PRIM&R's 2018 Advancing Ethical Research Conference

November 14-17 • San Diego, CA

Wednesday, November 14: Preconference Programs – Manchester Grand Hyatt San Diego

7:00 AM-2:30 PM
Preconference Programs On-Site Check-In
On-site check-in for those going to a preconference program or preconference program plus AER18. Breakfast on your own.

8:30 AM-4:30 PM
Biobanking in an Era of Research Towards Precision Medicine: Approaches to the Ethical, Regulatory, and Practical Challenges

8:30 AM-4:30 PM
Critical Topics in SBER

8:30 AM-4:30 PM
Implementing the Revised Common Rule

8:30 AM-4:30 PM
IRB 101℠

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

8:30 AM-4:30 PM
Single IRBs: From Idea to Implementation

8:30 AM-12:30 PM
Ethical and Practical Issues in Global Research

8:30 AM-12:30 PM
Tips and Tools for Effective Education and Training

1:00-4:30 PM
Ethical and Regulatory Review of Research Case Studies

1:00-4:30 PM
Ethical Study Design Is Good Science

4:00-7:00 PM
AER18 On-Site Check-In Opens at the San Diego Convention Center
On-site check-in for those attending AER18 only.

4:30-6:00 PM
Preconference Programs Networking Reception
All those registered to attend a preconference program are welcome to attend this networking reception. Drinks and light refreshments will be served.

ICON KEY

Double session	Call for Session Proposal	
Pre-registration required	Recorded session	Breakout sessions new for 2018
Reviews changes to the Common Rule	CIP eligible	CME accredited

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

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Thursday, November 15: AER18 – San Diego Convention Center

7:00 AM-5:30 PM
On-Site Check-In
Breakfast on your own.

7:00-8:00 AM
Continental Breakfast to Welcome First-Time Attendees

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. Pre-registration required.

8:00-8:15 AM
Conference Welcome Remarks

Albert J. Allen, MD, PhD, Senior Medical Fellow, Pediatric Capabilities, Eli Lilly and Company, and Elizabeth A. Buchanan, PhD, Endowed Chair and Director, Center for Applied Ethics; Acting Director, Office of Research and Sponsored Programs, University of Wisconsin Stout

8:15-9:00 AM
Remarks from PRIM&R's Executive Director and Chair of the Board of Directors

Elisa Hurley, PhD, Executive Director, PRIM&R, and Heather H. Pierce, JD, MPH, Board Chair, PRIM&R; Senior Director for Science Policy; Regulatory Counsel, Association of American Medical Colleges

9:00-10:00 AM
Keynote Address

Timothy Caulfield, BSc, LLB, LLM, FRSC, FCAHS Canada Research Chair in Health Law and Policy; Professor, Faculty of Law and the School of Public Health; Research Director, Health Law Institute, University of Alberta
*(**Note**: the date and time subject of Dr. Caulfield's talk are subject to change.)*

10:00-10:30 AM
Beverage Break Supported by Kinetiq
Join us for coffee in the exhibit hall. *PRIM&R would like to thank Kinetiq for helping support this break.*

Concurrent Plenary Sessions, 10:30-11:45 AM

Panel I: Gun Violence and Public Health: Facts, Fiction, and the Future

Gun violence, particularly mass shootings, captures the headlines on a regular basis. But, gun violence is much broader than these specific incidents; on average, 96 people are shot and killed each day in the United States. This is an epidemic. Other epidemics, such as smoking related deaths and car crashes, have been studied using a public health approach. That approach has then informed prevention and treatment strategies and policy change. Gun violence requires this same approach. During this session, the extent of this epidemic and the laws that affect the ability to do research into prevention and treatment strategies will be explained; the state of current evidence will be reviewed and research that could inform policy will be discussed; and challenges to policy change and suggestions for next steps will be identified.

Panel II: At the Crossroads of Hope and Hype: Recruiting the Desperately Ill for Clinical Trials

Clinical trials of new interventions are often seen as a "last hope" for patients with life-threatening conditions for which no curative therapy yet exists. Some trials, such as those involving "precision medicine" (i.e., interventions targeted to an individual's genome), generate an especially high level of public and professional expectation. Should investigators and IRBs be concerned about the ability of patients to give informed and voluntary consent when invited to enroll in such clinical trials? Does the "personalized" nature of the interventions being investigated add to the sense they will be therapeutic for participants, even in Phase I or II trials? How should the choice to enter a trial be understood, both in terms of the potential benefits of the trial and the costs in terms of other interventions, including palliative care, which may be forgone? What can physician-investigators do to frame the alternatives in a way that preserves hope while downplaying the hype?

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Panel III: The New Rule's Identity Crisis: Should Identifiability Be Changed?

The revised Common Rule includes a provision that, within one year of the implementation date (by July 19, 2019, at the earliest), and every four years thereafter, the rule's definition of "identifiable biospecimens" and "identifiable private information" must be re-evaluated. As such, the interpretation of these terms will perhaps change in light of scientific progress and other considerations. Moreover, the ability of technologies, such as whole genome sequencing, to render information and biospecimens "identifiable" also periodically will be assessed. This debate style plenary session will consider the pros and cons of revising the definition and the potential future impact of such assessments.

11:45 AM-1:00 PM

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 support this lunch.*

11:45 AM-1:00 PM

Meet the Author Lunch and Book Signing

Participate in a vibrant discussion with the author of a timely book related to the field (information on book and author forthcoming). The author's book will be available wherever books are sold online, and copies will be sold at the conference. Pre-registration required. ***Note**: Lunch will be served in this session. The formal presentation will start at 12:00 PM.*

12:30-1:00 PM

Meet and Greet With the AER18 Supporters and Exhibitors

Network with the AER18 Supporters and Exhibitors, and learn about their important services.

12:30-1:00 PM

Federal Agency Office Hours

During this time, representatives from select federal agencies will be available to answer attendee questions, engage in dialogue, provide clarification, and/or direct attendees to additional resources. Attendees are encouraged to come prepared with questions, which will be taken on a first come basis. *(**Note**: check back, as this list will be updated with additional agencies):*

- DOD
- FDA
- OHRP
- SACHRP

12:40-1:00 PM

Overview of the CIP Exam

Join us in the AER18 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 exam! If you are unable to join us at this time, but would like to learn more about the CIP exam while on-site at the conference, stop by the PRIM&R Booth or email us, for more information.

Breakout Session Series A, 1:15-2:30 PM

A1

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

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

A2

Reserved for Late-Breaking Session

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A3

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

CR Advanced

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 to assist the audience in determining when something is public health surveillance vs. public health research

A4

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

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 narratives 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

A5

Empirical Research on Ethical Issues in Patient Centered Outcomes Research (PCOR): New Data to Inform Deliberations *(Empirical Research Ethics Track)*

New

The rise of PCOR and comparative effectiveness research (CER) has sparked considerable interest in how well suited traditional ethics oversight systems and practices are for these new research contexts. Recent empirical studies provide some relevant data, but questions remain about whether and how those charged with the oversight and review of human subjects research should respond. In this session, speakers will share results from two new empirical studies to inform deliberations regarding oversight for PCOR/CER. During this session, speakers and attendees will:

- Summarize the ethical challenges for PCOR/CER relevant to IRB oversight and human subjects protections
- Describe original data measuring support for streamlined approaches to informed consent for low-risk CER studies
- Discuss consensus recommendations for oversight of PCOR developed through a Delphi process in response to a national survey of IRB chairs

A6

Demystifying Part 11 and Computer System Validation *(FDA Regulations Track)*

New

The FDA is placing increased emphasis on compliance with 21 CFR Part 11. Those involved in FDA-regulated activities needs to understand the basics of the regulation and how to comply. Part 11 touches everyone: institutions, IRB offices, private research clinics, mobile health application developers, etc. This session will address common misconceptions about Part 11 and review how to practically prepare for an eventual FDA Part 11 inspection. During this session, speakers and attendees will:

- Explain when Part 11 applies
- Review where to find additional information and resources
- Explore programs and systems to prepare for Part 11 inspection

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A7

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

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 and attendees will:

- Review the different models of national ethics review systems
- Discuss how context and concepts drive the structure and processes of different review structures
- Consider how the structure of ethics review systems can affect functionality

A8

The Certified IRB Professional (CIP®) Credential: How Do I Get Started? *(Hot Topics Track)*

This session will be led by a CIP Council member and two newly certified individuals. Participants are encouraged to come with questions about the CIP program and exam preparation. During this session, speakers and attendees will:

- Discuss the CIP credential and the eligibility guidelines
- Review the types of questions on the CIP exam
- Share study preparation strategies

***Note**: this session will not review specific exam questions.*

A9

Not Less Work, But Different: Re-Engineering for Single IRB Review

Advanced

(Institutional Officials and HRPP Leadership Track)

HRPPs and IRBs have often served as gatekeepers for research oversight and administrative functions beyond those required by the regulations. As institutions adapt to the brave new world of single IRB review, HRPPs and IRBs face new challenges. The shift to single IRB review offers the opportunity to rethink and reconfigure approaches to research oversight, and this session will tease apart institutional and IRB roles when using a single IRB, as well as highlight key administrative and operational efficiencies. Attendees are expected to have sufficient experience and understanding to actively contribute to the discussion of and solution to these difficult problems. This session will not review basic concepts. During this session, speakers and attendees will:

- Delineate distinct roles for reviewing IRBs and relying institutions by identifying and separating appropriate (non-IRB) responsibilities of institutions from functions that are, by regulation, within the purview of the IRB
- Explore the challenges and potential benefits yielded through inter-institutional cooperation when using a single IRB

A10

Back to Basics: Does My Project Fall Within the Scope of the Revised Common Rule? *(IRB 101 Track)*

CR

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 pre-2018 rule
- Explore the flexibilities provided by the revised Common Rule and use case examples to assist the audience with understanding and applying it

A11

Meeting Management for IRB Chairs *(IRB Chairs Track)*

This session will cover key topics in the management of an IRB from the IRB chair's perspective. During this session, speakers and attendees 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 build on attendees' skills and training as IRB chairs

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A12

It's Not as New as You Think: Understanding How to Operationalize the Final Rule

(IRB Operations Advanced Track)

When the revised Common Rule goes into effect, institutions and HRPPs will be faced, more than ever, with the management of varying review standards for research. This includes potential differing regulatory standards for research subject to oversight by OHRP (approved by IRBs both before and after the effective date of the revised Common Rule), as well as regulatory standards of other federal agencies that are not signatories to the revised Common Rule, Good Clinical Practices, and accreditation standards. This session will review how to appropriately manage the application of these various standards, and explore how they interact with each other, so HRPPs/IRBs can avoid substantive and operational confusion. The experience of organizations that have applied some of the revised Common Rule changes already through flexible approaches to review of research that is not federally funded (e.g., eliminating requirements for continuing review, incorporation of a summary intro into consent documents) will be highlighted. During this session, speakers and attendees will:

- Provide an overview of how the revisions to the Common Rule parallel flexibility efforts for unregulated research
- Identify key challenges when implementing different sets of regulations, including knowing which regulations to apply and when
- Discuss practical approaches to educating research teams and IRB members and staff about different sets of regulations and how to ensure compliance with them

A13

ClinicalTrials.gov: How Academic Institutions Can Respond to New Clinical Trial Disclosure Requirements

(Pharma/Biotech Perspectives Track)

