The University of Virginia
Office of the Vice-President for Research
Human Research Protection Program and
integrated Translational Health Research Institute of Virginia
are pleased to announce the

Twelfth Annual Virginia IRB Consortium Conference

Science, Ethics, and Regulations of Research Involving Big Data

Date and time  
Friday, October 19, 2018  
8:00 am – 3:00 pm

Location  
Pinn Hall  
University of Virginia  
Charlottesville, Virginia

Agenda

8:00-8:25 Registration

8:25-8:30 Welcome

8:30-9:30 Ethical and Regulatory Challenges to Conducting Precision Medicine Research  
Faculty: Carol Weil  
Learning Objectives:
(1) Attendees will appreciate the ethical issues that arise when precision medicine tools such as genome sequencing are employed in clinical research, including returning individual research results and avoiding therapeutic misconception
(2) Attendees will understand how federal regulations pertaining to clinical laboratories (CLIA) and data privacy (HIPAA) impact the disclosure of return of research results to patients
(3) Attendees will learn how gene editing, and particularly the technology of CRISPR, raise unique issues for community engagement

9:30-10:30 Real World Evidence (RWE) Challenges from the Drug Developer/Regulatory View  
Faculty: Robert Meyer  
Learning Objectives:  
1) Learn how FDA's law and regulations inform their hierarchy of evidence
2) Understand examples of where RWE findings have undermined public health
3) Understand restrictions on FDA and Industry in studying what matters to patients
10:30-10:45 Break

10:45-12:00 Big Data in Research
   Faculty: David Peloquin
   Learning Objectives:
   This session will examine the use of big data in research studies in a variety of contexts.
   The presentation will focus on three key topical areas:
   a. Use of mobile applications in clinical research
   b. Use of clinical data registries for research and quality improvement activities
   c. Issues arising in the cross-border transfer of data for research

12:00-1:00 Lunch

1:00-2:00 PM – Breakout Session #1

   · A conversation on building and using large health data sets
     Faculty: Philipp Bourne, Donald Brown, James Harrison
     Learning Objectives:
     1. Understand the types of data required to support new “Big Data” research methods including
        data mining and machine learning
     2. Describe the special challenges in building and securing large, multi-source data sets for
        research
     3. Explain the significance and application of FAIR Data Principles (Findable, Accessible,
        Interoperable, and Reusable) in biomedical research

   · The New Kid on the Block: Benign Behavioral Interventions Exemption
     Faculty: David Borasky, Michele Russell-Einhorn
     Learning Objectives:
     This session will focus on the nuts and bolts of the new exemption that relates to Benign Behavioral
     Interventions Exemption
     1. Review the criteria for the new exemption
     2. Review the specific limiting criteria
     3. Apply the new exemption to 3 case situations

2:00-3:00 PM – Breakout Session #2

   · Reliance Agreements: Operational Strategies for Staffing, Verifying IRB quality and
     Comprehensive Templates
     Faculty: Lauri Carlile
     Learning Objectives:
     This session will focus on operationalizing reliance agreements into an existing HRPP
     At the end of the session participants will:
     1. Be familiar with applicable AAHRPP standards
     2. Have learned ways to successfully integrate the reliance process into the HRPP
     3. Have knowledge of available options and templates

   · A New Type of IRB Review: Limited IRB Review of Exempt Data; IRB Review of Big Data
     Faculty: David Borasky, Michele Russell-Einhorn
     Learning Objectives:
     This session will focus on the new review type called “Limited IRB Review” as well as issues relating to
     IRB Review of Big Data Research
     1. Review the times when Limited IRB Review is to be utilized
     2. Review the Research involving Big Data and applicable IRB exemptions and Review types
Faculty

David Borasky, MPH, CIP
David Borasky is Vice President for IRB Compliance with the WIRB-Copernicus Group (WCG). In this role he is responsible for issues related to quality and compliance across the six IRBs in the WCG family. David has over 20 years of experience managing IRBs, and is a frequent speaker at conferences such as AAHRPP and PRIM&R. David also serves as co-chair of the Subpart A Subcommittee of the Department of Health and Human Services Secretary’s Advisory Committee for Human Research Protections.

