

**The University of Virginia**

**is pleased to announce the**

**Fourteenth Annual Virginia IRB Consortium Conference**

**HRPPs and Research: Adapting in an Ever-Changing World**

October 2, 2020 from 8:00 AM-2:00 PM

This year online (see Zoom information below)

***Agenda***

**8:00-8:25 Registration**

**8:25-8:30 Welcome**

**8:30-9:30 COVID-19 and Research**

*Faculty: Rebecca Hartley, Susie Hoffman, Adam Rubenstein, Kersten Wheeler*

*Moderator: Jean Gaare Eby*

Learning Objectives:

1. Describe processes institutions used to close down human subjects research (include criteria for phases/who made the decisions/how did you share the information)

o Differences between biomedical and SBS

o Differences between undergraduate and graduate students

1. Describe processes institutions used to reopen human subjects research (include criteria for phases/

who made the decisions/how did you share the information)

1. Describe restrictions (e.g. masks, social distancing, # of people in office etc.) that were in place for

each phase

4. Describe processes IRBs followed to address modifications that were COVID-related

**9:30-9:45 Break**

**9:45-10:45 Single IRB: Roles, Responsibilities and Best Practices for both Reviewing IRBs and Relying Institutions**

*Faculty: Leonard Caruana, Eileen Sembrowich, Erin Venegoni*

*Moderator: Jean Gaare Eby*

Learning Objectives:

1. Define the different Roles/Responsibilities
2. Describe the Reliance Process/SMART IRB
3. Identify key items for assisting Study Teams
4. Describe working with Reviewing IRBs
5. Describe the Importance of Communication/Communication Plan
6. Identify Best Practices

**10:45-11:00 Break**

**11:00-12:00 Collaboration between the IRB and COI Program: No Conflict!**

*Faculty: Barbara DeCausey, Cristen Jandreau, Monika Markowitz, Stacy West*

Learning Objectives:

1. Describe how the HRPP and COI Program independently and jointly manage conflicts of interest
2. Describe how the HRPP and COI Program communicate and how electronic systems facilitate this process
3. Identify strengths and areas for improvement given the university's approach, resources, etc.

**12:00-12:30 Networking lunch with smaller breakout groups**

**12:30-2:00 A Dad’s Perspective: Two Decades after Jesse Gelsinger’s Death**

*Faculty: Paul Gelsinger (with introductory remarks by Robin Fretwell Wilson)*

Learning Objectives:

1. To humanize the process of human subjects research from the perspective of families and participants
2. To demonstrate how to be able to reach ethical treatments and blameless prosperity in research, the need to help must outweigh the financial (and any other) interests
3. To demonstrate how to be able to achieveimproved protection for research participants, both informed consent and meaningful regulation of conflicts of interest are needed

**2:00 Adjourn**

***Zoom***

Register in advance for this meeting:

<https://virginia.zoom.us/meeting/register/tJUldeqspjgiE9c2382yYmI6OnZ5AOK00-zv>

After registering, you will receive a confirmation email containing information about joining the meeting.

***Faculty***

Leonard Caruana, CIM, CIP

Leonard Caruana is Multi-Site Research Administrator, Office of Research Subject Protection at Roswell Park Comprehensive Cancer Center. Leonard is certified as an IRB Manager (CIM) and also as a Certified IRB Professional (CIP). In addition, he is currently an active member of PRIM&R – Public Responsibility in Medicine and Research. His primary role at Roswell Park is responsibility for the coordination, facilitation and monitoring of the Roswell Park Single Institutional Review Board (sIRB) process for multi-site clinical/non clinical studies within the guidelines of the Code of Federal Regulations and New York State Law.

Barbara DeCausey, MPH, MBA

Barbara DeCausey is the Director of the Virginia Tech Human Research Protection Program. She has more than 10 years of experience in research ethics and public health. Prior to joining Virginia Tech last fall she was at the Centers for Disease Control and Prevention (CDC).  At the CDC she served as the deputy chief for the Clinical Research Branch, which manages the international Tuberculosis Trials Consortium, and prior to that she was the director for CDC’s Human Research Protection Office.

