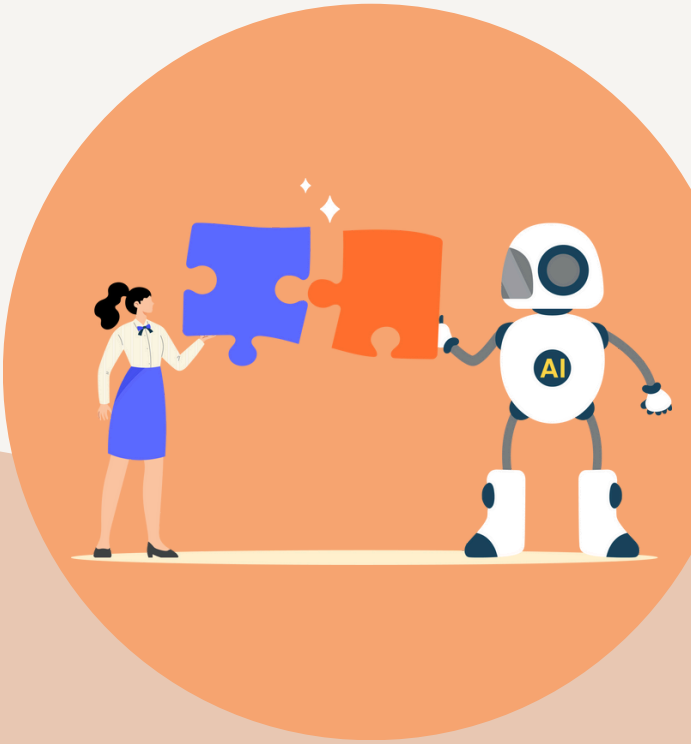
Human Research Protections:

HUMAN AFTER ALL

SEPTEMBER 25-26, 2025 - 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

REGISTER ONLINE

Visit https://cchmc.cloud-cme.com/course/courseoverview?P=0&EID=55545, and click "Register" at the top.
Capacity is limited; please register early.

CONFERENCE COST

- $75 registration
- An early-registration rate of $65 is available to all attendees through August 25, 2025.
- Includes material, CME and CEU credits.
- Registration ends September 24, 2025. All payments are non-refundable but transferable through September 24, 2025.

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. On the first day, sessions will run from 12:00 to 4:30 PM ET, and on the second day, from 9:00 AM to 1:30 PM ET.

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 25, 2025

Session Time	Title	Presenter
12:00 PM - 12:15 PM	**Welcome, Opening Remarks, and Introductions**	
12:15 PM - 1:30 PM	**Ethical and Conceptual Concerns in AI-Assisted Clinical Research** The presentation is designed to familiarize the audience with different types of artificial intelligence (AI), their applications in clinical research, and ethical concerns that arise from them. Topics to be covered include rule- versus data-driven AI, known technological and conceptual challenges to AI-assisted research, ethical issues in research, concerns about fraud, and the environmental impacts of AI. Objectives: • Identify different types of AI and their applications • Discuss social, ethical, and conceptual concerns emerging from artificial intelligence in clinical research contexts	Matthew A. Butkus, PhD, HEC-C
1:30 PM - 1:45 PM	**Break**	
1:45 PM - 3:00 PM	**Navigating the Review of Research Involving AI: Tips for Investigators & IRBs** Investigators and IRBs are both challenged by the process of IRB review of research involving artificial intelligence (AI). Using case examples, this interactive session will provide guidance for IRBs and researchers to effectively navigate this terrain. Objectives: • Identify practical tools and tips for submitting and reviewing research projects involving AI • Utilize existing tools and resources that can help facilitate preparation of applications involving AI for IRB review and assist IRB members and staff in performing their review	Megan Kasimatis Singleton, JD, MBE, CIP
3:00 PM - 3:15 PM	**Break**	
3:15 PM - 4:30 PM	**Bias in Human Physiology Methods and Results: What Compliance Officers Need to Know** This session will introduce both engineering and non-technical strategies to promote inclusion of individuals with different skin tones and hair types in neurotechnology-based studies. We will explore how these methodological choices raise critical questions in human subjects research. Objectives: • Identify how standard human research methodologies may result in the unintentional exclusion of participants • Discuss the ethical implications of this design bias • Evaluate research protocols and device-based methodologies for potential bias	Jasmine Kwasa, PhD

