Human Research Protections:

TIMES LIKE THESE

SEPTEMBER 26-27, 2024 - 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 September 2, 2024.
- Includes material, CME and CEU credits.
- Registration ends September 23, 2024. All payments are non-refundable but transferable through September 23, 2024.

Virtual Conference

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.

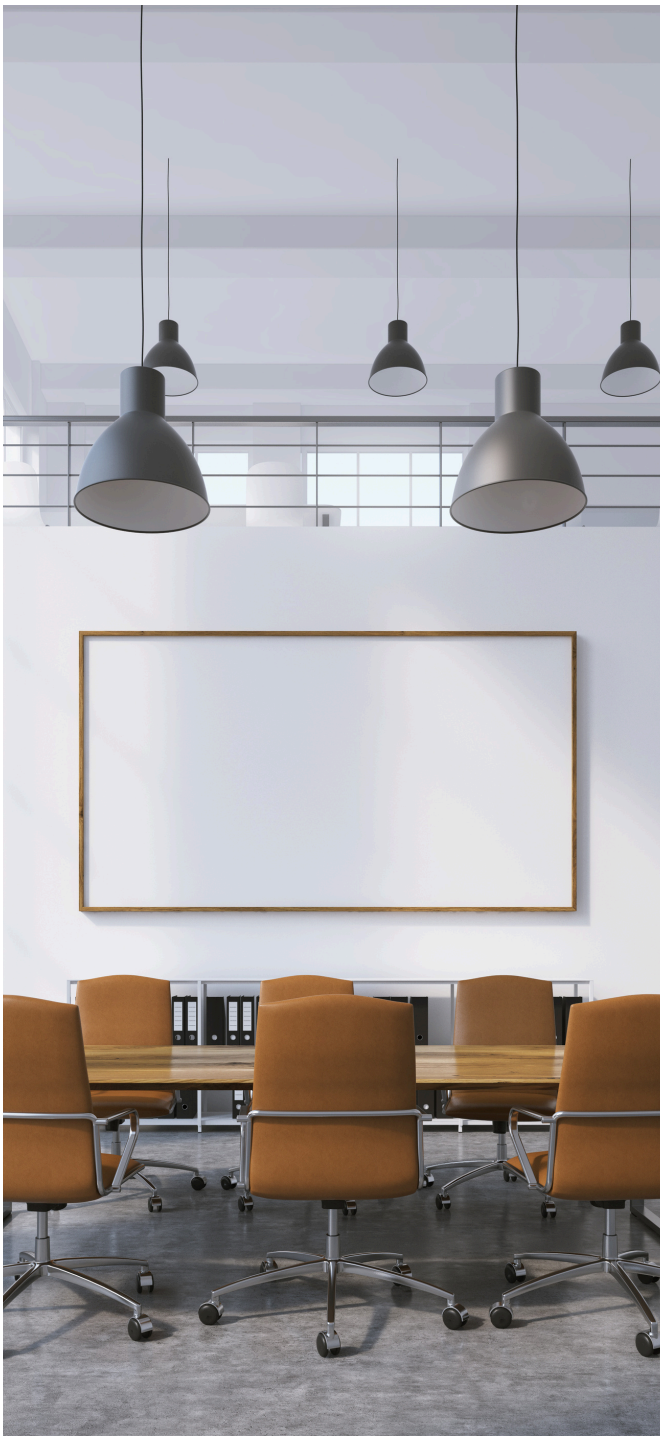
Daily Schedule

To accommodate busy schedules,
the conference will be spread over two days,
with three talks each day, from 12:00 - 4:30 pm ET.

Register online

Visit https://cchmc.cloud-cme.com/course/courseoverview?P=0&EID=52990 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, September 26, 2024