Jean Gaare Eby, MEd, MS, ScD

Jean Gaare Eby is the human subjects research education director in the Office of the Vice-President for Research, with a faculty appointment in the Department of Public Health Sciences, at the University of Virginia. In this role, she oversees education and training in human research protections across the University, serves as the education lead for the University Human Research Protection Program, and is a member of the University Conflict of Interest Committee. She holds a doctorate in epidemiology from the Harvard School of Public Health and has many years of experience teaching epidemiology and research methodology to undergraduate, graduate, and medical students. The focus of her work is education and training that integrate research ethics, regulations, and methodology.

Paul Gelsinger

Paul Gelsinger is Jesse Gelsinger’s father. Jesse Gelsinger became the first reported person to die in a human gene-therapy trial on September 17, 1999. Mr. Gelsinger has since been involved in raising awareness about the mistakes made in his son’s trial and those which ultimately lead to his death. He is an advocate of improved protection for human research subjects.

Rebecca Hartley, JD, MA

Rebecca Hartley leads Mason’s Office of Research Integrity and Assurance. She is Mason’s institutional official for human and animal subjects research as well as its empowered official for export controls, and she also serves as Mason’s research integrity officer. An attorney by training, she has spent nearly three decades supporting researchers in academia and the private sector: providing regulatory compliance guidance on issues such as biodefense and select agents, export controls, conflicts of interest, responsible conduct of research, insider threat and research security, and human and animal subjects research. She graduated with her A.B. from Dartmouth College, and with an M.A. (Foreign Affairs) and J.D. degrees from the University of Virginia.

Susie R. Hoffman, RN, BSN, CIP

Susie Hoffman is the director of the IRB for Health Sciences Research at the University of Virginia (UVA), a position she has held since 1999. A nurse by background, she has worked in the research field since 1987 as both a research coordinator and as the director of clinical trials for a radiopharmaceutical company. She served as president of the former Applied Research Ethics National Association (ARENA) Council. Ms. Hoffman has also been very involved with Public Responsibility in Medicine & Research (PRIM&R) having served as Co-Chair of the national conference planning committee in 2005, chair of Membership Committee 2005-2009, Co-Chair of the Workshop/Didactic Sub-Committee for the Advancing Research Ethics Conference from 2012-1015 and a faculty member for many years. Susie initiated and serves on the planning committee for the annual Virginia IRB Consortium conference held since 2007.

Cristen Jandreau, PhD

Cristen Jandreau is the Director of the Research Conflict of Interest (RCOI) Program in the Office of the Vice President for Research and Innovation’s division of Scholarly Integrity and Research Compliance (SIRC) at Virginia Tech. Her work primarily focuses on assessing and implementing management strategies for Investigator financial conflicts of interest in research in order to promote research objectivity and administering the university-wide Disclosure and Management System. Prior to joining Virginia Tech, Cristen served as the Assistant Director of the Office of Research Integrity and Ethics at VCU and in several previous roles as a senior scientist. Cristen received her B.S. in Biology from James Madison University and her Ph.D. in Biomedical and Veterinary Sciences from Virginia Tech, with an emphasis on molecular and epigenetic contributors to autoimmunity.

Monika Markowitz, PhD

Monika Markowitz is the Director of the Office of Research Integrity and Ethics at VCU. She directs the Conflict of Interest (COI) in Research Program and chairs the COI Committee. Monika is a research ethics consultant, serves as the VCU Research Integrity Officer, and directs RCR education at VCU. Monika is a former member of the AAMC Forum on Conflict of Interest in Academe Steering Committee and is currently co-chairing the SMART IRB Conflict of Interest Working Group. She is an AAHRPP site visitor and a member of the Council on Accreditation.

Adam J. Rubenstein, PhD

Dr. Rubenstein is the Assistant Vice President for Research Compliance at Old Dominion University. In this role, he is responsible for oversight of regulatory compliance related to human subjects, animal subjects, and biosafety-related research. He also oversees programs for review of export control and COI compliance. Dr. Rubenstein holds a doctoral degree in Developmental Psychology from the University of Texas at Austin and has a research background focusing on infant development.

