

TIME	SESSION DETAILS	SPEAKER DETAILS
9:30 - 10:00	Registration	
10:00 - 10:15	Welcome and Introductions	
10:15 - 11:30	<p>Case Discussion - Reviewing Research Under the Common Rule</p> <p>During this interactive session, OHRP will invite the audience to review and make decisions on the ethics and aspects pertaining to the human research protections regulations regarding a variety of research projects.</p>	<p>Speaker: Michael Grippaldi, JD, MA, Public Health Program Specialist, HHS Office of Human Research Protections</p>
11:30 - 12:30	<p>Participant-Centered Informed Consent</p> <p>This will be an interactive session to explore what a participant-centered informed consent may look like under the instructions of the Common Rule.</p>	<p>Speaker: Yvonne Lau, MBBS, MBHL, PhD, Director, Division of Education and Development, HHS Office of Human Research Protections</p>
12:30 - 1:15	Networking Lunch	
1:15 - 2:45	<p>The New NIH Data Management and Sharing (DMS) Policy and the Role of HRPPs</p> <p>The new NIH Data Management and Sharing (DMS) policy requires inclusion of a data management and sharing plan with applications for NIH funding submitted on or after January 25, 2023.</p> <p>This session will provide a general overview of the policy, highlighting aspects that impact IRBs and HRPPs. In addition, speakers will discuss various institutional approaches for operationalizing and ensuring compliance with this policy while supporting their researchers.</p>	<p>Panelists: Taunton Paine, Director, Scientific Data Sharing Policy Division, Office of Science Policy, NIH; Josh Fedewa, University of Michigan; Monica Malian, R.Ph., HRPP Director, Wayne State University; Kristen Koritnik, JD, HRPP Director, Michigan State University; Candi Loeb, Director, Huron Consulting Group</p> <p>Moderator: Elyse Summers, JD, AAHRPP President and CEO</p>
2:45 - 3:00	Break	
3:00 - 3:30	<p>Supporting Community Engagement - OHRP resources</p> <p>With the expansion of community engagement, many more entities and people may become involved in the conduct of research. This session will provide an overview of OHRP resources that could be used to train and engage the community in protecting participants of research.</p>	<p>Speaker: Zena Alhija, DrPH, MPH, Public Health Program Analyst, HHS Office of Human Research Protections</p>
3:30 - 4:30	<p>Building on Belmont - What New Approaches to Justice Might Mean for the Research Protections Enterprise?</p> <p>During this interactive session, OHRP will invite the audience to a conversation on how to promote diversity, equity, inclusion, accessibility, and justice in human research while upholding appropriate protections.</p>	<p>Speaker: Natalie Klein, Ph.D., Director, Division of Policy and Assurances, HHS Office of Human Research Protections</p>
4:30 - 4:45	Notices and Wrap up	
4:45 - 6:00	Networking Reception	

Day one sessions meet the criteria in the Certified IRB Professional (CIP) recertification guidelines and are eligible for up to 5.25 CIP credits.

TIME	SESSION DETAILS	SPEAKER DETAILS
7:45 - 8:15	Conference Registration/Check-in	
8:15 - 8:30	Welcome and Opening Remarks	Rebecca Cunningham, MD, Vice President for Research, Professor of Emergency Medicine, and Institutional Official for the Human Research Protection Program, University of Michigan
8:30 - 9:15	<p>Addressing Health Inequities: Bridging Science and Policy</p> <p>During this moderated discussion, a nationally recognized pediatrician, researcher, and public health advocate whose research uncovered the Flint water crisis and a public policy and a national expert on child allowances that founded the center for Poverty Solutions will engage in a conversation about the impact of poverty on early childhood development and lifelong health conditions and the role of academic-community partnerships in addressing health inequities through research that drives policy changes.</p>	<p>Speaker: Mona Hanna-Attisha, MD MPH, Professor Public Health, Professor of Pediatrics and Human Development, Director of Pediatric Public Health Initiative, Michigan State University, College of Human Medicine and author of What the Eyes Don't See</p> <p>Speaker: Luke Shaefer, Ph.D., Professor of Social Work, Professor of Public Policy, Director of Poverty Solutions, University of Michigan and author of \$2 a Day: Living on Almost Nothing in America and The Injustice of Place</p> <p>Moderator: Julie Lumeng, MD, Associate Vice President for Research, University of Michigan, Professor of Child Behavior and Development, Professor of Pediatrics, University of Michigan</p>
9:15 - 9:30	Break/Coffee	(copies of each of the speaker's books will be given out to session attendees)
9:30 - 10:15	<p>The Intersection of Emerging Technologies and Research Ethics: Challenges and Opportunities</p> <p>In this session, attendees will learn about emerging artificial intelligence (AI) technologies and the ways that these technologies may be implemented in the context of human subjects research. Attendees will also explore how to evaluate the ethics of using AI technologies through contextual integrity to better guide regulatory oversight of these studies.</p>	Speaker: Michael Zimmer, Ph.D, Director of Center for Data Ethics and Society, Marquette University and Co-founder of the Pervasive Data Ethics for Computational Research (PERVADE) project
10:15 - 11:00	<p>Diversity, Equity and Inclusion in IRB Review and Oversight</p> <p>This session will consider the role of the Human Research Protection Programs (HRPPs) in creating expectations for equity and justice within research and will discuss some innovative approaches and practical measures that HRPPs can adapt to promote diversity, equity, and inclusion within their programs.</p>	Speaker: Barbara Bierer, M.D., Professor of Medicine, Harvard and Director of the Multi-Regional Clinical Trials Center (MRCT)
11:00 - 11:30	<p>Current OHRP Policy Initiatives - A Brief Account</p> <p>During this presentation, OHRP will share information about recent policy and guidance initiatives that are intended to assist IRBs, institutions, and investigators.</p>	Speaker: Natalie Klein, Ph.D., Director, Division of Policy and Assurances, HHS Office of Human Research Protections
11:30 - 12:30	Networking Lunch	

