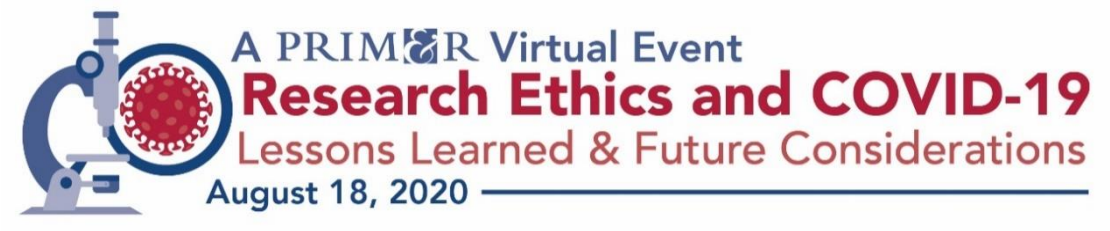

Morning Sessions: Lessons Learned

10:00-11:15 AM ET: Panel Presentation

Panel: The World of the COVID-19 Pandemic: The Big Picture

Moderator: *Holly Fernandez-Lynch, JD, MBE, University of Pennsylvania Perelman School of Medicine*
Panelists: *Christine Grady, MSN, PhD, NIH Clinical Center, NIH; Aisha Langford, MPH, PhD, NYU Langone Health; Susan E. Lederer, PhD, University of Wisconsin-Madison*
The COVID-19 pandemic has shaken the entire world, including the research enterprise. Many research studies have been delayed or suspended, while other research studies have been launched to address the public health crisis in various ways. Public health surveillance activities, observational studies, clinical trials, and compassionate use access have all been part of these efforts. Different countries have implemented various efforts to control the spread of COVID-19, with varying success. And, the pandemic has presented dire ethical challenges in the face of significant risks and resource shortages that have forced policymakers, medical care providers, and the affected public to make difficult decisions. This panel will discuss these issues in detail.

11:15-11:30 AM
Break

11:30 AM-12:30 PM ET: Breakout Series A

A1: Meaningful Informed Consent for Research During a Pandemic

Yvonne Lau, MBBS, MBHL, PHD, OHRP; Gianna McMillan, D. Bioethics, Loyola Marymount University; Michele Russell-Einhorn, JD, Advarra, Inc.
Pandemics create a sense of desperation. The public is likely to perceive any therapy, whether experimental or approved, to be an effective therapy for the pandemic disease. How can this strong therapeutic misconception, whether caused by desperation or claims about a cutting-edge therapy, be managed with research participants and their families? Speakers will discuss meaningful informed consent for research during a pandemic involving: a) therapies that were approved for other illnesses dissimilar to the pandemic disease; b) therapies approved for other similar diseases but not approved for the pandemic disease; and c) experimental therapies not approved for any indication.
Learning Objectives:

- Discuss prospective participants and what might motivate them to consider participation in research
- Share tips to help prospective participants navigate medical uncertainties when treatment for a novel infectious agent is being studied and how the uncertainties could affect them if they participate in the research
- Explore ways to adequately convey the implications of participating in a research study, including risks that may not yet be fully understood, to help prospective participants make informed decisions about participation

A2: Case Studies: Exploration of the Ethical Considerations for IRB Reviews Presented by Clinical Trials Developed in Response to COVID-19

R. Peter Iafrate, Pharm.D., University of Florida; Jody Power, MS, MBA, Duke University Medical Center

Clinical trials are being developed and rolled out in an extraordinarily fast pace as a response to the COVID-19 pandemic. In addition, the crisis itself creates many challenges to how best to conduct these research studies in an ethical manner that adequately takes into consideration the three fundamental ethical principles of autonomy, beneficence, and justice. This session will use examples of COVID-19 clinical trials to illustrate challenges that IRB reviewers were confronted with and some of the lessons learned in dealing with them.

Learning Objectives:

- Describe the challenges associated with developing and conducting clinical trials in response to COVID-19
- Review the ethical considerations that IRB reviewers have to confront when reviewing and approving these studies
- Share generalizable lessons that could be learned from the reviews of these studies

A3: Vaccine Research During a Global Pandemic: A Case Study of COVID-19

Karla Childers, BA, MS, Johnson & Johnson; Walter Straus, MD, MPH, Merck & Co., Inc.

