NIH Collaboratory *Rethinking Clinical Trials®*

Health Care Systems Research Collaboratory

AcademyHealth Seminar
Essentials of Embedded Pragmatic Clinical Trials
June 1, 2019

Speaker Biographies

Robin Elizabeth Boineau, MD, MA
National Center for Complementary and Integrative Health (NCCIH), NIH

Dr. Boineau joined the NCCIH Office of Clinical and Regulatory Affairs (OCRA) as a medical officer in 2015. A cardiologist with a background in exercise physiology, she is also an experienced National Institutes of Health (NIH) trialist with extensive experience in managing large NIH-funded clinical research operations. In OCRA, Dr. Boineau provides guidance on clinical study designs in the NCCIH portfolio and plays a leading role in large ongoing trial operations, including the Trial to Assess Chelation Therapy 2 (TACT2), as well as the NIH Health Care Systems Research Collaboratory. She is also a member of the Division of Extramural Research and manages a clinical research portfolio focused on NCCIH-supported clinical trials. Her focus at NCCIH is on the conduct of large-scale clinical studies.

Before coming to NCCIH, Dr. Boineau was a medical officer at the National Heart, Lung, and Blood Institute's (NHLBI) Division of Cardiovascular Diseases for more than 15 years, where she had a primary oversight role in many large-scale NIH-funded clinical studies. She was the NIH lead scientist and then project officer for the Treatment of Preserved Cardiac Function Heart Failure with an Aldosterone Antagonist (TOPCAT) trial and project officer on the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT), the Late Sodium Current Blockade in High-Risk ICD Patients—Ranolazine ICD Trial (RAID), Cardiovascular Health Study (CHS). She was deputy project officer on Future Revascularization Evaluation in Patients with Diabetes Mellitus: Optimal Management of Multivessel Disease (FREEDOM) trial, and the Multi-Ethnic Study of Atherosclerosis (MESA). She is also the primary developer of a self-administered questionnaire to determine functional capacity in cardiovascular disease patients, the Duke Activity Status Index (DASI).

Laura M. Dember, MD
University of Pennsylvania Perelman School of Medicine

Dr. Dember is Professor of Medicine and Epidemiology at the University Of Pennsylvania Perelman School of Medicine where she is a faculty member in the Renal-Electrolyte and Hypertension Division and a Senior Scholar in the Center for Clinical Epidemiology and Biostatistics. Dr. Dember conducts patient-oriented research in chronic kidney disease and end-stage renal disease and has particular interests in interventions to improve clinical outcomes for patients treated with maintenance hemodialysis. She has leadership roles in several multicenter observational studies and clinical trials including the Dialysis Access Consortium, the Hemodialysis Fistula Maturation Study, the Hemodialysis Novel Therapies Consortium, and the Chronic Renal Insufficiency Cohort study, all funded by the National Institutes of Diabetes and Digestive and Kidney Diseases, as well as two large pragmatic trial demonstration projects of the NIH Health Care

Systems Research Collaboratory: Time to Reduce Mortality in End-Stage Renal Disease (TiME) and HiLo. Dr. Dember has been a member of several committees of the American Society of Nephrology and is a Deputy Editor for the American Journal of Kidney Diseases.

Susan Huang, MD, MPH

University of California Irvine School of Medicine

Dr. Huang is Professor of Medicine in the Division of Infectious Diseases and Health Policy Research Institute at the University Of California Irvine School Of Medicine, and Medical Director of Epidemiology and Infection Prevention at UC Irvine Health. She received her medical degree from Johns Hopkins School of Medicine and her master's in quantitative methods from the Harvard School of Public Health.

For nearly 20 years, Dr. Huang has been studying healthcare-associated infections with a focus on multidrug-resistant organisms (MDROs). Her clinical epidemiologic research seeks to identify the burden and risk factors for acquisition and disease, and preventative strategies for containment. Dr. Huang has led several randomized clinical trials to prevent MRSA disease and other healthcare-associated infections. She also studies the regional prevention of MDROs in hospitals and nursing homes through epidemiologic studies as well as simulation models. Additional significant areas of research include surgical site infections, outbreak detection, and electronic efficiencies for infection prevention. Dr. Huang has 150 publications in peer-reviewed journals and received a Top 10 U.S. Clinical Research Achievement Award from the Clinical Research Forum in 2014.

