ADVARRA · Cincinnati Children's · University of Cincinnati · Office of Research Integrity · NKU Northern Kentucky University · CCTST Center for Clinical & Translational Science & Training · Center for Clinical and Translational Science

Program Overview

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

Conference Cost

New This Year: Combined with biennial Bioethics Conference!

$75 Registration

- An early-registration rate of $60 is available to attendees employed by the host institutions (listed above) as well as any full-time student. To receive the discount (max. $15), select the "employee/student rate" during registration. This early registration discount ends July 31, 2021.
- Includes material, CME and CEU credits as well as 30-day access to recorded presentations.
- Registration ends Wednesday, September 1, 2021. All payments are non-refundable but transferrable thru August 30, 2021.

Virtual Conference
As much as we'd 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 three days, with two talks each day, from 10:30-1:30 ET.

Register Online
Visit www.cincinnatichildrens.org/cme and click the "Continuing Education Portal" link on the right for event registration. Capacity is limited; please register early.

Recordings
Conference events will be recorded and available for later playback (with continuing education credit) for 30 days.

If you have any questions about the conference, please email hspconference@advarra.com or call 513.761.4100 and ask to speak with someone about the conference.

Bioethics, Citizen Science, & Human Subject Protection:
Waiting on the World to Change

Please note: Program agenda is subject to change.

Program Overview

Day 1 – Wednesday, September 8, 2021

10:30 am – 10:40 am **Welcome, Opening Remarks, and Introductions**
Rick Ittenbach, PhD; Cincinnati Children's
Ada Sue Selwitz, MA; University of Kentucky

10:40 am – 12:00 pm **Race for Rapid Review**
Bruce Gordon, MD; University of Nebraska
Michele Russell-Einhorn, JD; Advarra

Session Description: This session will address approaches to rapid IRB (and HRPP) review, while maintaining deep and meaningful ethical and regulatory oversight. Such processes include pre-review of generic protocols, implementation of novel review paradigms, and use of defined rapid response IRBs in either the single institution or sIRB setting.

12:00 pm – 12:15 pm **Break**

12:15 pm – 1:30 pm **From Data Donors and Community Biologists to Self-Trackers and Biohackers: Understanding the Biomedical Citizen Science Landscape**
Christi Guerrini, BA, MPH, JD; Baylor College of Medicine

Session Description: In this session, Christi will characterize the diverse biomedical citizen science landscape, detail specific initiatives and their accomplishments, and explore the values of autonomy, transparency, and inclusivity that animate participants.

Day 2 – Thursday, September 9, 2021

10:30 am – 10:35 am **Welcome and Introductions**
Belinda Smith, MS, RD, CCRC; University of Kentucky
James Heubi, MD; Cincinnati Children's

10:35 am – 12:00 pm **Keeping the Humanity in Human Subjects – A Research Participant and Caregiver Experience**
Mary Elizabeth Williams
Jeff Freiert

Session Description: From a stage 4 diagnosis through an early clinical trial and recovery, Mary Elizabeth Williams experienced firsthand the rollercoaster of unexpected experiences and emotions that come with serious illness. In this talk, we'll hear from a cancer survivor, and also from her primary caregiver, on what they both learned along that ride — and what would have made it less bumpy.

Day 2 – Thursday, September 9, 2021 *(continued)*

12:00 pm – 12:15 pm **Break**

12:15 pm – 1:30 pm **Trust, Privacy, and your Next-door-neighbor the Citizen Scientist**
Ross McKinney, MD; Association of American Medical Colleges (AAMC)

Session Description: In this session, Dr. McKinney will discuss the challenges of citizen science, access to huge data sets, and the meaning of privacy and confidentiality. Attendees should come away with an understanding of some successful examples of citizen science, as well as a better understanding of the meanings of "privacy" and "confidentiality."

Day 3 – Friday, September 10, 2021

10:30 am – 10:35 am **Welcome and Introductions**
Michele Russell-Einhorn, JD; Advarra
Holly Bante, PhD, MPH, University of Cincinnati

10:35 am – 12:00 pm **Double Feature: Revised Common Rule Implementation Three Years In, and FDA Perspectives on Community Engagement**
Lauren Hartsmith, JD, CIP; Advarra (formerly of HHS)
Connie Cullity, MD, MPH; Advarra (formerly of FDA)

Session Description: In this session, Lauren and Connie will address specific provisions of the revised Common Rule that HRPPs and IRBs continue to have questions about, as well as discuss ways in which the FDA engages directly with patients.

