8:00-8:05 AM
Welcome from the Conference Co-Chairs

8:05-9:00 AM
Keynote Address by Katie Shilton, MLIS, PhD, Associate Professor, Information Studies, University of Maryland College Park
(Re?)building Trust in Pervasive Data Research

Breakout Session Series A, 9:15-10:30 AM

A3: Scientific Merit and SBER (Advanced Track)
Julie Sloyton, University of Southern California; Matt D. Stafford, Boston Children's Hospital
Review for scientific merit is a perennial and often thorny issue. Is assessing scientific merit something IRBs should engage in? What are the differing perspectives regarding this issue? Before attending this session, attendees should have an understanding of SBER methodology and study challenges related to risk assessment, risk mitigation, and informed consent, as well as a working knowledge of 45 CFR 46. During this session, speakers and attendees will:
- Discuss the concept of scientific merit in SBER
- Examine and discuss whether review for scientific merit is an IRB obligation (e.g., what do IRBs need to review and evaluate scientific merit in a study? If it’s not the IRB’s obligation, should it be conducted by someone else at an institution? Who and under what circumstances?)
- Share strategies for assessing scientific merit and training resources for IRB members

A7: Continuing Review or No Continuing Review, That Is the Question (IRB Policy/Operations Track)
Andrew Hedrick, The Ohio State University; Sharon L. Zack, Westat
Under the revised Common Rule, continuing reviews are no longer required for minimal risk research. This specifically applies to projects reviewed under expedited authority or by full board, including studies that progressed to long-term follow-up or data analysis (even with identifiers), unless the research is FDA-regulated. Formally, the IRB is still responsible for oversight on research conduct and human subject protections. However, the elimination of the regulatory requirement to conduct continuing review annually has created a challenge for HRRPs that may still want to monitor the status of ongoing projects (e.g., how recruitment is progressing) and maintain an overall picture of their active research portfolio. Without formal, ongoing monitoring of project status, notification that the project is over could be the only time, aside from the initial review, that the IRB hears from an investigator. Without a check-in mechanism, will investigators forget about ongoing responsibilities (e.g., human subjects training, reporting incidents, changes to consent forms, unanticipated problems, and changes and additions to previously approved research)? During this session, speakers and attendees will:
- Discuss procedures for determining when projects receive continuing review or a status check-in review (e.g., introducing checklists and forms)
- Review how to roll out changes using new procedures and forms, and educate researchers and research staff
- Share data on investigator satisfaction of the process

Breakout Session Series B, 11:00 AM-12:15 PM

B1: From Flexible to More Flexibility—What’s Left to Review? (Advanced Track)
Rebecca D. Armstrong, University of California, Berkeley; Cecilia Brooke Chalka, University of Nevada, Reno
At institutions that already implemented extensive flexibility for non-federal minimal risk research, the 2018 regulatory revisions had limited impact in many ways. However, with limited IRB review, navigating whether projects previously triaged to greater than minimal risk could be reviewed at the exempt level and pose new challenges for the IRB. Attendees should be familiar with federal requirements and flexibility afforded to institutions who conduct some research that is not formally regulated by the common rule or FDA regulations before attending this session. During this session, speakers and attendees will:
- Explore the range of flexibility for minimal risk research pre- and post-the 2018 regulatory changes
- Learn to differentiate the nuances of proposed projects relative to their institutional policies for triage and review
- Assess the risks to subjects and develop recommendations to minimize risk to subjects while reducing burden on IRBs and principal investigators

ICON KEY

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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.
B6: Reliance—SBER Specific Issues (Hot Topics Track)
Robleinsky Dominguez, Boston Children’s Hospital; Ashley D. Hicks, Tufts University; Carissa Minder, Washington University in St. Louis
This session will review regulatory considerations, as well as the specific ethical issues that arise when negotiating and executing reliance agreements in SBER contexts between ceding institutions and central or single IRBs. During this session, speakers and attendees will:
- Discuss issues of local context and institutional knowledge as it pertains to ceding review to another IRB in SBER studies
- Review what an institution is responsible for when it is not the IRB of record, but remains charged with ensuring proper conduct of the study at their site and without the benefits biomedical research boards often receive from other oversight bodies (e.g., Data and Safety Monitoring Boards, Contract Research Organizations, etc.)
- Outline the issues that arise when ancillary reviews are required outside of IRB review, and learn strategies for handling them
- Learn about the challenges that arise when SBER and biomedical institutions collaborate in a ceded review arrangement

1:30-2:45 PM
Plenary Session: Strategies and Solutions for Working With Challenging Principal Investigators (PIs)
Moderator: Andrew Hedrick, The Ohio State University
Panelists: RoseAnn Fleming, University of Southern California; Jessica R. Williams, University of Kentucky; Julie Sloyton, University of Southern California
This panel will discuss strategies found to be effective in ensuring a productive working relationship with PIs in order to facilitate the IRB review process. Through scenarios and strategies presented by the moderator, panelists will discuss best practices and “insider tips” for how IRB staff and members can work in concert to deliver an effective review process, especially with challenging PIs, while maintaining a smooth running HRPP.