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 26, 2025

Session Time	Title	Presenter
9:00 AM - 9:15 AM	**Welcome and Introductions**	
9:15 AM - 10:30 PM	**Beyond the CV; Strength in the Face of Uncertainty** This is a story of unwavering love, dedication and determination. When you are in the depths of uncertainty you are not alone. Objectives: • Promote reflection and personal growth • Change the stereotype of Multiple sclerosis (MS) patients	Marietta Barton-Baxter, CCRC and Research Participant
10:30 AM - 10:45 AM	**Break**	
10:45 AM - 12:00 PM	**Ethical and Practical Considerations When Vulnerable Adults Participate in Research** At the most basic level, vulnerable populations are those requiring additional or special protections when enrolled in research. While there is a broad consensus that some groups need such protections, there is no universally agreed upon definition of vulnerability. In this presentation, we will consider different definitions of vulnerability and how they apply to adult populations. Once we are able to understand sources of vulnerability, we can identify ethical challenges as well as means of addressing them. Objectives: • Explain what is meant by “vulnerable” • Identify populations that may be vulnerable • Discuss ethical issues that arise when vulnerable populations participate in research • Consider practical means of addressing these issues	Emily A. Largent, JD, PhD, RN
12:00 PM - 12:15 PM	**Break**	
12:15 PM - 1:30 PM	**Beyond the Violation: Building Strong Corrective Action Plans in Clinical Research** The presentation will cover the definition scope of noncompliance, IRB regulatory responsibilities and general approaches to review these incidents. We will discuss the concept of Root Cause Analysis (RCA), types and limitations of various types of RCA, and its use as a tool by research teams as a framework for Corrective Action Plans (CAPs). Finally, we will address the proper components of CAPs that make them robust, meaningful, and achievable. Objectives: • Discuss the role of the IRB in determinations of noncompliance • Describe purpose and approaches to root cause analysis • Outline the various components of a robust corrective action plan	Bruce G. Gordon, MD

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

Conference Faculty

MATTHEW A. BUTKUS

Dr. Matthew A. Butkus earned undergraduate degrees from Georgetown University (BSLA – German/Philosophy) and the University of Pittsburgh (Psychology), graduate degrees from Duquesne University (MA – Philosophy; PhD – Health Care Ethics), and is a certified Healthcare Ethics Consultant (HEC-C) through the American Society for Bioethics and Humanities. He is a Professor in the Department of Social Sciences at McNeese State University in Lake Charles, LA. He has additional faculty appointments in the College of Nursing and Health Professions, School of Biomedical Engineering, Science and Health Systems, and the Dornsife School of Public Health at Drexel University in Philadelphia, PA. He is a national speaker on ethical issues in artificial intelligence and the responsible conduct of research. He has written on a variety of issues in medicine, public health, environmental ethics, and popular culture, as well as the textbook Biomedical Ethics and Decision-Making through Gegensatz Press. His research interests include artificial intelligence, neuroethics, and ethics in public health.

MEGAN KASIMATIS SINGLETON

Megan Kasimatis Singleton, JD, MBE, CIP is Associate Dean for Human Research Protections and Director of the Human Research Protections Program at Johns Hopkins University School of Medicine. In this role she is responsible for oversight and direction of the Johns Hopkins Medicine IRBs. Ms. Singleton is a licensed attorney in Pennsylvania. She earned her law degree from Temple University and her Masters in Bioethics from the University of Pennsylvania. Ms. Singleton serves as a member of the SMART IRB Harmonization Steering Committee, member of the PRIM&R Board of Directors and Co-Chair of the AAHRPP Council. She also serves as a member of the Steering Committee for AEREO, a consortium designed to advance effective research ethics oversight through empirical research. Ms. Singleton currently teaches at the graduate level at the University of Pennsylvania and Johns Hopkins University, leading courses in research ethics and clinical trial management. She has developed research ethics curriculum and practical training in IRB administration tailored for national and international audiences.