Philip E. Bourne, PhD
Dr. Bourne is the Stephenson Chair of Data Science at UVA, Director of the UVA Data Science Institute, and Professor in the Department of Biomedical Engineering. From 2014-2017, he was the Associate Director for Data Science at the National Institutes of Health. In this role he led the Big Data to Knowledge Program, coordinating access to and analyzing biomedical research data from across the globe and making it available to scientists and researchers. While there, he was also responsible for governance and strategic planning activities for data and knowledge management.

Donald E. Brown, PhD
Dr. Brown is the William Stansfield Calcott Professor of Systems and Information Engineering at UVA. He is also the founding director of the UVA Data Science Institute and the co-director of the Integrated Translational Health Research Institute of Virginia. He is a fellow of the IEEE. His research is in predictive modeling, data fusion, machine learning, and simulation optimization with applications to safety, security and logistics.

Lauri Carlile, MS, CIP
Lauri Carlile has over 20 years of experience in preclinical and clinical research. Before joining Advarra, Lauri directed Chesapeake IRB’s operations including regulatory compliance, client services, IRB Management, training and AAHRPP accreditation processes. Previously, Lauri served in various quality and compliance roles supporting the Human Research Protection Program as well as an administrative chair for Harvard/Partners HealthCare System in Boston. A frequent speaker on human research protections, Lauri is a certified IRB professional (CIP), and a member of several industry organizations including Public Responsibility in Medicine & Research (PRIM&R), Regulatory Affairs Professionals Society (RAPS) and Association of Clinical Research Professionals (ACRP). Lauri holds a bachelor’s degree in biological sciences from the University of Maryland, Baltimore County (UMBC) and a master’s degree in clinical investigation from MGH Institute of Health Professions where she received the first award for academic excellence in clinical investigation.

James H. Harrison, Jr., MD, PhD
Dr. Harrison is Associate Professor in the UVA Department of Pathology, Director of Clinical Laboratory Informatics in the UVA Health System, and Associate Director for Health Data in the UVA Data Sciences Institute. He has participated in informatics support for clinical research at UVA for over 13 years and also participates in the development of international data standards for clinical practice and research as a member of the HL7 and IHE standards organizations and the College of American Pathologists.

Robert Meyer, MD
As a Principal of Greenleaf’s Drug and Biologics group, Dr. Robert Meyer contributes a rich knowledge, gained through 25 years of regulatory and academic leadership, of the important issues facing the pharmaceutical sector today. Bob was previously the Director of the Virginia Center for Translational and Regulatory Sciences (VCTRS) at the University of Virginia (UVA) School of Medicine and will continue at UVA as an Associate Professor of Public Health Sciences while at Greenleaf. Before joining UVA in 2013, Bob headed worldwide regulatory and pharmacovigilance activities at Merck Research Laboratories (MRL), most recently as Vice President, Global Regulatory Strategy, Policy and Safety. Prior to his academic and corporate experience, Dr. Meyer had a notable career at the U.S. Food and Drug Administration (FDA), including five years (2002-2007) as the Director of the Office of Drug Evaluation II within the Center for Drug Evaluation and Research (CDER), with oversight of pulmonary and allergy, metabolic and endocrine, analgesic and anesthetic, and rheumatologic drug products. Bob received his medical degree from the University of Connecticut School of Medicine and completed his residency with the University of Connecticut School of Medicine at the VA Medical Center in Newington, CT, serving as Chief Medical Resident from 1987-88. At the Oregon Health Sciences University in Portland
(1991-94), he was an academic pulmonologist and critical care specialist, helping to establish the medical service for the Lung/Heart-Lung Transplantation program. He has also served as a volunteer staff physician in pulmonary and critical care medicine at the National Naval Medical Center in Bethesda, MD.

