

Speaker Information

DAY 1 · OHRP Forum Workshop · October 25, 2022



Marianna Azar

Program Specialist

*U.S. Department of Health and Human Services Office
for Human Research Protection*

Marianna Azar is a Program Specialist with the Division of Education and Development at the Office for Human Research Protections (OHRP), U.S. Department of Health and Human Services. Before joining OHRP, Ms. Azar served as Director and Chair of the Institutional Review Boards for the New York City Department of Education. Prior to that, she was employed as a Human Research Protection Program Manager at the City University of New York Graduate Center, and as an IRB Specialist at Columbia University's Human Research Protection Office.

Marianna holds a BA in Philosophy from the State University of New York at Oswego, an MA in Philosophy and a Graduate Diploma in Health Services and Policy Research from York University in Toronto, Canada, and is also working on completing her Ph.D. in Bioethics at York University.

Lisa R. Buchanan, M.A.O.M, C.I.P.

Director, Division of Compliance Oversight

*U.S. Department of Health and Human Services Office for Human
Research Protection*

Lisa R. Buchanan, M.A.O.M, C.I.P., Director, Division of Compliance Oversight, Office for Human Research Protections (OHRP), Department of Health and Human Services, Rockville, Maryland. Ms. Buchanan leads a team of professionals to provide compliance oversight of human subjects research that come under HHS's jurisdiction. Before moving to OHRP in 2008, she was Director of Operations for Chesapeake Research Review, an independent IRB in Columbia, Maryland. She has over 20 years of experience in the human subjects protections field; specifically, in areas of regulatory compliance, IRB operations and training. She has held leadership positions at Children's National Medical Center in Washington, DC, the National Institute of Allergy and Infectious Diseases (intramural IRB), George Washington University, and the National Cancer Institute's – Central IRB.



Speaker Information



Julia Gorey, JD

Public Health Analyst

U.S. Department of Health and Human Services Office for Human Research Protection

Julia Gorey serves as a Public Health Analyst in Office for Human Research Protections, Division of Policy, Department of Health and Human Services (HHS), and is charged with writing and interpreting guidance and policy for 45 CFR part 46, the HHS regulations for the protection of human subjects in research. In addition to general responsibilities, she oversees the administration of subpart C and the review and authorization of human subject research involving prisoners; she also serves as Executive Director of the Secretary's Advisory Committee on Human Research Protections (SACHRP), which provides expert advice and recommendations to the

Secretary, HHS, on issues relevant to research involving human subjects with a particular emphasis on vulnerable populations.



Yvonne Lau, MBBS, MBHL, PhD

Director of the Division of Education and Development

U.S. Department of Health and Human Services Office for Human Research Protection

Yvonne Lau, MBBS, MBHL, PhD is the Director of the Division of Education and Development (DED) at the U.S. Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP). Dr. Lau received her medical degree from the University of Hong Kong, and is a Fellow of the Royal College of Surgeons of Edinburgh (FRCSEd) in the United Kingdom. She obtained her Master in Bioethics and Health Law (MBHL) and her PhD in Bioethics from the University of Otago in New Zealand.

Speaker Information

John D. Tupin, JD

*Director of IRB Administration
University of California, Davis*

John Tupin serves as the Director of IRB Administration at the University of California, Davis. There are four campus-wide IRBs that review, monitor and administer oversight of over 2,500 active studies and over 400 reliance agreements.

Prior to UC Davis he served as the Chief of Research Compliance and Oversight with the McConnell Group at Travis AFB. He was the lead medical research ethicist for the 60th MDG and led reviews and technology reviews for the Air Force throughout the Western United States and Pacific Rim. His special interests were combat casualty care and expeditionary medicine.

Prior to the McConnell group he worked with Lovelace Respiratory Research and the Mann Foundation. He is the original founder of LifeWave Biomedical, a medical device firm that is in clinical trials with an ultra-wideband radar.



