



***Changing Trials for Changing Times:  
Essentials of Embedded Pragmatic Clinical Trials Workshop***

*HCSRN 2023 Annual Conference*

*Sheraton Downtown Denver, Denver, Colorado*

*February 20, 2023*

**8 a.m.-4:45 p.m. MT**

Join workshop by Zoom: <https://duke.zoom.us/j/93859922865?pwd=eIR4SUZTWw1yRWtWTUxmODJFTWRvdz09>

Meeting ID: 938 5992 2865; Passcode: 12345

## **Speaker Biographies**

### **Arne Beck, PhD**

**Kaiser Permanente Colorado Institute for Health Research**

**University of Colorado Denver**

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Dr. Beck is a health psychologist, Senior Investigator at Kaiser Permanente Colorado's Institute for Health Research, and Associate Professor of Family Medicine at the University of Colorado Denver Health Sciences Center. He serves as the Kaiser Permanente Colorado site lead for the Mental Health Research Network. His research interests include perinatal mental health, suicide prevention, feedback informed care for depression, health risk prevention programs for parents of early adolescents, and integrating behavioral health and medical care for patients with multiple chronic conditions.

### **Patrick Heagerty, PhD**

**University of Washington**

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Dr. Heagerty is Professor and former Chair of the Department of Biostatistics at the University of Washington. He received a PhD from the Johns Hopkins University, and a BS from Cornell University. He has extensive experience as an educator, independent and collaborative scientist, and administrator. He has developed fundamental methods for longitudinal studies with a focus on prognostic model evaluation and structural longitudinal models, and he has detailed rigorous methods for the design, analysis, and interpretation of cluster-randomized trials conducted within health care delivery systems. Dr. Heagerty has co-authored two leading texts (*Analysis of Longitudinal Data*, Oxford 2002; *Biostatistics: A Methodology for the Health Sciences*, Wiley 2004). He is an elected Fellow of the American Statistical Association and has twice been honored by professional societies for specific research contributions (in 2000 as the Snedecor Award winner; and in 2005 by the International Biometrics Society for the best paper published in the society's flagship journal, *Biometrics*). Dr. Heagerty directs the Center for Biomedical Statistics (CBS), a core partially funded by the NIH Clinical and Translational Science Award (CTSA) with responsibility for coordination of biostatistical collaboration in Seattle and the greater Northwest region (Wyoming, Alaska, Idaho, Montana). The CBS houses the data coordinating centers for several U01 and R01 funded projects

including GARNET (Genomics and Randomized Trials), BOLD (Backpain Outcomes using Longitudinal Data), UH3 funded pragmatic trials including LIRE (Lumbar Imaging Reporting with Epidemiology), and PCORI funded trials evaluating surgical interventions and psychiatric treatment strategies. The CBS has previously conducted high-impact multi-site randomized trials including INVEST (Investigational Vertebroplasty Safety and Efficacy Trial, NEJM 2009), the Carpal Tunnel Surgical Trial (Lancet 2009), and LESS (Lumbar Epidural Steroid Injections for Spinal Stenosis, NEJM 2014). Dr. Heagerty is the Director of the Biostatistics and Research Design Core for the NIH Health Care Systems Research Collaboratory, for the NIH Mental Health Research Network, and a member of the Executive Committee for the FDA Sentinel Innovation Center. Dr. Heagerty is also a licensed teacher (NY State: Mathematics, Biology, and Chemistry) and has taught from middle school to graduate school (UW SPH Outstanding Teacher Award, 2009).

**Michael Ho, MD**

**University of Colorado School of Medicine**

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Dr. Ho is a Staff Cardiologist at the VA Eastern Colorado Health Care System and Professor at University of Colorado School of Medicine. He is also the Co-Director of the Data Science to Patient Value Program and Vice Chair of Quality for the Department of Medicine. His research over the past 15 years has focused on understanding the quality and outcomes of cardiovascular care, including the prevalence of medication non-adherence in cardiovascular diseases, the adverse consequences of medication non-adherence, and testing different interventions to improve medication adherence.

**Beda Jean-Francois, PhD**

**National Center for Complementary and Integrative Health (NCCIH)**

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Dr. Jean-Francois is a program director in the Clinical Research Branch in the Division of Extramural Research of the NCCIH. She oversees a portfolio of clinical research, including health disparities, pediatric research on mental and emotional well-being, maternal morbidity and mortality, and pragmatic clinical trials. Additionally, she contributes to the Mental, Emotional, and Behavioral (MEB) initiatives as well as the NIH Pragmatic Trials Collaboratory, the NIH HEAL Initiative, and the Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing (PRISM) program. Dr. Jean-Francois is especially passionate about reducing children's health disparities. Other research interests include life-course perspective on health and disease, behavioral health prevention services, health information technology, reproductive health equity, and childhood obesity. Before joining NCCIH, Dr. Jean-Francois served as an NIH health scientist administrator at the National Institute on Minority Health and Health Disparities (NIMHD) since 2017. While at NIMHD, she served as a co-lead for the data coordinating center for the trans-NIH Rapid Acceleration of Diagnostics for Underserved Populations (RADxUP), which is a consortium of more than 85 multidisciplinary grantees working to target disparities in COVID-19 morbidity and mortality. She developed multiple funding opportunities, including Effectiveness of School-Based Health Centers to Advance Health Equity, Addressing Racial Disparities in Maternal Mortality and Morbidity, and Leveraging Health Information Technology to Address Health Disparities. Additionally, she served as project scientist for Center of Excellence research grants to promote research in health disparities and the training of a diverse scientific workforce.