Breakout Series C, 3:15-4:30 PM

C5: Benign Behavioral Interventions (BBI) in Practice (Hot Topics Track)
Alma Castra Harvard T.H. Chan School of Public Health; Matt D. Stafford, Boston Children’s Hospital
This session will focus on how IRBs are defining BBI in Exempt Category 3 and how IRBs are making the determination of whether an intervention meets the Exempt category 3 criteria or not. Sample cases of BBIs in SBER and mixed SBER/biomedical research will be explored. Additionally, IRB decision-making processes for each case will be discussed with the goal of promoting IRB best-practices. Before attending this session, attendees should have working knowledge of the revised Common Rule, its exemption categories, and familiarity with SBER disciplines. During this session, speakers and attendees will:
- Review the definition of BBIs per federal regulations, OHRP, and SACHRP guidance
- Explore real-life examples of SBER involving BBIs that IRBs reviewed, as well as the resulting determination of whether the intervention did or did not meet the BBI definition in Exempt category 3
- Discuss IRB best practices when determining whether research involving BBI in SBER and mixed SBER/biomedical research meets the federal regulatory definition in Exempt category 3

C6: College Students and Research—Challenges and Issues for IRBs (Basic Track)
Andrea McDonald, Seattle University; Julie F. Simpson, University of New Hampshire
A considerable amount of research takes place on college/university campuses involving college 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 the specific ethical issues that arise when reviewing research in which college students on campus are subjects, and when they may serve as investigators or study staff. During this session, speakers and attendees will:
- Provide a high level overview of pertinent laws and regulations affecting this population (e.g., the Family Educational Rights and Privacy Act, Title IX)
- Identify the 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 investigator
- Outline the issues that arise with the operation of university/college subject pools and best practices for addressing these issues
- Review the role of the HRPP in educating student researchers
Monday, November 18: AER19

8:00-8:15 AM
Welcome from the Conference Co-Chairs

8:15-8:40 AM
Remarks from PRIM&R’s Executive Director, Elisa A. Hurley, PhD

8:40-9:45 AM
Keynote Address by Janine Austin Clayton MD, Associate Director for Research on Women's Health; Director Office of Research on Women’s Health, NIH: It’s About Quality Construction—Advancing a Foundational Framework for Rigorous Research Relevant to the Health of Women

10:15-11:30 AM: Concurrent Plenary Sessions

Panel I: Diverse Representation in Clinical Trials—Why Does It Matter and How Do We Move Forward?
Moderator: Barbara E. Bierer, The Multi-Regional Clinical Trials Center of Brigham and Women’s Hospital and Harvard Medical School
Panelists: Denise Anne Dillard, Southcentral Foundation; Tesheia Johnson, Yale University School of Medicine; Paul Underwood, Boston Scientific Corporation
The prescribing and marketing of drug products to subpopulations for whom response and tolerability have not been studied represents a shortcoming in medical science and raises justice-related concerns about access to appropriate treatment. Despite healthcare and ethical mandates, little progress has been made towards ensuring the composition of clinical trials reflects the diversity of the population at large. When historically under-represented groups remain understudied, variability in treatment response and tolerability go undetected. Although scholars caution against inappropriate use of population descriptors, such as race as a variable in clinical research, considerable data support the scientific and social value of inclusiveness in clinical trial enrollment across sex, gender, race, ethnicity, age, and socio-demographic factors to ensure study findings are relevant to all populations who stand to benefit from new interventions. What is the scientific value of diversity and inclusiveness in drug development? How do we understand the mandate for diversity on a global scale? What conceptual, cultural, organizational, and scientific factors impede progress? This session brings together leaders from industry and academia to discuss the importance of diversifying trials, with reference to success stories within indigenous communities and the international context. The panel will propose and discuss actionable and scalable solutions to address impediments at the level of trial development and implementation to promote the goal of diversity in enrollment and to facilitate necessary subgroup analyses in clinical trials.

Panel II: Using Social Behavioral Data to Provide Insight into Health-Related Experiences
Moderator: Julie Slattery, University of Southern California
This panel will address questions and concerns that arise for IRBs as they review studies that may appear biomedical, but in actuality represent SBER. Studies may be related to health outcomes, yet focus primarily on participants’ experiences and behaviors (e.g., collecting social media posts from pregnant women with cancer to focus on their experience with pregnancy, not the progression of their disease; collecting Twitter data of smoking study participants to see their level of smoking-related advertising exposure; collecting Facebook data documenting interactions between a LGBTQ support group leader and LGBTQ participants on risky behavior in an effort to decrease risky behavior, etc.). The panel will also address how IRBs can help educate biomedical and social science researchers on the “rules” or ethical considerations of working in the social media space while conducting SBER.

Panel III: What to Expect When We Sequence Expecting Moms
Moderator: Jeremy Sugarman, Johns Hopkins University
Panelists: Ingrid A. Holm, Boston Children’s Hospital/Harvard Medical School; Josephine M. Johnston, The Hastings Center; Haley K. Sullivan, Duke University
Noninvasive prenatal testing can be used to perform prenatal whole genome sequencing (PWGS) by collecting fetal DNA from a simple maternal blood draw. Although prenatal genome sequencing isn’t yet part of routine clinical care during pregnancy, many believe it will be shortly, as the price of sequencing continues to plummet and commercial entities in the health and ancestry space push the public to obtain more personal genetic information. Public interest in PWGS may also be on the rise as concerns increase about conducting research on germline CRISPR therapies, and the recognized need for international engagement on that technology makes any policy consensus on germline CRISPR unlikely in the near future. This panel will explore the ethical issues surrounding clinical research into PWGS, both in terms of population justice and in terms of protecting the autonomy and beneficence interests of future persons. Recent research indicates that expecting parents and treating clinicians may have different priorities and concerns. This panel will also explore what types of genetic information should be returned to prospective parents who undergo clinical trials of PWGS and how directive healthcare providers should be when communicating the information.
John Heldens, University of Colorado Denver, Anschutz Medical Campus
Carissa Minder, Washington University in St. Louis