12:00 pm – 12:15 pm **Break**

12:15 pm – 1:30 pm **The Politics, Ethos, and Ironies of Citizen Science**
Michelle McGowan, PhD; Cincinnati Children's
Catherine Hammack-Aviran, MA, JD; Vanderbilt University Medical Center
Angela Potochnik, MA, PhD; University of Cincinnati

Session Description: Citizen science has helped move traditional science in important yet practical ways. Competing perspectives are not only useful but crucial to this transition. This session will offer examples from a range of perspectives, integrating ethical, moral, philosophical, and political perspectives. Ample time will be available for questions, answers, and dialog among attendees.

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

Conference Faculty

Connie Cullity, MD, MPH

Dr. Connie Cullity is Senior Director, Regulatory Compliance at Advarra. Her expertise is in the areas of human subject protection and Good Clinical Practice (GCP) regulatory compliance. Before joining Advarra, Connie completed a career in federal service, serving more than 20 years with the US Food and Drug Administration (FDA). During her lengthy career at the FDA, she held several positions including Supervisory Medical Officer in the FDA's Center for Drug Evaluation and Research (CDER), as well as the Associate Director for Human Subject Protection, and a Branch Chief in GCP Compliance Divisions. As a Branch Chief, Connie oversaw the full spectrum of CDER's GCP regulatory compliance activities related to clinical-trial conduct and served as a human subject protection (HSP) expert. She graduated from Kean College, obtained her medical degree from Robert Wood Johnson Medical School, and attended post-graduate medical training in psychiatry at Yale University. She also holds a Master of Public Health degree from Johns Hopkins University Bloomberg School of Public Health.

Jeff Freiert, MFA

Jeff Freiert is currently a copywriter for HarperCollins book publishers. He holds an MFA in Creative Writing and has been an adjunct college teacher as well as a published fiction writer. He lives in New York City with his wife, Mary Elizabeth Williams, and their two daughters.

Bruce Gordon, MD

Bruce Gordon is Vice-Chancellor for Regulatory Affairs, and Professor of Pediatrics at the University of Nebraska Medical Center (UNMC). Dr. Gordon has been a member of the UNMC institutional review board since 1992, served as chair since 1996, and as executive chair since 2011. He has served on numerous national committees, including the Secretary's Advisory Committee on Human Research Protections (SACHRP) Subpart A Subcommittee, the American Society of Clinical Oncology (ASCO) Task Force on Oversight of Clinical Research, the Association of American Medical Colleges (AAMC) Informed Consent Working Group, and the National Institute of Environmental Health Sciences (NIEHS) Best Practices Working Group for IRB Review of Disaster Research. He was the first chair of the National Cancer Institute (NCI) Pediatric Central IRB. Dr. Gordon has served on the Board of Directors for Public Responsibility in Medicine and Research (PRIM&R) and was the co-chair for the 2009 Advancing Ethical Research (AER) Conference. He has been a faculty member at every Applied Research Ethics National Association (ARENA)/PRIM&R national meeting since 2002. He is an active participant in PRIM&R's "At Your Doorstep" educational programs, including IRB 101, 200 and 250 programs. He co-developed of the Investigator Responsibility pre-conference workshop, the "Collaborating for Compliance" workshop, the "IRB Chairs Boot Camp" program, and the "Vulnerable Subjects" program. He is a founding member of the Collaborative Institutional Training Initiative (CITI) and co-developed a course on research involving vulnerable subjects. Dr. Gordon currently serves on the Association for the Accreditation of Human Research Protection Programs (AAHRPP) Council on Accreditation, is a frequent AAHRPP site visitor, and has been a faculty member at numerous previous AAHRPP conferences. Dr. Gordon is co-editor of the 3rd edition of *IRB: Management and Function* and is the author of numerous original papers, chapters, review articles, and abstracts regarding human subject protections and research ethics.

