# 2023 Protection of Human Subjects Conference Agenda

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| 8:00a-8:30a | Introduction |
| 8:45a-10:00a | Gigi McMillan - Personal Narrative and Research Ethics |
| 10:15a-11:30a | Keyonna King & Russell McCulloh - Understanding the Community-Based Participatory Research (CBPR) Approach for Community-Engaged Research Projects: Lessons Learned |
| 11:45a-12:45p | Lunch |
| 1:00p-2:15p | David Strauss - Re-examining the IRB's Role in Protecting Research Subjects |
| 2:30p-3:30p | John Windle – Uncovering Bias in Artificial Intelligence |
| 3:45p-4:45p | Joseph Brown & Dustin Krutsinger - Limits on the payment of subjects: Are they needed |

**Gigi McMillan**

Gianna “Gigi” McMillan, D. Bioethics, MFA, is the Associate Director for the Bioethics Institute at Loyola Marymount University in Los Angeles, where she develops academic curriculum and teaches graduate courses in Research Ethics and undergraduate Introduction to Bioethics. She received doctorate from Loyola Chicago and her MFA in Creative Nonfiction at Mount Saint Mary’s in Los Angeles. Dr. McMillan has been an adviser to the Children’s Brain Tumor Foundation, the National Brain Tumor Society, and the Pediatric Brain Tumor Consortium. She has extensive experience as a Subject/Patient Advocate on local and national IRBs, was a member of the Subpart A Subcommittee for the Secretary’s Advisory Committee on Human Research Protection and is a member of the FDA’s Pediatric Advisory Committee. Dr. McMillan has served on the board of the American Society for Bioethics and Humanities and is currently on the Board of PRIM&R (Public Responsibility in Medicine & Research.) She is the Director of Community Engagement for the academic journal, *Narrative Inquiry in Bioethics*. Her primary interests are consent issues in clinical research and the use of narrative as an educational tool in bioethics.

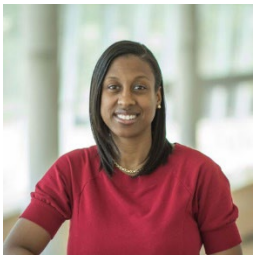
**David Strauss**

David H. Strauss, M.D. is a special lecturer in the department of psychiatry, Vagelos College of Physicians and Surgeons, Columbia University.

Dr Strauss heads the ethics unit of an NIMH Center grant, is an external advisor to Takeda Pharmaceutical's Ethics Advisory Council, and serves as senior advisor to the Multi-Regional Clinical Trials Center at Harvard and Brigham and Women's Hospital. He is faculty on Fordham's HIV and Drug Abuse Prevention Research Ethics Training Institute, and he is a newly appointed member of the Microsoft Research IRB within Microsoft's Ethics Review Program. Dr Strauss is a longstanding member of the Subpart A subcommittee of the HHS Secretary's Advisory Committee on Human Research Protections where he led the development of guidance for the inclusion of individuals with impaired consent capacity in research, guidance on minimal risk, and guidance on the effects of research risk on non-subjects, among other work.

Previously, Dr. Strauss, held leadership positions at the NYS Psychiatric Institute and Columbia's Department of Psychiatry over the course of a 30-year career there, including vice chair for research, director of research operations, IRB chair, clinical director, and chief of the schizophrenia research unit. At the University level, he chaired Columbia's committee on the conduct of research. He is a former member of the board of directors of Public Responsibility in Medicine and Research.

Dr. Strauss practices psychopharmacology and psychotherapy in NYC and Western Massachusetts. He teaches, lectures, and consults on matters of applied research and professional ethics.



**Keyonna King**

Keyonna King has a doctorate in public health with a concentration in preventive care from Loma Linda University, and a master's in psychology with a clinical emphasis from Pepperdine University. She also has a B.A. in psychology from Creighton University. She is trained in using mixed methods research designs and has extensive experience utilizing the Community-Based Participatory Research (CBPR) approach to address health disparities and health inequities with historically and systematically marginalized and excluded groups such as Black, Indigenous, and People of Color (BIPOC).

Dr. King is an Associate Professor at University of Nebraska Medical Center in the College of Public Health, Department of Health Promotion. She teaches the Foundations of CBPR (Fall) and the Applications of CBPR (Spring) to graduate and professional students. She practices the CBPR approach to engage community in projects to address health disparities and achieve healthy equity through UNMC's Center for Reducing Health Disparities. Specifically, she primarily partners with the North Omaha community to address priority health needs identified by the community. Some of her past and current projects focus on addressing mental health, chronic disease intervention and prevention, violence, and improving the diversity of the healthcare workforce.