George Bernard Shaw stated, “the biggest problem in communication is the illusion that it has taken place,” which presaged one of the key challenges for single IRB review: how reviewing IRBs can effectively work with relying institutions and study teams to obtain and share the information necessary to ensure adequate oversight of a multi-site research study. When communication does not occur or go well, frustration, potential increase in research risks, and failure to provide new information to subjects can occur. Before attending this session, attendees should have some experience working with IRB reliance arrangements, either as a reviewing IRB or a relying institution. This session will use case studies to explore how institutions can work together proactively and collegially under the single IRB model by addressing critical components of communication. During this session, speakers and attendees will:

- Review what local context information a reviewing IRB should collect, both about relying institutions and study implementation, how to tailor it for the study type, and mechanisms for retaining that information to reduce burdens on the relying institution
- Explore how to engage relying institutions so they address noncompliance and unanticipated problems (e.g., in the development of corrective action plans and reports to federal agencies and authorities)
- Determine when to reach out to relying institutions to obtain input on amendments
- Identify what information to include in approval notices or other documents to assist the relying institution with their oversight responsibilities
- Share written policies that are accessible to and take into account the perspectives of relying institutions and relying site study teams

Note: this session will be repeated on November 20, 10:00-11:15 AM.

A11: Legal and Regulatory Changes: A Year in Review (Legal Considerations for HRPPs Track)
Holly Fernandez Lynch, University of Pennsylvania Perelman School of Medicine; Laura Odwazny, DHHS; Michele Russel-Einhorn, Advarra, Inc.

A lot has happened this year! Get up to speed with this 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 issues-spotting exploration and analysis of changes in laws, regulations, and guidance issued by FDA, HHS, and NIH. During this session, speakers and attendees will:

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

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.

A12: Operationalizing Data Sharing Policies—Challenges and Solutions (Research Involving Data and Biospecimens Track)
Shannon Sowards, Harvard University; Carrie D. Wolinetz, Office of Science Policy, NIH

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. Many journals will not accept manuscripts unless it can be shown the data is being shared within some national database. 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:

- Review the NIH’s Genomic Data Sharing Policy
- Discuss the ethical and regulatory implications of data sharing
- Identify potential challenges for organizations and IRBs in complying with the policy
- Share examples to discuss operational solutions and review processes to facilitate compliance

A19: Fundamental Issues in Qualitative Research (SBER Track)
Patricia B. Condon, University of New Hampshire; Julie F. Simpson, University of New Hampshire

In qualitative inquiry, researchers study phenomena in their natural settings where the purpose is contextualization, interpretation, and/or understanding the perspectives of others. The role of qualitative researchers in a study is characterized by their personal involvement and empathetic understanding. This session will help IRB members facilitate the review of qualitative research applications by providing a better understanding of this type of research and the challenges faced by researchers using this paradigm, and will educate qualitative researchers on issues this research paradigm can present during review. Before attending this session, attendees should have a basic knowledge of SBER methodologies and of 45 CFR 46. During this session, speakers and attendees will:

- Examine the foundations of qualitative inquiry, and review its basic characteristics, including nomenclature and common data collection methods
- Identify the ethical issues qualitative research may present to study participants, including recruitment, informed consent, privacy and confidentiality, and conducting research online
- Share strategies for minimizing harm to participants in qualitative research studies
A23: Making Limited Review Work Without Reinventing the Wheel (IRB Operations Advanced Track)
David A. Borasky, Jr., WIRB-Copernicus Group; Teresa Doksum, Abt Associates, Inc.
Limited review is a new regulatory concept that was incorporated into the revised Common Rule as part of the review process for exempt research under categories 446.104(d)(2)(iii), (d)(3)(i)(C), or (d)(7) or (B)). However, the revised Common Rule does not describe how the limited IRB review mechanism should be implemented, and there has been no guidance from OHRP or SACHRP recommendations. In this session, speakers will review the limited IRB review requirement and describe a process for managing the review without adding significant burdens to IRB programs. During this session, speakers and attendees will:
- Review the regulatory requirements related to limited IRB review
- Describe a process for conducting limited IRB review
- Go over documentation requirements

B1: Standard of Care, Medical Innovation, or Research—How Should We Decide?
(Flexibility and Innovation in IRB Processes Track)
Alexander M. Capron, University of Southern California; Robert W. French, Jr., Cincinnati Children’s Medical Center/University of Cincinnati; Michele Ruster-Einhorn, Advarra, Inc.
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. For example: when a physician or group of physicians want to collect data on their consistently provided, but unique/novel practice (i.e.,” this practice “would be provided anyway” to their patients), is this standard of care, medical innovation, or research? If it is research, how should it be reviewed? This issue is important as it comes up frequently in IRB review, although it may be addressed differently by IRBs. This session will present the issue, discuss potential ways of addressing it, and attempt to problem solve 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, and interactive discussion, and assumes sufficient experience and actively contribute to the discussion of and solution to these problems. This session 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

B4: Investigational Device Exemptions (IDE), Mobile Medical Applications, and IRB Review
(FDA-Regulated Research Track)
Soma Kalai, Center for Devices and Radiological Health, FDA; Bakul Patel, Center for Devices and Radiological Health, FDA; James Riddle, Advarra, Inc.
In general, the IDE regulations apply to clinical investigations of medical devices designed to determine safety and effectiveness. When do you need an IDE for a clinical investigation of a medical device? What about mobile applications? When does a mobile application meet the definition of a medical device under the Food, Drug, and Cosmetic Act, and how does FDA intend to apply its regulatory authorities to mobile medical applications? IRBs may struggle with these questions and what their review responsibilities are when a protocol involves a mobile medical application. During this session, speakers and attendees will:
- Share a basic overview of the applicability of the IDE regulations that address when an IDE is required
- Distinguish when mobile applications meet the definition of a medical device
- Discuss FDA’s current approach to applying its regulatory authorities to oversight of mobile medical applications
- Provide IRBs with a review framework for studies involving mobile medical applications and suggest policies and procedures to develop to ensure HRPPs remain relevant in a tech savvy world