David Peloquin, JD
David Peloquin is an attorney at Ropes & Gray LLP where he practices in the firm’s health care group. He focuses his practice on advising academic medical centers, life sciences companies, and information technology companies on issues related to human subjects and animal research, Medicare/Medicaid and other third-party payor reimbursement, and data privacy. He frequently writes and speaks on topics related to each of these areas. He also serves as a community member of the Institutional Review Board at Partners Healthcare in Boston. David received his law degree from the Yale Law School and clerked for the Honorable Diana E. Murphy of the United States Court of Appeals for the Eighth Circuit. Before attending law school, David worked as a project manager for Epic Systems, a leading provider of electronic medical records.

Michele Russell-Einhorn, JD
Michele Russell-Einhorn is the Chief Compliance Officer and Institutional Official for Advarra, an independent Institutional Review Board Company. Michele’s academic, government and industry expertise stems from her work at the Dana-Farber Cancer Institute, the US Department of Health and Human Services, as well as the J Craig Venter Institute. She is the co-chair of the SACHRP subpart A subcommittee, co-founder of the NCCN IRB Directors Group among participation in other national initiatives focused on the protection of human subjects in research.

Carol Weil, JD
Carol Juliet Weil, JD, is a program director for ethical and regulatory affairs at the National Cancer Institute (NCI) and an expert in research protections pertaining to human biological samples and genomic and clinical data. In her work at the NCI, Ms. Weil navigates the ethical, legal, and social implications of cancer research including policies on consent, data sharing, biobank governance, community engagement, and disclosure of research results and incidental findings. She has helped develop embedded bioethics protocols in some of NCI’s precision medicine oncology trials, including the COMET sub-study in NCI MATCH. In addition, Ms. Weil has served as a non-scientist member of the NCI institutional review board since 2012.

Disclosures

Speakers: David Borasaky, MPH, CIP, Philipp Bourne, PhD, Donald Brown, PhD, Lauri Carlile, MS, CIP, David Peloquin, JD, Michele Russell-Einhorn, JD, and Carol Weil, JD do not have any personal or professional financial relationships with commercial entities producing healthcare goods and/or services. James Harrison, MD, PhD reports stock/ownership in Apple, Inc. (Clinical/Research Area: Personal Health Records). Robert Meyer, MD reports stock/ownership in Pfizer, Johnson & Johnson, Cardiome Pharma LTD, and GE (Common Stock and Imaging) and is a consultant for Greenleaf Health, LLC (Clinical/Research Area: Industrial and Academic Drug Development).

Planning Committee: Robert Banks, Bronwyn Blackwood, MPH, CIP, Elizabeth Dayag, CIP, CCRP, Elizabeth Dieffenbach, MS, Jean Eby, MS, MEd, ScD, Carley Emerson, MS, CIP, CCRP, Susie Hoffman, RN, BSN, CIP, Adam Rubenstein, PhD, Carolyn Strong, MRA, CRA, CIM, and Carrie Tillman, MA, CRA do not have any personal or professional financial relationships with commercial entities producing healthcare goods and/or services. Mark Leep, MA, JD, MBA, CIP reports that his spouse is employed by Takeda Pharmaceuticals.

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The University of Virginia School of Medicine is accredited by the ACCME to provide continuing medical education for physicians. The University of Virginia School of Medicine designates this live activity for a maximum of 5.25 AMA PRA Category 1 Credit(s)TM. Physicians should claim only the credit commensurate with the extent of their participation in the activity. The University of Virginia School of Medicine awards 5.25 hours of participation (equivalent to AMA PRA Category 1 Credit(s)TM) to each non-physician participant who successfully completes this educational activity. The University of Virginia School of Medicine maintains a record of participation for six (6) years.

Conference Support

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