Session Time	Title	Presenter
12:00 PM - 12:15 PM	**Welcome, Opening Remarks, and Introductions**	
12:15 PM - 1:30 PM	**Anticipating and Responding to the Ethical Challenges of Externally Disrupted Research** Armed conflicts, natural disasters, pandemics and limiting laws and regulations can externally disrupt research. Such disruptions can pose risks for research participants, communities where research is conducted and research staff. In addition, they may threaten research integrity and foreclose important future research efforts. Accordingly, researchers, sponsors, and those charged with research ethics oversight should anticipate the possibility of externally disrupted research and when necessary, implement approaches for mitigating their impact.	Jeremy Sugarman, MD, MPH, MA; Harvey M. Meyerhoff Professor of Bioethics and Medicine
1:30 PM - 1:45 PM	**Break**	
1:45 PM - 3:00 PM	**Can a Robot Write a Consent Form?** AI seems to be appearing more frequently and is useful in many contexts, so how might it be helpful in research compliance? Informed consent forms have been fraught with challenges that have persisted even after decades of improvement efforts, so how might AI be able to help us with consent writing? This session will share some basic information about natural language processing (a subset of AI) and ChatGPT specifically. Then with audience participation, we will use ChatGPT as we work on a consent form together.	Celia Brook Cholka, PhD, CIP; Human Research QA & Education Manager, Weill Cornell Medicine
3:00 PM - 3:15 PM	**Break**	
3:15 PM - 4:30 PM	**Human Subject Protections at FDA – Updates and Future Directions** In recent years, FDA has undertaken a number of activities to modernize and streamline human subjects protections (HSPs) for FDA-regulated research, including finalizing a regulation allowing IRBs to waive or alter informed consent for certain types of minimal risk research and developing multiple guidances providing Agency thinking on different aspects of informed consent. For this session, FDA representatives will discuss the main regulatory and policy changes that the Agency has undertaken for HSPs, as well as identify some specific HSP topics that are becoming increasingly important/relevant to FDA-regulated research.	Suzanne Patte, JD & Lauren Milner, PhD; Food & Drug Administration (FDA)

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

DAY 2 Program Overview

Friday, September 27, 2024

Session Time	Title	Presenter
12:00 PM - 12:15 PM	**Welcome and Introductions**	
12:15 PM - 1:30 PM	**Elevating Community Voices: A Participatory Approach to Research Governance - Insights from the NIH All of Us Research Program** This talk builds on last year's PRIM&R discussion of participant voices in research governance. Dr. Watson will delve deeper into community and participant engagement, exploring how the NIH All of Us Research Program integrates these principles. By analyzing the socioecological model, he will identify best practices for IRBs, researchers, and community members to forge stronger partnerships and ensure research reflects the needs and voices of the communities it impacts.	Karriem Watson, DHSc, MS, MPH; Chief Engagement Officer, NIH All of Us Research Program
1:30 PM - 1:45 PM	**Break**	
1:45 PM - 3:00 PM	**Evidence-based recommendations for ethical research practices with sexual and gender minority adolescents** This talk will summarize the importance of conducting health research with LGBTQ adolescents and over a decade of ethics research on how to do so in ways that maximize opportunities for teen involvement, participant safety, and regulatory compliance. Studies described LGBTQ youth comfort with answering questions about sexual and mental health overall and in comparison to everyday experiences, willingness to participate in different kinds of HIV research studies, perspectives about the impact of asking for parental permission, and capacity to understand and reason with the informed consent process. Other studies are described that interview parents about their perspectives on their children participating in health research and the impact of requiring parental permission. Novel multimedia approaches to describing research will be shown. The implications of this body of empirical evidence is then discussed in terms of the applications of human subjects regulations for adolescent research participation.	Brian Mustanski, PhD; Northwestern University Feinberg School of Medicine, Director, Institute for Sexual and Gender Minority Health and Wellbeing
3:00 PM - 3:15 PM	**Break**	
3:15 PM - 4:30 PM	**The Power of the Patient/Community Perspective in Research: Stories of Engagement and Advocacy** In this session you'll hear from two health research advocates who bring scientists and the lay public into community with each other to improve health outcomes – by facilitating bi-directional communication, fostering an atmosphere of trust and improving the dissemination of scientific information.	Julie Wijesooriya, MPA; Cincinnati Children's Hospital, & Terry Keys; University of Kentucky

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

CONFERENCE FACULTY

Jeremy Sugarman, MD, MPH, MA

Jeremy Sugarman, MD, MPH, MA is the Harvey M. Meyerhoff Professor of Bioethics and Medicine in the Department of Medicine and the Berman Institute of Bioethics at the Johns Hopkins University. He is an internationally recognized leader in bioethics with particular expertise in applying empirical methods for evaluating and analyzing bioethical issues. His contributions to bioethics and policy include work on the ethics of informed consent, umbilical cord blood banking, stem cell research, international HIV prevention research, global health and research oversight. Dr. Sugarman is the author of over 400 articles, reviews and book chapters. He has also edited or co-edited four books.

Dr. Sugarman consults and speaks internationally on a range of issues related to bioethics. He was senior policy and research analyst for the White House Advisory Committee on Human Radiation Experiments, consultant to the National Bioethics Advisory Commission, and Senior Advisor to the Presidential Commission for the Study of Bioethical Issues.

Dr. Sugarman has been elected as a member of the American Society of Clinical Investigation, Association of American Physicians, and the National Academy of Medicine (formerly the Institute of Medicine). He is a fellow of the American Association for the Advancement of Science, the American College of Physicians and the Hastings Center. He also received a Doctor of Science, honoris causa, from New York Medical College.

