



2017 SBER Conference Virtual Meeting – Sunday, November 5

8:00-8:15 AM

Welcome from the SBER17 Co-Chairs

Elizabeth A. Buchanan, PhD, Endowed Chair in Ethics; Director, Center for Applied Ethics, University of Wisconsin Stout
Julie F. Simpson, PhD, Director, Research Integrity Services, University of New Hampshire



8:15-9:00 AM

Keynote Address: Social Black Holes: The Ethics of Research on Illicit or Morally Compromising Market Actors

Kimberly Kay Hoang, PhD, Assistant Professor of Sociology, University of Chicago

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.



Didactic Sessions and Workshops Series A, 9:15-10:30 AM

A4

SBER IRBs Respond to the Revised Common Rule

Jennifer A. Graf, Julie Kaneshiro (OHRP resource person), Alison S. Orkin

IRBs need to begin implementing the changes to the Common Rule by January 2018. However, what does that mean for SBER IRB operations, policies, processes, or procedures? How will SBER IRBs effectively educate IRB members and researchers about these changes? How will they implement these changes? What will be the impact on staffing? During this session, speakers will:

- Provide an overview of the major changes in the revised Common Rule
- Identify key considerations when planning an institutional response to the revised Common Rule
- Share approaches to responding to the revised Common Rule on an institutional level, implementing changes, and educating IRB members and researchers



A8

Informed Consent in Mobile Technologies: Exploring Strategies for Participant Engagement

Megan Doerr, Sara Meeder

Big data and mobile technology studies are adding complexity to an already problematic process of making sure participants are fully informed before obtaining consent for study participation. This added complexity is due, in part, to participants' lack of familiarity with technology and the potential risks. Researchers in these fields are using previously tested consent process interventions in combination in an attempt to better engage and inform participants. This session will explore current innovations and results from these consent process interventions. Attendees should have an understanding of 45 CFR 46, informed consent for research, and basic consent processes before attending this session. During this session, speakers will:

- Provide a review of tested consent interventions and limitations of consent process research
- Outline what some large cohort studies have incorporated into their consent processes
- Discuss efficacy and feasibility of interventions for studies of differing scales



ICON KEY

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Pre-registration required	Recorded session	Sessions new for 2017	
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B1

Fundamental Issues in Qualitative Research

Julie F. Simpson, Julie Slayton



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 the issues this research paradigm can present during review. During this session, speakers 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

B2

SMART IRB for SBER: A National Roadmap to Single IRB Review

Daniel Alderson, Cynthia J. Monahan, Carol Pech



In this session, speakers will discuss the SMART IRB reliance platform and its utility for institutions engaged in and overseeing SBER. SMART IRB is funded by the National Center for Advancing Translational Sciences to serve as a roadmap for single IRB review while ensuring a high level of protection for research participants. SMART IRB's flexible master IRB reliance agreement, standard operating procedures, and complementary tools and resources enable participation by a wide range of institutions and support a broad spectrum of studies, including SBER. During this session, speakers will:

- Define the impacts of the single IRB policy on SBER/institutions
- Review the key elements of the SMART IRB master IRB reliance agreement, standard operating procedures, eligibility requirements, and joinder process
- Discuss how SMART IRB addresses specific needs and concerns related to the use of single IRB review for SBER

1:45-3:15 PM

Plenary Session: Research Ethics in Tech Companies: Similarities, Differences, and What IRBs Need to Know About Research Collaborations

Moderator: Elizabeth A. Buchanan

Panelists: Brenda L. Curtis, Lauri Kanerva, Kambria Tabor



A considerable amount of SBER takes place in industry settings, especially in fields like big data, computer-human interaction, internet based research, and others. Since industry researchers do not typically receive federal funding, they are not required to go through an IRB. This plenary session will discuss the ethics review processes at tech companies: What are the similarities between their reviews and IRB review? What are the differences? What are best practices for ethics review in environments where IRB regulations may not apply? In addition, this session will identify issues that industry research teams frequently face, including privacy, ethics, and legal considerations. Finally, speakers will discuss what universities should be aware of when researchers collaborate with industry partners in human subjects research, and the questions university IRBs should ask about these collaborative projects.

