Human Research Protections

UNSTOPPABLE

NOVEMBER 2-3, 2023 - VIRTUAL

Program Overview

The purpose of this program is to provide information to institutional review board (IRB) members, IRB administrators, clinical investigators, research support staff, research sponsors, contract research organizations (CROs), government regulators, and members of the clinical research community about current issues regarding human subjects protection in research.

SPONSORED BY:

Cincinnati Children's

NKU Northern Kentucky University

Office of Research Integrity

Center for Clinical and Translational Science

University of Cincinnati

CCTST Center for Clinical & Translational Science & Training

Conference Information

Conference Cost

- $75 registration
- An early-registration rate of $65 is available to all attendees through October 2, 2023.
- Includes material, CME and CEU credits.
- Registration ends October 30, 2023. All payments are non-refundable but transferrable through October 30, 2023.

Virtual Conference

As much as we would like to be able to meet again in person, this conference will be virtual until such time that large group gatherings can be conducted safely. This event will occur via ZOOM. Access details will be included with conference confirmation and reminder messages.

To help keep the event interactive, we will incorporate audience participation with live polling throughout the conference and open Q&A at the end of each talk.

Daily Schedule

To accommodate busy schedules,
the conference will be spread over two days,
with three talks each day, from 12:00 - 3:30 pm ET.

Register online

Visit https://cchmc.cloud-cme.com/course/courseoverview?P=0&EID=47973
and click “Register” at the top.
Capacity is limited; please register early.

If you have any questions about the conference, please email orcraeducation@cchmc.org and ask to speak with someone about the conference.

DAY 1

PROGRAM OVERVIEW

Thursday, November 2, 2023

Session Time	Title	Presenter
12:00 PM - 12:15 PM	**Welcome, Opening Remarks, and Introductions**	Ada Sue Selwitz, MA; University of Kentucky
12:15 PM - 1:15 PM	**Trust, Trustworthiness, and "Tuskegee,": The Legacy of the United Stated Public Health Syphilis Study** In this session, Dr. Gamble will trace the history of the United States Public Health Syphilis Study at Tuskegee while analyzing the legacy that the Syphilis Study had on health care and in medical research in African American communities. Dr. Gamble will discuss race, trust, and trustworthiness and identify factors important to the development of trustworthy relationships with the African American community.	Vanessa Northington Gamble, MD, PhD; The George Washington University
1:15 PM - 1:20 PM	**Break**	
1:20 PM - 2:20 PM	**Reimagining Research in the Age of AI** Ms. Cummings will address the topic of using AI and other novel technologies for research into existing and innovative crime prevention strategies and explore the special considerations for conducing this type of research with human participants and with private identifiable data.	Renee Cummings, MS; University of Virginia
2:20 PM - 2:25 PM	**Break**	
2:25 PM - 3:25 PM	**From Validation to Clinical Workflow: Human Subjects Research (HSR) Protection & Regulatory Considerations for Artificial Intelligence/Machine Learning (AI/ML) Predictive Models** This session will include an engaging talk on conducting IRB review of projects involving artificial intelligence in human subjects research. Ms. Eto will discuss the ethical and legal considerations in AI HSR, making AI HSR (and non AI HSR) determinations and when and why FDA regulations apply.	Tamiko Eto, CAIDP, CIP; Ann & Robert H.Lurie Children's Hospital at Chicago

Each session will include time for questions and answers with the presenters/panelists to allow for active learning opportunities.

DAY 2

PROGRAM OVERVIEW

Friday, November 3, 2023

Session Time	Title	Presenter
12:00 PM - 12:10 PM	**Welcome and Introductions**	Ada Sue Selwitz, MA; University of Kentucky
12:10 PM - 1:10 PM	**The Secrets of Big Data Research: Public, Private, or What?** This presentation will examine how the history of technology has transformed the meaning of "privacy" and how this could impact so-called "big data research". The presentation will include U.S. Constitutional, legal, and regulatory interpretations of the term and the right to privacy, to raise the question of how information could be considered public, private, or something else in today's world.	Ivor Pritchard, PhD; Office for Human Research Protections, Department of Health and Human Services
1:10 PM - 1:15 PM	**Break**	
1:15 PM - 2:25 PM	**Why DEI Initiatives in Research are Not Working: An Opportunity for a Deeper Dive** According to a CNBC Survey, since the death of George Floyd in May of 2020, 88% of companies have made DEI their number one priority. The job search engine, *Indeed*, cited a jump in DEI positions of 123% in the three months following the death of George Floyd. And Google has reported DEI as one of its a top search abbreviations for the past three years. With these very extensive responses and marked commitment to DEI, the notion that DEI is being adequately addressed is assumed. This talk will take a deeper dive into what DEI initiatives are and what they are designed to accomplish. The goal of the talk is to find and provide solutions. *"Winning is a habit...unfortunately, so is losing."* ~ Vince Lombardi	Quincy Byrdsong, EdD, CIP, CCRP; Ballad Health
2:25 PM - 2:30 PM	**Break**	
2:30 PM - 3:30 PM	**Ethical Review of Decentralized Clinical Trials (DCDs)** In this session, Dr. Bierer will assist paticipants in identifying differences between DCTs and traditional site-based clinical trials. Dr. Bierer will discuss risks and challenges specific to DCTs and ways to mitigate those risks. The presentation will explore tools and resources available for IRBs to advance ethical reviews of DCTs.	Barbara Bierer, MD; Harvard Medical School

Each session will include time for questions and answers with the presenters/panelists to allow for active learning opportunities.