DAY 2 · Conference · October 26, 2022



Katie Shilton, PhD

Associate Professor

*University of Maryland,
College Park*

KEYNOTE: Building A Trust Infrastructure for Research with Pervasive Digital Devices

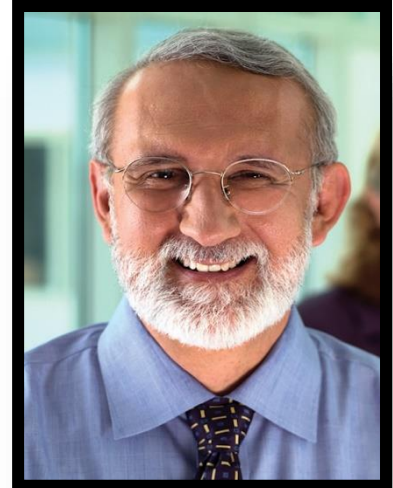
Katie Shilton is an associate professor in the College of Information Studies at the University of Maryland, College Park. Her research explores ethics and policy for the design of information technologies. She is the PI of the PERVADE project, a multi-campus collaboration focused on big data research ethics. Other projects include developing privacy-sensitive search for email collections; analyzing ethical cultures in computer security research; and building tools to facilitate ethics discussions in mobile application development. Her work has been supported by a Google Faculty Award and multiple awards from the U.S. National Science Foundation. Katie received a B.A. from Oberlin College, a Master of Library and Information Science from UCLA, and a Ph.D. in Information Studies from UCLA.

Speaker Information

Plenary 1: Trust Building and Creating Trustworthiness through Community Engagement: Bridging Researchers and Underserved Communities

Dr. Sergio Aguilar-Gaxiola is a professor of clinical internal medicine, School of Medicine, University of California (UC), Davis. He is the founding director of the Center for Reducing Health Disparities at the UC Davis Health System, the director of the Community Engagement Program of the UC Davis Clinical and Translational Science Center, the co-director of the UC Davis Latino Aging Research and Resource Center, and co-chair of NIH's Community Engagement Key Function Committee for the NIH-funded Clinical and Translational Science Awards. In 2007, he completed a 4-year term as a member of the National Advisory Mental Health Council of the National Institute of Mental Health. He was the chairman of the Board of Directors of Mental Health America for a 2-year term (2008-2010). He is currently a board member of the Steering Committee and Research Scientist member of the National Hispanic Science Network, a member of the Scientific Advisory Committee of Autism Speaks, a member of the International Advisory Committee of the Carlos Slim Health Institute, a member and treasurer of the Board of the Latino Physicians of California, first vice president of National Alliance on Mental Illness (NAMI) California, and a member of the California Medical Board's Cultural and Linguistic Competency Program Workgroup. He has held several World Health Organization (WHO) and Pan American Health Organization advisory board and consulting positions and is currently a member of the Executive Committee of the WHO World Mental Health Surveys Consortium and its coordinator for Latin America and the Caribbean.

Dr. Aguilar-Gaxiola's research includes cross-national comparative epidemiologic research on patterns and correlates of mental disorders and substance abuse in general population samples. His applied research program has focused on identifying unmet mental health needs and associated risk and protective factors to better understand and meet population mental health needs and reduce mental health disparities primarily in underserved populations. He is also very active translating mental health and substance abuse research knowledge into practical information that is of public health value to consumers and their families, service administrators, and policy makers. Dr. Aguilar-Gaxiola is the author of more than 120 scientific publications. He is the recipient of multiple awards including the Vanderbilt University Distinguished Alumnus Award, the Medal of Congress ("Medalla de la Cámara de Diputados") of Chile for work related to mental health research, the U.S. Department of Health and Human Services Office of Minority Health's 2005 National Minority Health Community Leader Award (Hispanic Community), the 2009 National Award of Excellence in Blending Research and Practice from the National Hispanic Science Network, and the 2012-2013 UC Davis Chancellor's Achievement Award for Diversity and Community in the Academic Senate category. Dr. Aguilar-Gaxiola was a member of the U.S. Institute of Medicine/National Research Council (IOM/NRC) Committee on Depression, Parenting Practices, and the Health Development of Young Children (2007-2009) report and the IOM/NRC Women's Health Research: Progress, Pitfalls, and Promise (2010) report.