B9: Taking the Plunge—Transitional Studies to the Revised Common Rule (IRB Operations Advanced Track)
Lauren Hartsmith, OHRP, John Heldens, University of Colorado Denver, Anschutz Medical Campus Nathalia Henry, Northwestern University
Many organizations working to adapt to the revised Common Rule are facing the decision of whether or not to transition existing research to the new requirements and, more importantly, how to operationalize this change. With the help of representatives from OHRP, this session will review the transition provisions outlined in the revised Common Rule, and discuss varied approaches to practical implementation of this transition. Speakers will review which studies to transition, the best timing for transition, what documentation is needed to reflect the change, and how the change and its implications should be communicated to researchers. Lessons learned to date from organizations that have begun to transition studies will be shared and tools to help manage the change will be reviewed. Before attending this session, attendees should have basic knowledge of the regulatory requirements related to informed consent and be familiar with the new key information requirement of the Revised Common Rule. During this session, speakers and attendees will:
- Review the transition provisions for the revised Common Rule
- Discuss different approaches for transitioning research and managing the change, and share lessons learned from making the change
- Explore tools to assist with the transition process

ICON KEY
- **Preregistration required**
- **Recorded session**
- **Breakout sessions new for 2019**
- **Call for Session Proposal**
  - **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.
  - **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.
B15: The Secrets of Big Data—Public, Private, or Something Else? (Research Conducted in the Digital World Track)
Ivor A. Pritchard, OHRP
Information is commonly thought to be either “public” or “private,” with no third alternative. However, a considerable portion of big data could be considered to be neither public nor private, but rather information with access that is controlled or limited by such things as “privacy agreements,” which actually serve to identify the extent to which information may be used and restricted. How should the norms of sharing information be constructed, and by whom? During this session, speakers and attendees will:
- Examine when there could be a difference between “private information” and “confidential non-public information,” and how this would alter the application of the regulations
- Share important legal cases regarding the evolving idea of privacy in US law
- Discuss current perspectives on how access to confidential information in various forms should be circumscribed in research

Note: this session will be repeated on November 20, 10:00-11:15 AM.

B18: A Comparison of Human Subjects Protections Auditing Between Biomedical and Social-Behavioral Human Subjects Research (SBER Track)
Narayan A. Escolin, Rutgers University; Kate Sasamoto, University of Michigan
While there are some similarities in the conduct of biomedical and SBE human subjects research, there are many differences: applicable regulations and guidelines, institutional policies, standard research practices, background/make-up of research teams, etc. As such, the approach to auditing these protocols must be distinct and depends on the type of research being conducted. Auditors must take into account subject populations, types of interventions, levels of research experience, and common research tools, among other things. A nuanced approach tailored by the appropriate considerations can affect factors such as principal investigator cooperation, comprehensiveness of the audit review, and duration of the audit process. During this session, speakers and attendees will:
- Compare and contrast the obstacles in each step of the auditing process for the two types of human subjects research
- Provide the reasons for these differences
- Share examples that highlight current practices and considerations

Tuesday, November 19: AER19

8:00-8:05 AM
Welcome from the Conference Co-Chairs

8:05-8:10 AM
Presentation of PRIM&R's Distinguished Service Award to Robert S. Bienkowski, PhD, Central Michigan University

8:10-8:15 AM
Presentation of PRIM&R's Applied Research Ethics National Association Legacy Award to Susan Z. Kornetsky, MPH, Boston Children's Hospital

8:15-8:40 AM
Remarks from PRIM&R's Chair of Board of Directors, Heather H. Pierce, JD, MPH

8:40-9:45 AM
Keynote Address by Scott D. Halpern, MD, PhD, Professor of Medicine, Epidemiology, and Medical Ethics and Health Policy, University of Pennsylvania Perelman School of Medicine: Financial Incentives and Nudges for Research Participation—Undue, Unjust, or Uncertain?

Breakout Sessions Series C, 10:15-11:30 AM

C5: European Union (EU) General Data Protection Regulation (GDPR) (Global Research Track)
Kristin J. Craun, University of California, Los Angeles; Michael A. DiMaio, Ropes & Gray LLP
The EU’s GDPR took effect on May 25, 2018, and applies to researchers in the European Economic Area (EEA), as well as those located outside the EEA, that process data of individuals located in the EEA. It is therefore essential researchers who use any personal data originating in the EEA have an understanding of the regulation. This session will begin with a brief overview of the critical elements that impact international research, identify areas where research has been restricted, and provide practical steps that American medical college and universities can use to ensure compliance with GDPR. During this session, speakers and attendees will:
- Explore the impact of the GDPR on human subjects research
- Highlight the challenges posed by the GDPR to clinical research, biobanking and data banking, and big data research
- Discuss how the GDPR interacts with the Health Insurance Portability and Accountability Act of and the revised Common Rule
- Identify operational practices that academic medical centers and universities can put in place to ensure compliance with GDPR
C7: Covering All Your Bases: Considerations and Tips for How to Identify and Apply the Appropriate Federal Regulations for IRB Review (IRB Basics Track)
Warren Capell, University of Colorado Denver; Danielle Gitner, Indiana University; Leslie M. Howes, Harvard T.H. Chan School of Public Health
This interactive session will assist IRB staff, chairs, and members with the initial review of non-exempt human subjects research. This session will provide the basic training necessary to determine whether a study qualifies for expedited or full board review; identify which regulations apply (e.g., Common Rule, FDA, the Family Educational Rights and Privacy Act, Health Insurance Portability and Accountability Act of, and other agency requirements), and what/how/where determinations should be documented (e.g., IRB minutes vs. reviewer checklist). During this double session, speakers and attendees will:
- Revisit the ethical principles underlying regulatory protections for research involving human subjects
- Identify and discuss regulations that impact 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
- Practice applying the 111 criteria to various case examples
- Share key methods of documenting regulatory and other requirements as part of the review