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C1

College Students and Research: Challenges and Issues for IRBs

Andrea R. McDowell, Julie F. Simpson



Basic

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

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

C5

IRB Guidelines and Data Sharing in the Social Sciences: Tensions and Strategies to Address Them

Lynette Hoelter, Diana Kapiszewski



This session will address the tension between two scholarly imperatives advanced by federal funding organizations, disciplinary associations, and publishers alike: the longstanding mandate to treat research participants with respect and to minimize the potential risks of participating in research, and the newer expectations of providing access to the results of that research including data generated through interaction with human participants. While IRBs tend to focus on the first concern, their decisions and practices also impact research transparency. This session will present the results of an empirical investigation of the language used in general guidelines and consent script templates that IRBs at 50 major research universities in the United States, discuss how the tension noted above might be resolved, and generate debate and discussion on several proposed models for revisions of consent language and general data management guidelines that individual IRBs might consider adopting. *Credit for this session proposal goes to Dessislava Pentcheva Kirilova, Qualitative Data Repository, who could not attend in person.* During this session, speakers will:

- Review the ongoing changes in expectations about data availability as they affect both scholarly communication and the evaluability of research
- Discuss the roles that trusted repositories can play in protecting research participants while facilitating data availability
- Explore models for consent language that assures the protection of human participants and allows data generated through interaction with them to be shared

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8:00-8:15 AM

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P. Pearl O'Rourke, MD, Director, Human Research Affairs, Partners HealthCare System, Inc.
 Laura Odwazny, JD, MA, Senior Attorney, Office of the General Counsel, DHHS



8:15-8:30 AM

Welcome from PRIM&R's Executive Director

Elisa A. Hurley, PhD



8:30-9:15 AM

Keynote Address

Amy Dockser Marcus, Staff Reporter, The Wall Street Journal



9:15-9:25 AM

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

Presented by Alexander M. Capron, LLB, University Professor; Scott H. Bice Chair in Healthcare Law, Policy and Ethics, University of Southern California



9:25-10:15 AM

Lifetime Achievement Award Plenary Address: Dealing with Controversies in Research Ethics: Four Decades of Experience

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



Concurrent Plenary Sessions, 10:45 AM-12:00 PM

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

Moderator: Michele Russell-Einhorn



Panelists: Melissa Abraham, John Baumann, Emily Chi Fogler

The past year has seen the promulgation of changes in Federal regulations, as well as new legislative and policy requirements, based on principles of protection of subjects, streamlining, and efficiency. These include the substantial changes to the Federal Regulations for the Protection of Human Subjects in Research (effective January 2018); the 21st Century Cures Act; and the NIH Policy on the Use of a Single IRB of Record for Multi-Site Research. Do these initiatives taken together provide both better protections for human subjects in research and streamline the review processes? What are the pros and cons of some of the flexibilities introduced by these changes and will implementation of these initiatives create a stronger platform for both the conduct of research and the safe and ethical participation of human subjects? This panel brings together three individuals who will discuss these changes in the context of: (1) social and behavioral research where there has been, for the first time, a significant elimination of types of research subject to IRB review raising both positive and negative questions regarding IRB oversight of research, human subject participation in research, and investigator responsibilities; (2) institutional responsibilities and the positive and negative implications of shifting research out of IRB oversight, as well as moving IRB review to a single IRB landscape for multi-site research; and (3) the concept of harmonization identified as a legislative mandate, but that may be difficult to implement.