Conference Faculty

Vanessa Northington Gamble, MD, PhD

Vanessa Northington Gamble, MD, PhD is University Professor of Medical Humanities at the George Washington University. She is the first woman and first African American to hold this prestigious, endowed faculty position. She is also Professor of Health Policy and Medicine and Professor of Medicine at the George Washington University. In addition, she is Adjunct Professor of Nursing at the University of Pennsylvania School of Nursing.

Dr. Gamble has frequently been a pioneer during her professional career. She was the first African American woman appointed, and later tenured, to the faculty of the University of Wisconsin School of Medicine. In , she became Founding Director of the University of Wisconsin's Center for the Study of Race and Ethnicity in Medicine – one of the first academic centers to address racial and ethnic inequities in health and health care.

Throughout her career, Dr. Gamble has worked to promote equity and justice in American medicine and public health. A physician, scholar, and activist, she is an internationally recognized expert on the history of race and American medicine, health equity, and bioethics. She is the author of several widely acclaimed publications on the history of race and racism in American medicine. She chaired the committee that took the lead role in the successful campaign to obtain the 1997 apology from President Clinton for the infamous United States Public Health Syphilis Study at Tuskegee.

Dr. Gamble has served on the National Advisory Council of the Agency for Healthcare Research and Quality, the National Advisory Council for Human Genome Research and the National Council on the Humanities, and the boards of Ibis Reproductive Health, the National Caucus and Center on Black Aged, Inc., and Hampshire College.

Renee Cummings, MS, MA

Professor Renée Cummings, a 2023 VentureBeat AI Innovator Award winner, is an artificial intelligence (AI), data, and tech ethicist, and the first Data Activist-in-Residence at the University of Virginia's School of Data Science, where she was named Professor of Practice in Data Science. She also serves as co-director of the Public Interest Technology University Network (PIT-UN) at UVA. She is also a nonresident senior fellow at The Brookings Institution and the inaugural Senior Fellow, AI, Data and Public Policy at All Tech Is Human, a leading think tank. She's also a distinguished member of the World Economic Forum's Data Equity Council and the World Economic Forum's AI Governance Alliance, an advisory council member for the AI & Equality Initiative at Carnegie Council for Ethics in International Affairs, and a member of the Global Academic Network at the Center for AI and Digital Policy. Professor Cummings is also a criminologist, criminal psychologist, therapeutic jurisprudence specialist, and a community scholar at Columbia University. Committed to stretching the imagination of data science, reimagining the relationship between data and society, and redefining the data power structure, she works at the intersection of technology, power, and society.

Justice, equity, diversity, and inclusion are critical aspects of her work as she promotes inclusive innovation and ethical, responsible, and trustworthy AI. Her work extends to include data, democracy, representation, identity, and governance, critically examining data rights, algorithmic justice, social justice, and design justice through a criminal justice lens.

A thought leader, motivational speaker, and mentor, she has given a multitude of talks to conferences, groups, and policymakers, and is a recognized expert who lectures, nationally and internationally, on ethical data science and ethical AI. She has mastered the art of creative storytelling, science communication, and deconstructing complex topics into critical everyday conversations that inform and inspire.

Conference Faculty

Tamiko T. Eto, MS, CIP

Ms. Eto has over 18 years of experience in the field of human subjects research protections managing research compliance, technology risk assessment, data sharing agreements; conducting the review of complex industry and federally funded AI research, and policy interpretation and development. She leverages this experience to implement policies and guidance to AI-enabled health care research projects. She works closely with AI researchers and regulatory bodies in addressing ethical and regulatory challenges related to AI. To facilitate researchers and IRB professionals across the US she has developed tools and checklists for IRBs to use in their review of AI research. Ms. Eto also serves as Associate Editor and Board Member of the of Systems Concepts, Theory and Policy in Biology and Medicine journal; serves on the AI Ethics Advisory Board for the Institute of Experiential AI (EAI) at Northeastern University, and is a Research Member at the Center for AI and Digital Policy (CAIDP).

Ivor Pritchard, PhD

Ivor Pritchard Ph.D. is the Senior Advisor to the Director of OHRP in the Office for Human Research Protections (OHRP) in the Department of Health and Human Services. He came to OHRP in 2004 from the Institute for Education Sciences at the U.S. Department of Education, where he was a Senior Research Analyst. He joined the U.S Department of Education in 1986. Prior to that he was a Visiting Professor in Philosophy at St. Mary's College of Maryland. He has a Ph.D. in philosophy from Boston University.

