This agenda is subject to change.

**2018 AER Conference Virtual Meeting - Thursday, November 15**

**8:00-8:15 AM**  
**Conference Welcome Remarks**  
Albert J. Allen, MD, PhD, Senior Medical Fellow, Pediatric Capabilities, Global Medical Policy Strategy and Operations, Medicines Development Unit, Eli Lilly and Company, and Elizabeth A. Buchanan, PhD, Endowed Chair in Ethics, Center for Applied Ethics, 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: Celebrities, Science-y, and Pseudoscience: Tackling Misinformation in the Era of Health Noise**  
Timothy Caulfield, 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; Fellow, the Royal Society of Canada; Fellow, the Trudeau Foundation; Fellow, Canadian Academy of Health Sciences

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

Moderator: Cynthia A. Gómez  
Panelists: Patrick Carter, Harold D. Cox, Zoe Grover  
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**  
Moderator: Alexander M. Capron  
Panelists: Andrea Denicoff, Betty R. Ferrell, Jodi Halpern, Carol Juliet Weil  
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?
Panel III: The New Rule’s Identity Crisis: Should Identifiability Be Changed?

Moderator: Laura Odwazny
Panelists: William E. Grizzle, Suzanne M. Rivera

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.

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

A9
Not Less Work, But Different: Re-Engineering for Single IRB Review
(Institutional Officials and HRPP Leadership Track)
Nichelle Cobb, Megan Kasimatis Singleton, Kimberly K. Summers

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

A12
It’s Not as New as You Think: Understanding How to Operationalize the Final Rule
(IRB Operations Advanced Track)
Jeffrey A. Cooper, Kristin J. Craw, Jessica H. Huening, Heather H. Pierce

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, incorporating 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)
Sarah A. White, Rebecca J. Williams
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

A19
IRB Review of Big Data Research
(Research Conducted in the Digital World Track)
Jacob Metcalf, Laura Odwany, Stephen J. Rosenfeld
This session will explore the evolution of the field of big data health research, discuss the Secretary’s Advisory Committee on Human Research Protections (SACHRP) recommendations on big data research and how provisions of the revised Common Rule apply in the context of big data research, and review some 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-blocks due to misapplied or un-empirical risk and privacy assessments. Some of those concerns may be ameliorated by new exemption categories in the revised Common Rule, which could operate to exclude a significant portion of big data health research from IRB review. Further, increased IRB expertise as to risk assessment and risk management in the context of big data health research can serve to dismiss “hype” regarding the actual risks and benefits to research participants and facilitate ethical research with these valuable data sets. Speakers will also discuss how big data research techniques pose new forms of risk that are largely invisible to the Common Rule and outside 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
A23
**Risk Mitigation in Mixed SBER and Biomedical Research**  
(*SBER Track*)

**Matthew Stafford, TBD**

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

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**Breakout Session Series B, 3:00-4:15 PM**

B1
**The Times, They Are a-Changing: Overview of the Latest NIH Changes and Their Implications on Research**  
(*A Dialogue With the Feds Track*)

**Maryana Saadeh-Helou, Carrie D. Wolinetz**

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 (eg., design, conduct, review, etc.)
- Explore the implementation challenges for investigators, IRBs, and institutions

B6
**When Is an Investigational Device Exemption (IDE) Needed for a Clinical Investigation of a Medical Device?**  
(*FDA Regulations Track*)

**Soma Kolb**

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

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**ICON KEY**

- **Double session**
- **Call for Session Proposal**
- **Reviews changes to the Common Rule**
- **Recorded session**
- **Breakout sessions new for 2018**

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B12

Meghan K. Scott, Jeanne Velders
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

B13
The European Union’s (EU) General Data Protection Regulation (GDPR) and US-Based Research: Implications, Problems, and Potential Solutions (Pharma/Biotech Perspectives Track)

Cecelia Alvarez, Mark Barnes, Karla Childers
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

B18
Ideas and Practices for Compliance and Auditing of Single IRB Studies (QA/QI and Post-Approval Monitoring Track)

Nichelle Cobb, Sarah A. White
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
8:00-8:30 AM
Welcome and Presentation of PRIM&R’s Distinguished Service Award to P. Pearl O’Rourke, MD, Director, Human Research Affairs, Partners Healthcare System Inc.; Associate Professor, Pediatrics, Harvard Medical School, and Presentation of PRIM&R’s Applied Research Ethics National Association Legacy Award to Jerry Castellano, BD, PharmaD, CIP, Corporate Director, IRBs, Christiana Care Health System

8:30-9:30 AM
Keynote Address: Clinical Trial Data Sharing: Perspectives From Participants
Michelle M. Mello, JD, PhD, Professor of Law, Stanford Law School; Professor of Health Research and Policy, Stanford University School of Medicine
Note: this talk will be livestreamed in real time only; it will not be available for 30 days post-talk, nor will it be included on the conferences proceedings.