TIME Note: Sessions will have 5 min transition time	TRACK 1: EMPOWERING PARTICIPANTS/ENGAGING COMMUNITIES	TRACK 2: PROTECTING AND SHARING DATA
12:30 - 1:30 60 min	<p>Consent Form Innovations: Building Trust through Communications</p> <p>The speakers in this session will discuss integrating health literacy best practices in the consenting process and will describe the process for developing video consents in multiple languages and incorporating them into the electronic medical record.</p> <p>Speaker: Steve Gruber, M.D., Ph.D., M.P.H, Vice President, City of Hope National Medical Center</p> <p>Speaker: Christopher Trudeau, J.D., Associate Professor of Law, University of Arkansas</p>	<p>Data Sharing: Ethical Considerations</p> <p>During this session the speaker will discuss ethical considerations related to data sharing with emphasis on improving the oversight for secondary use of research data.</p> <p>Speaker: Kayte Spector-Bagdady, J.D., MBioethics, Co-Director Center for Bioethics and Social Sciences in Medicine, University of Michigan</p> <p>Speaker: Cheri Pettey, MA, Chairperson, Advarra</p>
1:35 - 2:35 60 min	<p>Collaborating with Community Partners</p> <p>During this session, speakers will discuss the role of Community-Academic research collaborations from the perspective of a researcher and a community representative. The speakers will also discuss the role of Community Ethics Review Boards and how they complement the role of Institutional Review Boards.</p> <p>Speaker: Hayley Thompson, Ph.D., Professor of Population Science and Associate Director of Community Engagement, Wayne State University</p> <p>Speaker: Ella Greene, Community Ethics Review Board (CERB) Administrator, Flint, Michigan</p>	<p>Certificates of Confidentiality and Data Protection</p> <p>The goal of this session is to provide a refresher to IRB/HRPP staff and researchers, raise awareness about the significance and scope of this program and generate a discussion around some of the challenges that should be considered by researchers and their institutions.</p> <p>Speaker: Adam Berger, Ph.D., Director, Division of Clinical and Healthcare Research Policy Office of Science Policy, NIH</p> <p>Speaker: Maya Kobersy, J.D., Associate General Counsel, University of Michigan</p>
2:35 - 2:50	Break/Coffee	
2:50 - 3:50	<p>Empowering the Participant Voice: Building a Research Participant Experience Evidence-Base to Improve How Research is Done</p> <p>During this session the speakers will describe efforts for assessing research participant experiences through a Research Participant Perception Survey (RPPS) and will share lessons learned from a decade-long project. The speakers will also discuss the significance of participant perspectives to the mission of human research protection programs (HRPPs) and provide implementation tips.</p> <p>Speaker: Rhonda G. Kost, M.D., Associate Professor of Clinical Investigation, Vice-Chair Institutional Review Board, Rockefeller University Center for Clinical Translational Science</p> <p>Speaker: Sana Khoury-Shakour, Ph.D, HRPP Associate Director, University of Michigan</p>	<p>Data Sharing Resources and Best Practices for Social and Behavioral Research</p> <p>During this session, the speakers will discuss data sharing best practices for social sciences research projects and will describe methods used by an international consortium, lessons learned from a longitudinal panel study, and implications to ethical review and oversight of such projects.</p> <p>Speaker: Amy Pienta, Ph.D., Research Professor, Institute for Social Research, ICPSR Director of Business and Collection Development, University of Michigan</p> <p>Speaker: Amanda Sonnega, Ph.D., Associate Research Scientist, Survey Research Center, Institute for Social Research, University of Michigan</p>
3:50 - 4:50	A conversation with OHRP, NIH, and FDA/Wrap up	

Day two sessions meet the criteria in the Certified IRB Professional (CIP) recertification guidelines and are eligible for up to 6.75 CIP credits.