Conference Faculty

JASMINE KWASA

Jasmine Kwasa, Ph.D., is a postdoctoral fellow in the Neuroscience Institute at Carnegie Mellon University, where she leads cross-disciplinary work at the intersection of engineering, neuroscience, and ethics. Her research in the Neuroengineering "For All" group of Dr. Pulkit Grover focuses on developing brain sensing and stimulation technologies that are equitable by design. She has worked on EEG, fNIRS, and TES methods for coarse, curly hair and darker skin tones, helping to address long-standing methodological bias in human subjects research in neuroscience and psychology. Dr. Kwasa's work has advanced national conversations around structural inequities in biomedical device development, and has informed both technical standards and ethical review practices.

She is the recipient of numerous honors, including a Fulbright award to Kenya and the 2024 NOMIS-Science Magazine Young Explorers Award for her contributions to inclusive neurotechnology. Her research has been supported by the National Science Foundation, National Institutes of Health, Ford Foundation, and Burroughs Wellcome Fund.

MARIETTA BARTON-BAXTER

Marietta Barton-Baxter, CCRC is the Sr. Regulatory Program Director for the Center for Clinical and Translational Science at the University of Kentucky. She has 35+ years of clinical research experience including quality assurance, data management, coordination, regulatory and budgetary. She serves as the project manager for the CCTS global biobank and sits on the leadership team of the UK Clinical Research Support Office (CRSO). Marietta received a B.S in Clinical Research and Development from the University of Kentucky and is a Multiple Sclerosis Patient Advocate assisting newly diagnosed MS patients in their fight against the disease.

Conference Faculty

EMILY A. LARGENT

Emily Largent (she/her) is the Emanuel and Robert Hart Associate Professor of Medical Ethics and Health Policy and the Chief of the Division of Medical Ethics. She holds a secondary appointment at Penn Law, is a Senior Fellow at the Leonard Davis Institute of Health Economics, and is affiliated with the Center for Health Incentives and Behavioral Economics.

Dr. Largent's work explores ethical and regulatory aspects of human subjects research as well the social, legal, and ethical considerations that arise when research findings are translated into care. She has a particular focus on neurodegenerative diseases, including Alzheimer's disease. She was the 2023 recipient of the Baruch A. Brody Award & Lecture in Bioethics and is an elected fellow of the Hastings Center. Her work has been published in leading bioethics and biomedical journals, including The Hastings Center Report, American Journal of Bioethics, New England Journal of Medicine, and JAMA. She co-authored Clinical Research Ethics Consultation: A Casebook (Oxford University Press).

BRUCE G. GORDON

Bruce Gordon is Assistant Vice-Chancellor for Regulatory Affairs, and Professor of Pediatrics in the Division of Pediatric Hematology/ Oncology 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 a variety of national committees and task forces. He was the first chair of the National Cancer Institute Pediatric Central IRB. Dr. Gordon served on the Board of Director's for Public Responsibility in Medicine & Research (PRIMR) from 2015 to 2021. Dr. Gordon serves on the Council on Accreditation for the Association for Accreditation of Human Research Protection Programs (AAHRPP), and has been a faculty member at numerous AAHRPP conferences and a frequent AAHRPP team leader and site visitor. He is a founding member of the Collaborative Institutional Training Initiative (CITI) and served on the Executive Advisory Committee for the program. Dr. Gordon is the author of numerous original papers, chapters, and review articles and abstracts regarding human subjects protections and research ethics.

Continuing Education Information

ACCREDITATION

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

JOINTLY ACCREDITED PROVIDER™
WITH COMMENDATION
INTERPROFESSIONAL CONTINUING EDUCATION

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.

