



**Virginia Tech and The University of Virginia
are pleased to announce the**

16th Annual Virginia IRB Consortium Conference:

Ethical Oversight of Research: No Tricks, Only Treats

Date: Friday, October 28, 2022

Time: 8:00 am - 3:15 pm

Via Zoom

Register in advance for this meeting:

<https://virginiatech.zoom.us/meeting/register/tZwpfuirrDouHNI4EkurutSKXOzPI9co9njw>

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

Continuing Education provided by the University of Virginia School of Medicine and School of Nursing.

Part of the Research Ethics Series

Course Description: This series will address research rigor and integrity and the responsible conduct of research.

Target Audience: Physicians, Nurses, Clinical Research Professionals

Desired Outcomes:

At the conclusion of this activity, participants should be able to:

1. Describe how to conduct research responsibly
2. Explain how to protect human participants in research

Agenda

8:00 - 8:25 **Zoom Log On**

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

Randy Heflin: Senior Associate Vice President, Research and Innovation, Virginia Tech

8:30 - 9:30 **Borrowing Data without Permission: A Case Study Using an Ethical Reasoning Model, DEPICT**

Speakers: Mario Davidson and Jennifer Van Mullekom



- 9:30 - 10:30** **Statistical Issues in Responsible Conduct of Research**
Speaker: Sarah Ratcliffe
- 10:30 - 10:45** **Break**
- 10:45 - 11:45** **Ethical Principles for the All Data Revolution**
Speaker: Stephanie Shipp
- 11:45 - 12:15** **Lunch Break**
- 12:15 - 1:00** **Open Conversation on HRPP/IRB Issues**
Breakouts:
 -Navigating Single IRB
 -Informal conversations about post approval monitoring
 -Remote consent and electronic consent
 -Old consent, new requirements, and the future use of data
- 1:00 - 2:00** **Research Ethics and Big Data**
Speaker: Jarrett Zigon
- 2:00 - 3:00** **The Untold Story of Henrietta Lacks: A discussion with the author Ron Lacks who is the oldest grandson of Henrietta Lacks**
Speaker: Ron Lacks
- 3:00 - 3:15** **Closing Remarks**
Barbara DeCasey: Director, Human Research Protection Program, Virginia Tech

Speakers

Mario Davidson

Dr. Mario Davidson's career at Vanderbilt has been as the lead biostatistician and collaborator for medical education faculty and medical students. He has served as the director for an introductory biostatistics course for medical students and as the director and curriculum designer of one of the biostatistics department's staple courses, Statistical Collaboration in Health Sciences. Students receive skills in career development, ethics, communication, professionalism, presenting, writing and reviewing grantsmanship, teaching, and teamwork. He was the catalyst for a departmental group called Ethical Responsibilities Regarding Race in Research that seeks to understand how statisticians should use race (if at all) in research. Dr. Davidson's primary research is on statistical collaboration.

Ron Lacks

Ron L. Lacks is the Executor of the Henrietta Lacks Estate. He is the author of the memoir book *Henrietta Lacks: The Untold Story*. His late grandmother, Henrietta Lacks, was an African American woman whose cancer cells are the source of the HeLa cell line, the first known immortalized human cell line referred to



as the most important in the history of medical research. Her cells advanced cancer and scientific research and led to the development of vaccines including Polio, HPV, Covid-19 and countless more. Henrietta's story has been the subject of books and movies that has included some inaccurate facts about the persona of who his grandmother was. Ron was motivated to write his book to give an accurate account of who she was as a person. Ron became the sole executor of the Henrietta Lacks Estate in 2021 and embarked on the mission of sharing, restoring, and preserving the true legacy of his grandmother and the Lacks family, which is the subject of his book. He grew up in Baltimore, Maryland where he graduated from Northern High School before joining and serving in the United States Army. He is married to Hope Lacks and together they have raised four daughters. In revealing the untold story, Ron corrects the profile of his grandmother from being portrayed inaccurately, as a stereotype of a poor, illiterate, Black woman. Ron wants the world to see her in her true image as a smart, beautiful, Black woman who was a business owner and had the wealth of love and family.

Sarah Ratcliffe

Dr. Sarah J. Ratcliffe is Professor and Director of the Division of Biostatistics, and Senior Vice Chair for Research in the Department of Public Health Sciences at the University of Virginia School of Medicine. She is Director of the Research Methods core of the iTHRIV (CTSA), Interim Director of the UVA Comprehensive Cancer Center Biostatistics Shared Resource, PI of the U24 data coordinating center grant for the multi-site DIVA trial, and MPI of an R01 developing prediction algorithms in transplant patients. Her background is in statistics and computing, with specific training and expertise in the analysis of correlated data, especially longitudinal, time series and functional data, predictive modeling, missing data, as well as expertise in data and analysis ethics.