The session is intended to provide the audience with insight into ongoing and emerging issues in human research subjects protections and in public responsibility in the development and use of vaccines to prevent COVID-19. It will do so through examples drawn from the experiences of two vaccine manufacturers currently involved in the development of a vaccine.

Learning Objectives:

- Discuss the challenges of conducting vaccine research during a global pandemic
- Consider the balance between individual rights and societal interests as they pertain to vaccine research
- Share examples that describe different approaches to managing these challenges

A4: FDA's Emergency Use Authorization (EUA) of Medical Products and Related Authorities

Elizabeth Sadove, JD, Office of Counter Terrorism and Emerging Threats, FDA

The EUA is a legal mechanism that allows FDA to help strengthen the nation's public health protections against chemical, biological, radiological, and nuclear (CBRN) threats by facilitating the availability and use of medical countermeasures needed during public health emergencies. Under section 564 of the Federal Food, Drug, and Cosmetic Act, the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.

Learning Objectives:

- Provide an overview of FDA's EUA authorities
- Discuss how EUA authorities are separate and distinct from other FDA authorities, including investigational applications (e.g., Investigational New Drug Applications, Investigational Device Exemptions, or expanded access authorities)
- Present the requirements for data collection as a condition of an EUA
- Describe uses of EUAs during the COVID-19 pandemic and historically (e.g., other infectious diseases, chemical threats, for the military)

A5: Biobanking During an Infectious Disease Pandemic

Mary Catherine Beach, MD, MPH, Johns Hopkins University; Carol Juliet Weil, JD, National Cancer Institute

This session will address research uses of specimens gathered during or prior to an infectious disease pandemic, including issues of consent, storage and oversight.

Learning Objectives:

- Review the processes for obtaining, storing and using biological specimens, including broad consent and waiver of consent
- Explore the ethical challenges with biobanking under a public health surveillance framework without traditional research consent or oversight

12:30-1:15 PM: Mid-Day Break

Afternoon Sessions: Future Considerations

12:30-2:00 PM: CIP Office Hours
Whether you are someone who is considering certification, or a current CIP who has questions about recertification, drop in to speak one-on-one with a PRIM&R staff member and a member of the CIP Council. We look forward to speaking with you during this time!

12:45-1:15 PM: iMedRIS Presents: Adaptation and Awareness—Engaging Latinx Community for Clinical Trials Recruitment and Programmatic Resilience Using a Risk-Based Approach When Engaging with Vulnerable Populations
Patricia Squitiero, iMedRIS, Inc.
This is not a product demo. A speaker from iMedRIS will use a scenario-based approach where a Latinx patient enrolled in a trial experienced an Adverse Event. This event impacted the patient, their family, and the local community. The researcher and their institution received a For Cause Audit and Subpoena. The COVID-19 pandemic has brought awareness that global collaborations and initiatives are more important than ever. As Compliance Experts, we all know that 100% risk-free is not realistic and the real goal is to minimize risk and document the process in preparation of an audit or subpoena.
Learning Objectives:

- Learn how to approach the Latinx community about diversity enrollment clinical trials (i.e., increasing awareness of microclimates within Latinx communities, and identifying fear factors and strategies for building trust)
- Develop programmatic resiliency using a strategic methodology and a risk-based approach
- Understand how to make technology work for you
- #ProgrammaticResilience

1:15-2:30 PM ET: Panel Presentation

Panel: The Research Enterprise and COVID-19: Looking Backward, Moving Forward
Moderator: *Barbara E. Bierer, MD, Multi-Regional Clinical Trials of Brigham and Women's Hospital and Harvard Medical School*
Panelists: *CAPT John J. Eckert, PhD, CIP, Office of the Chief Scientist, FDA/US Public Health Service; Megan Kasimatis Singleton, CIP, JD, MBE, Johns Hopkins University School of Medicine; Karen E. Moe, PhD, University of Washington; Mark S. Sulkowski, MD, Johns Hopkins Bayview Medical Center/Johns Hopkins School of Medicine*
The COVID-19 Pandemic has had a big impact on the research enterprise. Institutions designed and launched a wide array of activities in response to the pandemic, including public health surveillance activities, observational studies, cohort studies, clinical trials, vaccine trials, and compassionate use access activities. At the same time, many ongoing research studies investigating all manner of topics have been suspended, delayed, or modified due to the threat of COVID-19 itself, or to the collateral impact of public health efforts to contain the spread of the disease, which have impeded the ability of investigators to conduct research studies. Other studies have not been launched. Regulatory agencies have attempted to respond appropriately to the changing circumstances. How is the research enterprise getting back up to speed? Are there lessons to be learned about the research response to COVID-19 which could inform the response to the next pandemic, and about the management of the research portfolio when the next pandemic or other widespread emergency strikes? In particular, what regulatory actions, provisions, or inactions constituted significant obstacles to effective action, and how could those obstacles be addressed?