Note: This is a double session and will end at 12:45 PM.

C9: Creative Solutions for Serving as a Reviewing IRB (IRB Operations Advanced Track)
Holly Bante, University of Cincinnati; Ann Johnson, University of Utah; Hallie Kasson, Northwell Health; Janelle A. Maddox-Regis, Johns Hopkins University School of Medicine
Is your organization contemplating whether to act as a single IRB (sIRB) for multi-site research? This lively, discussion-oriented session will candidly discuss the challenges in assuming this new role and offer practical solutions from organizations serving in this capacity. Topics to be covered include consent form development, handling conflicts of interest, methods of communicating with relying institutions and study teams (including obtaining local context information) during initial reliance arrangements and review, and addressing post-initial review requirements (e.g., amendments and continuing review). This session is designed to share experiences and offer practical tools for organizations embracing this new challenge. Before attending this session, attendees should be knowledgeable about sIRB requirements. Attendees will have the opportunity to ask specific questions relevant to serving as a sIRB. During this double 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 is a double session and will end at 12:45 PM.

C15: Social Media in Research—Recruitment, Subject Communication, and Data Source (Research Conducted in the Digital World Track)
Emily Largent, University of Pennsylvania Perelman School of Medicine; Holly Fernandez Lynch, University of Pennsylvania Perelman School of Medicine; Stephanie Morain, Baylor University of Medicine
Social media have become integrated into the fabric of modern life, making it no surprise these platforms are being used for, and are having 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. Finally, 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
- Provide tools for ethical oversight of research using social media platforms as a data source

ICON KEY
Pre-registration required
Sessions span two time periods
Recorded session
New Breakout sessions new for 2019
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.
C20: Implementing the Key Information Requirements of the Revised Common Rule—Perspectives on Early Approaches (IRB Operations Advanced Track)
Susan Z. Kornetsky, Boston Children’s Hospital; Sarah Fuller, University of Utah; Holly A. Taylor, Department of Bioethics, Clinical Center, NIH
The revised Common Rule includes a requirement that the consent form begin with a concise and focused presentation of the key information that is most likely to assist a subject in understanding why s/he may or may not want to participate in the research. With little guidance available about what key information is and how to address it, most organizations have developed their own guidance and approach to complying with this new regulatory requirement. With variations in approach, it is important to explore possible advantages and disadvantages of these varied approaches. This session will review existing approaches to addressing key information for clinical and non-clinical studies, incorporating IRB and participant perspectives on the requirements for the new provisions regarding key information in informed consent. Through case examples, attendees will have the opportunity to consider various approaches to implementation of the key information requirement and the potential pros/cons of each approach. Before attending this session, attendees should have a basic understanding of the revised Common Rule and be familiar with the transition provisions of the revised Common Rule. During this double session, speakers and attendees will:
- Review the new regulatory requirement for inclusion of key information in the consent form
- Identify varied approaches organizations have adopted to comply with this requirement
- Through case examples, practically identify the potential pros/cons of each approach
Note: This is a double session and will end at 12:45 PM.

Sessions 11:45 AM-12:45 PM

A Dialogue With DOD
Laura R. Brosch; Stephanie Bruce; John Lee Melton
This session will be led by senior leaders and subject matter experts from DOD’s HRPPs. During this session, speakers and attendees will:
- Discuss DOD Component policies and guidance for implementing the revised Common Rule in DOD-conducted and DOD-supported human subject research (HSR)
- Explore DOD guidance pertaining to the oversight of DOD-conducted and DOD-supported HSR involving DOD personnel, particularly DOD-unique requirements
- Participate in an open discussion about DOD-related topics relevant to the research protections community, internally to the DOD as well as the extramurally-supported partner

A Dialogue With FDA
Kavita C. Dada; Soma Kalb; Joanne P. Less; Diane M. Maloney; Pat J. McNeilly; Kevin A. Prohaska
This interactive session will be an open forum led by a panel of FDA representatives, and who will provide brief updates on FDA activities within their Center/Office. The session will then open up for audience 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

A Dialogue With OHRP
Lisa R. Buchanan; Julie Kaneshiro; Yvonne Lau; Ivor A. Pritchard; Irene Sitth-Coleman;
This session will be led by representatives from OHRP. Attendees are encouraged to come with questions of interest to all. During this session, speakers and attendees will:
- Hear from OHRP representatives about evolving initiatives, issues, and guidance
- Ask questions of OHRP representatives
- Participate in an open discussion on topics raised at the session