Stephanie Shipp

Dr. Stephanie Shipp is interim director and professor in the Social and Decision Analytics Division of the Biocomplexity Institute at the University of Virginia. Dr. Shipp's expertise is in economics, evaluation, and policy analysis. She leads, creates, and implements research programs to build ethics and data science capacity with cities and counties of all sizes, the official statistics community, and local, state, and federal agencies.

Jennifer Van Mullekom

After a 20-year career in industry, Dr. Jennifer Van Mullekom joined Virginia Tech in Fall 2016 as the Director of the Statistical Applications and Innovations Group (SAIG) and an Associate Professor of Statistical Practice. In addition to directing SAIG, she teaches a design of experiments class as well as a collaboration skills course to graduate students. Formerly, she was a Senior Consulting Statistician and Certified Six Sigma Master Black Belt in DuPont's Applied Statistics Group. supporting the DuPont Protection Technologies business. At DuPont, she provided statistical leadership to the Tyvek® Medical Packaging Transition Project in the areas of product development, commercialization, and regulatory. Jen is active in professional societies holding leadership roles in the American Statistical Association and the American Society for Quality. She holds three US Patents and has also worked at Lubrizol and Capital One. She holds an MS and PhD in Statistics from Virginia Tech and a BS in Mathematics and Mathematics Education from Concord University.



Jarret Zigon

Dr. Jarrett Zigon is the Porterfield Chair of Bioethics and Professor of Anthropology at the University of Virginia. He is the former founding director of the Center for Data Ethics and Justice at the University of Virginia. He has published five books on topics such as ethics, addiction, rehabilitation, the drug war, political activity, and social and political change.

Accreditation & Designation Statements



In support of improving patient care, the University of Virginia School of Medicine and School of Nursing is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team.

The University of Virginia School of Medicine and School of Nursing designates this live activity for a maximum of **5 AMA PRA Category 1 Credits™**. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

The University of Virginia School of Medicine and School of Nursing awards **5 contact hours** for nurses who participate in this educational activity and complete the post activity evaluation.

The University of Virginia School of Medicine and School of Nursing awards **5 hours of participation** (consistent with the designated number of *AMA PRA Category 1 Credit(s)™* or ANCC contact hours) to a participant who successfully completes this educational activity.

The University of Virginia School of Medicine and School of Nursing maintains a record of participation for six (6) years.

Disclosures:

The following speakers and planning committee members have no personal or professional financial relationships with a commercial entity producing healthcare goods and/or services:

Speakers: Mario Davidson, PhD; Ron Lacks; Sarah Ratcliffe, PhD; Stephanie Shipp, PhD; Jarrett Zigon, PhD.

Planning Committee: Ruth Bernheim, JD, MPH; Bronwyn Blackwood, MPH; Sandy Borucki, RN, CIP; Elizabeth Dayag, MLS, CIP; Barbara DeCausey, MPH, MBA, CIP; Lacey Doyle, MA Ed; Jean Gaare Eby, ScD, MS, MEd; Andrea Nash, MS, CIP; Andrea Ruhsam; Brynn Watson, BS.

The following speakers and planning committee members have personal or professional financial relationships with a commercial entity producing healthcare goods and/or services:

Speaker: Jennifer Van Mullekom, PhD with Best Medical, DuPont, and Vision Services Plan.

Disclosure of faculty financial affiliations

The University of Virginia School of Medicine and School of Nursing as a Joint Accreditation Provider adhere to the ACCME Standards for Integrity and Independence in Accredited Continuing Education, released in December 2020, as well as Commonwealth of Virginia statutes, University of Virginia policies



and procedures, and associated federal and private regulations and guidelines. As the accredited provider for this CE/IPCE activity, we are responsible for ensuring that healthcare professionals have access to professional development activities that are based on best practices and scientific integrity that ultimately supports the care of patients and the public.

All individuals involved in the development and delivery of content for an accredited CE/IPCE activity are expected to disclose relevant financial relationships with ineligible companies occurring within the past 24 months (such as grants or research support, employee, consultant, stock holder, member of speakers bureau, etc.). The University of Virginia School of Medicine and School of Nursing employ appropriate mechanisms to resolve potential conflicts of interest and ensure the educational design reflects content validity, scientific rigor and balance for participants. Questions about specific strategies can be directed to the University of Virginia School of Medicine and School of Nursing of the University of Virginia, Charlottesville, Virginia.

The faculty, staff and planning committee engaged in the development of this CE/IPCE activity in the Joint Accreditation CE Office of the School of Medicine and School of Nursing have no financial affiliations to disclose.

Disclosure of discussion of non-FDA approved uses for pharmaceutical products and/or medical devices

As a Joint Accreditation provider, the University of Virginia School of Medicine and School of Nursing, requires that all faculty presenters identify and disclose any off-label or experimental uses for pharmaceutical and medical device products. It is recommended that each clinician fully review all the available data on new products or procedures prior to clinical use.