2:30-2:45 PM
Break

Afternoon Sessions: Future Considerations

2:45-3:45 PM ET: Breakout Series B

B1: Preparing Your HRPP for the Post-Pandemic Era

Linda M. Coleman, CCEP-I, CHC, CHRC, CIP, JD, Yale University; Allecia A. Harley, MPH, CRA, Lakeshore Strategy

As organizations consider the impact the COVID-19 pandemic will have on their research portfolios, organizational leaders will be faced with difficult decisions about how to reorganize the functions and responsibilities of their HRPPs in a post-pandemic era. Consideration must be given to the impact of changes in an HRPP's research portfolio, staffing and budgetary constraints, restructuring while still maintaining a program dedicated to a core mission of human research protections, remote work, and more.

Learning objectives:

- Review organizational strategies for reimagining HRPPs and IRB offices to accommodate the post-pandemic research environment
- Discuss solutions for reallocating responsibilities given potential resource constraints and changing research portfolios

B2: The Role of the IRB in the Re-Opening of Research

Judith Carrithers, JD, MPA, CIP, Advarra, Inc.; Julie Ozier, CIP, MHL, Vanderbilt University

This session will explore the role of the IRB in evaluating the safe re-opening of research and the considerations IRBs will need to make as research activities "ramp up." The session will focus on the types of permanent changes needed to re-open that will require prospective IRB review, how IRBs should assess deviations that occurred during research "pauses" and their impact on the study, how IRBs might assess whether risks to subjects are minimized as part of their review of research ramp up activities. In addition, the session will highlight considerations for IRBs serving as the single IRB when the ramp-up of research activities may differ across sites.

Learning objectives:

- Understand the role of the IRB in re-opening of research that may have been impacted by the COVID-19 pandemic
- Discuss strategies for IRB review of deviations attributable to the pandemic
- Identify the types of permanent changes to research that require prospective IRB approval to enable research to restart

B3: Nuts & Bolts Session: Effective IRB Operations in an Emergency

Elizabeth Cothran, CHPC, CHRC, CIP, MS, Baylor Scott & White Research Institute; Stephanie Henderson, CIP, Ochsner Clinic Foundation; Kenia F. Viamonte, MA, University of Miami

This session would highlight considerations for effective IRB operations in an emergency with lessons learned from IRBs who have faced these operational challenges to date. Considerations may include how to ensure time sensitive and efficient reviews, how to work with ancillary review committees on an accelerated timeline, how to structure and formulate Emergency Response IRB panels, how to secure consultants when new expertise is needed, how to communicate changes in IRB policy or requirements to the research community, etc. Attention would be given to the resources needed for IRBs to effectively operate and provide solutions for those with more advanced operational systems, as well as those who have fewer advanced resources (e.g., still operate primarily in a paper world). Solutions for larger and smaller organizations would be discussed.

Learning objectives:

- Share lessons learned for successful IRB operations during an emergency, including tools and resources created to help sustain IRB functions
- Review process adjustments implemented to adjust to the COVID-19 pandemic that helped support continued IRB operations
- Identify operational solutions for both larger and smaller organizations

Afternoon Sessions: Future Considerations

2:45-3:45 PM ET: Breakout Series B

B4: Vulnerability in the Era of COVID-19

Amy Ben-Arieh, JD, MPH, The Fenway Institute; Glenn Ellis, CHCE, MPH, Strategies for Well-Being, LLC/Harvard Medical School; Dushyantha T. Jayaweera, MD, MRCOG (UK), FACP, CIP, University of Miami

During the COVID-19 pandemic, the phrase "particularly vulnerable" has taken on a new and very specific meaning. COVID-19 has disproportionately affected people of color—in infection and death rates and access to treatment—and new categories of vulnerability have emerged (e.g., healthcare workers, elderly/infirm, those with underlying conditions, essential workers, prisoners, the economically disadvantaged, those who live communally, etc.). This session will review how the evolving conception of vulnerability impacts IRB review of research, and what HRPPs/IRBs should consider in protecting those most vulnerable.