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Panel II: Sovereignty in Research

Moderator: Sara C. Hull



Panelists: Anita Frederick, Terry J. M. Powell, Bobby Saunkeah

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

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



Moderator: Steve Joffe

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

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

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

A4

You'll Know It When You See It, or Will You?: Defining "Human Subjects Research" Under the Revised Common Rule (*Boundaries & Balance Track*) Warren Capell, Dean R. Gallant, Julia G. Gorey



Evaluating whether an investigator is conducting research involving human subjects has many important ramifications for both the institution and the investigator in terms of cost, time, and requirements for the activity. Since interpretation of key definitions in the regulations, including "systematic," "generalizable," and "human subjects" can be tricky, thorough consideration is needed to ensure appropriate application of the regulations. This session is designed to provide attendees with insights into those things that fall in that grey area, and it will explore slightly more advanced concepts. Attendees are expected to have knowledge of the current and revised Common Rule definitions for "human subject" and "research," as well as knowledge and/or experience in making distinctions between activities that do/do not fall within the ambit of human subjects research oversight. During this session, speakers and attendees will:

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

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A5

Facilitating Informed Consent in Light of the Revised Common Rule (*Educating & Training Track*)

Susie R. Hoffman, Angela Hvitved, Jerry Menikoff



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

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

A8

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

(*FDA Regulations Track*) Owen Faris, Karen Ulisney



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

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

A14

Considerations When Transitioning to the Revised Common Rule (*IRB Operations Advanced Track*)

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



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

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

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A21

IRB Review of Big Data Research: SACHRP Recommendations and Changes to the Common Rule

(Research Conducted in the Digital World Track) Jake Metcalf, Laura Odwazny, Ivor A. Pritchard, Stephen Rosenfeld



This session will explore the evolution of the field of big data health research, discuss how perceptions of recent trends in IRB review practices led to some of the changes to the Common Rule, and suggest strategies for IRBs to help reduce the risks to participant privacy and confidentiality. Growing concerns about delays, over-regulation, and outright road-blocks created by IRBs who sometimes see risks to privacy and confidentiality as unacceptable and unalterable, rather than focusing on mechanisms and controls to reduce risk to acceptable levels, has led to the introduction of a new exempt category in the revised Common Rule that would exclude a significant portion of big data health research from IRB review requirements. IRBs must form alliances with institutional IT security groups and develop appropriate expertise to facilitate safer research with these valuable data sets, or risk being excluded from the process entirely. This session will include case studies. Attendees should be experienced with IRB review of research involving different types and sources of health datasets, familiar with the regulatory criteria for levels of IRB review required, and have a basic understanding of data security concepts prior to attending this session. During this session, speakers will:

- Define and describe big data health research
- Discuss the real and perceived risks and benefits of big data research, and how they are sometimes consistent and inconsistent with current regulations
- Explore IRB review of big data research gone awry, including cases SACHRP was aware of and why they made the recommendations to change the Common Rule
- Review the changes to the Common Rule that will establish a new exemption category for many types of this research
- Share options for increasing protection of subject privacy and confidentiality by utilizing IT solutions and institutional data management policies, resources, and tools to better safeguard information in identifiable health data sets

Didactic Sessions and Workshops Series B, 3:30-4:45 PM

B12

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

(IRB 101 Track) Angela Hvitved



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

- Review the definitions of research, human subjects, and exemptions under the revised Common Rule
- Identify how the revised Common Rule differs from the pre-2018 rule
- Discuss the flexibilities provided by the revised Common Rule and use case examples to assist the audience with understanding and applying the revised Common Rule

B14

Tips and Tools for Implementing Single IRB Review *(IRB Operations Advanced Track)*

Carol Pech, Kimberly Summers



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

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

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B16

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



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

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

B18

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



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

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

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

B24

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

(SBER Track) Yvonne Lau



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

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

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P. Pearl O'Rourke, MD, Director, Human Research Affairs, Partners HealthCare System, Inc.
 Laura Odwazny, JD, MA, Senior Attorney, Office of the General Counsel, DHHS



8:15-8:30 AM

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

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



8:30-9:15 AM

Keynote Address

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



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

The Innovations in... series features poster authors from this year's Poster Presentation Program whose cutting-edge research and practices are advancing the field of human subjects protections. These sessions are loosely grouped around a specific theme.

