

Essentials of Embedded Pragmatic Clinical Trials Workshop
HCSRN 2020 Conference
April 7, 2020

Speaker Biographies



Patrick Heagerty, PhD
University of Washington

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. Dr. Heagerty 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). Dr. Heagerty 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 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).



Jeffrey (Jerry) G. Jarvik, MD, MPH
University of Washington

Dr. Jarvik is Professor with Tenure of Radiology and Neurological Surgery in the School of Medicine and Professor of Health Services in the School of Public Health at the University of Washington. He is also Adjunct Professor of Orthopedics and Sports Medicine in the School of Medicine and Adjunct Professor of Pharmacy in the School of Pharmacy. Dr. Jarvik was the PI of the LIRE Study, one of the NIH Collaboratory's initial pragmatic trials. He is also the PI/Director of the NIH/NIAMS-funded UW Clinical Learning Evidence and Research (CLEAR) Center for Musculoskeletal Disorders, Co-Director of the Comparative Effectiveness, Cost and Outcomes Research Center (CECORC) and Co-Director of the Health Services

Research Section for the Department of Radiology. Dr. Jarvik is an internationally recognized expert in MR imaging of the spine as well as in the field of health services and comparative effectiveness research as it relates to radiology.



Stephanie Morain, PhD, MPH
Baylor College of Medicine

Stephanie Morain is an Assistant Professor in the Center for Medical Ethics and Health Policy. She conducts both empirical and normative research into issues at the intersection of ethics, law, and health policy. She also directs the BCM Health Policy Pathway for undergraduate medical education.

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 public health law, and the ethics and politics of disease control, 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.



Natalia Morone, MD
Boston Medical Center

Dr. Natalia Morone is an Associate Professor of Medicine at Boston University School of Medicine and Boston Medical Center. Over the past 17 years she established her research career in integrative nonpharmacological interventions to treat chronic pain, particularly mindfulness interventions for chronic low back pain. Her research portfolio also extends into mindfulness delivered via electronic health and telehealth. She has been or is currently principal investigator on seven randomized controlled trials (RCT). She has also been or is currently the co-investigator on six clinical trials. Her two RCTs for older adults with chronic low back pain demonstrated that mindfulness meditation reduces pain in the long-term and increases function in the short term. These results helped inform the American College of Physicians 2017 Guidelines to recommend meditation for the treatment of chronic low back pain. She is PI of the OPTIMUM study which is a pragmatic clinical trial of an adapted mindfulness based stress reduction program for patients with chronic low back pain delivered online and through primary care. She has a long-standing commitment to fostering the careers of underrepresented groups in research and is currently the co-PI of a U-award to retain URGs in research through the evaluation of a 12-month career development program.



Emily O'Brien, PhD
Duke University

Emily O'Brien, PhD, 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*.



Marcel Salive MD, MPH
National Institute on Aging, NIH

Marcel Salive, MD, MPH, is a medical officer in the Division of Geriatrics and Clinical Gerontology at the NIH's National Institute on Aging (NIA). He developed and oversees an innovative and successful research program on multimorbidity in older adults including national consortia, pragmatic clinical trials, clinical research projects and career development.

He has developed NIA's program to conduct research into improving the effectiveness of treatment strategies for the comorbid conditions that occur frequently in combination with Alzheimer's disease. Other topics in his grant portfolio include wound healing, incontinence, and clinical decision-making.

Dr. Salive has senior-level experience in multiple health agencies including the NIH, Centers for Medicare and Medicaid Services (CMS), and the Food and Drug Administration (FDA) and has made major regulatory and reimbursement contributions to public health. Dr. Salive earned chemistry and medical degrees from the University of Michigan and completed his preventive medicine residency and a master's in public health at Johns Hopkins University.



Miguel Vazquez, MD
UT Southwestern Medical Center

Miguel A. Vazquez, M.D., 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 J. Weber, ND, PhD, MPH

National Center for Complementary and Integrative Health (NCCIH), NIH

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 University School of Medicine

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.