

Date: Friday, September 13th, 2024

Time: 8:00am-4:30pm

## **2024 Agenda**

Last updated: 9/9/2024

- 8 a.m.: Introduction.
- 8:15 a.m.: Megan Singleton, "Remote Research: Navigating De-Centralized Trials."
- 9:25 a.m.: Lou Lukas, "Considerations for Patient Safety in Studies of Psychedelics and other Non-Ordinary States of Consciousness."
- 10:35 a.m.: Scott Campbell, "Big Data and Research Ethics."
- 11:40 a.m.: Lunch.
- 12:45 p.m.: Bruce Gordon, "Research on the Edge."
- 2 p.m.: Nichelle Cobb and Nancy Olson, "Let's Review Some Research."

## **Speakers and Panelists**

### **Megan Kasimatis Singleton, JD, MBE, CIP**

Ms. Singleton is the associate dean for human research protections and director of the Human Research Protections Program at Johns Hopkins University School of Medicine. In this role, she is responsible for oversight and direction of their eight IRBs. Ms. Singleton is a licensed attorney in Pennsylvania. She earned her law degree from Temple University and her masters in bioethics from the University of Pennsylvania. Ms. Singleton serves as a member of the SMART IRB Harmonization Steering Committee, member of the PRIM&R Board of Directors, Chair of PRIM&R's nominations and elections committee and co-chair of PRIM&R's public policy committee. Ms. Singleton is also an AAHRPP, Inc. site visitor and Co-Chair of the AAHRPP council. She also serves as a member of the steering committee for AEREO, a consortium designed to advance effective research ethics oversight through empirical research. Ms. Singleton currently teaches at the graduate level at the University of Pennsylvania and Johns Hopkins University, leading courses in research ethics and clinical trial management. She has developed research ethics curriculum and practical training in IRB administration tailored for national and international audiences.

### **Elizabeth Buchanan, PhD, CIP**

Dr. Buchanan is a research ethicist and research administrator with over 25 years of professional experience. She received her bachelor of arts with a double major in philosophy and English from Rutgers University (1992), after which she completed a master of library and information science (1996) and a multidisciplinary PhD (1999) from the University of Wisconsin-Milwaukee.

Dr. Buchanan has held numerous academic positions, including assistant then associate professor; director, Center for Information Policy Research (1999-2011, UW-Milwaukee); endowed

chair in ethics and director, Center for Applied Ethics (2012-2020, UW-Stout); senior research scientist and director, Office of Research and Sponsored Programs (2020-2023, Marshfield Clinic Research Institute), and currently, associate vice-president, Research Administration, University of Rhode Island. She is known for her scholarship in Internet research ethics, with one of the first scholarly handbooks in the field published in 2003. Her recent publications include: “How to Think About Online Research Ethics,” (Sage, 2022); co-author, “Navigating the Ethical and Methodological Dimensions of a Farm Safety Photovoice Project,” *Bioethical Inquiry* (2023); and co-author, “Capturing a Moving Target: Ethical Research Practices for Hashtag Activism,” in *Hashtag Activism Interrogated and Embodied: Case Studies on Social Justice Movements* (Utah University Press, 2023). Her administrative experience began in 2014, and has included oversight of sponsored programs, IRB, Institutional Animal Care and Use Committee, data and material transfer agreements, research navigation, and scientific writing.

A native of Wildwood Crest, New Jersey, Elizabeth now resides in Chippewa Falls, Wisconsin, with her husband, two kids (one a senior at UW-Eau Claire and one a freshman at University of Minnesota), two dogs, three cats, and lots of fish.

### **Lou Lukas, MD**

Dr. Lukas is an associate professor of palliative medicine and neurological sciences at UNMC and the chief of palliative medicine at the Nebraska and Western Iowa VA. She graduated from UNMC College of medicine, the Lehigh Valley Health Network’s Family Medicine Residency and the Robert Wood Johnson Clinical Scholars Fellowship at the University of Michigan. Originally a family physician, she migrated to palliative medicine when that field was new and is now leading a push for what she describes as Palliadelic Health, “relieving suffering by revealing the mind.”

She became interested in psychedelics for palliative medicine after being a participant in a clinical trial of psilocybin for spiritual development at Johns Hopkins University in 2012. She is the PI for an exploratory trial exploring a psilocybin- and IFS-based intervention for distress related to advanced GI cancers, and the site PI for phase III trial of psilocybin for major depressive disorder, and is currently collaborating on a large multisite proposal to test the safety and early efficacy of psilocybin for chronic pain in older adults.

### **Scott Campbell, PhD, MBA**

Dr. Campbell is a professor in the department of pathology at UNMC, the Peter C. Hinrichs endowed chair of informatics sr. director of research technologies, and the director of pathology and public health informatics

He received his BS in mathematics with emphasis in computer science and his MBA at the University of Wisconsin, and his PhD in health informatics at UNMC.

### **Nichelle Cobb, PhD**

Dr. Cobb is the senior advisor for strategic initiatives for the Association for the Accreditation of Human Research Protection Programs and previously a site visitor for AAHRPP and member of AAHRPP’s Council on Accreditation. Prior to joining AAHRPP, she was the Director of the Health Sciences Institutional Review Boards for 16 years at the University of Wisconsin-Madison and has

worked with IRBs for 20+ years. Nichelle has been involved in single IRB work for more than a decade and was instrumental in the development of the SMART IRB Master Reliance Agreement and serves as a senior advisor and ambassador for SMART IRB, a federally funded project that supports the implementation of single IRB. In addition, Dr. Cobb is a member of the SMART IRB harmonization steering committee and has co-lead working groups to harmonize IRB and Human Research Protection Program practices, such as for reportable events, ancillary reviews, continuing review, and local context. Dr. Cobb also has been a member and co-chair of the Workshop and Didactic Subcommittee for the Public Responsibility in Medicine and Research annual Advancing Ethics in Research Conference, contributed to the third edition of "IRB Management and Function," authored academic articles on single IRB and informed consent, and developed and taught PRIM&R courses for new IRB administrators and about the common rule.

### **Nancy Olson, JD**

Ms. Olson is an IRB analyst at UNMC. She has more than 20 years of experience working with IRBs, including as the former director of the human research office at the University of Mississippi Medical Center and consulting in the field of human research protections. Ms. Olson serves as a faculty member for PRIM&R's IRB administrator educational programs and as a speaker at regional and national meetings, including PRIM&R and AAHRPP. Ms. Olson was a member of the Secretary's Advisory Committee on Human Research Protections, a consultant to the Office for Human Research Protections, a past co-chair of PRIM&R's advancing ethical research conference poster abstract sub-committee, a PRIM&R Board Member, and ARENA president. She also contributed to the third edition of "Institutional Review Board Management and Function."

### **Bruce Gordon, MD**

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, 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.