**Stephanie Morain, PhD**  
**Johns Hopkins University**  
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Dr. Morain is an Assistant Professor at Johns Hopkins in the Department of Health Policy & Management in the Bloomberg School of Public Health and the Berman Institute of Bioethics. She conducts both empirical and normative research into issues at the intersection of ethics, law, and health policy.

Her work examines ethical and policy challenges presented by the integration of research and care, particularly issues pertaining to learning health care systems and pragmatic clinical trials. Other research interests include the ethics and politics of disease control and injury prevention, and women's reproductive health.

Stephanie received her AB from Lafayette College with a dual major in Biology and History, Government, and Law, her MPH from Columbia University's Mailman School of Public Health, and her PhD from Harvard University's Interfaculty Initiative in Health Policy. She completed her postdoctoral training at the Berman Institute for Bioethics at Johns Hopkins University. From 2016-2021, she was a faculty member in the Center of Medical Ethics & Health Policy at Baylor College of Medicine.

**Emily O'Brien, PhD**  
**Duke Clinical Research Institute**  
**Duke University School of Medicine**  
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Dr. O'Brien is an associate professor in the Departments of Population Health Sciences at the Duke University School of Medicine. An epidemiologist by training, Dr. O'Brien's research focuses on comparative effectiveness, patient-centered outcomes, and pragmatic health services research in chronic disease. Dr. O'Brien's expertise is in systematic assessment of medical therapies in real-world settings, including long-term safety and effectiveness assessment. She is the principal investigator for projects focusing on the linkage and use of secondary data, including administrative claims, clinical registries, and electronic health record data. Dr. O'Brien is the principal investigator for the HERO Registry, a national study of the impact of COVID-19 on healthcare workers in the US. She is an affiliated faculty member in the Duke Clinical Research Institute and the Duke Margolis Center for Health Policy, a fellow of the American Heart Association, and an editorial board member for *Stroke* and the *American Heart Journal*.

**Miguel A. Vazquez, MD**  
**UT Southwestern Medical Center**  
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Miguel A. Vazquez, MD, is professor of internal medicine at UT Southwestern Medical Center in Dallas and the clinical chief of the Nephrology Division at UT Southwestern and nephrology chief of service at Parkland Hospital in Dallas. His patient care specialties include chronic kidney disease, end-stage kidney disease, and kidney transplantation. He attended medical school at the University of Puerto Rico in San Juan, and moved to UT Southwestern for his internship and residency in internal medicine. He also completed his fellowship in nephrology and research in immunology and transplantation at UT Southwestern.

Dr. Vazquez is active in patient-oriented research. His current research efforts are focused on improving care for patients with chronic kidney disease and coexistent diabetes and hypertension as part of the

pragmatic clinical trial ICD-Pieces. His research efforts also include the Kidney Precision Medicine Project and studies related to dialysis vascular access. Dr. Vazquez is board-certified in internal medicine and nephrology by the American Board of Internal Medicine. He is a fellow of the American College of Physicians and was named a fellow by the American Society of Nephrology in 2011.

**Wendy Weber, ND, PhD, MPH**

**National Center for Complementary and Integrative Health (NCCIH)**

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Dr. Weber is the Branch Chief for the Clinical Research in Complementary and Integrative Health Branch in the Division of Extramural Research at the National Center for Complementary and Integrative Health (NCCIH) at NIH. She joined NCCIH as a program director in 2009. The Clinical Research Branch is responsible for the oversight of all NCCIH-supported clinical trials. Dr. Weber is coordinator for NCCIH's Clinical Trial Specific Funding Opportunity Announcements (FOAs) and point-of-contact for natural product-related clinical trial FOAs. She is a member of the NIH Common Fund-supported Health Care Systems Research Collaboratory and the program officer for the Coordinating Center. Dr. Weber is also a member of the planning and oversight team for the NIH-DoD-VA Nonpharmacologic Approaches to Pain Management Collaboratory and project scientist for its Coordinating Center.

At NCCIH, Dr. Weber oversees a portfolio of pragmatic clinical trials, natural product clinical trials, studies of complementary medicine to promote healthy behavior, and complex complementary/integrative medicine intervention research. Her interests include the use of complementary medicine interventions for common pediatric conditions, mental health conditions, promoting healthy behaviors, and health services research.

**Kevin Weinfurt, PhD**

**Duke Clinical Research Institute**

**Duke University School of Medicine**

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Dr. Weinfurt is Professor and Vice Chair for Research in the Department of Population Health Sciences in the Duke University School of Medicine. Dr. Weinfurt is also a Professor in the Duke departments of Psychiatry and Behavioral Science, Biostatistics and Bioinformatics, and Psychology and Neuroscience. He is a faculty member of the Duke Clinical Research Institute and Faculty Associate of the Trent Center for the Study of Medical Humanities and Bioethics. Dr. Weinfurt conducts research on measuring patient-reported outcomes, medical decision making, and bioethics.

Dr. Weinfurt was a principal investigator in the NIH PROMIS Network, where he led the development of the SexFS to measure male and female sexual function and satisfaction. Currently, he is co-chair of the coordinating center for the NIH Health Systems Research Collaboratory and served as the former President of the PROMIS Health Organization. As an educator, Dr. Weinfurt co-directs Duke's masters-level Clinical Research Training Program and has taught graduate courses in patient-reported outcomes research and multivariate statistics along with undergraduate courses in introductory psychology, judgment and decision making, and the psychology of medical decision making.

Dr. Weinfurt received his PhD in psychology at Georgetown University and did graduate work in the history of science and philosophy of mind at Linacre College, Oxford.