Sergio Aguilar-Gaxiola, MD, PhD
Professor

University of California Davis

Speaker Information

Plenary 2: Promoting Inclusion and Building Trust- Opportunities under the Common Rule

See page 2 for bio of speaker Yvonne Lau, MBBS, MBHL, PhD, Director of the Division of Education and Development, U.S. Department of Health and Human Services Office for Human Research.

Breakout Session 1 A: Participatory Research in the Age of Digital Health

Dr. Katherine Kim is a health informatics researcher and program developer specializing in digital health and community engagement. Dr. Kim is Principal, Consumer Health Informatics at MITRE, a non-profit research and development organization. She is also an Adjunct Associate Professor at the University of California Davis in the School of Medicine, Public Health Sciences Department. Dr. Kim leads ACTIVATE, a comprehensive model for equitable and sustainable digital health for underserved and rural communities. The ACTIVATE program provides community health centers with technology and assistance to develop virtual care, remote patient monitoring, and digital health literacy that engages patients and improves health outcomes. She serves as the Clinical Lead for MITRE's Age Better Lab™, a connector and collaborator with academia, government, and industry for aging research and digital health solutions.



Katherine Kim, PhD, MPH, MBA, FAMIA
Principle, Consumer Informatics at MITRE
Adjunct Associate Professor

University of California Davis

Dr. Kim has received numerous awards for community-engaged and participatory research related to mobile applications for cancer care coordination, precision health, and citizen science with Native American communities.

Dr. Kim has over 20 years of previous experience as a hospital and medical group manager, an entrepreneur – CEO of a venture-funded startup, leader of a technology incubator, and founder of a consulting firm – and in software product development with Oracle. She received a PhD at UC Davis, MPH/MBA at UC Berkeley, and BA at Harvard.

Speaker Information



**Rob Romanchuk, BSHS, CIP,
CCRC, CRCP**
Clinical Research professional

Breakout Session 2A: Privacy and Confidentiality in the Age of Mobile Apps and Connected Devices

Rob Romanchuk is a clinical research professional with over 2 decades of experience in research operations and human subjects protections. After spending 15 years building and managing a central research office for a large multi-hospital community health system, he went on to work as IRB member and Chair for a large independent IRB where he also specializes in medical device research reviews. He speaks widely on topics ranging from contract and budget negotiation to the protection of vulnerable subjects. He has a BSHS in Clinical Research Administration and has certifications as CCRC, CIP and CRCP.



Carla Figura, PharmD
*Clinical Pharmacy Specialist
in Pain Management*

VA Sierra Nevada HCS

Breakout Session 3A: Deploying Virtual Reality to Decrease Chronic Pain and Suffering within the Veteran Population

Carla Figura, PharmD, is a graduate of the University of Florida College of Pharmacy where she earned her PharmD degree in May 2018. She completed her residency training at VA Tennessee Valley Healthcare System in Nashville/Murfreesboro, TN, where she completed a PGY2 residency in Pain Management and Palliative Care in June 2020. Dr. Figura now serves as the Clinical Pharmacy Specialist in Pain Management at the VA Sierra Nevada Health Care System in Reno, NV.

Speaker Information

Breakout Session 3A: Deploying Virtual Reality to Decrease Chronic Pain and Suffering within the Veteran Population

Ms. Megan Rumzie is a registered nurse who currently works as the Virtual Reality (VR) clinical leader at the VA Sierra Nevada HCS. This multi-disciplinary modality to improve pain, stress, and improve mood has been implemented in the Community Living Center, the Mental Health Unit (MHU), and the Medical Surgical Units within the Reno VA. She has led an innovation ecosystem spread of VR to 6 VA facilities and recently completed a research study to explore the feasibility of using VR in the outpatient setting. Following up on this feasibility study she was awarded an innovation grant to further study the use of VR for Women Veterans with Post Traumatic Stress Disorder (PTSD). Her work with VR in the MHU was considered a national VA best practice and is featured on the VA Diffusion of Excellence Marketplace which is now accessible to community partners to help spread innovative practices beyond the VA. Her work also includes the use of this technology to reduce burnout among clinical staff.



