



NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

Driving Tomorrow's Outcomes Through Clinical Research in Real-World Settings: Essentials of Embedded Pragmatic Clinical Trials Workshop

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Speaker Biographies



Hayden B. Bosworth, PhD

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Hayden B. Bosworth, PhD, is a health services researcher and implementation scientist. He is currently a professor of population health sciences, medicine, psychiatry, and nursing at Duke University and the vice chair of education in the Department of Population Health Sciences. He is also the deputy director of the Center of Innovation to Accelerate Discovery and Practice Transformation (ADAPT) (COIN) at the Durham Veterans Affairs Medical Center and adjunct professor in the Department of Health Policy and Administration in the Gillings School of Global Public Health at the University of North Carolina at Chapel Hill. His research interests comprise 3 overarching areas of research: 1) clinical research that provides knowledge for improving self-management in chronic care; 2) implementing research to improve access to quality of care; and 3) eliminating health care disparities. His expertise is in patient-centered, multidisciplinary self-management programs for adults with chronic disease.

Dr. Bosworth also has expertise in developing and implementing scalable/sustainable interventions to improve health behaviors and reduce the burden of chronic diseases. These trials/programs focus on motivating individuals to initiate health behaviors and sustain them long term. He also has ample experience in conducting observational studies examining healthcare use and predictors of medication nonadherence. Current examples of his work include a multisite trial evaluating a nurse-administered intervention to extend the HIV treatment cascade for cardiovascular disease prevention (EXTRA-CVD) and a similar study being conducted in the VA (VA-EXTRA-CVD).

Dr. Bosworth is the recipient of numerous awards, including an American Heart Association Established Investigator award, a VA Senior Career Scientist Award, and the Under Secretary's Award for Outstanding Achievement in Health Services Research. He has been the principal investigator of over 30 trials resulting in over 400 peer-reviewed publications and 4 books. His work has been implemented in Medicaid of North Carolina, the UK National Health System, Kaiser Permanente, the Veterans Health Administration, as well as by a number of health care payers such as Humana.

In addition to his research experience, mentoring is an area to which he has devoted significant effort. He has mentored over 140 graduate students, postdoctoral fellows, and junior faculty, including 28

career development awardees over the last 10 years. In addition, he is the principal investigator of a K12 National Heart, Lung, and Blood Institute–funded grant to train faculty in dissemination and implementation.



Ardith Z. Doorenbos, PhD, RN, FAAN

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Ardith Z. Doorenbos, PhD, RN, FAAN is a Professor in the Department of Biobehavioral Nursing Science, College of Nursing at the University of Illinois Chicago. Dr. Doorenbos' research is centered on pain and symptom management. Dr. Doorenbos is a distinguished researcher with a well-funded program of research that has received funding from the National Institute of Health, Congressionally Directed Medical Research Programs, and other professional sources. In 2010, she was named a Fellow of the American Academy of Nursing and in 2018, was inducted into the Sigma Theta Tau, International Nurse Researcher Hall of Fame.



Patrick Heagerty, PhD

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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).



Beda Jean-Francois, PhD

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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.



Margaret Kuklinski, PhD

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Margaret Kuklinski, PhD, is associate professor and director of the Social Development Research Group (SDRG), School of Social Work, University of Washington. Her work aims to promote positive developmental outcomes by demonstrating the long-term impact of effective family-focused and community-based preventive interventions; partnering with communities, agencies, and services systems to implement and scale them; and building policy support for preventive interventions by demonstrating their benefits and costs.

Dr. Kuklinski currently serves as co-principal investigator on a multisite trial testing the feasibility and effectiveness of implementing Guiding Good Choices, a prevention program for parents of adolescents, in 3 large healthcare systems. She is also co-principal investigator on the longitudinal evaluation of the Communities That Care prevention system, which has demonstrated impact on preventing drug use and antisocial behavior from adolescence into young adulthood. Under NIDA's HEAL Prevention Initiative she cochairs the Health Economics Working Group, which is examining the cost-effectiveness of a set of projects aimed at developing effective approaches to preventing opioid misuse in adolescents and young adults.

Dr. Kuklinski received a PhD in psychology from the University of California, Berkeley, and an AB in economics from Harvard University.