Innovations A: Innovations in Emergency and Disaster Research Settings



Moderator: Emily E. Anderson

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

- **Pregnant Women and the Zika Virus Vaccine Research Agenda: Recommendations for Ethical Priorities and Pathways**
 Kristen Sullivan
- **FDA and IRB Approval of a Novel Prehospital Consent Process for Emergency Research**
 Michael Linke
- **Conducting Science in Disasters: Recommendations from the National Institutes of Health/National Institute of Environmental Health Sciences Working Group for Special IRB Considerations in the Review of Disaster Related Research**
 Joan Pakenham

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Innovations B: Innovations in IRB Function



Moderator: Cheryl Savini

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

- **Joint Ethics Review of a Clinical Trial in Sudan: Experiences and a Way Forward**
Serah Gitome
- **Clinical Coordination Center and Academic Central IRB: The Central IRB Liaison Team - The Tie That Binds Them**
Melissa Ricker
- **Improving IRB Application Success Through a Learning Management System**
Megan Williams

Innovations C: Innovations in Research With Overlooked Populations



Moderator: Warren Capell

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

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

Didactic Sessions and Workshops Series C, 11:00 AM-12:15 PM

C5

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



Colleen Gilrane, Joy Jurnack

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

- Outline how using approaches common in medical education can foster the medical staff's understanding of human subject 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

ICON KEY

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C12

Let's Review a Protocol: Identifying and Applying Federal Regulations to the Review of Research That Requires Expedited or Full Board Review (IRB 101 Track) Warren Cappel, Ada Sue Selwitz, Amy C. Waltz



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

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

This session will end at 1:15 PM.

C15

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

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



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

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

C19

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

Sean Cahill, John A. Guidry



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

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

This session will end at 1:15 PM.

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C21

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

Jeremy N. Block, Brenda Curtis

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

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

This session will end at 1:15 PM.



Concurrent Plenary Sessions, 1:30-2:45 PM

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

Moderator: Ruth Macklin

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

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



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

Moderator: Jeremy Sugarman

Panelists: Sean Cahill, Rimah Jaber

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



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



Moderator: Pearl O'Rourke

Panelists: Jamie Holloway, Sally Okun, Alicia Zhou

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

Didactic Sessions and Workshops Series D, 3:15-4:30 PM

D4

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



Mark Barnes, Julie Kaneshiro, Susan Stayn

The revised Common Rule introduced the option of broad consent and limited IRB review for secondary research, as well as two new exemptions for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens when broad consent is used. These options, and the new definitions of "human subject," offer new opportunities and challenges for the research enterprise and IRB professionals, but also raise many 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, exemptions 7 and 8 in the revised Common Rule, requirements for their use, restrictions to waiver and alteration of broad consent, and other problems that may be caused by these requirements
- Explore potential challenges in operationalizing the use of these options, including issues with tracking, IRB reviews, etc.
- Discuss how operational problems might or might not be overcome

D10

NIH-FDA Clinical Trial Protocol Template: Making Protocol Writing Easier for the Investigator, While Enhancing Quality (Hot Topics Track) Melissa Riddle, Melissa Robb, Carrie D. Wolinetz



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

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

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D12

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

Janet C. Donnelly, Ada Sue Selwitz, Irene E. Stith-Coleman



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

- Outline the basic federal requirements for IRB documentation, highlighting specific changes in the revised Common Rule
- Discuss the federal policies and requirements for maintenance of accurate, complete, and timely IRB records, including the joint OHRP/FDA guidance on minutes of IRB meetings
- Identify the components of a complete record of IRB meeting activities

D16

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

Kate Gallin Heffernan, Megan Kasimatis Singleton



This session will review challenging issues related to IRB and institutional liability under a single IRB model, with a specific focus on managing potential IRB noncompliance. Under both the NIH Policy on the Use of a Single IRB of Record for Multi-Site Research (effective September 2017) and the 2018 Common Rule single IRB mandate (effective January 20, 2020), research institutions will unavoidably be in the role of relying on external IRBs and, possibly, providing IRB review for external institutions. Furthermore, the 2018 Common Rule expands the application of the regulations to reviewing IRBs, with direct enforcement authority against the IRB (whether or not associated with a Federalwide Assurance-holding institution and/or internal to a site performing the research). What will this shift mean for institutional and IRB liability and how should institutions (whether relying or reviewing) approach risk mitigation in standard operating procedures and the terms of reliance agreements? What are the pitfalls institutions should consider before entering into reliance arrangements? This session will discuss how this shift creates a need for clearer policies related to the investigation of allegations of noncompliance when the IRB is potentially implicated (as opposed to more common investigator noncompliance standard operating procedures). It will also explore the challenge of defining clearly in reliance agreements the scope of each party's responsibility, particularly in academic collaborations, and the significance of certain agreement terms for relying institutions and reviewing IRBs. During this session, speakers will:

- Review responsibilities of the relying organization and reviewing IRB in addressing issues of noncompliance, with an emphasis on the division of responsibilities as outlined in current master IRB agreement models
- Discuss key considerations for institutions when addressing liability related to IRB reliance arrangements, including tools that may be used to guard against legal exposure
- Provide practical suggestions to assist institutions in considering models for addressing noncompliance, particularly IRB noncompliance, in the context of a single IRB review relationship
- Explore hypothetical cases to highlight noncompliance considerations for relying institutions and institutions providing single IRB services

D25

Understanding the Benign Behavioral Intervention Exemption (SBER Track)

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



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

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

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8:00-8:15 AM

Welcome from the Conference Co-Chairs

P. Pearl O'Rourke, MD, Director, Human Research Affairs, Partners HealthCare System, Inc.
 Laura Odwazny, JD, MA, Senior Attorney, Office of the General Counsel, DHHS



8:15-8:20 AM

PRIM&R Membership Update

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



8:20-8:25 AM

PRIM&R Certified IRB Professional® Credential Update

Presented by a member of the Council for CIP



8:30-9:15 AM

Keynote Address

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



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

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

Moderator: John J. Whyte

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

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



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

Moderator: David H. Strauss

Panelists: Neil Dickert, Rebecca S. Dresser, Jerry Menikoff

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



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



Moderator: Barbara E. Bierer

Panelists: Luann Van Campen, Karla Childers, Tatjana Poplazarova

Human subjects' protections regulations in the United States and IRB activities focus primarily on individual clinical trials conducted in the United States and/or for submission to the FDA. As major sponsors of clinical trials, biopharmaceutical companies are subject to the same human subjects research protections system as other organizations and institutions. What is less obvious outside of the biopharmaceutical industry is that, because of the global scale and complexities of modern drug development, as well as scientific advances, biopharmaceutical companies are increasingly utilizing corporate bioethics programs and committees to inform research decisions and planning that goes beyond the conduct of individual clinical trials. These industry bioethics activities draw upon fundamental bioethics principles, but seek to apply them in the context of biopharmaceutical industry research programs. This panel will include representatives involved in research bioethics activities at three different biopharmaceutical companies, and each panelist will briefly describe how research bioethics is organized within their company and provide a case example of how bioethics informs research decisions and planning. In addition, this panel will review the similarities and differences between bioethics in the biopharmaceutical industry versus in a NIH/academic setting. *Please note that Tatjana Poplazarova's presentation will not be included in the virtual meeting nor the conference proceedings.*

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

E5

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



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

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

E12

Writing and Updating Standard Operating Procedures (SOPs) in Light of the Revised Common Rule (101 Track) Jeffrey A. Cooper, Karen N. Hale, Lauren Hartsmith



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

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

E18

Secondary Research in the New Age: Thinking Through Your Options (Out-of-Body Experiences: Research Involving Tissue and Data Track) Karen Blackwell, Kate Gallin Heffernan, Julie Kaneshiro



This session will walk attendees through the regulatory options available for conducting secondary research with data or biospecimens. The goal is to help attendees understand the revised Common Rule and how it applies to secondary research. In this session, IRB professionals will learn how to apply the regulatory options in the revised Common Rule when reviewing secondary research, and investigators will learn how to think through the potential application when developing their proposals. During this session, speakers will:

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

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E22

The Regulatory Intersection of Research Misconduct and Human Subjects Protections

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

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

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



E24

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

(SBER Track) Leslie D. Cannold, Kelly O’Keefe, Katie B. Spearburg

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

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



1:00-2:15 PM

Closing General Session Luncheon: The “Nuremberg Code” After 70 Years: Foundational or Forgotten?

Moderator: Alexander M. Capron

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

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



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