation of allegations of noncompliance, especially when the IRB is potentially implicated. It will also explore the challenge of defining clearly in reliance agreements the scope of each party's responsibility, particularly in academic collaborations, and the significance of certain agreement terms when considering potential noncompliance of relying institutions and reviewing IRBs. During this session, speakers will:

- Review responsibilities of the relying organization and reviewing IRB in addressing issues of noncompliance, with an emphasis on the division of responsibilities as outlined in current master IRB agreement models
- Discuss key considerations for institutions when addressing liability related to IRB reliance arrangements with a particular focus on circumstance when a relying organization or reviewing IRB could be considered "noncompliant"
- Provide practical suggestions to assist institutions in considering models for addressing noncompliance, particularly IRB noncompliance, in the context of a single IRB review relationship
- Explore hypothetical cases to highlight noncompliance considerations for relying institutions and institutions providing single IRB services

D17

**Considerations and Strategies for Effective Communication for Non-Scientist and Unaffiliated IRB Members**

(Non-Scientist IRB Members Track) Michelle M. Feige, Dahron A. Johnson

Room 206B



By definition and regulation, unaffiliated IRB members come from outside the immediate community of professional colleagues that comprise any individual IRB. While this is meant to help correct any institutional blind spots, the comments of such members will have little impact within their boards if their considerations are not considered to have sufficient "warrant." That is, whether in the IRB or on the street, we determine what influence an individual has based on what rationales they use and on what authority they speak. The same can be said of non-scientists who, by definition, do not have the same expertise as other IRB members. What role does personal history, knowledge, professional experience, and "objective" facts play? During this session, speakers and attendees will:

- Review the regulatory responsibilities of non-scientist and unaffiliated IRB members, and examine their perceived roles
- Discuss the varieties of, and the priority given to, the various "warrants" commonly used by IRB members
- Provide strategies non-scientist and unaffiliated IRB members can use to communicate more effectively with their individual boards

ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

D18

**In the Era of Big Data: Data Sharing** (*Out-of-Body Experiences: Research Involving Tissue and Data Track*)

Moran Nataly Cabili, Laura Lyman Rodriguez

Data sharing is a key component of the Cancer Moon Shot, and all investigators agree that data sharing will be key to moving disease research forward. This session will provide practical information for IRBs and institutional staff to enable responsible data sharing based on original consent for use of the data/specimens. Speakers will also review the federal data sharing system and what can be learned from it, how scaling will be a challenge, and how institutions might prepare for the future. During this session, speakers and attendees will:

- Discuss the landscape and difficulty involved in data sharing
- Review a system developed to enable data sharing that is open source and available to any institution
- Share strategies for how to encourage standardization at the federal level, and the difficulty with inconsistent requirements by the institutes within NIH

Room 212



D19

**Conducting Research With Individuals Lacking Capacity to Consent**

(*Populations Requiring Additional Protections Track*) Jessica Huening, Amy C. Waltz

Events in recent years have brought research with vulnerable populations, especially inpatient psychiatric subjects, to the forefront of public discourse on research and ethics. This session will provide a comprehensive overview of best practices for research with subjects who cannot consent for themselves, including how and when to assess consent capacity, and the IRB's role in reviewing research with this population. This session will not only focus on the lack of consent ability due to mental health/psychiatric issues, but will look at how other vulnerable groups may experience diminished capacity both on a short and long term basis. During this session, speakers will:

- Define consent capacity, when to assess (and reassess) consent capacity, and identify individuals who cannot consent for themselves
- Identify individuals who should represent subjects lacking consent capacity
- Discuss the IRB's role and responsibility in reviewing research with individuals who cannot consent for themselves
- Explore how researchers and IRBs should address and manage the risks and protect human subjects

Room 214B



D20

**Advanced Investigator Post-Approval Monitoring Issues** (*QA/QI and Post-Approval Monitoring Track*)

Leslie M. Howes, Vivian Ota Wang, Jessica A. Randall

Using cases studies, this session will discuss challenging issues involved with post-approval monitoring of the investigator site. Topics will include audits of multicenter research, international research, and studies with big data. Speakers will also discuss a strategy associated with for-cause audits. Attendees should have a basic understanding of post-approval auditing of the investigator site, and be prepared to discuss challenges and solutions of given case studies. During this session, speakers will:

- Work through case studies that illustrate challenging investigator audit issues
- Discuss a strategy for approaching complex investigator audits
- Review the importance of collaborating with various departments within an institution during for-cause investigator audits and how information is exchanged
- Explore how aggregate audit findings can inform process improvement

Room 214C



Advanced

ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

D21

**Intersection of Research and Electronic Health Records With Privacy and Confidentiality Concerns: Considerations for IRB Review** (*Research Conducted in the Digital World Track*)

Gretchen L.J. Anding, Judith Birk, Martha F. Jones

The widespread use of electronic medical records presents challenges for IRBs regarding the assessment of privacy and confidentiality protections when clinical data are accessed, used, and shared for research purposes. Increasingly, institutions are leveraging technologies that interface with medical records systems and that allow a wide range of individuals to access and share private information to recruit subjects, institutions to flag when patients are enrolled in their studies, and that show the results of some research tests in patients' records. This session will explore assessments an IRB might make regarding privacy, confidentiality, and data security (e.g., should there be limits on who can access medical records? What data are available to which people?); the use of medical records for subject recruitment; sharing information from medical records with entities outside the institution or a covered entity; and when research and clinical records are linked. Attendees should have a basic understanding of the Health Insurance Portability and Accountability Act Privacy and Security Rule provisions before attending this session. During this session, speakers will:

- Identify specific examples of privacy and confidentiality challenges presented by the use of electronic medical records for research purposes
- Consider practical approaches for IRBs and other ethics committees to assess privacy and confidentiality issues related to the accessing and sharing of data in electronic medical records
- Discuss best practices, as well as policies and procedures, which can assist with the challenges posed by the research use of electronic medical records

Room 007AB



Advanced

D22

**Editorial Influence and Open Dialogue: How Editorial Decisions Shape the Debate Around Bioethical Issues** (*Responsible Conduct of Research Track*) Emily E. Anderson, Ruth Macklin

Editor's decisions about what will be published can shape the academic and political discourse around controversial issues. Providing a platform for open, vigorous examination of ideas is a fundamental goal of scholarly publishing, and this is reflected in the Committee on Publication Ethics' Code of Conduct and Best Practice Guidelines, which include several recommendations aimed at encouraging debate, responding to criticisms, and managing conflicts of interest. This session will address these issues from an IRB standpoint: Should journals require authors to prove IRB approval of their work? How universal is this practice? Should IRBs have an interest or play a role in determining where and how study results are published? During this session, speakers and attendees will:

- Review the submission process researchers use for journals, including the role some journals play in requesting proof of IRB approval
- Explore the importance of scholarly publications and their role in promoting balanced discussions, and fostering public trust and transparency
- Examine the role and impact that editorial decision-making can have on the academic and policy communities' perceptions related to human subjects research
- Discuss the impact of human subjects noncompliance and decisions related to article retraction, including examples and rationale journal editors use to retract publications (and withhold publications in light of known noncompliance)

Room 208



D23

**How to Identify, Navigate, and Manage Conflicts of Interest (COI) in a Small Research Organization** (*Small Research Programs Track*)

Heather H. Pierce, Kenia F. Viamonte

It is typical for members of small research organizations to wear many hats: researcher, academic administrator, IRB member, peer reviewer, thesis committee member, etc. These multiple roles, as well as the various personal and professional relationships between members of the organization, may lead to potential, actual, and perceived COIs. During this session, speakers will:

- Identify the different types of COIs: financial, institutional, professional, and personal, and review policies that help identify what these might look like
- Discuss how to handle COIs when declared, and what to do if quorum becomes an issue
- Consider what to do when the person with a COI is the only expert
- Explore what to do when the person with a COI is your boss (or boss' boss)

Room 209



ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	



**D24**

**Best Practices for Assessing Risk and Benefit in SBER**

(SBER Track) Jeffrey M. Cohen, Cheri M. Pettey

Room 006B



Basic

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

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

**D25**

**Understanding the Benign Behavioral Intervention Exemption (SBER Track)**

Karen Christianson, Ivor A. Pritchard, David H. Strauss

Room 007CD



This session will explore specific issues and challenges in interpreting and applying the new exemption 3. Attendees are invited to bring examples to the session for discussion. During this session, speakers and attendees will:

- Review the meaning of key terms (e.g., benign, behavioral, intervention, type of data collection, prospective agreement)
- Explore the applicability of regulatory Criteria A, B, and C
- Discuss the new eligibility criterion C requiring limited IRB review
- Go over other requirements (e.g., brief in duration, harmless, painless, not physically invasive, significant adverse lasting impact, and subjects likelihood of finding the interventions offensive or embarrassing)
- Address the exclusion of some deception studies

**4:30-5:30 PM**

**Networking Reception with the Supporters and Exhibitors**

Join us in The Exhibit Hall to meet and greet the Supporters and Exhibitors. Light refreshments will be served, and a cash bar will be available.

Exhibit Hall 4B

**4:30-5:30 PM**

**Meet the AER17 Poster Authors**

Visit with the authors of the posters featured in the AER17 Poster Presentation Program and learn more about their innovative and important work on new program initiatives, empirical research, and conceptual analysis. The presentation of the posters promotes interdisciplinary sharing and collaboration, and facilitates the exchange of ideas, information, and practical strategies for managing the many challenges faced by research professionals.

Exhibit Hall 4B

**4:30-5:30 PM**

**Federal Agency/Accrediting Body Office Hours**

Do you have specific questions for federal agency or the accrediting body representatives? Or, do you have a follow-up question after attending a session that featured a federal agency or accrediting body representative(s)? If so, representatives from the following federal agencies/accrediting body will be available during this time slot to help answer your questions:

- AAHRPP
- CDC
- DOE
- FDA
- OHRP
- VA

Exhibit Hall 4B



**ICON KEY**

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

4:55-5:15 PM

Exhibit Hall 4B

**Overview of the Certified IRB Professional (CIP®) Exam**

Join us in the demo theatre in the Exhibit Hall to learn the ins and outs of the CIP examination. During this time, CIP Council members will provide background on how the examination is constructed, and will review sample examination questions and answer options. Please join us for this unique insight into the CIP examination! If you are unable to join us at this time, but would like to learn more about the CIP exam while onsite at the conference, stop by the PRIM&R Booth or [email us](#), for more information.