A Dialogue With the VA
Kristina C. Borror; Cynthia L. Boudreaux; Charlotte K. Jeans; Mary M. Klite
This session will be led by representatives from the VA. Attendees are encouraged to come with questions about VA research. During this session, speakers and attendees will:
- Hear from representatives of the VA’s Office of Research and Development and Office of Research Oversight about issues and activities related to the conduct of VA research
- Participate in an interactive dialogue about topics related to VA research
- Ask questions about the VA’s current policies related to human subjects protections and the direction of the VA’s future policies

ICON KEY
- Pre-registration required
- Sessions span two time periods
- Recorded session
- CIP eligible
- Now: Breakout sessions new for 2019
- Call for Session Proposal

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Panel IV: Identifying and Avoiding the Conduct of Low Value Clinical Trials
Moderators: Laura Odwazny, DHHS
Panelists: Eileen M. O’Reilly, Memorial Sloan Kettering Cancer Center; Stephen J. Rosenfeld, Freepoint Research Systems, LLC; Deborah A Zarin, ClinicalTrials.gov, National Library of Medicine, NH

Clinical trials are conducted and subjects are recruited in the name of advancing science. However, a growing body of research suggests that many initiated trials have little or no chance of providing valuable information (e.g., trials that address a question that has already been answered; trials that address a trivial question that is of no scientific or clinical import; trials that have design flaws that predictably would block them from producing a valid answer; trials that are very unlikely to complete as planned because of lack of subject recruitment). More broadly, human experimentation that has little to no prospect of generating valuable knowledge violates basic ethical principles and can cause considerable harm. First, participants may be burdened by the demands of study enrolment, while mistakenly believing that they are contributing to medical progress. Second, trials lacking social value divert participants, researchers, and other resources from other endeavors, including more valuable trials. Third, valueless trials degrade the evidence used in research, care and policy. Academic medical centers and IRBs frequently serve as the main gatekeeper to the initiation of new studies, and thus must do what we can to ensure that the promise of scientific advancement is reasonably likely to be achieved. This panel will address the role academic institutions and IRBs can play in identifying and reducing the initiation and continuation of low value trials by (a) understanding key principles underlying potential value of a trial; (b) ensuring a landscape analysis has been conducted to enable consideration of the scientific context in which the research will occur; and (c) ensuring the trial will be registered and reported in accordance with current legal and other policies.

Panel V: Bioethics Turns 50—Reflections from The Hastings Center
Moderator: Mildred Z. Solomon, The Hastings Center
Panelists: Steven Joffe, University of Pennsylvania Perelman School of Medicine Nancy M. P. King, Wake Forest School of Medicine; Alex John London, Carnegie Mellon University; Karen J. Maschke, The Hastings Center

In honor of The Hastings Center’s 50th anniversary, this panel will compare and contrast 21st century biomedical technologies with those of the mid-20th century, when the field of bioethics was just forming. This panel will explore historical continuities and discontinuities, and consider challenges to oversight across the contemporary research enterprise, from discovery to post-trial monitoring, including comparative effectiveness research and other modes of continuous learning. Panelists will consider the roles bioethicists, scientists, healthcare leaders, patients, and the public should play in ensuring today’s powerful, transformative technologies—including artificial intelligence, gene editing, human-animal chimeras, emerging neuro-technologies, and more—enhance our collective human flourishing.

Panel VI: Studying Suicide and Subjects at Risk for Suicide—Identifying and Minimizing Risk to Promote Necessary Research
Moderator and panelists: David H. Strauss, Columbia University
Panelists: Celia B. Fisher, Fordham University; Samantha Marquez McKetchie, Massachusetts General Hospital

Suicide is a major public health concern and is among the leading causes of death in the US. While the National Institute of Mental Health, the National Action Alliance for Suicide Prevention, and suicide researchers all agree the lack of suicide and related research limits developing novel suicide prevention and treatment approaches, research with patients at risk for suicide presents a range of safety and ethical questions. This panel will discuss what IRB members need to know about suicide starting with a brief overview of the epidemiology of suicide and suicide risks. Panelists will then discuss the types of research that raise concerns about increased risks for suicide (i.e., safety plans aren’t just for “suicide studies”), which begs the question of how to best identify risks and how researchers should respond to risks. Finally, speakers will review how to assess proposed safety plans and how to help investigators create these plans.

Breakout Sessions Series D, 3:45-5:00 PM

D7: Writing and Updating Standard Operating Procedures (SOPs) for the Revised Common Rule (IRB Basics Track)
Elizabeth A. Bankert, Dartmouth College; Lauren Hartsmit, OHRRP; Cheryl A. Savini, HRP Consulting Group

This session will provide guidance on how to effectively develop and maintain essential HRPP/IRB SOPs. Speakers will provide guidance, tools, and share best practices designed to craft regulatory compliant SOPs and ensure available guidance is incorporated, as necessary. During this session, speakers and attendees will:
- Discuss the components of comprehensive and effective HRPP/IRB SOPs
- Identify key areas in which OHRR/FDA guidance has become available and may warrant revision or review of existing SOPs
- Share how to effectively evaluate SOPs and make revisions as necessary

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D8: The Role of IRBs Chairs in Protocol Exceptions, Violations, Noncompliance, and Unanticipated Problems
(IRM Chairs Track)
Francis J. DiMario, Connecticut Children’s Medical Center/University of Connecticut School of Medicine; Michael J. Linke, University of Cincinnati College of Medicine
This session will discuss "best practice" operational procedures when reviewing protocol exceptions, violations, noncompliance, and unanticipated problems. Before attending this session, attendees should have an understanding of violations and deviations, experience managing noncompliance, and familiarity with reviewing protocol exception requests. 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