Ivor's most recent authored or coauthored publications include "Framework for the Ethical Conduct of Research: The Ethical Principles of the Belmont Report" (in Handbook of research ethics in psychological science), "Research Involving Deception" (with Abraham, in Institutional Review Board: Management and Function, 2021), "The Ethics of the Biospecimen Package Deal: Coercive? Undue? Just Wrong? Or Maybe Not?" (with Kaneshiro, in Specimen Science, 2017) and "The Common Rule, Updated" (with Menikoff and Kaneshiro, in The New England Journal of Medicine, January 19, 2017). He has also published in the areas of moral education and education policy.

Conference Faculty

Quincy Byrdsong, EdD, CIP, CCRP

Dr. Quincy J. Byrdsong is the Vice President for Research Operations at Ballad Health in Johnson City, Tennessee. In this role, Dr. Byrdsong has strategic, operational, and programmatic oversight of all research efforts within Ballad in conjunction with the System Chair for Clinical Research and the Chief Academic Officer.

Dr. Byrdsong is charged with the development and implementation of Ballad's strategic research plan. Additionally, Dr. Byrdsong leads all research administration and compliance functions of Ballad Health including advising the Institutional Review Board and collaborating regularly with Ballad Health executive leadership, Corporate Compliance, Medical Affairs, Patient Care Services and other departments as indicated to develop research policies and procedures.

Before coming to Ballad, Dr. Byrdsong served as the Vice Provost for Health Affairs at Lipscomb University in Nashville, Tennessee.

Dr. Byrdsong received his Bachelor and Master Degrees in Biology from Middle Tennessee State University (MTSU) as well as his Specialist in Education. At MTSU, Dr. Byrdsong went on to receive his Doctor of Education degree from Tennessee State University (TSU). He is a Certified Institutional Review Board (IRB) Professional (CIP) and a Certified Clinical Research Professional (CCRP). Dr. Byrdsong is a past President of the Society of Clinical Research Associates (SOCRA) and Member of the Board of Directors for both the Association for the Accreditation of Human Research Protections Programs (AAHRPP) and Public Responsibility in Medicine and Research (PRIM&R).

Barbara Bierer, MD

Barbara E. Bierer, M.D., a hematologist-oncologist, is Professor of Medicine at Harvard Medical School and the Brigham and Women's Hospital (BWH). Dr. Bierer co-founded and now leads the Multi- Regional Clinical Trials Center of BWH and Harvard, a collaborative effort to improve standards for the planning and conduct of international clinical trials to harmonize policies for and approaches to clinical trial regulation. In 2017, the MRCT Center launched the nonprofit organization, Vivli, a global clinical research data sharing platform. In addition, she is the Director of the Regulatory Foundations, Ethics, and the Law program at the Harvard Catalyst, the Harvard Clinical and Translational Science Award, working across the academic spectrum to enable the clinical trial enterprise from study planning through recruitment to data acquisition and dissemination. She is the Director and PI of SMART IRB, a national effort to align single site IRB review of multi-site trials.

In addition to her academic responsibilities, Dr. Bierer served or serves as Chair of the Secretary's Advisory Committee for Human Research Protections, Department of Health and Human Services (2008-2012); as a member of the National Academies of Sciences Committee on Science, Technology and the Law (2007-2016), and NASEM Forum on Drug Discovery, Development, and Translation (2023-); on the Executive Committee, Clinical Trials Transformation Initiative (2023-); on the Board of Directors of Public Responsibility in Medicine and Research (PRIM&R) (2011-2020), Management Sciences for Health (MSH) (2013-2022), Vivli (2017-), North Star Review Board (2020-), and Generation Patient (2023-). She chairs the Board of Trustees of the Edward P. Evans Foundation, a foundation supporting biomedical research, and is on the board of directors of Clinithink, a company that transforms unstructured clinical text into computable data for clinical trials and population health management. Dr. Bierer received a B.S. from Yale University and an M.D. from Harvard Medical School.

Continuing Education Information

Accreditation

In support of improving patient care, this activity has been planned and implemented by Cincinnati Children's, Northern Kentucky University, and Advarra. Cincinnati Children's 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.

JOINTLY ACCREDITED PROVIDER™
INTERPROFESSIONAL CONTINUING EDUCATION

AMA PRA

Physician: This activity has been approved for *AMA PRA Category 1 Credit*™.

CNE

Nursing: This activity is approved for continuing nursing education (CNE) contact hours.

IPCE

This activity was planned by and for the healthcare team, and learners will receive Interprofessional Continuing Education (IPCE) credits for learning and change.

IPCE CREDIT™

Certified IRB Professional (CIP)

Conference participants who hold the CIP® credential may apply up to 6 credits from this program towards their CIP recertification credit hours. Credential holders should retain their certificate of attendance and include it as part of their CIP recertification by continuing education applications. Learn more.

Credits

The credit hours listed below are not final, please check back closer to the activity for final approved credit hours.

AMA PRA Category 1 Credits™ (6.25 hours), CME - Non-Physician (Attendance) (6.25 hours), Nursing CE (6.25 hours), IPCE (6.25 hours)

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