Explorations in... Panel Series, 10:00-11:00 AM
Research and scholarly exploration is how progress is made in any field, and the field of research ethics and oversight is no exception. The Explorations in... panel series spotlights selected scholarly works submitted for this year’s AER conference, grouped around a central theme. The novel scholarly works include empirical research, institutional program assessments, and conceptual thought pieces. Authors will present their work in a research-conference-style format, followed by a brief question and answer period. The Explorations in... panel series offers an opportunity to hear about some of the current work impacting our field. Access to the abstracts will be made available in October.

Explorations A: Explorations in Optimizing Informed Consent and Assent
Improving the informed consent process for research subjects is a priority for investigators and research oversight professionals, as it is key to protecting human subjects and ensuring that the highest ethical standards are upheld. Three authors of projects related to facilitating subject consent, assent, and understanding of research will share their work in this panel, including the development of a checklist to address challenges faced by pregnant women in HIV-related research, a mobile app game designed to assist children with understanding research so they can provide informed assent, and an animated video aimed at children and families to educate them about research.

• A Novel Approach to Engage Stakeholders in Creating Educational Tools for Future Research Participants: The “What is Research?” Video
  Jessica Macha, CIP

• Developing a Novel App to Educate Children on the Human Subject Assent Process
  Moore Rhys, CIP

• Prototype Checklist for Informed Consent in Clinical Trials with Pregnant Women: An Engagement-Informed Tool to Support Ethical Inclusion
  Kristen Sullivan, PhD, MSW, MBA

Explorations B: Explorations in Navigating the Single IRB Mandate
The recent NIH guidelines requiring single IRB oversight for multi-site research are intended to streamline the review process and allow research to proceed quickly, but adjustments to the new requirements present new challenges and opportunities for IRBs. In this panel, three poster authors will discuss their projects related to implementing these new guidelines, including an institutional program to facilitate local context review, an evaluation of attitudes and experiences of IRB stakeholders regarding local context review, and a system for liaising between research sites and the single reviewing IRB.

• Success With a Single Reviewing IRB Serving a Federally-Funded Consortium
  Jeanie Bailey, BS, MT(ASCP), CIP

• Local Context Assessment: A Mixed-Methods Study of an IRB’s Process
  Adrianne Haggins, MD, MS

• Evaluating Local Context Review: Early Data From the Implementation of Local Context Review
  Megan Kasimatis Singleton, JD, MBE, CIP
Explorations C: Explorations in Engaging Communities to Promote Ethical Research

Respecting community perspectives in the research process is a central goal of IRBs; it is of utmost importance to take into account the diverse views and voices of stakeholders in research, including the targeted human subjects and other parties involved. The projects being presented in this panel include the creation of a community oversight board to connect community members to research and protect their interests, designing a webpage to share research publications with participants, and a study of participant attitudes toward HIV and sexual health research with migrant sex workers in Mexico.

- **Enhancing the Ethical Conduct of HIV Research with Migrant Sex Workers: Empirical Research on Human Rights, Policy, and Social Contextual Considerations**
  - Shira Goldberg, PhD, MSc
- **Amplifying the Voices of Participants and their Communities: Developing an Independent Community Oversight Board on Research with Human Subjects**
  - Bethany Hansen, MA

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

**C5**

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

*Barbara E. Bierer, Holly Fernandez Lynch, Stephen J. Rosenfeld*

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

**C8**

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

*Maryana Saadeh Helou, Richard Klein, Marjorie A. Speers, Walter L. Strauss*

During his first State of the Union Address, President Trump endorsed the proposed federal "Right-to-Try" law, which aims to allow individuals with life-threatening illnesses to obtain experimental drugs prior to FDA approval. The bill was signed into law by President Trump on May 31, 2018. 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

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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)

Ann Johnson, Michele Kennett, Robert E. Nobles II
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 have had a 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 workload reallocation and departmental staffing and budget requirements at academic medical centers, universities, and hospitals. Attendees should have an understanding of the revised Common Rule changes, familiarity of the revised Common Rule’s impact on IRB operations, and an understanding of operational and compliance considerations related to sIRBs before attending this session. 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.