The Federal regulations (42 CFR Part 11) and NIH Policy on Dissemination of NIH-Funded Clinical Trial Information have been in effect since January 2017. The regulations and policy expand the expectations for sponsors and investigators to register clinical trials and submit summary results information to ClinicalTrials.gov. This session will explain these expanded requirements, provide an update on the status, and describe specific examples of how research institutions are implementing processes to support investigators in ensuring prospective compliance with these requirements. This session will provide details about the following areas critical to the successful posting of summary results in ClinicalTrials.gov: effective planning for reporting results at the end of the trial; preparing and posting study protocols and statistical analysis plans; and quality control review process at ClinicalTrials.gov. This session will also examine the tools some institutions are using to support compliance efforts based on the experience of a National ClinicalTrials.gov Taskforce comprised of over 100 academic institutions. During this session, speakers and attendees will:

- Explore legal requirements and policies for the submission of registration and results information by trial sponsors to ClinicalTrials.gov, including which information must be submitted and when
- Describe resources and specific examples of how institutions are implementing processes to support ClinicalTrials.gov reporting and identify ways in which institutions can help ensure compliance with registration and results submission requirements
- Understand recent updates at ClinicalTrials.gov, including information on the quality control process, posting of study protocols, and new tools available to support institutions in their compliance activities

A14

Legal and Regulatory Changes: A Year in Review *(Legal Track)*

A lot has happened this year! Get up to speed with this overview session designed to bring you the highlights and breaking news since last year's AER Conference. How are recent legal and regulatory changes fundamentally affecting research? What should institutions be ready for in the coming months and years? Get answers to these questions and more through this session's issue-spotting exploration and analysis of changes in laws and regulations promulgated by FDA, DHHS, and the NIH. (Note: this is an overview session; speakers will not review each change in detail, but will endeavor to point attendees to other conference offerings relevant to each topic covered). During this session, speakers and attendees will:

- Identify recently proposed and adopted legislative and regulatory initiatives affecting research
- Illustrate likely impact on current practices and evaluate importance of change
- Evaluate whether further change is necessary or likely forthcoming

A15

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A16

Implementing NIH's Genomic Data Sharing Policy: Challenges and Solutions

New

(Research Involving Data and Biospecimens Track)

The NIH Genomic Data Sharing Policy became effective in January 2015, and the policy applies to all NIH-funded research that generates large-scale human or non-human genomic data, as well as the use of these data for subsequent research. Compliance with the policy requires engagement of both the organization receiving federal funds and the IRB to complete the required institutional certification and provide assurances that the requirements of the policy have been met. This process is not without challenge and involves complex considerations (e.g., assessment of the adequacy of consent to permit sharing; potential limitations on data sharing that should be indicated by the organization; certifications when multiple institutions are contributing). During this session, speakers and attendees will:

- Provide an overview of the NIH's Genomic Data Sharing Policy
- Review the ethical and regulatory implications of the policy
- Identify potential challenges for organizations and IRBs in complying with the policy
- Discuss operational solutions and review processes to facilitate compliance

A17

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

Advanced

Speakers will provide 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 and attendees will:

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

A18

Beyond Auditing and Monitoring of the IRB Towards Quality Improvement

New

(QA/QI and Post-Approval Monitoring Track)

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

A19

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

CR Advanced

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 real-life cases that exemplify considerations of risk assessment about big data research. Data scientists are concerned that IRBs create delays, over-regulate, and put up road-block 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. Speakers will also 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 before attending this session. During this session, speakers and attendees will:

- Explore the overlap in big data health research 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 revised Common Rule requirements
- Explore changes to the revised 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

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A20

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

This session focuses on best practices for orienting committees convened to undertake inquiry and investigation proceedings in response to allegations of research misconduct. Often, such committees 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-naive 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, 3) minimizes institutional and personal legal exposure, and 4) promotes efficient and fair dispositions. This session will offer practical advice and suggestions for how institutions can maximize compliance and meet their regulatory obligations through the individuals who are called to serve on investigative committees. Practical tools (including curriculum checklists and template committee charging documents) will be provided. During this session, speakers and attendees will:

- Discuss how investigation-naive committees convened to address research misconduct allegations can be adequately prepared to undertake their charge
- Identify the elements of a mini-curriculum or training that can be provided to faculty members to assist them and protect the institution against potential legal exposure that may arise when committees are inadequately supported or trained in their response
- Explore the primary traps that can interfere with research misconduct committees' effectiveness and potential preventative solutions

A21

Challenges and Opportunities for Institutions With Small Research Programs *(Small Research Programs Track)*

Small research programs are identified as having fewer than 200 open protocols and three or fewer (usually one or two) IRB staff. This interactive session will review the challenges faced by small to mid-sized academic IRBs and possible solutions. During this session, speakers and attendees will:

- Identify specific challenges and opportunities encountered by small research programs
- Provide possible solutions to overcome these challenges and how to harness opportunities
- Offer guidance on how best to use the resources available and comply with the regulations

A22

Different Minimal Risk Review Models *(SBER Track)*

The revised Common Rule provides clear instructions for the conduct of convened meetings, but offers little guidance when it comes to minimal risk review procedures. This session will present two models for minimal risk reviews: a traditional model with designated reviewers, and a model of minimal risk review boards. An effective minimal risk research model decreases researcher burden while maximizing protections for research participants. This didactic session will outline the benefits of each review model, while exploring opportunities to streamline minimal risk review methods. During this session, speakers and attendees will:

- Discuss minimal risk review regulatory requirements
- Explore different minimal risk review models and identify opportunities to streamline minimal risk review
- Consider minimal risk review models for the revised Common Rule (e.g., limited IRB review)

A23

Risk Mitigation in Mixed SBER and Biomedical Research *(SBER Track)*

Advanced

Using case studies, this session will focus on risk mitigation in research involving both biomedical and social science methods. Case studies will include piloting initiatives to overcome reluctance to utilize support/recovery services for persons affected by opioid abuse, and an evaluation of an early intervention program to ameliorate psychosocial effects of Chronic Traumatic Encephalopathy in youth who play contact sports. Attendees should have a basic foundation in human research protections ethics and principles, including the criteria for approval and definitions from DHHS and FDA regulations before attending this session. During this session, speakers and attendees will:

- Review the nature of the risks, harms, and impacts associated with mixed SBER/biomedical research
- Explore factors likely to contribute to increased risk in research spanning both medical and social/behavioral arenas
- Discuss how to design research with sufficient protections and minimize risk through study design

2:30-3:00 PM

Beverage Break

Join us for coffee and cold drinks.

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B1

The Times, They Are a-Changing: Overview of the Latest NIH Changes and Their Implications on Research

(A Dialogue With the Feds Track)

This session will present an overview of recent regulatory and policy changes at the NIH and conduct a deeper dive into some of the more notable changes, including the new policy and guidelines on the inclusion of individuals across the lifespan as participants in research involving human subjects, revisions to the definition of "clinical trials," and the revisions to the Certificates of Confidentiality policy. This session will also review the NIH's thought process and aims behind these changes, the obstacles to implementation, and the overall impact on research. During this session, speakers and attendees will:

- Describe the current lay of the land at NIH
- Discuss how these changes will affect different aspects of the research (e.g., design, conduct, review, etc.)
- Explore the implementation challenges for investigators, IRBs, and institutions

B2

The Generation and Utilization of Real-World Evidence (RWE): Ethical and Regulatory Considerations

(FDA Regulations Track)

The generation and utilization of RWE is receiving significant attention for its potential to both improve the efficacy of drug development programs and inform regulatory decision-making. However, generating and using RWE presents a unique set of ethical and regulatory challenges that must be addressed by different stakeholders including researchers, sponsors, and research funding and regulatory agencies. During this session, speakers and attendees will:

- Explore ethical and regulatory considerations associated with generating and using RWE in regulatory decision-making
- Assess a RWE case study that highlights these issues
- Discuss the roles of different stakeholders in the development and use of RWE in clinical research

B3

You'll Know It When You See It, or Will You? Defining "Human Subjects Research"

Advanced

(Boundaries and Balances Track)

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 before attending this session. During this session, speakers and attendees will:

- Define a process and a set of criteria for determining whether an activity is research
- Explore key decision points for determining whether or not a research study involves human subjects
- 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.)
- Discuss implications of the revised Common Rule definitions for "research" and "human subjects" (e.g., if it is no longer human subjects research, then who should review these activities?)

B4

Want to Be a Great Research Ethicist (or Just a Better One)? Here's an Educational Map

(Educating and Training Track)

Research regulatory systems are designed to allow scientists and researchers to pursue ethically appropriate research with the ultimate goal of protecting human and animal research subjects. It is arguably the people within the system who work to make it well-intentioned, purposeful, and helpful. Now, its own respectable discipline, research ethics, seeks the knowledge to help establish such structures with competent individuals at the helm. But, given the vast, thorny, and constantly changing fields of ethics, science, and law, knowledge is a necessary, but insufficient condition for gaining competence. This session aims to apply empirically substantiated learning principles to form an educational map for the research ethicist that transcends organizational, associational, or sociopolitical boundaries. This session will focus on the limitations in human knowledge of research ethics and how to empower learners. During this session, speakers and attendees will:

- Outline ways of knowing as a core element of learning (e.g., federal and institutional policies, academic theory, empirical research, discipline-specific issues, and decision-making models)
- Assess ways in which human prior knowledge-gaps may become obstacles or even be detrimental to regulatory system goals as a consequence of organizational, associational, or sociopolitical forces
- Apply Ambrose, et al. "How Learning Works" (2011) principles to examine ways to improve research ethics education through knowledge organization, motivation, mastery, practice and feedback, developmental climates and environments, and self-direction

ICON KEY

Double session	Call for Session Proposal	
Pre-registration required	Recorded session	Breakout sessions new for 2018
Reviews changes to the Common Rule	CIP eligible	CME accredited

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B5

Designing Trials for Completion *(Empirical Research Ethics Track)*

Despite passing through ethical review, receiving approval, and initiating enrollment, many clinical trials fail to complete and fail to produce the data necessary to answer the driving research question. While some of these trials are terminated early for safety concerns, often inadequate enrollment or retention of research participants leaves studies underpowered and unable to meet their primary research objectives. These underpowered or terminated trials give rise to a number of ethical concerns, particularly since the risks and burdens borne by human subjects are often justified by the assumption that the study will answer the research question and, in so doing, provide socially valuable knowledge. This session will identify ethical and practical issues with clinical trial completion and encourage reflection on strategies for minimizing the risks of non-completion. The session will begin with a review of the existing empirical evidence on non-completing studies in order to define the scope and magnitude of the ethical concerns raised by non-completing trials. It will then explore several potential levers for mitigating the risks (e.g., employing methods from prediction science to help identify over-optimistic or otherwise unrealistic assumptions built into the trial's operation or design; analyzing the current research landscape in order to identify external conditions that may threaten trial completion; alleviating competition between trials at the institutional level via a system of research priority-setting). During this session, speakers and attendees will:

- Assess the empirical data on the frequency of non-completing trials and the number of subjects who participate in them
- Understand the ethical concerns raised by non-completing trials
- Discuss different mechanisms for facilitating trial completion

B6

When Is an Investigational Device Exemption (IDE) Needed for a Clinical Investigation of a Medical Device? *(FDA Regulations Track)*

Basic

In general, the IDE regulations apply to clinical investigations of medical devices designed to determine safety and effectiveness. The IDE regulations at 21 CFR 812 describe three types of device studies: significant risk, nonsignificant risk, and exempt studies. What studies require the submission of an IDE application, and who determines whether they require an IDE? What are the IRB's responsibilities for review and oversight of each type of device study? During this session, speakers and attendees will:

- Provide a basic overview of the applicability of the IDE regulations that address when an IDE is required
- Review sponsor responsibilities and IRB responsibilities for review and oversight of device studies
- Discuss how to apply the IDE regulations to studies involving investigational and marketed medical device products
- Assess case examples to assist IRBs in understanding when an IDE might be needed for a clinical investigation of a medical device

B7

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

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 (both SBER and biomedical 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

B8

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

PRIM&R's commitment to diversity is a core value. During this session, speakers and attendees will brainstorm and strategize how to champion the important benefits of diversity in all aspects of regulatory affairs and compliance career pathways, spanning from human subjects protections personnel, to the IRB office and membership, to researcher partners. During this session, speakers and attendees will:

- Discuss the benefits and challenges of implementing diversity in IRBs and workplaces
- Describe unconscious bias and stereotype threats, and articulate the implications this has on learning and/or supporting career development
- Share approaches for building a toolbox that can assist individuals in learning how to manage/leverage diversity within committees; increase diversity and points of view of committees (e.g., strategies for inclusion of all participants, including nonscientist and nonaffiliated members); and navigate the opportunities and challenges of a diverse workplace, including for communication and problem-solving among diverse IRB administrative, committee, and research personnel

ICON KEY

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B9

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

CR New Advanced

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 and attendees 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

B10

Essential Documentation: IRB Membership, Record Keeping, Minutes, and More *(IRB 101 Track)*

CR Basic

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 and attendees 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; discussion to include the joint OHRP/FDA guidance on IRB minutes and guidance on IRB written procedures
- Identify the components of a complete record of IRB meeting activities

B11

The Evolving Role of the IRB Chair in the World of Single IRBs *(IRB Chairs Track)*

This session will explore the changing roles and responsibilities that fall within the purview of the IRB chair in light of the paradigm shift to single IRB review of multi-site human subjects studies. During this session, speakers and attendees will:

- Discuss the changing roles and responsibilities of the IRB chair when his/her institution cedes IRB oversight or serves as the IRB of record for multi-site research
- Examine "best practice" solutions that lead to enhanced participant protections when IRB review is ceded or when serving as the IRB of record

B12

The After Party: Tools and Techniques for the Assessment of IRB Operations During and After Implementation of the Revised Common Rule *(IRB Operations Advanced Track)*

New CR

As the revised Common Rule goes into effect, it is easy to get caught up in the initial implementation planning and efforts. But, what happens after implementation? How should an institution monitor IRB operations for ongoing compliance with new regulatory requirements and new local policies and procedures? This session will present a continuous QA/QI plan that assesses a broad range of factors impacting the quality of IRB operations and review functions. The session will also demonstrate the use of a common database tool developed to track and report QA/QI findings for use in staff education and evaluation, and for early identification of gaps in policies and procedures. In an ever changing environment, this plan and associated reporting database provide robust tools in support of compliant and effective IRB operations. During this session, speakers and attendees will:

- Discuss strategies for preparing for the implementation of the regulations, such as the revised Common Rule, when there is uncertainty about what will go into effect and when
- Explore what to think about in terms of policies, processes, and systems that will be affected by the changes
- Assess how to educate and roll out changes
- Understand how to monitor for compliance with revised policies and procedures

ICON KEY

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B13

The European Union's (EU) General Data Protection Regulation (GDPR) and US-Based Research: Implications, Problems, and Potential Solutions *(Pharma/Biotech Perspectives Track)*

The EU GDPR became effective on May 25, 2018, and involves a number of changes to the European privacy law. The regulation was designed to harmonize data privacy laws across Europe, to protect and empower all EU citizens' data privacy, and to reshape the way organizations across the region approach data privacy. The GDPR not only applies to organizations located within the EU, but also to organizations outside of the EU if they offer goods or services to, or monitor the behavior of, EU data subjects. And, it applies to all companies processing and holding the personal data of human subjects residing in the EU, regardless of the company's location. During this session, speakers and attendees will:

- Review the scope of the EU GDPR and discuss the key points, as well as information on the impact it has on businesses involved in the conduct of clinical research
- Discuss the implications, problems, and potential solutions for informed consent, data sharing, and transparency
- Explore how the EU GDPR lines up with transparency efforts outlined in the European Medicines Agency (EMA) Policy on Publication of Clinical Data for Medicinal Products for Human Use (EMA Policy 0070), as well as voluntary efforts underway to share clinical trial data for secondary research

B14

1-800-RESEARCHLAWYER: Five Reasons to Have Your Institution's Legal Counsel on Speed-Dial *(Legal Track)*

The degree to which IRBs and research institutions utilize legal counsel may depend on a variety of factors, including the availability of lawyers with relevant expertise, resources to access counsel, and perceptions about the value or nature of interactions with lawyers. This session will begin with a discussion of the most common and most important day-to-day issues directed to legal counsel in the research context, including questions about informed consent (including reliance on legally authorized representatives), noncompliance with regulatory or IRB requirements, subject injury coverage provided by sponsors or others, privacy and confidentiality protections applicable to research, and state research or confidentiality-related laws. Speakers and attendees will explore the potential role of counsel in advising on these issues, including the blending of legal and policy considerations, potential conflicts among institutional clients, and the preservation of IRB independence. Speakers will not provide specific legal advice, but will give their perspective on the nature of the issues and requests frequently brought to their attention and on their approach to providing advice. Attendees will then have an opportunity to discuss concerns, barriers, and success stories in their interactions with counsel on these and other topics. The session will be facilitated by two clinical research attorneys who have practiced both in-house at institutions and as outside counsel to institutions and IRBs, and by an in-house director of a human research protection program who will provide a client perspective on when involvement of counsel may be most useful.. During this session, speakers and attendees will:

- Learn the types of issues that may benefit most from a consultation with counsel even in situations when IRBs and other members of research administration may be reluctant to bring counsel in
- Identify strategies for utilizing counsel most effectively, especially when legal resources (whether internal or external) are limited
- Understand counsel's perspectives on the unique practice of clinical research law

B15

Reserved for Late-Breaking Session

B16

Research with Data and Biospecimens Under the Revised Common Rule: An Overview of Changes and Challenges *(Research Involving Data and Biospecimens Track)*

With the shifting regulatory environment, and, in particular, an expanding approach to what constitutes "identifiable" information and materials, research on data and biospecimens is entering a new era. Although the Final Rule declined to adopt the NPRM's proposal to regulate non-identified biospecimens, there are several aspects of the Final Rule and associated regulatory developments that suggest we may be moving in that direction regardless. What do all of these recent changes mean for data and biospecimen research? This session will provide an overview for participants of the forthcoming changes to data and biospecimen research under the revised Common Rule, including options available for conducting secondary research.

- Explore the new definition of "human subject" and the evolving standards of identifiability and how that may impact data and biospecimen research (including indirect ways research using currently non-identifiable biospecimens may be impacted)
- Understand the new rule's additional exemptions and how to apply them, including how to implement limited IRB review and the pros and cons of the new "broad consent" option
- Use specific case studies (in both the SBER and biomedical realms) to discuss practical approaches to implementing the new rule to enhance data and biospecimen research, including challenging issues raised by research using sensitive data

***Note**: attendees with a more specific interest in how research data and specimen repositories will be operated under the Final Rule may consider attending D3: Tissue Repositories and Data Banks in the Era of the Revised Common Rule.*

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B17

Conducting Research With Children: Complexities in Practice

Advanced

(Populations Requiring Additional Protections Track)

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

B18

Correcting and Avoiding Noncompliance: Examining Real-life Cases

New

(QA/QI and Post-Approval Monitoring Track)

After a brief introduction, attendees will be presented with several real-life scenarios to discuss and determine how best to resolve. Scenarios will include both the routine and the unique, and the resolutions are intended to include a variety of components designed to both correct and avoid future instances of noncompliance. Attendees are encouraged to share their own "cases" for group discussion. During this session, speakers and attendees will:

- Discuss key concepts, including noncompliance, corrective, and protective action
- Provide methods for identifying root cause
- Use case studies developed by speakers to analyze noncompliance and identify proposed corrective and preventive action
- Review common noncompliance and corrective and preventative actions

B19

Privacy and Security Risks in Research With Wearable Technology

New Basic

(Research Conducted in the Digital World Track)

Wearable technology has great potential to expand healthcare quality, ease of data collection, and improve personal wellness. However, wearable technology also raises significant privacy and security challenges. Mobile-sensor data provides researchers unprecedented opportunities to collect objective data without patient's awareness. For instance, GPS data provides geo-exposure risk, movement patterns, and activity levels, among other data, which may disclose privacy information about the user. This session will cover the risks associated with wearable technology and strategies to lower those risks. During this session, speakers and attendees will:

- Explain the data types collected via wearable technology
- Assess the research data risk with wearable technology
- Discuss strategies to lower risk in doing research with wearable technology

B20

Case Studies in Research Misconduct *(Responsible Conduct of Research Track)*

New Basic

Research integrity is of paramount importance to our institutions and noncompliance with modern Responsible Conduct of Research (RCR) standards can result in severe penalties to the organization, the individual(s), and their reputations. However, the modern definition of research misconduct is relatively new, having evolved from hundreds of years of social and ethical issues that have arisen in the practice of scientific research. What may have been an acceptable practice a century ago may be considered unacceptable by today's standards. This highly interactive session will include a review of new and historic cases involving accusations of research misconduct in biology, chemistry, physics, and medicine, and provide insightful examples of both responsibly and irresponsibly conducted science. Participants will become familiar with a case history of research misconduct and will engage in discussion of how these prominent cases have shaped contemporary perspectives on the responsible conduct of research. This session will use a wireless audience response system to engage participants, evaluate feedback, and formulate group consensus on a variety of ethical issues and questions. During this session, speakers and attendees will:

- Describe a variety of famous cases involving ethical issues in research and apply modern RCR standards to better assess and work through those issues
- Explain the relevant rules and regulations of modern RCR standards and the ethical principles and cases that justify current institutional compliance policies
- Discuss a variety of ethical issues and questions, evaluate different views, and formulate opinion on case influence on the meaning of responsible conduct of research

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B21

How to Identify, Navigate, and Manage Conflicts of Interest (COI) at a Small Research Organization

Basic

(Small Research Programs Track)

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 and attendees will:

- *Identify different types of COIs (e.g., financial, institutional, professional, personal)*
- *Review policies that help identify what various COIs 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)*

B22

College Students and Research: Challenges and Issues for IRBs *(SBER Track)*

Basic

A considerable amount of research takes place on college/university campuses involving students as subjects. This includes research on novel educational strategies and the use of departmental pools of introductory-level students to participate in research studies and other projects for credit (subject pools). This session will review regulatory and legal standards, as well as specific ethical issues that arise when college students on campus are subjects, and when they serve as investigators or research personnel. During this session, speakers and attendees will:

- Identify different types of issues that frequently arise when conducting research on a university/college campus, including best practices for addressing ethical issues (e.g., instructors recruiting their own students, students who are minors, etc.)
- Discuss the issues that arise when college students conduct research, either as principal investigator or student investigators
- Outline the issues that arise with the operation of university/college subject pools and best practices
- Review the role of the HRPP in educating student researchers
- Provide a high level overview of pertinent laws and regulations affecting this population (e.g., the Family Educational Rights and Privacy Act, Title IX)

B23

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

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 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 the 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

4:15-5:30 PM

AER18 Welcome Reception

Join us in the AER18 Exhibit Hall to celebrate the opening of the conference. During this time, you'll be able to meet the supporters and exhibitors and view the posters. Drinks and light refreshments will be served.