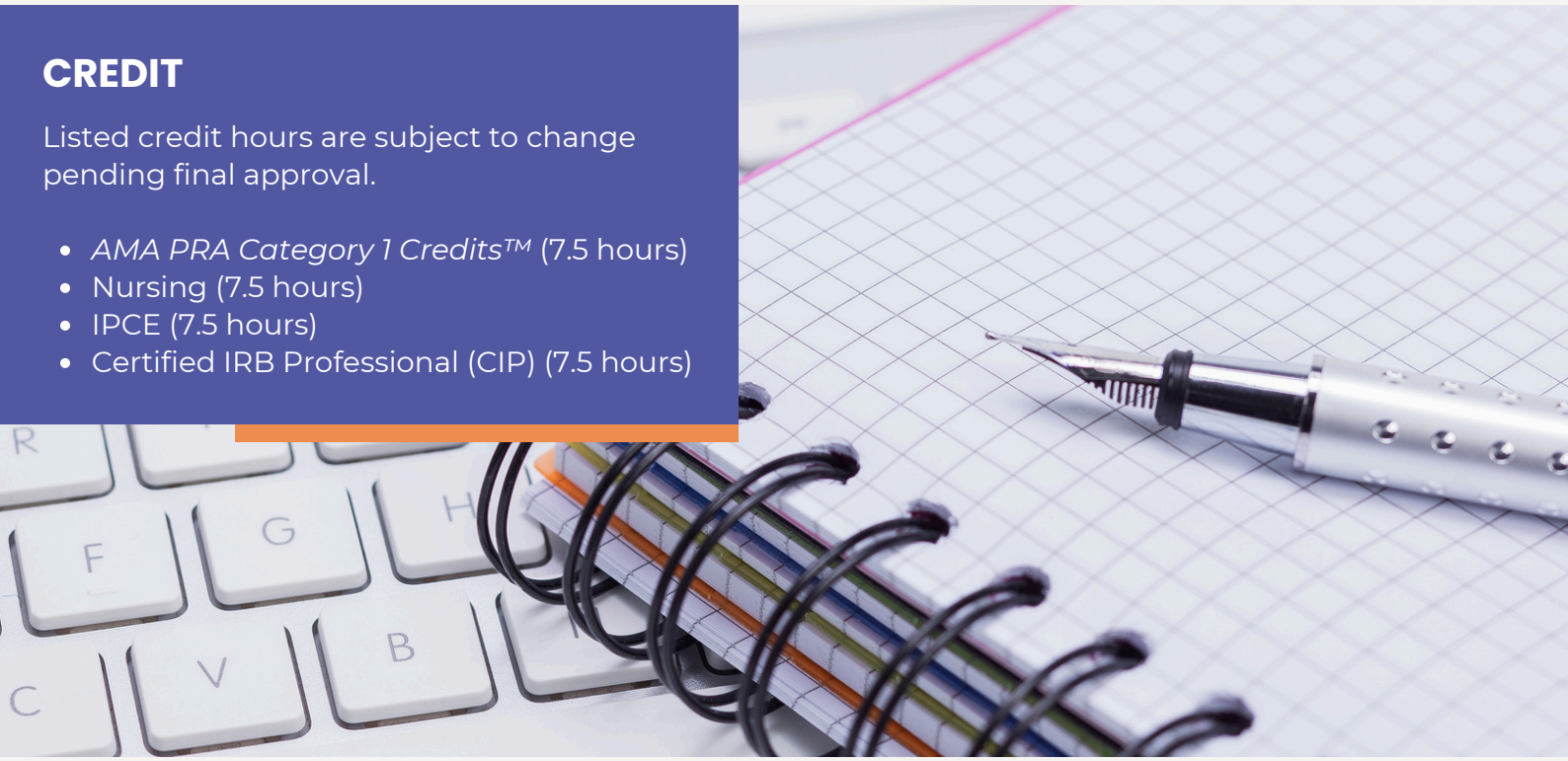
CERTIFIED IRB PROFESSIONAL (CIP)

This activity is approved for CIP continuing education hours.

CREDIT

Listed credit hours are subject to change pending final approval.

- *AMA PRA Category 1 Credits™* (7.5 hours)
- Nursing (7.5 hours)
- IPCE (7.5 hours)
- Certified IRB Professional (CIP) (7.5 hours)



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