**Megan Rumzie, MSN, MBA, RN, CNL,
HNB-BC**

Virtual Reality Clinical Leader

VA Sierra Nevada HCS

Ms. Rumzie recently received the GX2 Disruptor Award which is a Federal IT award to honor innovative practices within the federal government. She was named the Northern Nevada Nurse of Distinction Nurse Innovator of the Year Award in 2021, has received a commendation from the US Senate for her service to Veterans, and recently was selected as one of the top graduates of University of Nevada, Reno with her picture featured on the “Wolf Walk Way.” She has a Master’s in Nursing as well as a Master’s in Business Administration. She is a certified Clinical Nurse Leader and a certified Holistic Nurse. She completed her Doctorate of Nursing Practice in the Spring of 2022 and is committed to challenge the status quo by embracing innovative practices to improve the lives of Veterans. In her free time, she enjoys hiking, skiing, and boating with her family, reading, and traveling (anywhere).

Breakout Session 2A: Research with non-traditional vulnerable populations: People who engage in illicit and illegal activity

See page 1 for bio of speaker Julia Gorey, JD, Public Health Analyst, Office for Human Research Protections.

Speaker Information

Breakout Session 2A: Research with non-traditional vulnerable populations: People who engage in illicit and illegal activity

Dr. Julie Roddy (Economist) is the James Wurgler, MD Chair of Criminal Justice and Behavioral Health within the Criminology and Criminal Justice Department at Northern Arizona University and a Northern Arizona Behavioral Health Authority Institute Transformational Fellow. Dr. Roddy participates in research and offers subject matter expertise to both large national institutions and small community organizations in support of evidence-based practices delivered in a cost-effective manner. She is currently participating in two NIH funded studies: one to examine resilience among Arizona tribal members in recovery and another that develops training in culturally-centered tele-behavioral health practices. Other research focuses on substance use, recovery, incarceration and re-entry and the role of housing in each of these areas. She is an executive member (treasurer) on the Board of Directors of Native Americans for Community Action in Flagstaff. She also sits on the board of Flagstaff Shelter Services, on the Indigenous Peoples' Advisory Council for Coconino County, the Flagstaff Police Department's Citizen Liaison Committee and is a lifetime member of the Native Research Network. Dr. Roddy has served as a prisoner representative on the University of Michigan and Northern Arizona University. She consults with other University, organizational and community boards on the proper protections for human subjects participating in research and reviews research for SAMSHA, NIH, NSF and the Administration for Native Americans. Dr. Roddy is a member of the Sault Ste. Marie Tribe of Ojibwe Indians, Migizi clan.



Juliette Roddy, PhD
Chair of Criminal Justice and Behavioral Health
Northern Arizona University

Julie moved from Detroit, Michigan to Flagstaff in January 2020 with her dog, Maxine. Thus far, she and Max have enjoyed every moment of their new mountain home.



Nicole Walters
Associate Director
University of California, Davis

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

Nicole Walters is the Associate Director for UC Davis IRB Administration. She holds a bachelor's degree in Biological Sciences from University of the Pacific and is certified as both an IRB professional and project manager. Nicole started her research career at the UC Davis MIND Institute where she worked with children and their families participating in autism research. Through her experience with research participants she became interested in the ethical conduct of research and transitioned into research administration. She has more than a decade of IRB Administration experience and her current focus is process improvement, education, and training.

Speaker Information

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

Dr. Wei Yang is the Associate Dean and Foundation Professor of Epidemiology and Biostatistics at the School of Public Health, University of Nevada, Reno. He also serves as the Executive Director of the Nevada Center for Surveys, Evaluation, and Statistics (CSES). His research focuses on population-based surveillance on health status and behaviors, environmental epidemiology, and applied statistical methodology for clinical and translational research. Prior to joining the University of Nevada, Reno in 2007, he served as a physician and a clinical epidemiologist in occupational medicine, the Nevada State Chief Biostatistician, and the Director of the Center for Health Data and Research at the Nevada State Department of Health and Human Services.



Wei Yang, PhD, MD

Associate Dean

*Foundation Professor of
Epidemiology and Biostatistics*

University of Nevada, Reno