5:45-7:15 PM

Young Professionals Networking Reception

Connect with other young professionals interested in research ethics and relax after a busy day in San Diego (location forthcoming). Don't forget to bring the drink ticket you will receive when you check in on-site. While all attendees are welcome, complimentary drink tickets will be provided for young professional registrants only.

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Friday, November 16: 2018 AER Conference – San Diego Convention Center

7:00 AM-5:00 PM
On-Site Check-In
Breakfast on your own.

8:00-8:30 AM
Welcome and Award Presentations

8:30-9:30 AM
Keynote Address
Michelle Mello, BA, MPhil, PhD, JD, Professor of Law, Stanford Law School; Professor of Health Research and Policy, Stanford University School of Medicine

9:30-10:00 AM
Beverage Break With the Supporters and Exhibitors
Join us for coffee in the exhibit hall.

Explorations in... Panel Series, 10:00-11:00 AM
The Explorations 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. The sessions are loosely grouped around a specific theme, and each session features three posters.

More information on this series is forthcoming.

Breakout Session Series C, 11:15 AM-12:30 PM

C1
A Dialogue With the Department of Defense (DOD): Updates for DOD and DOD-Sponsored Research Protections Personnel *(A Dialogue With the Feds Track)*
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

C2
A Dialogue With the Secretary's Advisory Committee on Human Research Protections (SACHRP)
(A Dialogue With the Feds Track)
This session will be led by representatives from SACHRP. Attendees are encouraged to come with questions of interest to all. During this session, speakers and attendees will:

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

C3
Standard of Care, Medical Innovation, or Research: How Should We Decide? *(Boundaries and Balances Track)*
New Advanced

A frequent regulatory issue is whether a practice conducted by a physician or an institution, when consistently practiced in that institution, but novel and not (yet) adopted by the community, counts as medical innovation or research. In other words, when a physician or group of physicians want to collect data on their consistently provided, but unique/novel practice, but this practice "would be provided anyway" to their patients, is this standard of care, medical innovation, or research, and how should it be reviewed? This issue is important as it comes up frequently in IRB review, although it may be addressed very differently by different IRBs. This session will present the issue, discuss with the audience potential ways of addressing it, and attempt to problem solve to come up with the best treatment of these common situations. This session will make heavy use of active learning techniques, such as small group work, case studies, hands-on activities, participant-created content, and interactive discussion. Attendees are expected to have sufficient experience and understanding to actively contribute to the discussion of and solution to these problems. These sessions will not review basic concepts. During this session, speakers and attendees will:

- Recognize how standard of care, medical innovation, and research are highly intertwined in medical contexts
- Analyze a case(s) where an IRB is faced with the decision of how to regulate a particular study, and the strengths and weaknesses of different approaches
- Suggest best practices when faced with this type of situation

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C4

Advancing Yourself as a Regulatory Professional: Education, Cooperation, and Self-Advocacy

New Basic

(Educating and Training Track)

This interactive session aims to help regulatory professionals exercise agency in their professional development. Regulatory professionals are responsible for staying current with regulations and policies and educating others, but personal and professional development is of equal importance. Speakers will explore novel strategies for professional development, discuss how to be your own advocate, and review the importance of cooperation and building networks. During this session, speakers and attendees will:

- Discuss novel strategies for professional development and the importance of self-advocacy
- Review the importance of cooperation and building professional networks
- Identify educational opportunities for the regulatory professional and discuss how to integrate learning into the work environment
- Explore tools to enhance individual and operational effectiveness in the HRPP profession and consider how new challenges lead to new capabilities

C5

The Pressing Need for IRB Precedent *(Legal Track)*

New

In this session, speakers will discuss one important element of IRB quality: decisional inconsistency within and across IRBs. This problem has been identified in numerous empirical studies, and will continue to be a concern in a world of single IRBs. A system of precedent building on a legal model and mechanisms could help, but raises challenges of its own. Through a series of lectures and open group discussion, speakers will introduce the problem and proposed solution, and call on the audience to better understand how a system of precedent could be built and implemented for the IRB community. During this session, speakers and attendees will:

- Identify the primary concerns around IRB inconsistency
- Understand how the system of legal precedent works, and how it could be translated for IRBs
- Clarify key barriers to adopting and implementing a system of IRB precedent, and address how they might be overcome

C6

The Rise of the Patient Voice at FDA *(FDA Regulations Track)*

New

As part of the FDA's long-standing commitment to patients, caregivers, and advocates, the agency is advancing its efforts to ensure various perspectives from these stakeholders are incorporated into medical product development and regulatory discussions. Establishing crossroads for patient communities and mechanisms for increasing engagement are testaments to that commitment. Learning more about the unique experiences that patients have with their respective disease/condition, therapies, and devices greatly impacts the important work of the agency. Come hear from representatives of FDA's new Patient Affairs staff about new ways the agency has enhanced patient engagement efforts and also learn about FDA's flagship Patient Representative Program[sm]. During this session, speakers and attendees will:

- Present information about FDA's new Patient Affairs staff in the Office of Medical Products and Tobacco, which is responsible for the coordination of agency-wide and cross-center projects related to patient engagement
- Discuss the evolution of patient engagement at FDA and share information about the new initiatives underway at FDA
- Share information about FDA's ongoing Patient Representative Program[sm], including opportunities for becoming a patient representative and learning how FDA Patient Representatives currently inform the agency

C7

Research Passport: Regulatory and Ethics Review Implications for International Participants in US-Based Clinical Trials *(Global Research Track)*

New

Human subjects research has become an increasingly global and integrated space, with international borders that traditionally separate participants physically now minimized with the advent of electronic clinical trials and other initiatives, such as telemedicine. While international participants may now have greater access to enrolling in clinical trials in the US, questions related to the need for local ethics review, obtaining appropriate informed consent while balancing potential cultural norms and linguistic factors, and ensuring sufficient data privacy protections can often result in a regulatory and operational quagmire. This session will highlight ethics review and regulatory considerations when foreign participants enroll remotely in US-based research. During this session, speakers and attendees will:

- Discuss regulatory and operational implications of allowing and/or limiting remote enrollment of international participants in US-based research
- Provide examples of the varying standards of ethics review globally, including local categorizations for human subjects research, informed consent, and data privacy
- Identify strategies and procedures for triaging, reviewing, and ensuring compliance with appropriate international regulatory criteria

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Pre-registration required	Recorded session	New Breakout sessions new for 2018
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Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.	**Basic** – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

C8

Developments Regarding the Federal "Right-to-Try" Law and its Impact on the FDA's Expanded Access Program *(Hot Topics Track)*

During his first State of the Union Address, President Trump President Trump called on Congress to pass a bill allowing terminally ill patients to request access to experimental drugs without first obtaining the FDA's approval. The bill was signed into law by President Trump on May 30, 2018. The evolving legislative landscape has many stakeholders wondering what are the pathways available today to request – and receive requests – for patient access to investigational drugs? What are the key provisions of the federal "Right-to-Try" law? How will it affect conflicting state laws and the FDA's recently expanded Compassionate Use Program? Will IRBs' reviews of expanded access requests and the negotiations of expanded access agreements become obsolete? What will the contractual relationship between the manufacturer, the patient, and the prescribing physician look like? During this session, speakers and attendees will:

- Learn about the federal "Right-to-Try" bill and its impact on state laws and the FDA's Expanded Access program
- Discuss how the passing of the federal "Right-to-Try" bill will affect expanded access requests, IRBs' review of these requests, and the negotiation of expanded access agreements
- Understand the arguments for and against the federal "Right-to-Try" bill from the point of view of physicians, medical ethicists, the drug industry, and patients
- Identify the practical considerations for stakeholders involved in requests for expanded access given the shifting legislative frameworks and the potentially competing requirements at the state and federal levels

C9

Use It or Lose It: Re-Calibrating and Re-Engineering the HRPP/IRB Office in Response to the Changing Regulatory Climate *(Institutional Officials and HRPP Leadership Track)*

Advanced

Changes to NIH policies, the 21st Century Cures Act, and the pending revisions to the Common Rule, are driving many changes to operational procedures in the HRPP/IRB office. As a result, institutions are busy redefining workflows, job descriptions, and staffing levels. For example, the paradigm shift to single IRB (sIRB) review of multi-site research has resulted in institutions creating reliance departments whose sole responsibility is to oversee studies whose IRB oversight has been ceded to a sIRB and/or re-characterization of existing staff roles, an addition of staff and redistribution of traditional IRB activities to other components of the human subjects protections program. This session will review the logistical details of work-load reallocation and departmental staffing and budget requirements at academic medical centers, universities, and hospitals. During this session, speakers and attendees will:

- Review the operational changes that are required to comply with the evolving regulatory environment and potential budgetary and structural impact
- Explore operational solutions to manage sIRB, including presentation of case examples from the perspectives of a reviewing IRB and relying institution and how existing IRB staff roles may be re-purposed or re-defined in the era of sIRB review to avoid loss of staff
- Discuss other proposed changes to IRB review processes independent of sIRB, such as limited IRB review, broad consent, and other newly created procedural requirements
- Illustrate examples of revised job descriptions and staffing levels in response to the changing operational systems
- Provide practical strategies to assist organizations in re-evaluating their own staffing structures

***Note**: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.*

C10

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)*

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 which regulations might apply (e.g., the Common Rule, FDA, the Family Educational Rights and Privacy Act, the Health Insurance Portability and Accountability Act of 1996, and other agency requirements), and what determinations should be documented, how they are documented, and where they are documented (e.g., minutes vs. checklist). During this session, speakers and attendees will:

- Revisit the ethical principles underlying regulatory protections for research involving human subjects
- Identify and discuss regulations that can affect IRB review and how to identify when they should be considered
- Discuss 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
- Understand key methods of documenting regulatory and other requirements as part of the review

***Note**: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.*

ICON KEY

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C11

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

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 the 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 and concrete solutions

***Note**: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.*

C12

Creative Solutions for Serving as a Reviewing IRB *(IRB Operations Advanced Track)*

Is your organization contemplating whether to act as a central (CIRB) or single (sIRB) IRB for multi-site research? This lively, discussion-oriented panel will candidly discuss the challenges in assuming this new role and offer practical solutions from organizations serving as the reviewing IRB for multi-site research. Topics to be covered include the collection and review of local considerations from relying sites, working with coordinating centers and lead study teams, and systems solutions to facilitate the sIRB review process. This session is design to share experiences and offer practical tools for organizations embracing this new challenge. Attendees will have the opportunity to ask specific questions relevant to serving as a sIRB. During this session, speakers and attendees will:

- Share lessons learned from early implementation of sIRB review
- Engage the audience in a discussion of the challenges and solutions for operationalizing sIRB review from the perspective of the reviewing IRB
- Provide practical tools to facilitate serving as the IRB of Record for multi-site research

***Note**: this session is also on the preconference agenda for Single IRBs: From Idea to Implementation. This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.*

C13

Scientific and Ethical Considerations in Choosing a Study Control Group *(Pharma/Biotech Perspectives Track)*

This session will cover the scientific and ethical issues raised in the review of clinical trial protocols involving a control group. There is a balance between two competing obligations: conducting a clinical study that is unable to answer the research question is unethical, but exposing study subjects in the control group to excessive and unjustified risks is also unethical. The issues raised by the following control groups will be reviewed, along with potential solutions (e.g., placebo, active control, dose-ranging, no treatment and historical controls, including the role of randomization and masking treatment assignment). During this session, speakers and attendees will:

- Describe the scientific considerations involved in the choice of different control groups
- Identify the ethical issues raised by the choice of different control groups
- Share potential solutions to address the tension between scientific and ethical concerns

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C14

Just When You Thought You Understood the Health Insurance Portability and Accountability Act of 1996 (HIPAA): What's New and What We Still Need to Worry About *(Legal Track)*

Institutions, IRBs, and investigators have been navigating the impact of HIPAA on research from its inception and must continue to digest new interpretive guidance and the ongoing dance between HIPAA and other regulatory frameworks. In 2016, the DHHS Office for Civil Rights (OCR) moved new initiatives forward related to its HIPAA Audit Program and, complying with the 21st Century Cures Act, offered clarification on various aspects of HIPAA's application to research, including when researchers need to obtain authorization from participants and when the "preparatory to research" provision of HIPAA can be applied. This session will provide attendees with a review of HIPAA's application to research, as well as explore the impact of recent developments from OCR. Speakers will explore what research-related HIPAA requirements entities should be attending to in preparation for the possibility of an audit and how covered entities and IRBs can best prepare to respond to breaches in the research context. In addition, the session will discuss the topics identified in the Cures Act pertaining to HIPAA authorizations and future research, as well as preparatory to research. During this session, speakers and attendees will:

- Discuss OCR's Phase II HIPAA Audit Program and audit protocol and how those might impact covered entities using and disclosing Protected Health Information for research
- Share practical strategies for improved coordination of multiple processes, communication among institutional stakeholders, and investigator compliance with reporting requirements
- Understand the impact of HIPAA-relevant provisions within the Cures Act on research
- Develop approaches for integrating the new guidance into IRB practices and procedures

***Note**: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.*

C15

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

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

***Note**: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.*

C16

Considerations for Return of Results Under the Revised Common Rule

Advanced

(Research Involving Data and Biospecimens Track)

The return of individual research results seems like a simple enough expectation that respects a subject's rights to information about themselves. In practice, though, the highly complex considerations, finding the right balance for protecting autonomy, and promoting beneficence are not easy. Have recent regulatory changes made this already challenging area easier or harder to navigate? 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 sharing of results, and how recent changes to the Common Rule and other statutory frameworks impact the analysis
- Understand how IRBs and researchers grapple with the ethical considerations of sharing results and address the new requirements for inclusion of consent language related to plans for sharing clinically relevant results
- Review the potential limitations on sharing results under select new exemption categories
- Discuss whether new questions should be added to IRB applications regarding whether results will be shared, and when, as well as what other concrete steps institutions can take to return research results under the revised Common Rule and other applicable legal frameworks

***Note**: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.*

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C17

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

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)

***Note**: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.*

C18

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

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 general complex audits (including biomedical and SBER). Speakers will also discuss strategies 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 before attending this session. During this session, speakers and attendees will:

- Use case studies to illustrate challenging investigator audit issues
- Explore strategy of complex investigator audits
- Outline the importance of collaborating with various departments within your institution during for-cause investigator audits and how information is exchanged
- Discuss how aggregate audit findings can inform process improvement

***Note**: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.*

C19

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

Basic

The session will provide a basic introduction to the concepts, challenges, and opportunities with digital and mHealth research. Relevant technologies include text messages, mobile applications, 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 mHealth. During this session, speakers and attendees will:

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

***Note**: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.*

C20

The Regulatory Intersection of Research Misconduct and Human Subjects Protections

(Responsible Conduct of Research Track)

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, yet often suspected violations of both sets of regulations occur simultaneously. How should IRBs handle this? What do they need to know? During this session, speakers and attendees will:

- Gain an understanding of the scope and focus 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

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C21

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

Basic

(Small Research Programs Track)

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

***Note**: This session will end at 1:30 PM. Attendees should get their boxed lunch in the exhibit hall before going to the session room.*

C22

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

CR 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 and attendees will:

- Review considerations, including an overview of the Common Rule revisions that effect research in K-12 settings
- Discuss consent considerations, including assent, parental permission, and possible alternatives
- Go over the Family Education Rights and Protections Action, 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

C23

Understanding and Applying Family Educational Rights and Privacy Act (FERPA) Guidelines *(SBER Track)*

Advanced

This session will focus on FERPA-related issues and how they apply to research in higher education. The session will address what is and is not FERPA-protected data, how that impacts research, and how to interpret FERPA guidelines. Several scenarios will be presented illustrating common pitfalls in research with FERPA-protected data, and the audience will be encouraged to identify problems and come up with solutions. Attendees should have understanding of the Common Rule and exemption categories, as well as a basic foundation in human research protections ethics and principles, including the criteria for approval and definitions from DHHS and FDA regulations, before attending this session. During this session, speakers and attendees will:

- Review what data is covered by FERPA
- Demonstrate how to safeguard FERPA-covered research
- Share strategies for assisting researchers with FERPA compliance

12:30-1:30 PM

Networking Lunch

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

Panel IV: What Do Patients Want: Does Majority Rule?

There has been a welcome, yet sometimes complex move towards including patients and families in the process of clinical research. To direct IRB decision making, patient and human subjects input has been sought on privacy and data sharing, return of results, and recruitment. It is often stated that the "public" wants more control of and access to both research and non-research information about themselves. To elucidate the public's needs and wants and direct policy decisions, there is a move towards gathering crucial empirical data from patients and the general population. However, "data" is only as good and meaningful as its methods. Do IRBs make decisions based on "majority rules," and how do they incorporate the "silent minority"? Surveys of patients/subjects, community consultation, the bioethics community, as well as IRB members all are meant to represent the voice of the subject. This panel will discuss sources of data and input regarding what patients want and summarize key findings; provide a patient's perspective of the findings and how the findings resonate with the patient's experience; and address issues and concerns around minority and underserved populations, as well as the impact of data sources on non-participating populations.

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Panel V: Ethical Challenges in HIV Cure Research

Research into potential cures for HIV is increasing. These trials raise novel ethical and regulatory issues that may pose challenges for investigators and IRBs, including: assessment of risks and benefits in patients with minimal to no clinical illness and undetectable viral load; perception of risk and benefit among potential subjects regarding both the interventions being tested and interruption of effective therapy; and potential bystander effects related to increased risk of transmission with viral re-emergence. Panelists will discuss how IRBs and investigators should think about these issues when conducting and reviewing research, and their impact on research and the community.

Panel VI: To Participate or Not to Participate, That Is the Question

The revised Common Rule includes several revisions to the requirements for informed consent, including the introduction of new terms, which focus on deciding whether or not to participate in research. The new provisions include the following: (1) "…information that a reasonable person would want to have in order to make an informed decision about whether to participate…" (.116(a)(4)); (2) "key information…to assist a prospective subject… in understanding the reasons why one might or might not want to participate in the research." (.116(a)(5)(i)); and (3) "…information…organized in a way that…facilitates the…understanding of the reasons why one might or might not want to participate." (.116(a)(5)(ii)). How will these provisions be operationalized? Does the informed consent form need to include every reason a person might use to make a decision? Are the reasons listed on the form what an average person would use to decide? Do research studies vary enough that a template approach won't work? Some research institutions, and the Secretary's Advisory Committee on Human Research Protections, have already begun to consider how to put these ideas into practice, and panelists will discuss their current thinking on this topic, and speculate about how the field may evolve.

3:00-3:30 PM

Beverage Break Supported by CITI Program, a division of BRANY

Join us for coffee and cold drinks. *PRIM&R would like to thank CITI Program, a division of BRANY, for helping support this break.*

D1

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

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

- Hear from FDA representatives 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

D2

Pharmacogenetics and Precision Medicine: Partnering to Enable DNA Research in Global Clinical Trials *(Issues Pharma/Biotech Track)*

As industry increasingly focuses on developing precision medicine, and the regulatory agencies increasingly support biomarker (including pharmacogenetics) research, the Industry Pharmacogenomics Working Group engaged member companies to understand current practices and challenges in implementing pharmacogenetics research in global clinical trials. IRB/ethics committees are important stakeholders, and their views on pharmacogenetics have significant impact on industry's ability to conduct this research in many countries and institutions. This session will engage IRB stakeholders in a dialogue to understand their perspectives and the difficulties they face in reviewing this research. In addition, the session will aim to collaboratively identify opportunities to enhance mutual understanding to further enable pharmacogenetics research. During this session, speakers and attendees will:

- Understand the value of pharmacogenetics in clinical development and current practices of industry in conducting this research
- Improve industry's understanding of the difficulties faced by various IRB and ethics professionals in reviewing this research
- Generate dialogue to help develop strategies to mitigate concerns and facilitate pharmacogenetics research

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D3

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

CR

The revised Common Rule introduces the option of broad consent and limited IRB review for secondary research, as well as two new exemptions (exemptions seven and eight) for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens when broad consent is used. These options, and the revised 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 seven and eight 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
- Use case studies to explore potential challenges in operationalizing the use of these options, including issues with tracking, IRB reviews, etc.
- Review how operational problems might or might not be overcome

D4

Paving the Road to Success: Meeting the Challenges of Investigator and Study Team Education

New

(Educating and Training Track)

Once a clinical researcher meets the basic education requirements, professional development is often left to the discretion of the individual or their institution. In an effort to create a coordinated solution to close this educational gap, interactive training focused on enabling investigators to enhance knowledge of research ethics, quality standards, and regulations, and apply best practice principles throughout the complex life-cycle of research studies, has been utilized. This session will explore challenges in meeting the educational needs of a diverse team of clinical research team members. During this session, speakers and attendees will:

- Identify and describe how to utilize research-related competencies in the design of research team education
- Discuss best practices related to adoption of new knowledge among research team members
- Explore strategies for engaging study team members in training design and implementation
- Describe how to assess, implement, and evaluate training for research investigators and teams

D5

Promises and Perils of HIV Phylogenetics Research *(Empirical Research Ethics Track)*

New

Considerable global efforts are now being directed at conducting research involving HIV phylogenetics, which involves characterizing specific viruses among infected individuals. By doing so, it is possible to identify networks of tightly connected individuals defined by highly related strains of HIV viruses and indicative of putative HIV transmission. In an effort to decrease transmission, prevention efforts can be focused on these genetically defined clusters, known to be important in the spread of HIV. Such approaches have recently been used to control some HIV outbreaks. However, phylogenetics also make it possible to infer transmission linkage between individuals with genetically similar HIV sequences, raising substantial ethical, legal, and social issues. For example, without adequate privacy protection, someone who transmits HIV may be stigmatized, harmed, and/or prosecuted depending on local laws. In this session, speakers will explain the science of phylogenetics and the types of research being done with it, and describe the associated ethical, social, and legal issues. Speakers will also address regulatory considerations that are relevant for researchers and IRBs. During this session, speakers and attendees will:

- Describe how phylogenetics might be used to decrease HIV incidence
- Review the basic ethical, legal, and social implications related to HIV phylogenetics
- Explore key considerations for IRB review of research involving HIV phylogenetics

D6

FDA's Oversight of ClinicalTrials.gov Requirements *(FDA Regulations Track)*

New Basic

Responsible parties conducting clinical trials of FDA-regulated drug, biologic, and medical device products must submit registration and results information to ClinicalTrials.gov, as required by Title VIII of the FDA Amendments Act of 2007 (FDAAA) and its implementing regulations at 42 CFR part 11. FDA has been given certain implementation and compliance/enforcement responsibilities related to these requirements. What are FDA's activities related to enforcement of registration and results information reporting to ClinicalTrials.gov? How can academic medical centers and universities be prepared to comply with the regulations at 42 CFR part 11? During this session, speakers and attendees will:

- Provide a basic overview of the requirements for registration and results information submission to ClincialTrials.gov and the potential consequences of noncompliance
- Discuss FDA's role in the compliance and enforcement of ClinicalTrials.gov requirements
- Explore FDA's approach to conducting its compliance activities involving under FDAAA and 42 CFR part 11
- Identify the common challenges investigators and institutions face when submitting information to ClinicalTrials.gov
- Share information about tools and resources available to help investigators and institutions ensure compliance with FDAAA and 42 CFR part 11

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D7

Lessons From the Trenches: Avoiding Legal and Operational Pitfalls in International Research Studies

Basic

(Global Research Track)

US institutions are faced with various unique legal and operational challenges when conducting or collaborating with institutions outside of the United States on international research studies. While US institutions are generally familiar and comfortable with the application of the Common Rule and other legal requirements that apply in the context of domestic research studies, many do not have extensive experience dealing with international human subjects research laws or other legal requirements. This session will highlight select legal and compliance challenges of participating in international research studies and offer practical tips and best practices for ensuring compliance. Following this discussion, the session will provide a presentation of practical tips and best practices for identifying and triaging the various legal and operational issues that may arise when an institution decides to become involved in an international research study, including how to develop a plan for reducing risk and ensuring compliance. During this session, speakers and attendees will:

- Learn about international human subjects research laws that not only apply to international collaborators, but also to US institutions (e.g., laws that may designate the US institution as the "sponsor" of the study and/or require the US institution to register with foreign regulatory bodies, such as the European Union (EU) Clinical Trials Directive (Directive 2001/20/EC) and the various EU member state laws implementing the same)
- Explore international privacy laws that impose significant restrictions on the collection, use, and transfer of subject data and may apply directly to US institutions involved in international research studies, such as the EU's new General Data Protection Regulation
- Discuss how to identify other key legal and contractual issues that impact the development and implementation of an international research study, such as those regarding intellectual property, insurance, subject injuries, import and export restrictions, foreign country registration, labor and employment, medical licensure, fraud and abuse laws, etc.

Note: *This session will not discuss the difficulties associated with applying the Common Rule in the context of international research studies.*

D8

Public Health Emergencies, Research, and Bioethics *(Hot Topics Track)*

The World Health Organization (WHO) defines a public health emergency as, "an occurrence or imminent threat of an illness or health condition, caused by bio terrorism, epidemic or pandemic disease, or a novel and highly fatal infectious agent or biological toxin, that poses a substantial risk of a significant number of human facilities or incidents or permanent or long-term disability (WHO/DCD, 2001)." During this session, speakers and attendees will:

- Examine the application of bioethics in the context of research being conducted as part of the response to a public health emergency, such as the recent Ebola epidemic, or a future epidemic/pandemic (e.g., avian influenza), and public health crises that emerge as a result of natural emergencies (e.g., hurricanes, earthquakes).
- Discuss experiences and/or research related to human subjects protections during public health emergencies

D9

How to Investigate, Mitigate, Report, and Learn from Noncompliance: Avoiding Pitfalls and Seizing Opportunities for Improvement *(Institutional Officials and HRPP Leadership Track)*

In this session, speakers will explore how institutions can use incidents of alleged noncompliance (both investigator and IRB) as learning opportunities, and will identify strategic and substantive pitfalls to avoid. Topics covered will include: preventative measures to prepare for managing noncompliance; how to undertake a thorough and effective noncompliance investigation; strategies to manage interactions with federal agencies when reporting and implementing corrective actions; and the unique challenges presented when IRB noncompliance is implicated. During this session, speakers and attendees will:

- Understand what constitutes "noncompliance" with applicable federal regulations and when institutions have an obligation to report to federal agencies
- Explore how institutions structure their policies and approach investigations into alleged noncompliance to effectively and consistently uncover the relevant facts and best position the institution, vis-a-vis federal agencies and the targets of such investigations, and review challenges when potential IRB noncompliance is at issue
- Discuss the ways institutions can use these experiences for programmatic improvement and opportunities for increased compliance moving forward; specific approaches to corrective action plans will be discussed

ICON KEY

Double session	Call for Session Proposal	
Pre-registration required	Recorded session	Breakout sessions new for 2018
Reviews changes to the Common Rule	CIP eligible	CME accredited
Advanced – assumes mastery of ethical concepts and principles, the regulations, and research oversight processes. Attendees should have sufficient experience and understanding in order to actively contribute to discussion and solutions. These sessions will not review basic concepts.	**Basic** – for those who have little or no knowledge of the topic or who are looking for a refresher. The focus is on introducing, explaining, and illustrating basic concepts, principles, regulations, policies, or best practices relevant to the topic.	

D10

Writing and Updating Standard Operating Procedures (SOPs) with the Revised Common Rule in Mind

CR

(IRB 101 Track)

Revisions to the Common Rule mean updates to HRPP and IRB policies and procedures. This session will provide attendees with guidance and tools that can help them address revisions to the Common Rule and beyond. During this session, speakers and attendees will:

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

D11

The Revised Common Rule: Operational Considerations for the IRB Chair *(IRB Chairs Track)*

New CR

Speakers will discuss key operational challenges that directly affect the IRB chair as a result of the revised Common Rule. During this session, speakers and attendees will:

- Identify key operational challenges as a site prepares for implementation to the requirements of the revised Common Rule
- Present solutions that are in the process of development
- Discuss alternative operational solutions

D12

Single IRB: The Next Generation *(IRB Operations Advanced Track)*

★ New Advanced

This session will explore the next frontier of single IRB review (beyond master agreements or changes to electronic systems), and how to reduce the challenges this paradigm presents. Topics will include the harmonization of critical IRB and institutional processes, and how institutions can work together to collaborate when problems occur and communicate when disagreements arise. During this session, speakers and attendees will:

- Use case studies to illustrate differences in institutional approaches that are creating challenges for the single IRB review process
- Discuss approaches to resolving issues, including when to be flexible and when to push back
- Identify key areas and efforts to harmonizing processes surrounding single IRB review to reduce challenges for study teams and institutions

D13

New

Post-Trial Access: A Look at the Challenges of Ensuring Continued Access to Investigational Medicine

(Pharma/Biotech Perspectives Track)

Clinical trials are an important way many patients gain access to life saving treatment they might not otherwise be able to obtain. Once the trial ends for an individual patient, what happens during the time treatment stops and the investigational agent becomes approved? Sponsors of clinical trials for life threatening diseases have an obligation to plan proactively for the management of this transition and engage with downstream stakeholders to ensure continued access to beneficial treatments. This session will provide a brief overview of the ethical obligations of post-trial access, then explore some cases that highlight the challenges, as well as best practices, to consider when exploring how to implement post-trial access within a sponsor organization. During this session, speakers and attendees will:

- Describe what is meant by post-trial access and the ethical obligation to provide continued access to investigational medicines for trial participants
- Explore the challenges associated with providing post-trial access and how the obligations are shared by trial sponsors, as well as other stakeholders
- Identify best practices for implementing post-trial access programs based on lessons learned from sponsor cases

ICON KEY

Double session	Call for Session Proposal	
Pre-registration required	Recorded session	New Breakout sessions new for 2018
CR Reviews changes to the Common Rule	CIP CIP eligible	CME accredited

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D14

Wrangling IRB Reliance Agreements: How to Manage Flexible Terms, Addenda, and Implementation

(Legal Track)

With the transition to single IRB review, institutions must manage an increasing number of reliance agreements with different terms. In addition, several institutions are requiring addenda to master agreements (e.g., letters of indemnification) or using agreements to accommodate institutional preferences. What is an institution to do? This session will review common issues that arise with reliance agreements, including the SMART IRB Master Agreement, with an overview of key issues to attend to with agreements and practical solutions regarding how to track the terms of an agreement and communicate key requirements to appropriate institutional officials, IRBs, and research teams. During this session, speakers and attendees will:

- Provide an overview of common terms of reliance arrangements and some challenges they present
- Discuss how reviewing IRBs should communicate and document implementation of flexible provisions within agreements
- Share methods for tracking obligations under a reliance agreement
- Explore strategies for separating operational procedural details of single IRB operations from the agreements and working with institutions around these issues

D15

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

The regulations dictate that experience, expertise, and diversity of members are important attributes of an effective IRB, and they require the inclusion of non-scientific members 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 productive, efficient, and effective. During this session, speakers and attendees will:

- Review the definition of a non-scientific IRB member
- Go over the responsibilities of the non-scientist IRB member
- Address where non-scientist IRB members can be found and how they should be trained
- Explore how to retain non-scientist IRB members once they've been recruited

D16

Assessing Plans to Maintain Confidentiality: How IRBs Can Determine Whether Data Security and Management Plans Are Sufficient *(Research Involving Data and Biospecimens Track)*

The criteria for IRB approval have always included a requirement that IRBs consider, when appropriate, that there are sufficient protections in place to maintain the confidentiality of data. The revised Common Rule, specifically the new requirements for limited IRB review, place emphasis on this review criterion. Minimal guidance exists to assist IRBs in determining whether proposed safeguards for research data are sufficient. This session will review the challenges IRBs face in reviewing protocols to determine if the plans for maintaining confidentiality are sufficient, and it will highlight solutions for how data management and security review may be incorporated into the IRB review process. This session is appropriate for biomedical and social/behavioral audiences. During this session, speakers and attendees will:

- Review the requirements IRBs need to consider in creating plans to maintain confidentiality as part of the IRB review process
- Highlight the ways in which the changes to the Common Rule may impact the IRB's review of confidentiality plans
- Discuss practical solutions for incorporating the review of data security and management plans in the IRB review process

D17

Looking Through the Bars: Responsible Research With Prisoners

(Populations Requiring Additional Protections Track)

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. 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 to serve on 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 and attendees 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

ICON KEY

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D18

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

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 and attendees will:

- Provide considerations and mechanics for QA/QI review of IRB files, meeting minutes, and membership composition
- Identify triggers that may prompt QA/QI 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

D19

Social Media in Research: Recruitment, Participant Communication, and Data Source

New

(Research Conducted in the Digital World Track)

Social media have become integrated into the fabric of modern life. Thus, it is no surprise these platforms are being used for, and have an impact on, human subjects research. Through a series of brief lectures, this session will address three important facets of social media in research. First, speakers will introduce a methodology for assessing the ethics of participant recruitment to research studies via social media based on the norms of respect for privacy and investigator transparency. Next, speakers will identify some of the ways in which social media communication by study participants can jeopardize study integrity and participant safety, and describe strategies for mitigating these challenges. And, speakers will discuss ethical issues that arise when social media platforms are used as the source of research data, including considerations related to public awareness and trust, when data can be viewed as "publicly available," and how IRBs can best review such research. Case studies will be used to demonstrate key concepts. During this session, speakers and attendees will:

- Clarify similarities and differences between recruitment via social media and recruitment via traditional means, to evaluate ethically acceptable approaches
- Identify the risks that social media communication amongst study participants can pose for a trial, and strategies for mitigation
- Share tools for ethical oversight of research using social media platforms as a data source

D20

Agents and Rogues: The Limits of Agency, Institutional Engagement, and Institutional Responsibility

New

(Responsible Conduct of Research Track)