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)

Jeremy N. Block, Brenda L. Curtis
The session will provide a basic introduction to the concepts, challenges, and opportunities with digital and mHealth research. Relevant technologies include text messages, mobile 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 SBIR 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.
C22
Research in K-12 Settings (*SBER Track*)

Shannon Sowards Julie Slayton
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 Act, the Protection of Pupil Rights Amendment, and common misconceptions about the IRB’s role in ensuring investigator compliance with these laws
- Share scenarios that may be encountered in the classroom, including undue influence as a result of teachers as investigators, incidental subjects, and how to respect the rights of students who do not wish to participate
- Explore the potential benefits of “flex policies” for institutions
- Address other IRB considerations, including privacy and protection of data

Concurrent Plenary Sessions, 1:45-3:00 PM

Panel IV: What Do Patients Want: Does Majority Rule?
Moderator: Neal W. Dickert, Jr.
Panelists: Diana T. Chingos, Jonathan D. Jackson, Matthew McCoy
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.

Panel V: Ethical Challenges in HIV Cure Research
Moderator: Stephanie S. Cargill
Panelists: Nir Eyal, Rowena Johnston, Jeremy Sugarman
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.

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

Moderator: Ivor A. Pritchard
Panelists: Celia B. Fisher, Jonathan M. Green, Ada Sue Selwitz

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, investigators, 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.

Breakout Session Series D, 3:30-4:45 PM

D3 Tissue Repositories and Data Banks in the Era of the Revised Common Rule (Boundaries and Balances Track)

Mark Barnes, Julie Konoshiora, Susan Stayn

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

D8 Public Health Emergencies, Research, and Bioethics (Hot Topics Track)

Nicky J. Cohen, Christine Grady

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

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D10
Writing and Updating Standard Operating Procedures (SOPs) with the Revised Common Rule in Mind (IRB 101 Track)
Elizabeth A. Bankert, Lauren Hartsmith, Cheryl A. Savini
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

D12
Single IRB: The Next Generation
(IRB Operations Advanced Track)
Daniel Alderson, Jenni Beadles, Aaron Kirby
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

D23
Navigating Uncertainty: Research With Undocumented/Unauthorized Immigrants (SBER Track)
Gene Gloeckner, Elizabeth Jach, Colleen Kohashi
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 institutions’ 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 human subjects, 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

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Panel VII: IRB Decision-Making From a Behavioral Economics Perspective
Moderator: Christine Grady
Panelists: Charles W. Litz, Ivor A. Pritchard, Michele Russel-Einhorn
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 moves 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?
Moderator: Brenda L. Curtis
Panelists: Matthew J. Bietz, Mary L. Gray, Mark MacCarty
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?
Moderator: John D. Lantos
Panelists: Monica Mila, Sally Okun
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.
E3
The Seven Habits of Highly Effective and Flexible IRBs (Boundaries and Balances Track)
Cecilia Brooke Cholka, Jeffery A. Cooper, Jonathan M. Green
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)
Mina P. Busch, Colleen P. Gilrane, Belinda Smith
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
Correcting and Avoiding Noncompliance: Examining Real-life Cases (QA/QI and Post-Approval Monitoring Track)
Martha Jones, TBD
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 preventive actions

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E10
IRB Review of Informed Consent: Moving Beyond the Form
(IRB 101 Track)

Elizabeth A. Bankert, Joshua Fedewa, Jaime O. Hernandez
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

E22
How to Create an Undergraduate Research Training Program (SBER Track)

Jonathan M. Girard, Shannon Sowards
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 session will provide insight on how to create an undergraduate research training program, regardless of the size of your institution or budget. During this session, speakers and attendees will:
- Examine 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, and how to identify and gain support from stakeholders
- Share strategies for creating and implementing a monitoring plan for continued oversight

Closing General Session: 1:15 PM-2:30 PM

1:15-2:30 PM
Closing General Session Luncheon: Research Ethics, Race, and Opioids—The Evolution of the Perfect Epidemic
Moderator: Elizabeth A. Buchanan
Panelists: Brenda L. Curtis, Alexis Roth, Ekow N. Yankah
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.

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