D12: Assessing Plans to Maintain Confidentiality—How IRBs Determine Whether Data Security and Management Plans Are Sufficient (Research Involving Data and Biospecimens Track)
Gretchen L J. Anding, University of Wisconsin-Madison; Elizabeth A. Buchanan, University of Wisconsin-Stout
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 SBE research audiences. During this session, speakers and attendees will:
• Review the requirements IRBs should consider in creating plans to maintain confidentiality as part of the IRB review process
• Highlight the ways in which the revised 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
• Provide case examples to help evaluate when data needs to be protected, how to know that, and what IRBs can do, particularly when there isn’t a robust IT security department, or one that is not engaged

D14: Ideas and Practices for Compliance and Auditing of Single IRB (sIRB) Studies
(QA/QI and Postapproval Monitoring Track)
Nichelle Cobb, University of Wisconsin-Madison; Neda Lane, Indiana University; Sarah A. White, The Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard Medical School
sIRB is becoming commonplace in the human subjects clinical trial enterprise. As institutions transition to reviewing or relying on IRBs, they face new challenges with respect to ensuring appropriate oversight of the clinical trial and study team, communication between the reviewing and relaying IRBs, and compliance with requirements. QA/QI and postapproval monitoring programs can play a critical role in ensuring study teams are aware of their responsibilities, remain in compliance, and identify communication gaps if they occur. During this session, speakers and attendees will:
• Identify key changes in the regulatory landscape that affect oversight responsibilities and processes for research under the sIRB model
• Review key challenges to QA/QI audits of sIRB studies
• Explore effective QA/QI audit processes
• Use case studies to discuss effective QA/QI audit opportunities and successes

D19: IRBs and Ethnographers—Unpacking the Dimensions of a Challenging Relationship to Increase Mutual Understanding
(SBER Track)
Shannon Sowards, Harvard University; Montana Miller, Bowling Green State University
Anthropologists’ core method of ethnography can be argued to offer the greatest challenges for the IRB review process, for researcher and review alike. These challenges are also appearing more frequently for many IRBs, with increasing numbers of researchers across disciplines adopting ethnographic approaches. This session will present a dialogue across three perspectives: (1) the anthropological view informed by the field; (2) the practice of ethnographic review; and (3) the overarching regulations. The conversation aims to identify legacies, trends, patterns of process, ways that perspectives are articulated, and moments of struggle for mutual understanding that characterize the IRB-anthropologist relationship, aiming to contribute to an improved IRB ethnographer dialogue within the review process. Before attending this session, attendees should have a working knowledge of 45 CFR 46, particularly regulatory flexibility for informed consent, and of ethnography as a research methodology. During this session, speakers and attendees will:
• Discuss the unique challenges ethnographic research poses for IRBs
• Identify specific areas in research protocols that require special attention in order to capture research methods and achieve regulatory compliance
• Address the assumptions that can impede the review communication process
Wednesday, November 20: AER19

8:00-8:10 AM
Welcome from the Conference Co-Chairs

8:10-8:20 AM
PRIM&R Membership Update

8:20-8:30 AM
PRIM&R CIP® Update

8:30-9:30 AM
Keynote Address by Mary Elizabeth Williams, BA, Writer, Speaker, Consultant: Keeping the Humane in Human Subjects Trials

10:00-11:15 AM: Plenary Sessions

Panel VII: From Fortnite to Facebook—Data Security and Breaches, Downstream Harms, and the (Precarious) Role of IRBs
Moderator: Elizabeth A. Buchanan, University of Wisconsin-Stout
Panelists: James R. Fouls, University of Maryland, Baltimore County; Jacob Metcalf, Ethical Resolve, LLC/Data Society and Research Institute; Stephen J. Rosenfeld, Freeport Research Systems, LLC
By mid-April, 2019, we had already experienced upwards of 50 major data breaches in the US (those are the ones we know of). We’ve heard Facebook’s admission that it has not secured 600 million user passwords since 2012, and we’ve been alerted to the 540 million records, including account names, Facebook IDs, and user activity, that were left exposed. Even our favorite pastime, the amazingly popular game Fortnite, and its 200 million users’ accounts, were compromised and personal account information left vulnerable. And, the list of medical institutions or hospital systems breaches continues to grow daily. All too often, the end result is the same: “The sensitive data included names, patient ID numbers, dates of birth, addresses, phone numbers, health insurance information, payment information, driver’s licenses, and Social Security numbers,...” As data sources, from our social media to our medical records, become more co-mingled and accessible, what is the role of the IRB in this contested space of industry, government records, and the research enterprise? This panel will provide an overview of the current state of data risks and security as they pertain to this unregulated space, while delving into topics including the continuing loss of privacy and its impact on minimal risk.

Panel VIII: The Challenges of Studying Marijuana Use in the U.S.
Moderator: Albert J. Allen, Eli Lilly and Company
Panelists: Juliette Roddy, University of Michigan; Dearborn Benjamin C. Silverman, Partners HealthCare System, Inc.; Beth Watters, Partners HealthCare System, Inc.
This panel will discuss the need for and challenges of conducting scientific and behavioral research into the potential medical uses and risks of cannabis and its components. The importance of scientific scrutiny is growing as more states legalize recreational and medical marijuana. This plenary session will discuss the regulatory challenges of studying marijuana use in both the lab and community settings, the chasm between federal and state laws, and special considerations for IRB review of marijuana research.