7:30 PM-10:30 PM

AT&amp;T Center

**San Antonio Spurs vs. Los Angeles Clippers Basketball Game**

Join your fellow attendees to cheer on the San Antonio Spurs! Two rows of seats have been set aside at the AT&T Center. Ticket pricing is \$25-\$30, and \$5 of each ticket sold will go to benefit the Hurricane Harvey Relief Fund. Tickets may be purchased on November 7, 2:45-5:00 PM at the pop-up box office that will be located in the on-site Check-In Area, or directly through the AT&T Center's online group ticket sales: <https://groupmatics.events/event/2017aer>. Online sales close on October 31 at 11:59 PM CST. Attendees are responsible for their own transportation to/from the AT&T Center.

## ICON KEY

 Didactic session	 Interactive workshop	 Double session	 Call for Session Proposal
 Pre-registration required	 Recorded session	 Sessions new for 2017	
 Reviews changes to the Common Rule	 CIP eligible	 CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

7:00 AM

**On-Site Check-In Opens**

Breakfast on your own.

Hall 4 West Lobby

7:15-8:00 AM

**A Capella Musical Performance**

Join us before the conference starts for a musical performance by a local a capella group.

Exhibit Hall 4A

8:00-8:15 AM

**Welcome from the Conference Co-Chairs**

*P. Pearl O'Rourke, MD, Director, Human Research Affairs, Partners HealthCare System, Inc.; Associate Professor of Pediatrics, Harvard Medical School*

*Laura Odwazny, JD, MA, Senior Attorney, Office of the General Counsel, Department of Health and Human Services*

Exhibit Hall 4A



8:15-8:20 AM

**PRIM&R Membership Update**

*Presented by Sharon Freitag, Director, Research Ethics Office, St. Michael's Hospital; Member, PRIM&R's Membership Committee*

Exhibit Hall 4A



8:20-8:25 AM

**PRIM&R Certified IRB Professional® (CIP) Credential Update**

*Presented by Gregorio Lim, CIP, Senior Manager, Global Occupational Health, Health Services, Shared Services Group, The Boeing Company; Chair, CIP Council*

Exhibit Hall 4A



8:30-9:15 AM

**Keynote Address: The Challenges of Clinical Trials and Community Trust in the 21st Century**

*Robert A. Winn, MD, Associate Vice Chancellor for Community-Based Practice; Director, University of Illinois Cancer Center, University of Illinois Hospital and Health Sciences System, Chicago; Professor of Medicine, Division of Pulmonary, Critical Care, Sleep and Allergy, University of Illinois College of Medicine at Chicago*

Exhibit Hall 4A



9:15-9:45 AM

**Beverage Break**

Join us for coffee in the Exhibit Hall.

Exhibit Hall 4B

9:30-9:40 AM

**Treasure Hunt Prize Drawing**

Join us in the demo theater as we draw names of the prize winners of those who participated in the Supporter and Exhibitor Treasure Hunt! Your completed sheet must be turned into the PRIM&R booth by 9:15 AM on November 8 and you must be present at the time of the drawing to win.

Exhibit Hall 4B

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

**Panel VII: Race Matters: Ethical Challenges for the Use of Racial Categories in Research**

**Moderator:** John J. Whyte

**Panelists:** Albert J. Allen, Khiara M. Bridges, Owen Garrick

IRBs are often asked to approve research that focuses on, ignores, or proposes comparative designs to study racial/ethnic group health disparities. In many instances, investigators' racial groupings do not reflect the complexity or socio-political dimensions of such definitions that, in turn, can limit the validity of conclusions drawn from such studies and its potential impact on alleviating or sustaining systemic influences underlying health inequities. The increasing integration of genomic science into biomedical and social and behavioral research raises additional issues regarding group representation and generalization of findings. This panel will introduce attendees to the growing influence of Critical Race Theory in empirical science, the promise and challenge of racial classifications in studies of personalized medicine and studies on behavioral risk, and the importance of participant perspectives for the promotion of socially just science.

Hemisfair Ballroom 1



**ICON KEY**

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	



## Panel VIII: Making Consent Meaningful in the Context of the Revised Common Rule

**Moderator:** David H. Strauss

**Panelists:** Neil W. Dickert, Jr., Rebecca S. Dresser, Jerry A. Menikoff

This panel will address whether (and, if so, how) the revised Common Rule's new requirements for informed consent will address the recognized flaws within the current process for obtaining research informed consent. The field has been talking about improving informed consent for a long time, and some say the process is spiraling downward instead of improving. Will these new regulatory provisions help actualize change? Panelists will discuss the intent behind the revised requirements for informed consent, how to operationalize the reasonable person standard, the role of the subject perspective in reasonable consent, including how it applies to various subject populations, and the interplay between the revised requirements and an ethical and empirical framework for consent.