Christi Guerrini, BA, MPH, JD

Christi Guerrini is an Assistant Professor in the Center for Medical Ethics and Health Policy at Baylor College of Medicine, where she teaches medical ethics and health policy and conducts research focused on the ethical, legal, and social implications of biomedical citizen science and technologies that facilitate these activities. She is the principal investigator of research examining ethical oversight of and ownership approaches for biomedical citizen science initiatives and a co-principal investigator of research studying the use of genetic genealogy databases by law enforcement. Prof. Guerrini has published over 35 articles on these and related topics in scientific journals and law reviews, including *Science and Nature Biotechnology*. She is a member of the Ethics Working Group of the Citizen Science Association and the investigative genetic genealogy committee of the Scientific Working Group on DNA Analysis Methods (SWGDAM). Prior to joining Baylor College of Medicine, Professor Guerrini was a practicing attorney and law school faculty. She received a JD from Harvard Law School, MPH from The University of Texas School of Public Health, and BA from the University of Virginia.

Catherine Hammack-Aviran, MA, JD

Catherine Hammack-Aviran, MA, JD, is an empirical bioethicist and core faculty member in the Center for Biomedical Ethics and Society as well as in the Department of Health Policy at Vanderbilt. She co-directs research in ethics, policy, and social issues in the Vanderbilt School of Medicine and teaches several courses in ethics, law, policy, and regulation in the biomedical area. Professor Hammack-Aviran received her Master's in Bioethics and Juris Doctor degrees from Wake Forest University, where she is now Adjunct Assistant Professor of Law. She has been integrally involved in over 50 empirical investigations in health and medicine, including more than fifteen NIH-funded studies. Drawing on her interdisciplinary expertise, Professor Hammack-Aviran serves on multiple expert committees and working groups, including the Ethical, Legal and Social Implications (ELSI) Brain Trust for the national All of Us Research Program as well as the American Society for Reproductive Medicine Ethics Committee.

Conference Faculty

Lauren Hartsmith, JD, CIP
Lauren Hartsmith is Director of Regulatory Affairs at Advarra. She previously served as Policy Analyst for the Department of Health and Human Services' Office for Human Research Protections (OHRP). In that position, she led scientific, regulatory, and legal experts to develop and revise policies and regulations. Lauren was a key analyst involved in all aspects of the revised Common Rule rulemaking process, where she developed reports analyzing and summarizing over 2,000 public comments submitted in response to proposed Common Rule revisions. Lauren has also conducted analyses and provided advice for the FDA's human subjects protection regulation. She holds a Juris Doctorate degree from Wake Forest University School of Law, where she was a recipient of the Kilpatrick Stockton and Wake Forest University Law Scholarships. She holds a bachelor's degree from Vassar College, where she majored in Geography.

Michelle McGowan, PhD
Michelle McGowan is a Research Associate Professor in the Ethics Center at Cincinnati Children's and the Departments of Pediatrics and Women's, Gender, and Sexuality Studies at University of Cincinnati. Dr. McGowan holds a PhD in Women Studies from the University of Washington and completed a postdoctoral fellowship in Bioethics at the Center for Genetic Research Ethics and Law of Case Western Reserve University. Dr. McGowan studies the ethical and social implications of reproductive and genomic technologies and policies. She led a National Human Genome Research Institute (NHGRI)-funded study on citizen scientists' approaches to genomic research, and currently leads another NHGRI-funded study on implications of facilitating adolescent and young adults' decision-making about receiving actionable genomic research results.

Angela Potochnik, MA, PhD
Angela Potochnik is Professor of Philosophy and Director of the Center for Public Engagement with Science at the University of Cincinnati. Her research addresses the nature of science and its successes, the relationships between science and the public, and methods in population biology. She is the author of *Idealization and the Aims of Science* (2017) and coauthor of *Recipes for Science* (2018), an introduction to scientific methods and reasoning. She earned her PhD from Stanford University in 2007.