This session will explore the limits of agency, institutional engagement, and institutional responsibility when a faculty member "goes rogue" and conducts unapproved human subjects research. We will consider two different scenarios: (1) when research is conducted at a university and uses institutional resources; and (2) when research based on intellectual property developed by a faculty member is licensed to an offsite company founded by the faculty member. Attendees will participate in developing recommendations for strengthening compliance oversight activities to detect unapproved research conducted on campus, and analyzing the limits of compliance oversight when research is conducted by an entity with which the university has a distant relationship. During this session, speakers and attendees will:

- Review the concepts of agency and engagement as treated in the Common Rule, OHRP guidance, and institutional standard operating procedures
- Consider IRB and institutional procedures for responding to allegations of conducting unapproved research
- Analyze compliance monitoring processes to detect unapproved research involving human subjects conducted using institutional resources, and develop recommendations for improvement
- Discuss the limits of compliance oversight authority when evaluating how a licensee conducts human subjects research

D21

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

Advanced

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 HRPP and IRB can be archived and stored
- Consider strategies for succession planning
- Explore on-boarding and off-boarding of staff and members to retain institutional memory

ICON KEY

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D22

Clinical Trials in the SBER Context *(SBER Track)*

SBER IRBs need to understand the requirements expected of NIH-funded SBER studies that meet NIH's definition of a clinical trial (e.g., Good Clinical Practice training, ClinicalTrials.gov registration, single IRB review). During this session, speakers and attendees will:

- Review the NIH definition of "clinical trial"
- Discuss requirements related to SBER clinical trials
- Outline options for Good Clinical Practice that are SBER-focused
- Provide examples of SBER studies that fall under these requirements

D23

Navigating Uncertainty: Research With Undocumented/Unauthorized Immigrants *(SBER Track)*

Institutions in states that have a high number of undocumented/unauthorized immigrants, often review IRB submissions requesting to enroll this vulnerable population, which lies outside the scope of vulnerable populations named in the code for federal regulations. This didactic session will delve into institution's review strategies and best practices (including privacy and confidentiality protections, as well as flexibility in providing protections). Using case studies (e.g., longitudinal studies, studies with unaccompanied minors, undocumented students, etc.), speakers will discuss how IRBs can negotiate protecting these research participants while supporting the advancement of research in the midst of the current, and uncertain, political climate. During this session, speakers and attendees will:

- Discuss and provide case examples of protocol applications proposing to enroll undocumented and unauthorized immigrants
- Apply ethical standards to research involving undocumented students
- Explore strategies for review at all levels, with emphasis on full committee review
- Engage audience members to share their own ideas, experiences, and best practices for approving protocols involving undocumented and unauthorized immigrants

4:45-6:00 PM

Networking Reception With the Supporters and Exhibiters

Join us in the AER18 Exhibit Hall to meet and greet the supporters and exhibitors. Light refreshments will be served, and a cash bar will be available.

4:45-5:45 PM

Meet the AER18 Poster Authors

Visit with the authors of the posters featured in the AER18 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.

4:45-6:00 PM

Federal Agency Office Hours

During this time, representatives from select federal agencies will be available to answer attendee questions, engage in dialogue, provide clarification, and/or direct attendees to additional resources. Attendees are encouraged to come prepared with questions, which will be taken on a first come basis. *(Note: check back, as this list will be updated with additional agencies):*

- DOD
- FDA
- OHRP
- SACHRP
- AHRQ

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Saturday, November 17: 2018 AER Conference – San Diego Convention Center

7:00 AM-12:30 PM
On-Site Check-In
Breakfast on your own.

8:00-8:30 AM
Welcome and PRIM&R Membership and CIP Updates

8:30-9:30 AM
Keynote Address

9:30-10:00 AM
Beverage Break With Supporters and Exhibitors
Join us for coffee in the exhibit hall.

Concurrent Plenary Sessions, 10:00-11:15 AM

Panel VII: IRB Decision-Making From a Behavioral Economics Perspective

It is known that IRBs are not all the same. There seems to be variation in process, risk assessment, time to decision, and requirements for consent, to name a few areas. This variation has been cited as a reason to reform the IRB system and has driven calls for centralized IRB review. However, there is no real evidence or consensus about what the IRB process ought to be, what makes for an effective review, and how IRBs ought to be composed. Similarly, it is not clear when variability is problematic or when it reflects sensitivity to local context or culture. As the field move toward more centralized IRB review, it is essential to confront these questions. This panel will address these challenging issues and will incorporate expertise in group decision-making and process, as well as experienced IRB professionals and individuals who have studied IRB processes.

Panel VIII: Big Data: Who's Minding the Store?

Companies often combine data from diverse sources to create databases that can be mined to create better predictions and to more precisely tailor content. This is often considered quality improvement, as the goal is often to "sell" a product or improve the user experience. However, due to the impact on consumer's lives, potential discriminatory practices, legal implications, and the threats to their privacy, the field must question if industry-conducted "big data" studies should abide by the rules that guide human subjects research. The currently unfolding Cambridge Analytica case calls sharp attention to industry responsibility, as it has revealed how these data are tailored and targeted. The field is at a critical point where industry leaders and governmental officials are questioning the systemic risks of allowing companies to hold this much information. This panel will discuss possible issues and remedies, with the goal of fostering a big data industry that respects users, is non-exploitative, and "does no harm."

Panel IX: Is a Misconception Always a Misconception?

Avoiding therapeutic misconception in research has long been appreciated as an important concept. The premise being that research is not care and distinction between the two is important for the research design, as well as for the understanding of the participant(s). While, historically, "therapeutic research/trials" have challenged these distinctions, there are now new challenges (e.g., the return of research results as a proposed benefit or novel cancer protocols that select research participants based on the genetic footprint of their specific cancer). Is the boundary between research and clinical care eroding? Are participant expectations changing? Do researchers assume new responsibilities for providing or referring a participant to clinical care? What is the effect on recruitment strategies when there is promised benefit? What should be included in informed consent? These and other issues will be discussed.

Breakout Session Series E, 11:30 AM-12:45 PM

E1
A Dialogue With AAHRPP, Inc. *(A Dialogue With the Feds Track)*

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 web resources available to all wishing to maintain or achieve a robust system of human research protections

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E2

Two Offices Divided by a Common Goal: Conflict of Interest (COI) and IRB *(IOs and HRPP Leadership Track)*

Both the COI committee and IRB are concerned with the real or potential influence of researcher and institutional financial interests on the conduct of human subjects research. Their regulatory authority and missions, however, are quite different. This becomes all the more significant when the IRB relies on the COI review and management of these outside interests. This session explores the point of intersection between COI and IRB review with a focus on where these processes overlap and where they diverge, and how this combination of overlap and divergence may introduce gaps in the review and management of said conflicts. During this session, speakers and attendees will:

- Identify points of overlap and divergence in the COI and IRB processes
- Understand best practices for COI and IRB review of outside financial interests related to human subjects research

E3

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

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 and attendees 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

E4

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

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 and attendees 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

E5

Ideas and Practices for Compliance and Auditing of Single IRB Studies

(QA/QI and Post-Approval Monitoring Track)

With the transition to single IRB review, institutions will need to find new ways to monitor for problems that occur during the course of research then collaborate with one another to ensure appropriate communication occurs (e.g., to reviewing IRBs, study teams, regulatory agencies) to ensure compliance with applicable regulations and the protection of human subjects. In this presentation, speakers will describe the changes to the research landscape that affect oversight of research and reporting requirements, and will then present scenarios to the audience that explore how different compliance situations (e.g., reviewing IRB requests for audits, determinations of serious noncompliance or unanticipated problems) may play out in the single IRB landscape and strategies that can be used to address them. During this session, speakers and attendees will:

- Identify key changes in the regulatory landscape that affect oversight responsibilities and processes for research under the single IRB model
- Explore case studies to identify issues reviewing IRBs, study teams, and relying institutions may encounter
- Discuss potential best practices for addressing oversight challenges for multisite research when a single IRB oversees a study

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E6

FDA Clinical Hold *(FDA Regulations Track)*

New

A clinical hold is an order issued by the FDA to the sponsor of an Investigational New Drug (IND) application to delay a proposed clinical investigation or to suspend an ongoing investigation. All or some of the investigations conducted under an IND application may be placed on clinical hold. When a proposed study is placed on clinical hold, subjects may not be given the investigational drug. When an ongoing study is placed on clinical hold, no new subjects may be recruited to the study and given the investigational drug (patients already in the study are expected to be taken off therapy involving the investigational drug unless treatment continuation is specifically permitted by FDA in the interest of patient safety). During this session, speakers and attendees will:

- Provide a general overview of FDA's grounds for imposing a clinical hold and the procedures for issuing a clinical hold
- Present data on situations where deficiencies in Subpart D (Additional Safeguards for Children in Clinical Investigations) resulted in a clinical hold
- Share best practices for IRBs to stay informed about the FDA status of a proposed or ongoing study

E7

Applying US Human Research Protections Regulations and Embedded Cultural Values to Research Conducted in Different Cultures: Challenges, Cultural Considerations, Collaborations, and Experiences *(Global Research Track)*

Advanced

The US human subjects research protections regulations reflect the cultural values and worldviews of some groups within the United States. US institutions that conduct research outside the United States may face challenges in applying US regulations and departmental policies (e.g., the Department of Defense) within the local cultures. In this session, speakers will discuss possible strategies for HRPP staff who are tasked with ensuring compliance with US-based human research protections requirements within diverse cultures. During this session, speakers and attendees will:

- Recognize that US human research protections regulations reflect cultural values of US groups
- Discuss the importance of being sensitive to local culture when conducting human subjects research
- Identify possible strategies for dealing with challenges applying US-based regulations for research involving subjects who have a cultural background different than mainstream US culture

E8

User Agreements in Human Subjects Research During the Burgeoning Technology Age *(Research Conducted in the Digital World Track)*

Human subjects research is experiencing an unprecedented era of technology growth and integration, from study management with the use of online platforms, to delivery of study materials and therapies through eConsent and telemedicine, to technology representing the experimental facets of research itself with the development of mobile medical device applications. With this proliferation comes a need to consider the often long, boilerplate ridden, user agreements associated with technology use in human subjects research. This presentation will identify key points for HRPPs and IRBs to consider for research that involves user agreements. Attendees are expected to have sufficient experience and understanding to actively contribute to the discussion of and solution to these difficult problems. These sessions will not review basic concepts. During this session, speakers and attendees will:

- Characterize the purpose of user agreements in technology use, and discuss scenarios where user agreements are present in human subjects research
- Discuss methods to develop institutional approaches and policy related to user agreements in human subjects research, including considerations both for internal user agreements, and those developed by third parties
- Explore the role of the IRB in evaluating user agreements in human subjects research, including considerations for informed consent and other special topics

E9

Ethical and Operational Issues Related to Clinical Trial Billing: What HRPPs and IRBs Should Consider *(Institutional Officials and HRPP Leadership Track)*

Basic

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 clinical trial billing requirements
- Examine the implications of the Centers for Medicare and Medicaid Services requirements as they apply to the ethical review of research, particularly the review of revised informed consent requirements
- Illustrate best practice to integrate Medicare Coverage Analysis with IRB review of research

ICON KEY

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E10

IRB Review of Informed Consent: Moving Beyond the Form

(IRB 101 Track)