Hemisfair Ballroom 3



## Panel IX: Bioethics in the Biopharmaceutical Industry: A Glimpse of Bioethics in a Different Setting

**Moderator:** Barbara E. Bierer

**Panelists:** Karla Childers, Tatjana Poplazarova, Luann E. Van Campen

Human subjects' protections regulations in the United States and IRB activities focus primarily on individual clinical trials conducted in the United States and/or for submission to the FDA. As major sponsors of clinical trials, biopharmaceutical companies are subject to the same human subjects research protections system as other organizations and institutions. What is less obvious outside of the biopharmaceutical industry is that, because of the global scale and complexities of modern drug development, as well as scientific advances, biopharmaceutical companies are increasingly utilizing corporate bioethics programs and committees to inform research decisions and planning that goes beyond the conduct of individual clinical trials. These industry bioethics activities draw upon fundamental bioethics principles, but seek to apply them in the context of biopharmaceutical industry research programs. This panel will include representatives involved in research bioethics activities at three different biopharmaceutical companies, and each panelist will briefly describe how research bioethics is organized within their company and provide a case example of how bioethics informs research decisions and planning. *Please note that Tatjana Poplazarova's presentation will not be included in the conference proceedings.*

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

E1

### A Dialogue With the NIH (A Dialogue with the Feds Track)

Carrie D. Wolinetz

This session will be led by a representative from the NIH, and will include discussion of NIH's new website and clarifications on the 2014 definition of clinical trials. Attendees are encouraged to come with questions of interest to all. During this session, speakers and attendees will:

- Hear from a representative of the NIH Office of Science Policy about activities that are pertinent to clinical research policy and the protection of human 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 214A



E2

### A Dialogue With AAHRPP, Inc. (A Dialogue With the Feds Track)

Michelle M. Feige, Robert Hood, Sarah H. Kiskaddon, Elyse I. Summers, Rob Withrow

AAHRPP, Inc., founded by PRIM&R and six other research-focused organizations in 2001, is an international nonprofit organization that accredits high quality HRPPs. It provides peer-based, collaborative, collegial evaluations of HRPPs, based on applicable standards and elements. This interactive session is designed to answer questions about accreditation for organizations that are already AAHRPP-accredited and those considering AAHRPP accreditation. During this session, speakers and attendees will:

- Review the process of achieving or maintaining AAHRPP accreditation
- Discuss AAHRPP's approach to cutting edge issues in the human research enterprise
- Become familiar with AAHRPP staff and the web resources available to all wishing to maintain or achieve a robust system of human research protections

Room 006B



## ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

E3

### Considering Incidental Findings in Genomics Research

(Advanced Forum for IRB Professionals Track) Benjamin E. Berkman, Laura Lyman Rodriguez,

This session will explore the issues related to the rapidly changing knowledge base of genomic information and approaches to developing plans for managing incidental findings in the course of genomics research. Short presentations will include a synopsis of background information, but will focus on strategies being applied today and real-world experience. This session will also provide an opportunity for the audience to discuss the application of emerging approaches to different research study designs. Attendees should have basic familiarity with participant protections issues related to genetics and genomics research, as well as an understanding of the considerations with regard to returning research results. During this session, speakers and attendees will:

- Explore the nuances to consider in assessing when/if to return genomic research findings
- Define the parameters to be addressed in a plan for returning genomic research findings
- Discuss the regulations to be consulted when assessing proposed plans submitted by investigators for returning genomic research findings

Room 217B



Advanced

E4

### The International Committee of Medical Journal Editors' (ICMJE's) New Policy on Data Sharing Statements for Clinical Trials (Hot Topics Track) John Baumann, Pamela Miller, Heather Pierce

In June 2017, the ICMJE published their final policy on data sharing statements for clinical trials, appealing to a vision of a "global research community in which sharing deidentified data becomes the norm." This policy requires manuscripts submitted to ICMJE journals that report the results of clinical trials to include a data sharing statement, and clinical trials enrolling participants on or after January 1, 2019 to include a data sharing plan in the trial's registration. ICMJE believes "there is an ethical obligation to responsibly share data generated by interventional clinical trials because trial participants have put themselves at risk." This this session will explore what this new policy means for the field. During this session, speakers will:

- Review what should be included in a data sharing statement
- Outline what should be included in a data sharing plan
- Discuss future challenges in data sharing, including what kind of support institutions/HRPPs need from funders and other stakeholders who are pushing for increased data sharing
- Review best practices for IRBs when they work with investigators who want to share deidentified individual participant data

Room 205



E5

### Improving Informed Consent Through Effective Communication Strategies and the Potential Use of Decision Aids (Educating and Training Track) George Gasparis, John Saucedo

Obtaining effective informed consent from research subjects is vital to promoting autonomy and safeguarding public trust in research. A great deal of research has been done on the communication and perception of information and risk that focuses on doctor-patient communication in a therapeutic setting, but there should be clear applicability of that research to the informed consent process. During this session, speakers will:

- Describe these challenges, including what thoughts and considerations are needed in the framing and the delivery of complex information to the general public
- Discuss the use of decision aids in helping patients make decisions on clinical treatments, and whether there is a role for their use in helping research volunteers make informed decisions about participating in research studies

Room 007CD



#### ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

E6

**Justification, Authority, and Accountability in IRB-Investigator Correspondence** (*Empirical Research Ethics Track*)

Justin T. Clapp, Steven Joffe

This session will examine how IRBs “do” medical ethics in their review of human subjects research protocols. The discussion will focus on how IRBs communicate with investigators. In particular, speakers will present an analysis of the frequency with which IRBs provide justifications for the changes they require and the nature of these justifications. This analysis will be combined with data from other empirical studies of IRB practice to explore a central question: Where does the authority of IRBs reside? The ramifications of these findings for the broader enterprise of research ethics will be discussed. During this session, speakers will:

- Review research on how IRBs practice ethics review, particularly examining how IRBs communicate their concerns to investigators
- Identify patterns in how IRBs ground their stipulations in ethical, regulatory, or bureaucratic authority
- Discuss how these findings can help us understand the manner in which the research community views ethics review, and how shifts in IRB practice may improve IRB-investigator relations

Room 214C



E7

**The Boundaries of Privacy and Public Health Concerns** (*Hot Topics Track*)

Micah H. Bass, Alexander M. Capron, Natalie Gonzalez, Alexa Limeres

Public health surveillance activities lead to the accumulation of large quantities of clinical biospecimens and data. Materials such as these provide a rich resource for conducting research, only some of which will involve improving knowledge about the disease under surveillance. Other research extends to using a collection of public health biospecimens to ascertain the utility of a new assay for a disease not related to the reason for which the specimens were originally collected. In either case, consent for research is unlikely to exist, both because collecting the materials may have been mandatory under the law and because the materials typically originate when practitioners send a sample to a lab for a test that reveals the presence of a reportable condition. Thus, the solutions suggested for academic medical centers—for example, that they should routinely inform patients about the storage of biological material removed during diagnostic and surgical procedures and seek patients’ consent (or non-objection) to the use of data and biological materials in research—would probably not be feasible for public health repositories. Focusing on biospecimens and data derived from public health activities, this session will examine when and if it is acceptable to conduct research without consent of the individuals from whom the specimens and data came. During this session, speakers and attendees will:

- Discuss the importance of individual privacy in the context of research participation
- Explore trade-offs between personal privacy and public interests
- Gain basic tools for analyzing ethical dilemma in public health research

Room 215



E8

**Who’s Participating in Drug Clinical Trials and Does it Matter?** (*FDA Regulations Track*)

John J. Whyte

In the past, many stakeholder groups have raised questions about adequate and equal inclusion of women and people of racial minority backgrounds in clinical trials. The FDA created the Drug Trial Snapshots Program in November 2014, to ensure easy access to and to unveil demographic data for the pivotal clinical trials used to approve new drugs. With more details on who participated in the pivotal trials and whether there were any observed differences in safety and efficacy by demographic subgroups of sex, race, and age, the Drug Trial Snapshots Program raises important questions about population based drug development and variability in response to drugs overall, focusing on the demographic transparency of clinical trials. When analyzed for subgroup differences, several drugs showed differences based on demographic characteristics of sex, race, and age. Does health equity and ethics have a role in clinical trials, and why does it matter? During this session, speakers will:

- Provide an overview of the Drug Trials Snapshots Program as part of FDA’s efforts to make demographic data more available and transparent
- Discuss how this data may provide information on who is participating in clinical trials and why that matters from a scientific perspective of biologic variability of drug response
- Explore how demographic representation of clinical trials may help to inform future drug trial design, considerations for assessing risks/benefits of participation, and subject selection in drug clinical trials

Room 211



ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	



E9

**Data Access Versus Patient Privacy in the European Union (EU): Ethical Mandates in the Crucible of Public Debate** (*Global Research Track*) Mark Barnes

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

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

Room 209



E10

**It's Mine: "Biorights" and Benefit Sharing from Specimen Research** (*Hot Topics Track*)

Marianna J. Bledsoe, Laura Odwazny, Michele Russell-Einhorn

Human biospecimens are extraordinarily valuable as resource tools for scientific discovery and have led to major improvements in healthcare. However, in what some have recently termed the "biorights" movement, some patients and patient advocates are calling for some form of direct benefit in exchange for their specimens, such as financial compensation, the return of research results, or more control over how their biological specimens will be used in research. During this session, speakers and attendees will:

- Discuss what rights individuals have (or should have) when providing their specimens for research (e.g., how they are used in research, any profits from research discoveries made possible from them, etc.)
- Explore how much control individuals should/can have regarding how their biological specimens will be used in research
- Examine the practical considerations and limitations regarding any such "biorights"
- Consider how autonomy rights should be best balanced with societal benefits that derive from the use of human specimens in research

Room 214D



E11

**Top Considerations for Institutional and HRPP Leadership When Accepting Department of Defense (DOD) Support of Research** (*Institutional Officials and HRPP Leadership Track*)

Jean Barone, Kimberly Odam, T. Howard Stone

When the DOD supports research, it imposes upon institutional officials (IOs) and HRPP leadership many unique human research protections requirements distinct from the Common Rule. These requirements challenge IOs and HRPP leaders to develop and exert robust, compliant oversight processes. This session will provide attendees with special insight into how IOs and HRPP leaders can meet and overcome these challenges. Attendees should have experience with and/or knowledge about research that is conducted or supported by the DOD before attending this session. During this session, speakers will:

- Review the unique DOD requirements when research is supported by the DOD, including changing requirements in light of the revised Common Rule (32 CFR 219)
- Discuss key challenges and common pitfalls faced by IOs and HRPP leaders in complying with DOD requirements, including changing requirements in light of the revised Common Rule
- Share IO and HRPP leaders' lessons learned, best practices, and management strategies