Michele Russell-Einhorn, JD
Michele Russell-Einhorn is the Chief Compliance Officer and Institutional Official for Advarra, a research compliance company with IRB services, IBC services, consulting, and technology solutions for clinical research. Her expertise is in the areas of protection of human subjects in research, scientific review of cancer research and research administration generally. Previously, she was the Vice President for Human Research Protections at Schulman IRB and served for 11 years as the Senior Director, Office for Human Research Studies at the Dana-Farber Cancer Institute where she was responsible for the management and support of scientific review and IRB review, as well as other regulatory matters, involving all cancer relevant research involving human subjects conducted at the five Harvard clinical institutions under the umbrella of the Dana-Farber/Harvard Cancer Center. She has over 30 years of professional experience including service as the Conflicts of Interest Attorney for the National Institutes of Health; Director of Regulatory Affairs for the U.S.D.H.H.S Office for the Protection from Research Risks (OPRR) and its successor office OHRP; Director in the Global Pharmaceuticals Practice at PWC; as well as the Associate General Counsel for the J. Craig Venter Institute. She is a co-chair of the SACHRP Subcommittee on Subpart A, as well as a founder of the IRB Directors Group of the National Comprehensive Cancer Center. She served as the Co-Chair for three years and a core planning committee member for five years of the annual Ethics in Research Conference sponsored by PRIM&R. More recently, she helped to initiate and run the new AAHRPP collaborative network. She is a speaker at numerous conferences on various topics relating to research involving human subject protections, bio-repositories and FDA regulations.

Ross McKinney, Jr., MD
In his role as chief scientific officer, Ross McKinney Jr. leads an array of Association of Medical Colleges (AAMC) programs that support all aspects of medical research and training. He also represents the AAMC nationally on issues related to research and science policy, administration, and workforce development, and education and training. Dr. McKinney joined the AAMC in 2016 after serving as a member of the Duke faculty since 1985. During his time at Duke, he was director of the Division of Pediatric Infectious Diseases, vice dean for research at Duke University School of Medicine, and director of the Trent Center for Bioethics, Humanities, and History of Medicine. Among his career highlights, Dr. McKinney was first author of the key Phase I and II studies on Zidovudine (AZT) use in children, and he conducted research on the natural history, prevention, and treatment of pediatric HIV disease. Dr. McKinney received his bachelor's degree from Dartmouth College in 1975. He earned his medical degree from the University of Rochester School of Medicine and Dentistry and completed his internship and residency in Pediatrics, and fellowship in Pediatric Infectious Diseases, at Duke University Medical Center.

Mary Elizabeth Williams
Mary Elizabeth Williams is an award-winning journalist and author of *A Series of Catastrophes and Miracles: A True Story of Love, Science, and Cancer*. She has a certification in narrative medicine from Columbia University and is currently studying for her master's degree in medical humanities. She's also working towards her DMH at Drew University. She lives in New York City with her family.

Continuing Education Information

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.

CME: Cincinnati Children's designates this live activity for a maximum of 8 (2.5W, 2.75H, 2.75F) AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

IPCE: This activity was planned by and for the healthcare team, and learners will receive a maximum of 8 (2.5W, 2.75H, 2.75F) Interprofessional Continuing Education (IPCE) credits for learning and change.

Nursing: This activity is approved for a maximum of 8 (2.5W, 2.75H, 2.75F) continuing nursing education (CNE) contact hours.

CIP: Conference sessions that meet the criteria in the Certified IRB Professional (CIP) recertification guidelines are eligible as accredited continuing education units.

Conference participants who hold the CIP credential® who wish to apply the 8.0 credits from this program toward CIP recertification may submit their Certificate of Attendance as documentation of their participation. This program has received advance recognition from the CIP Council. Additional information about CIP recertification can be found here:
www.primr.org/certification

About the Host Institutions and Sponsors

Advarra: www.advarra.com
Cincinnati Center for Clinical and Translational Science and Training (CCTST): https://cctst.uc.edu/
Cincinnati Children's: www.cincinnatichildrens.org/research
Northern Kentucky University: https://inside.nku.edu/rgc/research-compliance.html
University of Cincinnati: http://www.researchcompliance.uc.edu/HSR/Overview.aspx
University of Kentucky Office of Research Integrity: www.research.uky.edu/ori
University of Kentucky Center for Clinical and Translational Science (CCTS): www.ccts.uky.edu

We look forward to seeing you September 8-10!