Research in the Age of Technology – The Impact of Innovative and Emerging Technologies on Human Subjects Research

OHRP Research Community Forum with Oak Ridge Associated Universities, East Tennessee State University, and the University of Tennessee

Proposed Agenda for Day 1 Forum Workshop March 29, 2023

Primary Goal

The one-day Research Community Forum Workshop provides an opportunity for the research community to engage directly with OHRP staff to explore important aspects of human research protections. Distinct from the Forum Conference, the Forum Workshop combines didactic instruction and engaging interactions to help participants understand how to interpret and apply the U.S. federal regulations and policies on human research protections.

Target Audience

Investigators conducting biomedical or socio-behavioral human subjects research, research coordinators, and key personnel involved with a human research protections program (HRPP) including institutional review board (IRB) chairs and reviewers, IRB administrators, and institutional officials.

Participants are expected to have a working knowledge of the HHS regulations on human research protections.

Learning Objectives

- Understand and apply the ethical principles of research and the HHS policies for human research protections when conducting research
- Recognize the expectations and requirements for the IRB review process and understand how to fulfill the responsibility of protecting the rights and welfare of research subjects
- Explore the operational and implementational challenges in supporting an adequate institutional framework for protecting research participants

Educational Credits

This workshop meets the criteria in the Certified IRB Professional (CIP) recertification guidelines for a maximum of 315 minutes (5.25 credits) of accredited continuing education credits.

Time	Duration	Item
9:00 – 9:45	45 min	**Registration** ***Continental Breakfast**
9:45 – 10:00	15 min	**Welcome and Introductions (Organizer & OHRP)**
10:00-11:00	60 min	**A Philosopher's Look at the Belmont Principles** This session will discuss the Belmont Report Principles and offer insights on how to apply them to research studies where the regulations do not apply or are silent. Speaker: Ivor Pritchard
11:00-12:00	60 min	**Participant-Centered Informed Consent** This will be an interactive session to explore what a participant-centered informed consent may look like under the instructions of the Common Rule. Speaker: Yvonne Lau
12:00-1:00	60 min	***Networking lunch**
1:00-2:15	75 mins	**Case Discussion - Reviewing research under the Common Rule** 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. Speaker: Marianna Azar and Michael Stidham
2:15-2:30	15 min	**Supporting community engagement – OHRP resources** 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. Speaker: Michael Grippaldi
2:30-2:45	15 min	***Break**
2:45-3:45	60 min	**Case Studies Presented by HRPP Staff and IRB Chairs** The session will allow HRPP staff and IRB Chairs to present several case studies for audience discussion and analysis.

		Speakers: ORAU and other conference organizers (Lindsay Motz, Jennifer Engle, Katie Sellers)
3:45-4:30	45 min	**But what does the Common Rule mean by "Readily Ascertained" Anyway?** This session will review when the identity of the subject is or may readily be ascertained by the investigator or associated with the information or biospecimen. Audience will be invited to conduct mock reviews of studies and discuss what we commonly understand to be "readily ascertainable". Speaker: Michael Grippaldi
Total time = 315 mins (no basic content) * *Food and beverages provided courtesy of [Local Organizers/External sponsors]. OHRP funding does not support this portion of the event.*		

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Research in the Age of Technology
Crowne Plaza Hotel in Downtown Knoxville, Tennessee

Day 2 – Conference Day
March 30, 2023

7:30 – 8:30 am	**Registration** ***Breakfast**
8:30 – 8:45 am (15 mins)	**Welcome and opening remarks—**RCF Co-Hosts (Davyda Hammond, Program Manager for Organizational Culture Assessments at ORAU) and the Office for Human Research Protections (OHRP)
8:45 – 9:45 am (60 mins)	**Keynote Address: Renee Cummings, MA, MS, Professor of Practice in Data Science, UVA School of Data Science** 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 conducting this type of research with human participants and with private identifiable data.
9:45 – 10:45 am (60 mins)	**Plenary Session 1: Karriem Watson, MPH, DHS, Chief Engagement Officer at NIH All of Us Research Program** Dr. Watson will describe where the NIH "All of Us" research program is now and address how the research aims to overcome challenges it has faced since its launch. Dr. Watson will also describe how "All of Us" leveraged the use of technology for recruitment, retention, and data collection and explore whether technology has hindered or helped the "All of Us" effort.
10:45 – 11:00 am (15 mins)	***Break**
11:00 – 12:00 pm (60 mins)	**Plenary Session 2: Big Data Research** **Ivor Pritchard, PhD, Senior Advisor to the Director at the Office of Human Research Protections (OHRP)** ***Regulation and the Secrets of Big Data: Public, Private, or What?*** The presentation will examine how the history of technology has transformed the meaning of "privacy". The examination 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.
12:00 am – 1:00 pm (60 mins)	***Networking Lunch**

1:00 pm – 2:00 pm (60 mins)	**Artificial Intelligence and Machine Learning** This session will explore how we can work to reduce the risk that data used in AI/ML research will further perpetuate societal biases and cause harm to disadvantaged or marginalized populations; ethical practices and codes being developed or adopted to address the ever-growing field of AI/ML research; emerging challenges in AL/ML research; and when AL/ML research involves "human subjects." **Georgia Tourassi, Ph.D, Director of the National Center for Computational Sciences, Oak Ridge National Laboratory** **Jacob Metcalf, Ph.D., Data and Society Research Institute**	
	BREAKOUT SESSIONS	
	TRACK 1	**TRACK 2**
2:00 – 2:10 pm (10 mins)	***Break**	
2:10 – 3:10 pm (60 mins)	**Big Data and Biometric Research** Session speakers will address the ethical and regulatory considerations for conducting research using publicly available private information, including biometric data and other data the public or individuals might consider sensitive or confidential. Speakers will also grapple with privacy and security tradeoffs, our understanding of identifiable information, our responsibility to safeguard private identifiable information, and potential regulatory gaps. Recent research and technology examples about the use and protection of biometric data will be shared for the audience's consideration. **Hector Santos-Villalobos, PhD, Amazon.com** **Lynne Parker, PhD, Min H. Kao Department of Electrical Engineering and Computer Science, University of Tennessee, Knoxville**	**Mobile Health Technology and Mental Health and Psychiatric Research** In this session, speakers will discuss ethical considerations when conducting research using digital health data. First, Dr. Jessica Vitak will provide a broad overview of the research space, including considerations for collecting data from mobile devices and wearables and working with diverse populations. Second, Dr. Şerife Tekin will examine recent research trends in psychiatry that uses digital technologies to conduct research on mental disorders and discuss the potential risks and ethical problems that may arise therein. **Jessica Vitak, PhD, Associate Professor, HCIL Director, University of Maryland** **Şerife Tekin , PhD, Associate Professor, Director of Medical Humanities, University of Texas at San Antonio**

3:10 – 3:15pm (5 mins)	***Break**
3:15 – 4:00 pm (45 mins)	**A Conversation with OHRP and Wrap-up**

Educational Credits

This workshop meets the criteria in the Certified IRB Professional (CIP) recertification guidelines for a maximum of 240 minutes (4 credits) of accredited continuing education credits.