Dr. Huang has served as a member of HICPAC (federal guidelines committee for infection prevention), the Antibiotic Resistance Working Group for the Centers for Disease Control and Prevention, and the Antibiotic Resistance Committee for the Infectious Diseases Society of America. She has also served on the technical expert panel for infection prevention and care transitions between acute and long-term care facilities for the Centers for Medicare and Medicaid Services.

Julie Kaneshiro, MA

Office for Human Research Protections (OHRP)

Ms. Kaneshiro is Deputy Director of OHRP and shares the Director's responsibility and authority to develop, coordinate, and execute the full range of OHRP programs and activities. Previously she was Policy Team Leader at OHRP and played a central role in the development of regulations and policies related to the HHS regulations for the protection of human subjects. Prior to joining OHRP, she worked in several different institutes at the National Institutes of Health, and in the Office of the Director, where she assisted in developing the research provisions of the proposed and final versions of the HIPAA Privacy Rules. Ms. Kaneshiro received her undergraduate degree in English Literature from the University of Maryland in 1991, and her graduate degree in Public Policy with Concentrations in Philosophy and Social Policy (MA) from George Washington University in 1996.

Catherine M. Meyers, MD

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

Dr. Meyers is Director of NCCIH's Office of Clinical and Regulatory Affairs (OCRA), which plays a major role in the planning, coordinating, and monitoring of the clinical research program. She and her staff serve as a resource for NCCIH's program staff and clinical investigators to facilitate safe implementation of NCCIH-funded clinical studies. As NCCIH plays a major role in leadership of the National Institutes of Health (NIH) Common Fund Health Care Systems Research Collaboratory, Dr. Meyers is also a lead scientist for the Collaboratory. This Common Fund program is a 10-year effort to conduct pragmatic clinical trials in partnership with clinical investigators, patients, and health care

systems in the United States. Prior to her 2009 arrival at NCCIH, Dr. Meyers devoted nearly a decade to work focused on clinical research of end-stage kidney disease. After a 3-year tenure at the FDA, where she provided oversight for trials of products for extracorporeal therapies, Dr. Meyers joined NIH in 2002 as a Senior Scientific Advisor within the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), where she was Director of Renal Inflammatory Programs within the Kidney, Urology, and Hematology Division. She also worked on several NIH projects, including the NIH Transplantation Research Coordinating Committee, and was a co-chair of the NIDDK Clinical Studies Working Group.

Dr. Meyers earned her undergraduate degree in chemistry at the University of Chicago and received her MD from the University of Illinois College of Medicine at Chicago. She completed postgraduate residency training in internal medicine at the University of Chicago (Michael Reese Hospital) and a clinical nephrology fellowship at the University of Pennsylvania, Philadelphia. She then completed a research fellowship in renal immunology at the School of Medicine at the University of Pennsylvania. In 1992, she joined the faculty of the School of Medicine at the University of Pennsylvania with an appointment in the Department of Internal Medicine, Renal-Electrolyte and Hypertension Division. Dr. Meyers's research program focused on characterizing mechanisms of immune-mediated kidney injury. Her research interests include autoimmune mechanisms of disease and vascular inflammation, as well as the ethics of clinical research oversight. She has authored more than 100 research articles and other scientific publications. She is a Fellow of the American Heart Association, and a long-standing member of its Council on the Kidney in Cardiovascular Disease. She is the recipient of several awards, including the Donald B. Martin Teaching Award from the University of Pennsylvania, an FDA Honor Award for her work in dialysis products oversight, and the NIH Director's Awards for her role in the development of the NIH Health Care Systems Research Collaboratory and for her leadership of the NCCIH/OCRA process for oversight of clinical research.

Susan L. Mitchell, MD, MPH

Harvard Medical School

Hebrew SeniorLife

Dr. Mitchell is Professor of Medicine at Harvard Medical School and Senior Scientist at the Hinda and Arthur Marcus Institute for Aging Research at Hebrew SeniorLife in Boston. She is a geriatrician and health services researcher. Dr. Mitchell's research interests focus on decision-making, health outcomes, and resource utilization for older people near the end of life, particularly those with dementia. She is widely published and the Principal Investigator on several large NIH-funded projects, including pragmatic clinical trials, in this field. Dr. Mitchell is a recipient of an NIH-NIA K24 Mid-Career Investigator Award and an NIH-NIA R37 MERIT Award. She is also an attending geriatrician at the Beth Israel Deaconess Medical Center in Boston.