Basic

This session will discuss the importance of reviewing and monitoring recruitment, the informed consent process, and informed consent documents to determine whether the approval criteria 45 CFR 46.111(a)(4-5) are met. Research regularly shows that research participants don't fully understand what they have signed up for; however, IRB reviews and the revised Common Rule still largely focus on the document rather than the process. This session will utilize video tools and group discussion to highlight how the process can fail, even with IRB-approved documents, and what IRBs can do during review and post-approval monitoring to ensure participants are protected. During this session, speakers and attendees will:

- Review and discuss 45 CFR 46.111(a)(4-5) (regulatory criteria for approval regarding informed consent)
- Explain failures in informed consent processes that may occur in spite of approved consent documents
- Analyze the IRB review and monitoring process to address the informed consent process to better protect participants

E11

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

(IRB Chairs Track)

Advanced

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

E12

Overlapping Roles of Data Safety Monitoring Boards (DSMBs) and IRBs in the Protection of Human Research Participants *(IRB Operations Advanced Track)*

IRBs and DSMBs have unique, but overlapping responsibilities in assessing safety of multi-site clinical trials and protection of participants. IRBs may require investigators to modify or halt protocols or alter informed consent when new information changes assessment of safety and risk. DSMBs are responsible for advising when to make changes to trials based on accumulating data or information on safety or efficacy. DSMBs typically have more complete access to trial data and more content expertise then IRBs, but IRBs have the ultimate authority to make changes to ensure the safety of human subjects. In traditional local IRB review, the IRB is only privy in real-time to limited safety data collected at the site which they oversee. In the NIH single IRB review model, the IRB will receive safety data and other information from all study locations and is able to take action for all of the sites. This creates a situation where the reviewing IRB can circumvent the DSMB process or make study-wide decisions independent of the DSMB. This session will review how IRBs might best interact with DSMBs, including when serving as the single IRB. Two real-world situations will be presented to illustrate differences in local IRB and single RIB interactions with DSMBs and the scope of IRB decision-making in each scenario. A proposed model to improve communications between IRBs and DSMBs will also be presented. During this session speakers and attendees will:

- Identify the overlapping responsibilities of IRBs and DSMBs in assessing safety of multi-site clinical trials and protection of participants
- Illustrate differences in local IRB and single RIB interactions with DSMBs
- Explore ways to improve communications between IRBs and DSMBs so that both boards are able to fully meet their responsibilities to ensure the safety of participants

E13

Designing and Implementing Expanded Access Programs *(Pharma/Biotech Perspectives Track)*

Advanced

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. Attendees should be familiar with expanded access provisions that exist for patients before attending this session. During this session, speakers and attendees 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., does 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

ICON KEY

Double session	Call for Session Proposal	
Pre-registration required	Recorded session	Breakout sessions new for 2018
Reviews changes to the Common Rule	CIP eligible	CME accredited

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E14

From Shield to Sword? How the 21st Cures Act and NIH Policy Have Altered Certificates of Confidentiality (CoCs) *(Legal Track)*

New

This session focuses on the NIH's recent changes to the CoC requirements under the 21*st* Century Cures Act (as further modified by NIH policy). As of October 1, 2017, NIH presumes the issuance of a CoC as a term of the award for certain research rather than requiring institutions to request CoC coverage. This session will discuss interpretation and implementation of the NIH Policy, such as what NIH-supported research is and is not covered, what does "sensitive information" mean, what are institutional and investigator responsibilities when CoCs cover the research, and what rules apply if a study is not directly funded by NIH, but NIH funds support the research (e.g., redistributed funds from core or program grants). How do these recent changes in the context of CoCs relate to the larger shift in definitions around identifiability and applicable privacy protections? During this session, speakers and attendees will:

- Review the history of CoCs and the context for the recent changes
- Explore the impact of the 21st Century Cures Act and NIH Policy to the requirements for CoCs going forward (and how these requirements intersect with other applicable regulations)
- Provide concrete guidance to investigators and institutions conducting research subject to CoCs in order to avoid pitfalls and ensure compliance with the new rules

E15

Considerations and Strategies for Maximizing Contributions and Promoting Effective Communication for Non-Scientist IRB Members *(Non-Scientist IRB Members Track)*

In this session, speakers will identify the barriers that impede the optimal integration of IRB members' contributions to IRB deliberations and conclusions, and explore how members can overcome these barriers through effective communication. Speakers will discuss strategies for crossing the barrier from an "outsider" to an "IRB insider" to ensure that their essential perspective is heard. Through initial presentations and follow-up discussions, speakers and attendees will:

- Establish strategies for non-scientist/unaffiliated members to communicate more effectively within their individual boards
- Explore how to overcome structural barriers (e.g., lack of networks) and cultural barriers (e.g., lack of shared expertise) that are intrinsic to the non-scientist/unaffiliated members' position
- Discuss "IRB lingo" and identify opportunities to elicit and integrate views from IRB members
- Provide strategies for avoiding adversarial framing of IRB roles

E16

Building a Better Biobank: How Recommendations from the Blue Ribbon Panel for the National Cancer Institute Cancer Moonshot Biobank May Inform Future Biobanking Initiatives

New

(Research Involving Data and Biospecimens Track)

Congress passed the 21st Century Cures Act in December 2016, authorizing 1.8 billion dollars in funding for the Cancer Moonshot initiative over seven years. The Cancer Moonshot Biobank aims to accelerate cancer research through increased focus on pressing questions in cancer research, including why some patients respond to a particular cancer treatment and some do not. To be able to ask such questions, researchers need access to biospecimens collected from human subjects both before and after cancer treatment. The Cancer Moonshot Biobank will develop new approaches to engage with cancer patients over the course of their cancer treatment, collect longitudinal biospecimens and associated data, and distribute the biospecimens and data to qualified researchers. Speakers will describe the hallmarks of this new program and highlight specific recommendations of the Blue Ribbon Panel (a panel of experts advising the Cancer Moonshot's approaches) that may have implications for future biobanking efforts. During this session, speakers and attendees will:

- Provide an overview of the Cancer Moonshot initiative and its objectives
- Review the recommendations of the Blue Ribbon Panel
- Discuss ways in which the recommendations of the panel, particularly in areas such as patient engagement and data sharing, may inform the development of future biobanking initiatives

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E17

Tribal Research Futures: Resources to Strengthen Governance, Trust, and Culture in Research Partnerships

(Populations Requiring Additional Protections Track)

With support from the Indian Health Service/NIH Native American Research Centers for Health Initiative, the National Conference of American Indians Policy Research Center and the University of Nevada Reno partnered to develop a research-based toolkit titled, *Holding Space: A Guide for Partners in Tribal Research* to promote meaningful tribal academic research partnerships. The toolkit consists of a discussion guide and Tribal Research Future Game that were developed from a mixed methods inquiry that revealed culture, governance, and trust to be three key drivers of meaningful community-academic partnerships. The toolkit content focuses on issues of governance, trust, and culture in the tribal research space and how tribal and academic research partners might navigate issues in a way that builds tribal sovereignty and research sustainability. The game develops these core concepts by allowing participants to engage with strategic and challenging scenarios on topics of data resources, design, implementation, and dissemination in research relationships. During this session, speakers and attendees will:

- Review the critical importance and impact of governance, culture, and trust in research partnerships through an introduction to the modules in *Holding Space: A Guide for Partners in Tribal Research*
- Discuss the intermediate and long-term outcomes of tribal academic research partnerships over time in an abstracted setting, through the Tribal Research Future Game
- Build knowledge of the role of stewardship in decision making

E18

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

Investigator site audits are the hallmark of post-approval monitoring and are integrated into many IRB QA/QI programs. This session will introduce participants to the key concepts and practical strategies for developing investigator on-site audit activities while being mindful of the institution's research portfolio, whether primarily biomedical or SBER. During this session speakers and attendees will:

- Provide an overview of the investigator site review/audit process
- Address specific considerations of the investigator audit activity including, but limited to: research portfolio (biomedical research vs. SBER), 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 that sites can modify for their own use

E19

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

Advanced

The widespread use of electronic medical records present 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, flag when patients are enrolled in their studies, and show the results of some research tests in patients' records. This session will explore the 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 and attendees 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

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E20

Data Acquisition and Management: Concepts Every Researcher and Research Administrator Should Know

New

(Responsible Conduct of Research Track)

This session will focus on the principles of data management practices, which include data ownership, collection, protection, and sharing in the context of research teams. The session will also provide case examples of challenges related to data reproducibility, and recommendations for research administrators on the mechanisms they can employ to prepare research teams to improve their effectiveness related to data management practices. In this session, speakers and attendees will:

- Review the principles of data management practices
- Discuss case examples that outline success and challenges related to data transcription and storage (and retrieval for post-approval monitoring)
- Share insight and suggestions for incorporating a robust training and an awareness related to acquiring, storing, sharing, and protecting research data

E21

Managing Small Research Programs in Healthcare Settings *(Small Research Programs Track)*

New Basic

Small research programs may exist in small, medium, and even large healthcare settings, and involve unique concerns and requirements. This session will focus on the unique challenges for small IRB offices within healthcare. During this session, speakers and attendees will:

- Review how to maintain identity and ensure compliance when the culture is not research-oriented
- Explore how to be creative with current resources and how to request new resources
- Share strategies for working with other centers on multi-site research

E22

How to Create an Undergraduate Research Training Program *(SBER Track)*

New Basic

Undergraduate students are encouraged to become involved in the research life of their universities. There is an array of opportunities for students of all experience levels to participate in academic inquiry, from research assistantships to independent projects. While some undergraduate research activities that involve human subjects require approval by the IRB, others do not. In the absence of comprehensive oversight for undergraduate research, IRBs have been tasked with providing review for these projects whether or not the activity meets the requirements for IRB review. While this provides a mechanism for ensuring projects include appropriate precautions for protecting human subjects, it does so at the cost of increased workloads, continued absence of oversight from other areas of the institution, and a missing, holistic program to create better prepared undergraduate researchers. This interactive session will provide insight on how to create an undergraduate research training program. During this session, speakers and attendees will:

- Learn step-by-step how to develop an undergraduate research training program, including developing a plan, creating materials, and implementing a process
- Discuss how to locate resources for such a program, even on a tight budget, and how to identify and gain support from stakeholders
- Share strategies for creating and implementing a monitoring plan for continued oversight

E23

You Want to Do What? Developing Best Practices for IRB Review of Research Investigating Illegal/Illicit Behaviors *(SBER Track)*

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, risk and risk/benefit assessment, and issues related to mandatory reporting, confidentiality, and privacy. Attendees should have basic foundation in human subjects research protections ethics and principles, including the criteria for approval. Before attending this session. 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

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12:45-2:30 PM

Closing General Session Luncheon: Research Ethics, Race, and Opioids—The Evolution of the Perfect Epidemic

The opioid epidemic claims the lives of 116 individuals in the United States every day. This fact has contributed to recent public policy responses, and has fueled considerations of overdose reversing medications and harm reduction (e.g., safe-injection sites). This epidemic, as with those before, is not only about addiction: epidemics are about culture, politics, prejudice, and stereotypes. The current opioid crisis provides a lens through which the impact of race, class, gender, and social injustices can be considered. Some argue the current crisis is partly the result of a stark racial divide. When white Americans become addicted, it's seen as proof of a breakdown of society, but when minorities become addicted, it's viewed as evidence of an individual's moral failing. This panel will consider how society as a whole, including the research enterprise, frame the language and discourse around epidemics, how racial and economic injustices are perpetuated through public policy and research responses, and will examine the politics and framing of epidemics, stigma, and morality. ***Note:*** *Lunch will be served during this session. The formal presentation will begin at 1:15 PM.*

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