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

Speaker: Mridul Gautam, PhD, Vice President for Research and Innovation, University of Nevada, Reno

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 (Session A or Session 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: Deploying Virtual Reality to Decrease Chronic Pain and Suffering within the Veteran Population**

**Speakers:**
Megan Rumzie, MSN, 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 use of virtual reality as an innovative technology and practice to improve pain within the Veteran population. The presenters will highlight outcomes and learnings gathered during a feasibility study using virtual reality headsets in the outpatient setting.

Breakout Session B – Research with Vulnerable Populations
<table>
<thead>
<tr>
<th>Time</th>
<th>Track 1B: Border and Refugee Populations: IRB Considerations and Risks for These Vulnerable Populations</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:45 pm</td>
<td>This session speaker and topic will be announced soon.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time</th>
<th>Track 2B: Operationalizing Gender-Neutral Language in Research Consent Documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:50 pm - 2:50 pm</td>
<td>Speaker: Nicole Walters, University of California, Davis</td>
</tr>
<tr>
<td></td>
<td><strong>Description:</strong> 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.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time</th>
<th>Break</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Time</th>
<th>Track 2C: Teenage Mothers Pregnancy Risk Research: Navigating Ethical and Regulatory Requirements to Protect Sensitive Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>3:10 pm - 4:10 pm</td>
<td>Speaker: Wei Yang, PhD, MD, University of Nevada, Reno</td>
</tr>
<tr>
<td></td>
<td><strong>Description:</strong> 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.</td>
</tr>
</tbody>
</table>