Trust, Technology and Consent
OHRP – Research Community Forum · Reno, Nevada
Day 2 Conference · October 26, 2022

7:30 am - 8:15 am	**Registration and Breakfast**

8:15 am - 8:45 am   **Welcome and Opening Remarks**

8:45 am - 9:45 am   **Keynote**

Building a Trust Infrastructure for Research with Pervasive Digital Devices

Speaker: Katie Shilton, PhD, College of Information Studies, University of Maryland, College Park

Description:
Researchers using increasingly available digital data streams (such as from embedded devices and online interactions) face a significant challenge defining norms or practices for ethical and trustworthy research. This talk will present the work of the collaborative PERVADE project on two entwined trust problems: participant awareness of such research, and the relationship of digital data research to corporate datafication and surveillance. Ways to address these problems will be suggested, as inspired by a research method which has also struggled with the trustworthiness of its practices: ethnography. To grapple with the colonial legacy of their methods, ethnographers have developed analytic lenses and researcher practices that foreground relations of power and participant awareness. The talk will then discuss ways that might form a trust infrastructure around such principles, supported by both researcher practices and Institutional Review Board expertise.

9:50 am - 10:50 am   **Plenary 1**

Trust Building and Creating Trustworthiness through Community Engagement: Bridging Researchers and Underserved Communities

Speaker: Sergio Aguilar-Gaxiola, PhD, UC Davis Center for Reducing Health Disparities

Description: The UC Davis Health Clinical and Translational Science Center's (CTSC) Community Engagement program is a well-established resource linking investigators and community partners to implement the mission of building capacity and infrastructure for clinical and translational research among investigators, patients, health care providers, policymakers, and community-based organizations. The program leverages institutional centers such as the Center for Reducing Health Disparities and resources focused on meaningful community and

stakeholder partnerships to support engagement between health-related researchers with underserved communities to advance health equity. This presentation will discuss an example of a successful community engagement effort on effectively advancing health equity at a county level. This evidence-based project is being scaled up to 40+ counties across California through a learning collaborative.

10:50 am - 11:00 am	**Break**

11:00 am - 11:45 am   **Plenary 2**

Promoting Inclusion and Building Trust – Opportunities Under the Common Rule

Speaker: Yvonne Lau, MBBS, MBHL, PhD, Division of Education and Development (DED) at the U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP)

Description:
The pandemic has highlighted issues with social equity and justice in our society. In response, there's increasing interest in broadening representation and facilitating engagement in research participation.
This presentation will:
• Review the Belmont principle of justice in human research ethics and how its interpretation has changed with time
• Explore how to leverage the Common Rule review criterion of equitable selection of subjects to promote inclusion in research
• Examine how the requirements for informed consent in the revised Common Rule may facilitate engagement and promote trust in research participation

11:45 am - 12:45 pm	**Networking Lunch**

12:45 pm - 4:00 pm	**Breakout Sessions (Track A or Track B)**

4:15 pm - 4:45 pm   A Dialogue with OHRP

4:45 pm - 5:00 pm   Closing Remarks

Breakout Session A – Technology

12:45 pm - 1:45 pm   **Track 1A: Participatory Research in the Age of Digital Health**

Speaker: Katherine Kim, PhD, MPH, MBA, FAMIA, MITRE

Description:
The availability of technology allows patients and community members to identify and communicate challenges that research may help address, contribute to data collection for studies, and co-design and deliver evidence-based public health and healthcare interventions. New models of research in which academic and community organizations collaborate such as citizen science and participatory research are being applied to a wide range of areas. In this session, citizen science and participatory research examples from clinical research to digital health-enabled chronic illness to community-based health assessment will be described along with challenges and lessons learned.

1:50 pm - 2:50 pm   **Track 2A: Privacy and Confidentiality in the Age of Mobile Apps and Connected Devices**

Speaker: Rob Romanchuk, BSHS, CIP, CCRC, CRCP, Advarra

Description: The widespread use of mobile apps and connected devices has become ubiquitous in clinical research, especially in the era of decentralized trials, further complicating the considerations of privacy and confidentiality in the protections of research subjects. This session will describe the scope and reach of digital devices and apps, their regulatory status and oversight, and zero in on how their use impacts subject privacy and confidentiality. What should researchers consider in selecting and using such apps and devices? What expectations can or should research subjects reasonably hold and how can subjects be adequately informed? What should IRBs consider in their review of protocols employing mobile apps and connected devices? These and other questions will be addressed.

2:50 pm - 3:10 pm

Break

3:10 pm - 4:10 pm   **Track 3A: Virtual Reality Research: Risks, Benefits, and Regulatory Challenges**

Speakers:
Megan Rumzie, DNP, MBA, RN, CNL, HNB-BC, VA Sierra Nevada Health Care System
Carla Figura, PharmD, VA Sierra Nevada Health Care System

Description:
This session will focus on the particularities and regulatory challenges of conducting research on virtual reality (VR) in the Veteran population. VR is an innovative technology with the potential to improve challenging conditions such as chronic pain and suffering among Veterans. The presenters will offer concrete examples of VR research projects designed to leverage this technology while also addressing concerns about its safety and minimizing participant risks.

12:45 - 1:45 pm

Track 1B: Research with non-traditional vulnerable populations: People who engage in illicit and illegal activity

Speakers:
Julia Gorey, JD, Office for Human Research Protections, Division of Policy
Juliette Roddy, PhD, Northern Arizona University

Description: The session offers an overview of research protections for those specifically defined as vulnerable populations and then focus on non-traditional vulnerable populations. Although people who engage in illicit and illegal activities are not specifically defined as a vulnerable population, investigators who engage with this population as human subjects in their research should plan for protections beyond what is offered for typical human subjects. Learning objectives include: (1) Identifying the nature, severity, and probability of risks inherent to research of illegal/illicit behaviors and (2) Developing best practices for: (a) meliorating risks in study design and (b) conducting IRB review of study protocols. These objectives are accomplished by examining practical, ethical and legal considerations; discussing case studies; and summarizing best practices.

1:50 pm - 2:50 pm

Track 2B: Operationalizing Gender-Neutral Language in Research Consent Documents

Speaker: Nicole Walters, University of California, Davis

Description: Using gender-neutral language builds inclusion into research documents and demonstrates respect for participants of all gender identities. This session will focus on one institution's efforts to eliminate gendered language from research consent documents. Attendees will hear about the actions taken to remove gender-specific language in consent templates as well as some lessons learned during the first year of implementation.

2:50 pm - 3:10 pm

Break

3:10 pm - 4:10 pm

Track 3B: Teenage Mothers Pregnancy Risk Research: Navigating Ethical and Regulatory Requirements to Protect Sensitive Information

Speaker: Wei Yang, PhD, MD, University of Nevada, Reno

Description:
Nevada Pregnancy Risk Assessment Monitoring System is a project that works with a sample of women who have had a recent live birth which is drawn from the state birth certificate file. Sensitive information including subject identifier, medical history and risk behaviors are collected, as well as under age mother could be sampled as part of the study. The protection of human subjects is a critical part of the project and the procedures and considerations will be discussed.