Eileen Sembrowich, BS, BA, CCRP, CIP

Eileen Sembrowich is the Associate Director of the IRB for Health Sciences Research at the University of Virginia. Eileen has been working in Clinical Research since 1997: first as a study coordinator for oncology research in San Antonio, and for the last 15 years, as an IRB administrator at UVA. She received her BSc and BA from the University of Calgary, Canada.

Erin Venegoni, JD, MPH, CIP

Erin Venegoni is the Reliance Manger in the Human Research Protection Office at Hennepin Healthcare and previously held a similar role at the University of Minnesota. Prior to working in human research protections, Erin worked with managed care organizations in regulatory compliance and practiced as an attorney.  The theme of her professional career suggests a deep fondness for reading the Federal Register. She holds a Juris Doctor from the University of St. Thomas School of Law and a Master’s of Public Health from the University of Minnesota. She received her CIP credential in 2018.

Stacy West, MS, CASR, CIP

Stacey West is the IRB Reliance Agreement specialist at VCU, and works to facilitate the single IRB review process both as a relying and a reviewing site. Prior to this, she served as a Coordinator for several large, multi-site social-behavioral research studies, and continues to support large collaborative research initiatives in her current role.

Kersten Wheeler, MS

Kersten Wheeler isDeputy Department Head and Human Research Protections Director in the Clinical Investigation Department at Naval Medical Center Portsmouth (NMCP).She directs the regulatory administration of human subjects research and laboratory animal studies in support of graduate medical education programs and operational readiness throughout the17 supported commands of Naval Medical Forces Atlantic. In managing the day-to-day operations of NMCP’s four research committees (2 IRBs, IACUC, and Scientific Review Committee), Ms. Wheeler ensures regulatory compliance is maintained, develops policies and procedures, and negotiates research agreements to protect Navy assets.NMCP’s protocol portfolio spans a wide variety of topics; including, sponsored clinical trials, suicide prevention, continuing medical education, and Combat Casualty Care training. Ms. Wheeler is passionate about NMCP’s translational research initiatives that improve patient care and impact outcomes on the battlefield, affecting the lives of both active duty members and military beneficiaries.

Robin Fretwell Wilson, JD

Professor Robin Fretwell Wilson is the Director of the Institute of Government and Public Affairs for the University of Illinois System, of which the University of Illinois Urbana-Champaign is a part, as well as the Mildred Van Voorhis Jones Chair in Law at the University of Illinois College of Law. She has written extensively on human subjects research and conflicts of interests in particular, especially in the Gelsinger trial.

***Disclosures***

**Speakers:** Leonard Caruana, CIM, CIP, Barbara DeCausey, MPH, MBA, Jean Gaare Eby, MEd, MS, ScD, Paul Gelsinger, Rebecca Hartley, JD, MA, Susie Hoffman, RN, BSN, CIP, Cristen Jandreau, PhD, Monika Markowitz, PhD, Adam Rubenstein, PhD, Eileen Sembrowich, BS, BA, CCRP, CIP, Erin Venegoni, JD, MPH, CIP, Stacy West, MS, CASR, CIP, Kersten Wheeler, MS, and Robin Fretwell Wilson, JD report having no personal or professional relationships with commercial entities producing healthcare good and/or services.

**Planning Committee:** Bronwyn Blackwood, MPH, Elizabeth Dayag, MLS, CIP, CCRP, Elizabeth Dieffenbach, MS, Jean Gaare Eby, MEd, MS, ScD (committee lead), Danielle Faulkner, MBA, CIP, Susie Hoffman, RN, BSN, CIP, Monika Markowitz, PhD, Adam Rubenstein, PhD, and Carrie Tillman, MA report having no personal or professional relationships with commercial entities producing healthcare goods and/or services.

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***A special thank you***

A special thank you to Robin Fretwell Wilson and the Epstein Health Law and Policy Program at the University of Illinois College of Law.