Vincent Mor, PhD
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Vincent Mor, PhD, is a professor of health services, policy & practice and Florence Pirce Grant Professor in the Brown University School of Public Health, and has been principal investigator of 40+ NIH-funded grants focusing on use of health services and outcomes of frail and chronically ill people. He has evaluated the impact of programs and policies including Medicare funding of hospice, changes in Medicare nursing home payment, and the introduction of nursing home quality measures. He co-authored the Congressionally-mandated Minimum Data Set (MDS) and was architect of an integrated Medicare claims and clinical assessment data structure used for policy analysis, pharmaco-epidemiology and population outcome measurement. Dr. Mor developed summary measures using MDS data to characterize residents' physical, cognitive and psycho-social functioning. These data resources are the heart of Dr. Mor's NIA-funded Program Project Grant, "Changing Long Term Care in America," which examines the impact of Medicaid and Medicare policies on long-term care. These data are also at the core of a series of large, pragmatic cluster randomized trials of novel nursing home-based interventions led by Dr. Mor.

Dr. Mor is one of the Principal Investigators of the National Institute on Aging (NIA) **IMbedded Pragmatic Alzheimer's Disease (AD) and AD-Related Dementias (AD/ADRD) Clinical Trials (IMPACT) Collaboratory** which was established in 2019 to meet the urgent public health need to deliver high quality, evidence-based care to people living with dementia (PLWD) and their care partners within the healthcare systems (HCS) that serve them. The Mission of IMPACT is to build the nation's capacity to conduct pragmatic clinical trials of interventions embedded within health care systems for people living with dementia and their care partners.



Stephanie Morain, PhD
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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
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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*.



Michael L. Parchman, MD, MPH
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Michael L. Parchman, MD, MPH, is a primary care physician and a senior investigator at the Center for Accelerating Care Transformation within the Kaiser Permanente Washington Health Research Institute. He has over thirty years of primary care clinical experience and work as a medical educator. Dr. Parchman's research has examined the effectiveness of strategies to improve primary care for people with chronic illnesses, methods to advance research in primary care settings, and the theoretical underpinnings of the delivery of primary care. His current work focuses on addressing overuse of low-value care services. Building on his work as director of a Robert Wood Johnson Foundation fellowship program to train clinician value champions, he currently serves as Principal Investigator of a two-year IMPACT Collaboratory pragmatic trial to decrease the use of potentially inappropriate medications among patients with dementia across two Accountable Care Organizations.



Angelo Volandes, MD, MPH
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Angelo Volandes, MD, MPH, is a physician, researcher, filmmaker, and author. He is an associate professor at Harvard Medical School and Massachusetts General Hospital, and co-founder of ACP Decisions Nonprofit Foundation. He is an internationally recognized expert on the use of video decision support tools, decision science, and ethics. He leads an internationally recognized group of innovators and video artists who create video support tools to better inform patients about their options for medical care.

His work has been funded by the National Institute on Aging, the National Cancer Institute, the National Institute of Nursing Research, the National Heart, Lung, and Blood Institute, the NIH Common Fund, the Agency for Healthcare Research and Quality, the Alzheimer's Foundation, and the Gordon and Betty Moore Foundation, among others.

Dr. Volandes's work has been featured in major publications and national media and he is the author of *The Conversation: A Revolutionary Plan for End-of-Life Care*. He lectures widely around the country.

Born and raised in Brooklyn, New York, he is a proud product of the New York City public school system. He went on to receive his undergraduate degree in philosophy from Harvard, a medical degree from Yale, and a master's degree in public health from Harvard. In 2005, he was named the Edmond J. Safra Fellow at the Harvard University Center for Ethics.



Wendy Weber, ND, PhD, MPH

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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

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Kevin P. Weinfurt is Professor and Vice-Chair of Research in the Department of Population Health Sciences at Duke University Medical Center and a faculty member of the Duke Clinical Research Institute. He holds secondary appointments as a Professor of Psychology and Neuroscience, Professor of Psychiatry and Behavioral Sciences, Professor of Biostatistics and Bioinformatics, and as a Faculty Associate of the Trent Center for the Study of Medical Humanities and Bioethics. Dr. Weinfurt also co-directs the Center for Health Measurement at Duke and is co-director of the Clinical Research Training Program (Masters degree offered through the School of

Medicine). Dr. Weinfurt currently works as Special Governmental Employee for the U.S. Food and Drug Administration, helping to create the Patient-Focused Drug Development guidance series. He is also a member of the Secretary's Advisory Committee for Human Research Protections.

Dr. Weinfurt conducts research on measuring patient-reported outcomes, medical decision making, and bioethics. In addition to conducting research, Dr. Weinfurt has taught undergraduate courses in introductory psychology, judgment and decision making, and the psychology of medical decision making, and graduate courses in multivariate statistics, patient-reported outcomes, and research ethics