Celia Brook Cholka, PhD, CIP

Cecilia Brooke Cholka serves Weill Cornell Medicine as a Human Research & QA Manager and works to demystify IRB processes and expectations so that researchers and the IRB can work together collaboratively to ensure ethical conduct of research. Brooke is a Certified IRB Professional and has 10 years of experience in research administration (human and animal research) including as the head of the training and education components of a Human Research Protections Program (HRPP), achieving and maintaining accreditation, and programmatic redesign. She is co-founder and co-facilitator of the SBER Network, a professional community for social, behavioral, and educational research IRB professionals. As part of her passion for IRB, she has presented at several national conferences including Advancing Ethical Research (AER) Conference, Social, Behavioral, and Educational Research (SBER) Conference, AAHRPP Annual Conference, and is a contributing author to the third edition of IRB Management and Function by Bankert, Gordon, Hurley, and Shriver (Eds). In addition to her work in IRB, she has a PhD in Health Communication with 20 years of research experience. Her research interests include human sexuality, health disparities, and health risk behaviors, particularly in Latinx communities. Research projects include early education experiences and their impact on health in later life with older American Indians using Community Based Participatory Research methodologies and representations of mental health in communication research.

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Suzanne R. Pattee, JD

Suzanne Pattee is a regulatory counsel with the Office of Clinical Policy in the Office of the Commissioner where she addresses policy for the ClinicalTrials.gov data bank, clinical trial design, and informed consent. She previously worked in CDER for the Division of Clinical Trial Quality in the Office for Medical Policy (OMP), and in the Office of Policy in the Office for Pharmaceutical Quality (OPQ).

Before joining FDA in 2009, Suzanne was a vice president at a rare disease foundation where she led policy initiatives in clinical trials, orphan drug policies, and many others. She also led bioethics issues and outreach for a biotechnology trade association, and addressed health policy for a biotechnology company. Suzanne was a member of the Secretary's Advisory Committee for Human Research Protections, and served on the board of an accreditation association. Suzanne earned her law degree from The George Washington University, and her bachelor's degree in biology from The College of William and Mary.

Lauren Milner, PhD

Lauren Milner, PhD is a regulatory policy advisor in the Office of Clinical Policy at FDA where she works on Federal regulations and policies associated with informed consent and human subject protection (HSP) issues arising in FDA-regulated research. Dr. Milner previously worked in CDER's Office of Medical Policy, where she focused on regulatory and ethical issues associated with real-world evidence and emerging technologies in clinical research.

Before joining FDA, Dr. Milner was a health science policy analyst in the Clinical and Healthcare Research Division of the Office of Science Policy at the National Institutes of Health. Dr. Milner received postdoctoral training in biomedical ethics at Stanford University, where she conducted research on the ethical implications of emerging genomic technologies and research using "big data." She received her PhD in Behavioral Neuroscience from Oregon Health and Science University and has a BA in Psychology from the University of Colorado at Boulder.

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Karriem S. Watson, DHSc, MS, MPH

Karriem S. Watson, DHSc, MS, MPH is the Chief Engagement officer for the NIH All of Us Research Program. Dr. Watson comes to the NIH after 16 years in academia and community health. He previously served as the Associate Executive Director of a group of Federally Qualified Health Centers (FQHCs) in the Illinois area where he developed a community engaged and implementation science research program. He was also faculty at the University of Illinois School of Public Health Division of Community Health Sciences. Dr. Watson's research focused on cancer prevention and control and he previously had a Multi-PI R01 from the National Institute on Minority Health and Health Disparities (NIMHD) looking at epigenetics in lung cancer screening among African American men and was funded in a Multi-PI project through the NHLBI UG3/UH3 looking at the implementation of evidence based tobacco cessation in Federally Qualified Health Centers (FQHCs). Dr. Watson also received funding from the NCI to develop a Citizen Science program that engaged African American men in prostate and lung cancer screening. In addition to his research, Dr. Watson has been recognized as a national leader in community engagement having served as the past chair of Community Campus Partnerships for Health (CCPH) and being recognized by the Lungevity as a Community Champion. He is also passionate about mentoring and training up the next generation of young scientists and was recognized by the Chicago Urban League as an Innovator in STEM.

Brian Mustanski, PhD

Brian Mustanski, PhD is director of the Northwestern University Institute for Sexual and Gender Minority Health and Wellbeing and the NIH-funded Third Coast Center for AIDS Research (CFAR). He also serves as Associate Vice President for Social and Behavioral Research for Northwestern University. His research focuses on the health and development of LGBTQ youth and the application of new media and technology to HIV prevention. He has been a Principal Investigator of over $70 million in federal and foundation grants, including an R01 to study ethical and regulatory issues associated with LGBTQ adolescent participation in HIV research. He has published over 380 journal articles and according to Clarivate his papers citations make him one of the most highly cited researchers globally. Dr. Mustanski is a frequent advisor to federal and local agencies on LGBTQ health and sexual health, including being appointed to multiple federal advisory committees. NBC News selected him from 1,600 nominees to their inaugural list of 30 changemakers and innovators making a positive difference in the LGBTQ community.