Learning Objectives:

- Review the concept of vulnerability in the Common Rule and the way it shows up in the regulations
- Compare the traditional regulatory understanding regarding who requires additional protections with new conceptions, and discuss areas of overlap, new areas, and gaps in populations protected
- Discuss how to responsibly include or exclude vulnerable populations in research, and barriers to participation, access, etc.
- Share strategies for creating a culture of trust
- Consider lessons learned and what we can carry forward

B5: Lessons learned from the COVID-19 Crisis: A Discussion with IRB Chairs, Institutional Officials (IOs), and HRPP Leadership

Quincy J. Byrdsong, CCRP, CIP, EdD, Wellstar Health System; Brenda Klement, PhD, Morehouse School of Medicine; Rebecca Rousselle, CIP, Emory University

HRPP leadership and IOs were faced with challenging decisions about research prioritization and resource constraints. In this session, a panel of HRPP leaders, IRB chairs, and IOs will share lessons about their roles and about their HRPPs during one of the most pervasive global crises of our time, the COVID-19 pandemic. The panel will reflect on their experiences during the pandemic and provide strategies for managing the expectations of institutions and their research communities in difficult times.

Learning Objectives:

- Describe the challenges facing institutions and researchers during a global crisis
- Discuss areas specific to the COVID-19 crisis which allowed the roles of the HRPP leader, IRB Chair, and Institutional Official to be more clearly defined for the institution and impacted communities
- Identify gaps and opportunities in the ethical and regulatory structures of human research protections overall which were exposed during the COVID-19 crisis and strategies to mitigate these issues should a similar incident occur

3:45-4:00 PM

Break

3:45-5:00 PM: CIP Office Hours

Whether you are someone who is considering certification, or a current CIP who has questions about recertification, drop in to speak one-on-one with a PRIM&R staff member and a member of the CIP Council. We look forward to speaking with you during this time!

Afternoon Sessions: Future Considerations

4:00-5:00 PM ET: Community Conversations

PRIM&R's Community Conversations will provide an opportunity to discuss common challenges, obstacles, and solutions related to a specific topic. During these informal, moderated discussions, attendees will have the opportunity to share their experiences, challenges, and approaches to the topics listed, as well as ask questions of the moderator(s) and peers. These sessions are meant to provide interaction and dialogue with the community, share insight and knowledge, and continue discussions on topics presented earlier in the day. F***ormal presentations will not be provided during these sessions.*** These sessions will take place in Zoom where attendees can use their video/audio to participate. These sessions are open to all attendees of the event, but are typically a member benefit. If you're interested in signing up for membership or attending Community Conversations outside of this virtual event, learn more here.

Community Conversation: Single IRB Review of Multi-Site Review in COVID-19 Research CIP

Moderator: *Barbara E. Bierer, MD, Multi-Regional Clinical Trials of Brigham and Women's Hospital and Harvard Medical School; Nichelle Cobb, PhD, University of Wisconsin; Polly Goodman, BS, CIP, Harvard Catalyst and the Harvard Clinical and Translational Science Center/Harvard Medical School*

Community Conversation: Virtual/Remote Educational Models for IRB Training CIP

Moderators: *David Borasky, MPH, CIP, WCG; Erika Stevens, MA, Recherche Transformation Rapide*

Community Conversation: Remote Study Auditing & Monitoring Best Practices CIP

Moderators: *Stephanie deRijke, RN, MSN, Emory University; Piper Hawkins-Green, BA, MS, CIP, Northwestern University*

Community Conversation: Preparing Your HRPP for the Post-Pandemic Era (follow-up to session B1) CIP

Moderators: *Judith Birk, JD, University of Michigan; Brenda L. Ruotolo, BA, CIP, Columbia University*

Community Conversation: Power, Privilege, & Oppression: COVID's Illumination of Intersectional Vulnerabilities CIP

Moderator: *Glenn Ellis, CHCE, MPH, Strategies for Well-Being, LLC/Harvard Medical School; Tonya Ferraro, M.Ed., Boston Children's Hospital*