Room 213



ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

E12

### Writing and Updating Standard Operating Procedures (SOPs) in Light of the Revised Common Rule

(IRB 101 Track) Jeffrey A. Cooper, Karen N. Hale, Lauren Hartsmith

Revisions to the Common Rule mean HRPPs and IRBs need to update their policies and procedures. This session will provide attendees with guidance and tools on how to update policies and procedures. During this session, speakers and attendees will:

- Discuss the components of comprehensive and effective HRPP/IRB SOPs
- Identify the areas of SOPs that will need revising in response to the revised Common Rule
- Share experience and strategies on revising SOPs

Room 217A



E13

### The Role of the IRB Chair in Protocol Exceptions, Violations, Noncompliance, and Unanticipated Problems

(IRB Chairs Track) J. Andrew Bertolatus, Francis J. DiMario, Jr.

This session will discuss "best practice" operational procedures when reviewing protocol exceptions, violations, noncompliance, and unanticipated problems. During this session, speakers and attendees will:

- Describe institutional procedures when reviewing protocol exceptions, violations, noncompliance, and unanticipated problems
- Evaluate challenges and present solutions to difficult scenarios

Room 006CD



E14

### You've Found Noncompliance... Now What? (IRB Operations Advanced Track)

Nichelle Cobb, Scott J. Lipkin, Sarah A. White

At many institutions, the IRB is the entity responsible for evaluating noncompliance and determining corrective actions. However, the regulations do not define oversight of noncompliance an IRB responsibility. With the shift to more research being reviewed by external IRBs and single IRBs, is using the IRB as the oversight mechanism for noncompliance the best model? Attendees should have familiarity with the Common Rule and FDA regulations related to noncompliance, as well as the Guidance on Reporting Incidents to OHRP, before attending this session. During this session, speakers will:

- Explore alternatives to the traditional IRB oversight model for noncompliance
- Review the elements of an effective noncompliance oversight system, for both biomedical research and SBER programs
- Discuss different models for addressing noncompliance determinations and corrective action plans in both biomedical research and SBER
- Share considerations institutions must make regarding noncompliance monitoring in light of single IRB review

Room 007AB



Advanced

#### ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

E15

**Beyond Good Clinical Practice (GCP) Training: Expanding the Tool Set for Preparing Investigators** (Issues Pharma/Biotech Track) Judith Birk, Gerrit Hamre

Room 216B



"In the United States, trial sponsors generally require investigators to complete GCP training prior to participating in each clinical trial to foster GCP and as a method to meet regulatory expectations (i.e., sponsor's responsibility to select qualified investigators per 21 CFR 312.50 and 312.53(a) for drugs and biologics and 21 CFR 812.40 and 812.43(a) for medical devices). Those who participate in multiple clinical trials are often required by sponsors to complete repeated GCP training, which is unnecessarily burdensome" (Source: Clinical Trials Transformation Initiative (CTTI)). CTTI is currently examining whether current GCP training methods actually provide the knowledge and skills necessary to conduct quality clinical trials and recently released recommendations directed toward strengthening the investigator and study team community with respect to the site-specific conduct of clinical trials. During this session, speakers will:

- Discuss why GCP training, though not legally required, may be a de-facto method for assuming investigators and study teams are properly educated and qualified to conduct clinical trials
- Present recommendations from CTTI's Investigator Community project and early findings from CTTI's Investigator Qualification project
- Explore how GCP training requirements completed at one organization can be leveraged by another (e.g., the TransCelerate Initiative)

E16

**Certificates of Confidentiality (CoC): When, Why, and So What?** (Legal Track)

Petrice Brown-Longenecker, Elonna Ekweani, Mary Ramirez, Leslie E. Wolf

Room 206A



CoCs are often an area of confusion and consternation for investigators and IRBs. Determining when a study warrants a certificate and what the process is for obtaining one are only the first steps. Confusion and misinformation also exist as to the scope of protection this document offers. During this session, speakers will:

- Define the scope of legal protection and privilege afforded to researchers under a CoC, including a review of the applicable regulations and federal guidance
- Review considerations around when it would be prudent to obtain a CoC and how to avoid potential pitfalls when implementing one
- Outline how a CoC interfaces with state requirements
- Share strategies for defending a CoC if challenged
- Explore the implications of the 21<sup>st</sup> Century Cures Act's new required process and standards for CoCs in federally funded research

Note: this session is also on the SBER17 agenda (session A3)

E17

**Recruiting, Educating, and Retaining Non-Scientist IRB Members** (Non-Scientist IRB Members Track)

Charlotte H. Coley, Gianna McMillan

Room 208



The regulations dictate that experience, expertise, and diversity of members are important attributes of an effective IRB, and require the inclusion of a non-scientific (aka "community") member to uphold that vision. The non-scientist is often the one member with a perspective unfettered by an institutional affiliation, and therefore adds enormous value to the IRB, its deliberations, and discussions. It is therefore critical that the energy, time, and resources that are devoted to the recruitment, education, and retention of these crucial members be streamlined, efficient, and effective. During this session, speakers will:

- Review the definition of a non-scientist IRB member
- Go over the responsibilities of the non-scientist IRB member
- Address where non-scientist IRB members can be found and explore training options
- Explore how to retain non-scientist IRB members

ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

E18

### Secondary Research in the New Age: Thinking Through Your Options

(Out-of-Body Experiences: Research Involving Tissue and Data Track)

Karen Blackwell, Kate Gallin Heffernan, Julie Kaneshiro

Room 217D



This session will walk attendees through the regulatory options available for conducting secondary research with data or biospecimens. Speakers will discuss how IRB professionals can apply the regulatory options in the revised Common Rule the the review of secondary research, and how investigators can think through the potential application when developing their proposals. During this session, speakers will:

- Review the definition of “human subject” and its implications for secondary research
- Discuss applicable exemptions and how to apply them (e.g., exemptions 4, 7, and 8)
- Explore the regulatory concept of broad consent (i.e., what it is and how and whether to use it)
- Address the long-term aspects of secondary research, including, developing a proposal and maintaining future research options

E19

### Looking Through the Bars: Responsible Research With Prisoners

(Populations Requiring Additional Protections Track) Wayne Carriker, Julia G. Gorey

Room 210



Speakers will discuss the regulatory fundamentals of using prisoners in research, as well as what it means to truly see things from the eyes of a prisoner. During this session, speakers will use the seven additional approval criteria from Subpart C of 45 CFR 46 as a framework to present important insights, as well as discuss the experience of recruiting a former prisoner and integrating them onto the IRB. Case studies and personal experience will illustrate how including a former prisoner on the IRB can provide a perspective not available from someone who has only worked with prisoners, and how that person can improve the ability of the IRB to protect prisoners as research subjects. During this session, speakers will:

- Review the regulatory requirements and certification process when working with prisoners
- 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
- Discuss how an academic IRB was able to incorporate a former prisoner as a valued member of their board

E20

### Nuts and Bolts of Assessing IRB Compliance (QA/QI and Post-Approval Monitoring Track)

Lisa Denney, Keren R. Dunn

Room 214B



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, speakers will:

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

#### ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

E21

### Clinical Trials Transformation Initiative (CTTI) Mobile Clinical Trials, Legal, and Regulatory Project

(Research Conducted in the Digital World Track) David C. Babaian, Jan L. Hewett

The use of technology in clinical research, such as telemedicine and mobile devices, offers the potential to increase the quality and efficiency of research, impacting all stakeholders in the clinical trial enterprise. Some or all study activities, including participant engagement, data collection, monitoring, and follow up, can be performed remotely. Yet, remote research activities are not widely incorporated into existing clinical research. Current laws and regulations that govern or affect the conduct of remote clinical research, as well as the perceived willingness of regulators to accept data collected remotely, may be a barrier to their widespread use. During this session, speakers and attendees will:

- Discuss the legal and regulatory opportunities and barriers to utilizing telemedicine and other remote monitoring models to conduct high-quality, efficient clinical trials
- Compare various models that are currently enabling remote monitoring of patients in clinical trials
- Receive input from clinical enterprise stakeholders willing to reflect and contribute to understanding potential ethics implications of conducting remote clinical trials

Room 206B



E22

### The Regulatory Intersection of Research Misconduct and Human Subjects Protections

(Responsible Conduct of Research Track) Yvonne Lau, Kathy M. Partin, Lisa Rooney

Two separate, yet overlapping regulatory structures govern research with human subjects (the Common Rule, 45 CFR 46) and research misconduct (42 CFR 93). These regulations have different requirements and different enforcement mechanisms. However, suspected violations of both sets of regulations can occur simultaneously. How should IRBs handle this? What do they need to know? During this session, speakers and attendees will:

- Review the scope of various regulations governing research with human subjects and research misconduct, and the mechanisms prescribed for oversight and investigations
- Identify the overlapping and independent responsibilities of committees tasked with investigating possible violations of human subjects research regulations and research misconduct
- Explore various scenarios and case studies highlighting appropriate mechanisms and best practices for handling situations in which violations of human subjects and research misconduct regulations may have occurred simultaneously

Room 217C



E23

### How to Maintain Institutional Memory at a Small Research Program (Small Research Programs Track)

Elizabeth A. Buchanan, Sharon C. Freitag

It is important for HRPPs and IRBs to understand decisions and policies as being part of a larger institutional context. To do so, it is essential that institutional memory is preserved and can be easily accessed and shared with IRB staff, chairs, and members. During this session, speakers and attendees will:

- Create policies and procedures to assist in preserving institutional memory
- Discuss how documents related to the IRB and HRPP be archived and stored
- Consider strategies for succession planning
- Explore on-boarding and off-boarding of staff and members to retain institutional memory

Room 218



#### ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

E24

**SBER in International Settings: Identifying Challenges and Finding Solutions Through Case Studies**

(SBER Track) Leslie D. Cannold, Kelly O'Keefe, Katie B. Speanburg

Conducting research in an international setting presents unique challenges for the reviewing IRB. In 2015, a group of IRB professionals housed in international Non-Governmental Organizations (NGOs) formed a working group to provide each other with technical advice and share resources to address challenges related to reviewing SBER in international settings. Members of this group are offering, through a collection of international SBER case studies, an opportunity for attendees to examine and explore solutions to common, thorny issues. These issues include recruitment of marginalized populations, inclusion of minors, stigmatized health areas, appropriateness of study design, sensitivity to cultural norms, and respect of local laws and regulations. During this session, speakers and attendees will:

- Work through case studies on the challenging issues in international SBER
- Learn from international NGOs experience in SBER what has worked and what hasn't
- Discuss how to adhere to local laws that apply to SBER, as well as the Common Rule, especially when the two may not align

Room 008AB



E25

**Yours, Mine, and Ours: IRB Arrangements for Multiple Institutions Involving Research With Vulnerable Populations and Sensitive Topics** (SBER Track)

Kip M. Kantelo, Matthew D. Stafford, Sharon L. Zack

Using three case studies from different HRPPs (a university, a hospital, and a private sector survey firm), this session will highlight the IRB review, approval, and partnership collaborations necessary to conduct research involving sensitive topics and vulnerable populations. The decision to collaborate on research with another institution, or numerous institutions, may slow down the process and add additional layers of frustration. Not only must investigators negotiate through the application for review and approval by their own institution's review process, but they must also consider the involvements of numerous other stakeholders from partnering institutions such as institutional officials, HRPPs, IRBs, and their legal departments. It is also crucial to speak the same language, whether it refers to reliance or IRB authorization agreements, IRB of record, or what it means to be "engaged" in the research. During this session, speakers will:

- Examine three research protocols to determine how to meet the regulatory requirements and oversight responsibilities for all stakeholders involved
- Explore challenges faced to secure IRB approval and execute numerous institutional agreements
- Share lessons learned and discuss best practices for improving this process

Room 212



12:30-2:15 PM

**Closing General Session Luncheon: The "Nuremberg Code" After 70 Years: Foundational or Forgotten?**

**Moderator:** Alexander M. Capron

**Panelists:** Tessa Chelouche, Alex John London, Susan Miller, Sheldon Rubenfeld

In August 1947, a tribunal of three American judges, sitting in Nuremberg, Germany, rendered judgment in the "The Doctors' Trial" of 23 physicians and their colleagues who had carried out horrific experiments on inmates in the Nazi concentration camps. The judges distinguished what the Nazi doctors had done from experimentation conducted in accord with 10 principles that characterize ethical research with human beings. The 70<sup>th</sup> anniversary of those principles—known as the Nuremberg Code, the first international statement on research ethics—provides an occasion to ask several basic questions: What is the Code, and how was it created? Why, over the next 25 years, did organized medicine not only fail to adhere to the Code, but actively sought to replace it? The often-quoted Declaration of Helsinki, adopted by the World Medical Association in 1964, was actually a retreat from the Code, based on the medical paternalism and scientific triumphalism of that era. What part did the Code's uncompromising demand for informed consent and its focus on biomedical research play in making it seem inapplicable for pediatric and psychiatric studies or social and behavioral research? The session will explore how recent revelations of post-War research abuses have underlined the Code's importance as a foundation for research ethics—for example, in shaping the standards for ethical research in such documents as the Council of Europe's Oviedo Convention—and ask whether it is still relevant when evaluating the ethics of research proposals in an era of biobanks, big data, and epidemiological studies of emerging diseases. **Note:** Lunch will be served during this session. The formal presentation will begin at 1:00 PM.

Exhibit Hall 4A



ICON KEY

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	



**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 a maximum of 20 *AMA PRA Category 1 Credits™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

This program includes 20 credit 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, Boston University School of Public Health, Boston University School of Medicine

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

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

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

**Faculty disclosure statement:** 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.

The conference content is not related to products or services of any commercial interests. Through thorough review of all faculty and planning committee members in consideration of the content of this meeting during the planning period, it was determined that there are no relevant financial relationships to identify and no possibility of bias or conflicts of interest.

A full list of faculty can be found [here](#) and on pages 68-75 of the onsite conference guide. All faculty presenters have indicated that they do not plan on discussing unlabeled uses of a commercial product.

**Disclaimer:** THESE MATERIALS AND ALL OTHER MATERIALS PROVIDED IN CONJUNCTION WITH CONTINUING MEDICAL EDUCATION ACTIVITIES ARE INTENDED SOLELY FOR PURPOSES OF SUPPLEMENTING CONTINUING MEDICAL EDUCATION PROGRAMS FOR QUALIFIED HEALTH CARE PROFESSIONALS. ANYONE USING THE MATERIALS ASSUMES FULL RESPONSIBILITY AND ALL RISK FOR THEIR APPROPRIATE USE. TRUSTEES OF BOSTON UNIVERSITY MAKES NO WARRANTIES OR REPRESENTATIONS WHATSOEVER REGARDING THE ACCURACY, COMPLETENESS, CURRENTNESS, NONINFRINGEMENT, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE MATERIALS. IN NO EVENT WILL TRUSTEES OF BOSTON UNIVERSITY BE LIABLE TO ANYONE FOR ANY DECISION MADE OR ACTION TAKEN IN RELIANCE ON THE MATERIALS. IN NO EVENT SHOULD THE INFORMATION IN THE MATERIALS BE USED AS A SUBSTITUTE FOR PROFESSIONAL CARE.

**ICON KEY**

Didactic session	Interactive workshop	Double session	Call for Session Proposal
Pre-registration required	Recorded session	Sessions new for 2017	
Reviews changes to the Common Rule	CIP eligible	CME accredited	
<b>Advanced</b> – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.		<b>Basic</b> – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	