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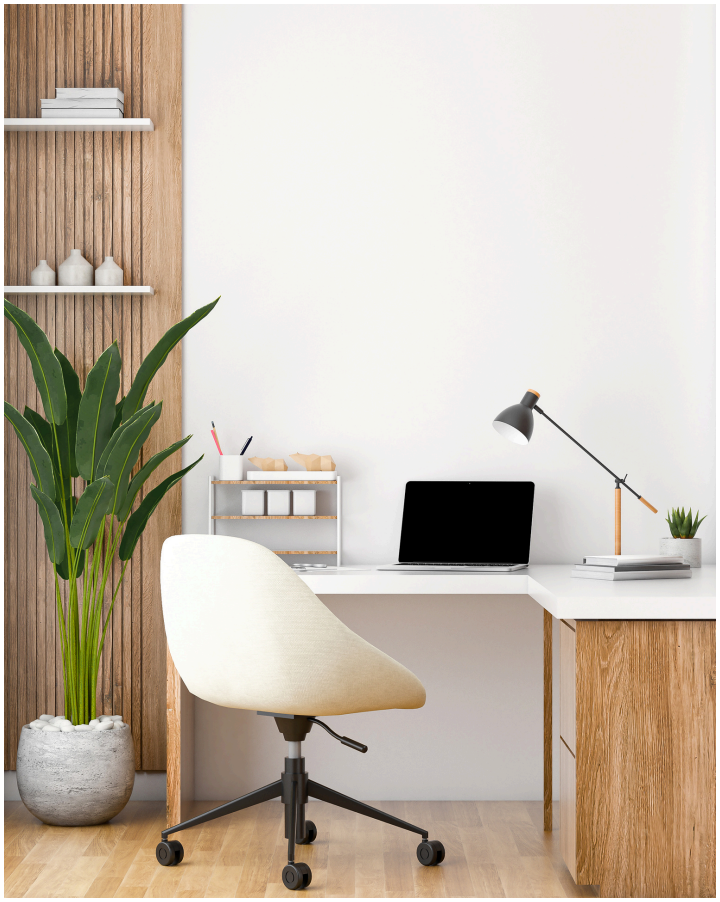
Julie Wijesooriya, MPA

Julie has been an integral part of Cincinnati Children's Hospital since 2016. As the Research Community Liaison within the Clinical and Translational Science Training (CCTST) program, she brings over 15 years of experience working closely with Cincinnati communities and engaging in urban policy research. She leads the Research Participant Advisory Group (RPAG), a vital resource for researchers, that informs research practices at Children's and the University of Cincinnati. The RPAG includes two standing advisory councils that meet monthly: One, based at Children's, focuses on the participant experience within Children's Hospital, while the other, situated in the West End neighborhood, concentrates on community research, collaborating with researchers to improve community-based research. In addition to the RPAG, Julie is a member of Cincinnati Children's Institutional Review Board (IRB) as a non-scientist, where she helps ensure research participant rights are protected in research studies conducted at Children's. She is a Human Subject Research Ethics Training instructor for community members as part of the CCTST's Community Leaders Institute, as well as a guest instructor for research ethics and community advisory boards as part of a Community-Engaged Research for Health graduate certificate. In her role, Julie focuses on enhancing the research experience for participants, patients, families, and the broader community. She actively addresses critical issues affecting research participants and their families, as well as the greater research community. She reviews and analyzes the entire research study process, looking for areas of improvement and creating better connections between research, clinical practices and the greater community.

Terry Keys

A native of Breckinridge County, Kentucky, Terry merges his considerable experience in the areas of marketing, public relations, special events and graphic design with his penchant for creating community among disparate groups of people, whether that's on campus, in town or across the globe. Terry works to integrate the personal experiences of the Markey Cancer Center patients, their families and their caregivers into the world of researchers. In 2009, Terry began promoting the latest advances in cancer research through seminars and conferences and facilitating Markey's Patient Advisory Group, comprised of former Markey patients, family members and caregivers. As of July 2022, as Markey's new Research Advocacy Manager, Terry works to integrate the worlds of science and community, making science more understandable and bringing the life experiences into the sciences.

CONTINUING EDUCATION INFORMATION



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™ (7.5 hours)
- CME - Non-Physician (Attendance) (7.5 hours)
- Nursing CE (7.5 hours)
- IPCE (7.5 hours)

Accreditation

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

CME

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

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.

Certified IRB Professional (CIP)

This activity is approved for CIP continuing education hours.

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