Breakout Sessions Series E 11:30 AM-12:45 PM

E2: Strategies for IRB Member Education (Educating and Training Track)
Emily E. Anderson, Stritch School of Medicine, Loyola University Chicago; Toby L. Schonfeld, Prime Review Board
This session will offer innovative strategies and resources for developing and delivering IRB member education. Speakers will highlight educational methods and materials that are interactive and adaptable, particularly case studies, and that cover a range of topics including clinical and SBER. During this session, speakers and attendees will:
- Identify resources for IRB member education
- Develop strategies for increasing buy-in and engagement of IRB members in educational activities
- Assess the potential of different educational strategies for teaching about different topics
Note: this session was previously held on November 20, 10:00-11:15 AM.

E5: Applying US Human Research Protections Regulations and Embedded Cultural Values to Research Conducted in Different Cultures (Global Research Track)
Edward E. Bartlett, OHRP, Derek Englis, US Naval Human Research Protection Program; Karen M. Hansen, Fred Hutchinson Cancer Research Center; A. Roxana Lescano, United States Naval Medical Research Center; Bussara Sukapanichnant, Institute of Medical Sciences (AFRIMS)
The US human research protections regulations reflect the cultural values and worldviews of some groups in the US, and institutions that conduct research outside of the US may face challenges in applying the US regulations and departmental policies (e.g., 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:
- Review how 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 to the challenges that arise when applying US-based regulations for research involving subjects from different cultures

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E14: Impact of the Revised Common Rule on the Work of a QA/QI Program (QA/QI and Postapproval Monitoring Track)

Leslie M. Howes, Harvard T.H. Chan School of Public Health; Mary-Tara Roth, Boston University Medical School/Boston Medical Center

Institutions and universities have changed policies and procedures to be in compliance with the revised Common Rule. Some of the new provisions decrease the oversight and administrative burden of the IRB while simultaneously increasing the investigator's responsibility. QA/QI programs have long been instrumental in educating and auditing investigator sites to ensure compliance, and this is another opportunity. During this session, speakers and attendees will:

- Identify key changes in the revised Common Rule where QA/QI programs can collaborate with IRBs, or other components of the HRPP, to ensure compliance
- Discuss options for flexing a QA/QI program's auditing efforts as a result of the revised Common Rule
- Use case studies to highlight different QA/QI program monitoring models.

Note: Attendees are encouraged to bring their own case studies (including works in progress) for group discussion and further brainstorming.


Jeffrey M. Cohen, Clarkson University; Juliette Roddy, University of Michigan-Ann Arbor

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. In addition, institutions in states that have a high number of undocumented/authorized 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 session will use a case study approach to identify practical, ethical, and legal complexities in order to discuss and develop best practices for reviewing such research. Topics to be discussed include: informed consent, risk and risk/benefit assessment, and issues related to mandatory reporting, confidentiality, and privacy, as well as flexibility in providing protections. Before attending this session, attendees should have a basic foundation in human subjects research protections ethics and principles, including the criteria for approval. During this session, speakers and attendees will:

- Discuss and provide case examples of protocol applications proposing to enroll undocumented and authorized 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

E22: Implementation of a System to Promote Compliance With 45 CFR 46.116(h)—Posting Consent Forms

(HRPP Leadership and Institutional Officials Track)

Lauren Hartsough, OHRP; Matthew Ogrodnik, Boston Medical Center/Boston University Medical Campus

This session will explore the use of a monitoring system designed to comply with 45 CFR 46.116(h) of the revised Common Rule, which requires an unsigned copy of one IRB-approved consent form (ICF) that has been used in enrolling participants in a clinical trial conducted or supported by a Common Rule department/agency be posted on a publicly available federal website. This posting must occur after recruitment closes, and no later than 60 days after the last study visit. Although this specific timeframe poses challenges, it's possible to leverage a number of extant policies and resources to develop and implement an ICF Posting System to promote compliance with this requirement. During this session, speakers and attendees will:

- Review the requirements of 45 CFR 46.116(h)
- Discuss how existing institutional HRPP policies can provide a framework for implementation of a system designed to comply with 45 CFR 46.116(h) of the revised Common Rule
- Describe a plan for ongoing monitoring of compliance

12:45-2:30 PM: Closing General Session Luncheon—Designing Ethical Cars and Computing Clinicians: Research and the Ethics of Artificial Intelligence (AI) Programming

Moderator: Neal W. Dickert Jr., Emory University

Panelists: Marshall Chin, University of Chicago; Tamiko Eto, SRI International; David Magnus, Stanford University

Autonomous cars will need to be programmed to execute ethical decisions in life-threatening situations; if there's an accident, the car may go straight or swerve, with different results for the affected parties. Should cars be programmed to value all lives equally (e.g., should they sacrifice adults to save children?)? Similarly, when AI programs are designed to make recommendations to clinicians about medical diagnosis and treatment, those programs may reflect different ethical perspectives about what the "right" course of action should be (e.g., should programs favor the most efficient use of medical resources or should they favor the patient's ability to choose their desired treatment?). Will these AI programs serve to increase the gap between those who get better or worse healthcare, or can and should they be designed to reduce those differences? Many of these decisions are made implicitly at present, but development of AI algorithms forces us to make these decisions explicitly. This session will consider the policy and research issues raised by these two developing technologies. Someone-government, producers, or consumers-will be making decisions about which ethical perspectives will be built into autonomous cars and clinical assistance programs, and everyone will feel the consequences. If research is to inform any of these decisions, IRBs may be reviewing research proposals designed to compare different ways to implement autonomous cars and computing clinicians, almost certainly without the informed consent affected by the interventions (and, who are the subjects?)? Before you leave the conference in a car or make your next doctor's appointment, you might want to hear what these panelists say about what's coming down the road. Note: The formal presentation will begin at 1:15 PM.
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