Dr. King is also the Director of the Community Engagement & Outreach core of the Great Plains IDeA Clinical Translational Research Network (GP IDeA-CTR) at UNMC. She leads the core in developing and implementing community engagement and outreach trainings and dissemination of resources to ensure the research/work is relevant and meeting the needs of underserved people and areas of Nebraska.

Dr. King focuses her independent research efforts on using CBPR to understand and address depression in Black men; and improving mental and physical health outcomes.

Twitter: @kmk_fitness

**Russell McCulloh**

Russell McCulloh, MD, serves as the vice president for research for Nebraska Medicine and the associate vice chancellor for clinical research for the University of Nebraska Medical Center (UNMC), leading man of the clinical research initiatives for the academic health system.

Dr. McCulloh also serves in a research operation director's role at Children's Nebraska. He previously served as assistant dean for clinical research for the College of Medicine and director for clinical and translational research operations for Children's Nebraska.

Dr. McCulloh joined UNMC in 2018, in part to direct the NIH-funded Nebraska Pediatric Clinical Trials Unit, which focuses on conducting high-quality clinical trials engaging children and families and increasing the capacity to conduct clinical research across Nebraska.

**Dustin Krutsinger**

Dustin Krutsinger, MD, MS is an Assistant Professor of Medicine in the Division of Pulmonary, Critical Care, and Sleep Medicine. His primary research focus is on the efficient, equitable, and ethical conduct of critical care clinical trials. His prior research has shown that enrollment into critical care trials is extremely slow, due in part to the reliance on family members who are under extreme stress to serve as surrogate decision makers. He has conducted studies to understand how ICU surrogate decision makers make enrollment decisions. He has also conduced empiric evaluations of both financial and non-financial incentives to encourage research participation.

**John Windle**

In 1985, Dr. Windle joined the faculty at the University of Nebraska Medical Center and established the first adult electrophysiology program in Nebraska. He began projects into digitizing the EP lab and working on advanced cardiac mapping with Drs. Olson and Throne from the University of Nebraska-Lincoln. Also in the 1990's he became involved in quality improvement and became the Associate Dean for Continuing Medical Education with a charge to bring computer-based education online. The emergence of the electronic medical record provided an opportunity to move learning into the clinics. Dr. Windle has spent the past 25 years working to make digital technology work for clinicians with extramural funding from the National Science Foundation, National Institute for Standards and Technology, the National Library of Medicine, and the Agency for Health Care Quality and Research.

After 16 years as Chief of the Division of Cardiovascular Medicine, Dr. Windle stepped away from administration and now concentrates on clinical care and directing the Center for Intelligent Health Care. Dr. Windle's research interests are in optimizing the electronic health record, and developing artificial intelligence solutions that make clinicians more efficient and effective, and patients safer and more satisfied with their care with an emphasis on explainable AI and causality algorithms.

**Joseph Brown**

Joseph S Brown received his PhD in Cognitive Psychology from Michigan State University in 1991. After joining the UNMC/UNO IRB, he has pursued an interest in human research subject protection and general ethical issues in medicine. He has written a number of articles on research protections for women and children and well as assessments of risks and the cognitive psychology of research participation. He has been recognized for both his teaching and scholarship in ethics, including receiving the James R. Schumacher Professorship of Ethics. He is a frequent ethics reviewer for federal grant panels, and has been invited faculty for the Public Responsibility in Medicine and Research (PRIMR) annual conference on numerous occasions. He is currently a professor in the Psychology Department of the University of Nebraska-Omaha, where he serves as vice-chair and chair

of the graduate program committee.  He also serves as Chair for one of the IRB's of the University of Nebraska Medical Center and University of Nebraska-Omaha.

**Bruce Gordon**

Dr. Gordon is UNMC's Assistant Vice Chancellor for Regulatory Affairs and a Professor of Pediatrics in the section of Pediatric Hematology/Oncology and Stem Cell Transplantation at the UNMC. Dr. Gordon has been a member of the UNMC Institutional Review Board since 1992 and served as Chair since 1996, and Executive Chair since 2011. He organized and is first Chair of a Joint Pediatric IRB with the Children's Nebraska in Omaha.

He has served on a variety of national committees and task forces (including the DHHS Secretary's Advisory Committee on Human Research Protections Subpart A subcommittee) and served as the first chairman of the National Cancer Institute Pediatric Central IRB. He has been faculty at PRIM&R regional and national meetings, served as the co-chair for the 2009 PRIM&R national conference, and is the author of numerous original papers, review articles and abstracts regarding human subjects protection and research ethics.