

2025 Agenda

Last updated: 8/12/2025

8:00am-8:15am: Introduction

8:15am-9:15am: Susan Fish - *Ethical Study Design IS Good Science*

9:30am-10:30am: Tonya Ferraro - *The AI Middle Game: From Panic to Proportionate IRB Oversight*

10:45am-11:45am: Kristi DeHaai & Abbey Lowe - *Integrating IRB Review into US Special Pathogens Research Readiness*

11:45am-12:45pm: Lunch

12:45pm-1:45pm: Bruce Gordon - *Informed Consent: Why Do We Do It, What Do They Want, And How Can We Do It Better?*

2:00pm-3:30pm: Megan Berger & Brigitte Vaughan - *Best Practices for the Informed Consent Process Panel (including: LuAnn Larson, Beth Beam, Matt Lunning, Sheilah Snyder, Ben Teply, and Jackie Hankins)*

3:30pm-4:00pm: Q&A/Conclusion

Speakers and Panelists

Susan Fish is Professor in the Department of Medical Sciences & Education at the Boston University Chobanian & Avedisian School of Medicine where she lectures on biomedical research design and conduct, and in research ethics. Dr. Fish received her Doctor of Pharmacy degree from the University of Minnesota and her Masters of Public Health from Boston University, as well as a Bachelor's Degree in pharmacy from Massachusetts College of Pharmacy and Allied Health Sciences and a Bachelor's Degree in chemistry and education from the University of Massachusetts.

Dr. Fish has been a medical researcher for more than 40 years, primarily in the fields of clinical toxicology and emergency medicine. She has also been involved in research ethics for almost as long. In a variety of forums, Dr. Fish lectures on the design, conduct, and management of clinical trials, as well as research ethics and protection of human research subjects. She teaches courses at the Boston University Schools of Public Health and Medicine, and is frequently an invited speaker nationally and internationally. In addition, she has consulted with a variety of human research protection programs at universities, community hospitals, academic medical centers, and specialty hospitals.

Dr. Fish previously held positions as Professor of Biostatistics and Epidemiology at the Boston University School of Public Health, as well as Director of the MA in Clinical Investigation program at Boston University School of Medicine, Director of Human Subjects Protection and Associate

Director of the Office of Clinical Research at Boston University Medical Center (BUMC), Director of the BUMC Institutional Review Board and Director of Research Participant Safety at the General Clinical Research Center at Boston University School of Medicine. She has also served as Director of Regulatory Affairs at CareStat, Inc, (a contract research organization) and as Vice Chair for Research in the Department of Emergency Medicine at Boston City Hospital/Boston Medical Center and Associate Professor of Emergency Medicine at Boston University School of Medicine. Prior to that, she was Associate Director of the Massachusetts Poison Control System and Associate Professor at Massachusetts College of Pharmacy and Allied Health Sciences.

Tonya Ferraro is AAHRPP's Accreditation Policy Analyst and a former Site Visitor. Prior to joining AAHRPP, she held senior-level roles in quality assurance/quality improvement and IRB administration at Boston Children's Hospital and Harvard University. Earlier in her career, she served as a Research Project Manager at the University of Vermont's Health Behavior Research Center, where she developed technologies to enhance patient engagement. Tonya co-chaired PRIM&R's (Public Responsibility in Medicine & Research) Social, Behavioral, and Educational Research (SBER) Conference in 2023 and 2025, and she is part of PRIM&R's Education Advisory Group. She has also contributed to several of PRIM&R's conference planning committees and served on its Diversity Advisory Group. Through Harvard Catalyst, she is a member of the Emerging Technologies, Ethics & Research, and QA/QI subcommittees. In addition to her professional roles, Tonya has been a board member of Boston Korean Adoptees, Inc. During her tenure, she created a national research-literacy program developed by and for adoptees. For this initiative, she received the Boston Children's Hospital Employee Community Volunteer Award. Tonya holds a BA in Studio Art (Sculpture) from Northeastern University and an interdisciplinary MEd in Research Methodology from the University of Vermont. She also completed a Bioethics Fellowship at Harvard Medical School. With a background spanning the arts, research ethics, and innovative technology implementation, she brings a creative and interdisciplinary perspective to research oversight and education.

Abbey Lowe, PhD, MA is an associate professor in the Department of Health Promotion of the UNMC College of Public Health. She is affiliate faculty of Medical Humanities at the University of Nebraska at Omaha. Abbey's interests are at the intersection of ethics, health policy, and health security, and her research focuses on ethics in public health emergencies.

Megan Berger is an IRB Analyst and the IRB Education Coordinator with the UNMC IRB. She has been with the UNMC IRB for two years and was previously a high school math teacher. Megan reviews central IRB applications and works with UNMC, NM, Children's NE, and UNO to develop and coordinate educational efforts related to human subject research and the IRB.

Kristi DeHaai is an IRB Analyst in the Office of Regulatory Affairs at the University of Nebraska Medical Center (UNMC). She has been a member of the UNMC IRB since 2013, where she currently specializes in single IRB review and oversight. Kristi served as the Pediatric IRB Administrator from 2013 to 2018. Prior to her work with the IRB, Kristi worked in the department of Genetic Medicine at Munroe-Meyer Institute at UNMC. Kristi has been a member of the Nebraska Medicine Hospital

Ethics Committee since 2020 and is the Chair of the Ethics sub-committee on policy. She has a master's degree in the Medical Sciences Interdisciplinary Area (MSIA) with a focus in genetics and behavior and has authored a chapter in the 3rd edition of "IRB: Management and Function".

Brigette Vaughan MSN, APRN-BC, NP is a clinical research nurse practitioner, Instructor in the UNMC Department of Neurological Sciences, and a Clinical Associate in the UNMC College of Nursing. She has over 25 years of experience as a research coordinator in pediatric psychopharmacology research, and is active in novel pharmacotherapy trials of CBD and psychedelic agents. She serves as an American Psychiatric Nurses Association abstract reviewer, and is a member of the Child and Adolescent Suicide Working Group tasked with drafting the APNA's position statement on this topic. Brigette has served on the UNMC IRB (adult, pediatric and single-site boards) since 2007, including serving for the last 8 years as a vice chair. She has been a family psychiatric nurse practitioner for 21 years, working with children, adolescents and adults with mental health and developmental disabilities. She provided medication management to children and adolescents in a rural pediatric practice for 16 years. Brigette's research interests include novel pharmacotherapies, mental health, the assessment and tracking of psychiatric adverse events, and the informed consent process.

Dr. Bruce 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.