Vincent Mor, PhD

Brown University School of Public Health

Dr. Mor is the Florence Pirce Grant Professor of Community Health in the Brown University School of Public Health and a senior health scientist at the Providence VA Medical Center. He has been Principal Investigator for more than 40 NIH-funded grants and has published over 400 peer-reviewed articles focusing on the use of health services and the outcomes frail and chronically ill persons experience. He received the Robert Wood Johnson Foundation health policy investigator award, a MERIT award from the National Institute on Aging, the Distinguished Investigator Award from AcademyHealth, the John Eisenberg Mentoring Excellence Award from the Agency for Healthcare Research and Quality (AHRQ), and is a member of the National Academy of Medicine. He has evaluated the impact of programs and policies in aging and long-term care including Medicare funding of hospice, changes in Medicare nursing home payment, and the introduction of quality measures. He was one of the authors of the congressionally mandated

Minimum Data Set (MDS) for Nursing Home Resident Assessment and the architect of an integrated Medicare claims and clinical assessment data base used for policy analysis, pharmaco-epidemiology, population outcome measurement, and cluster-randomized clinical trials. He has had extensive experience working with CMS mandatory assessment data such as the OASIS and MDS, merging these data with Medicare fee-for-service (FFS) claims as well as Medicare Advantage (MA) HEDIS data for the purpose of comparing the use of post-acute care service use by MA and FFS beneficiaries and how that has changed over time and across different markets in the US. He has been particularly focused on the disenrollment from MA of complex, chronically ill patients using post-acute care.

David M. Murray, PhD

Office of Disease Prevention, NIH

Dr. Murray completed his Bachelor of Arts in Psychology from Denison University in 1973. He completed his PhD in Experimental Psychology at the University of Tennessee, Knoxville, in 1978. In 1981, he completed a National Heart, Lung, and Blood Institute (NHLBI)-funded postdoctoral fellowship in cardiovascular health behavior in the Laboratory of Physiological Hygiene, a division of the School of Public Health at the University of Minnesota. He joined the faculty of the Laboratory immediately after his fellowship. The Laboratory was founded by Ancel Keys and was the home of Henry Taylor, Henry Blackburn, and other pioneers in cardiovascular epidemiology. Over the past 40 years, Dr. Murray has worked on more than 50 health promotion and disease prevention research projects funded by the NIH and other agencies. He served on more than 40 grant review panels for the NIH and as the first Chair of the Community Level Health Promotion study section. He has published more than 250 articles in the peer-reviewed literature.

Wynne E. Norton, PhD

National Cancer Institute, NIH

Dr. Norton is a program director for the Implementation Science Team in the Office of the Director in the Division of Cancer Control and Population Sciences at the National Cancer Institute (NCI). Within the Division, she assists with the expansion of research activities in implementation science, focusing on health care delivery and de-implementation across the cancer control continuum. Before joining the NCI in July 2015, Dr. Norton was an assistant professor in the School of Public Health at the University of Alabama at Birmingham. She was a fellow in the Implementation Research Institute (2009–2010) and a scholar in the Mixed Methods Research Training Program (2015). She has received funding from NIH, AHRQ, the Commonwealth Fund, CDC, the Bill and Melinda Gates Foundation, and the Donaghue Foundation. Dr. Norton is on the editorial board of the journal *Implementation Science*. She received her PhD in social psychology from the University of Connecticut (2009).

Emily O'Brien, PhD

Duke University School of Medicine

Dr. O'Brien is Assistant Professor in the Department of Population Health Sciences at the Duke University School of Medicine and an outcomes researcher at the Duke Clinical Research Institute. After completing undergraduate training at Duke University, she received a PhD in Epidemiology at the University of North Carolina in Chapel Hill in 2012. Dr. O'Brien's research focuses on comparative effectiveness, patient-centered outcomes, pharmacoepidemiology, and pragmatic health services research in cardiovascular and pulmonary disease. She has expertise in the use of administrative claims data for longitudinal outcomes assessment in Medicare populations and national registries.

Dr. O'Brien's projects include a PCORI-funded study examining commonly-used stroke therapies, an NHLBI-funded study assessing cardiovascular risk factors in the Jackson Heart Study, in addition to multiple projects evaluating patient-reported outcomes in idiopathic pulmonary fibrosis, atrial fibrillation, and familial hypercholesterolemia. She

is the Director of the DCRI Research Conference and serves on the editorial boards of the *American Heart Journal* and *Stroke*.

Marcel Salive MD, MPH

National Institute on Aging, NIH

Dr. Salive joined the Division of Geriatrics and Gerontology and administers the research portfolio on comorbidity (multiple chronic conditions) treatment and prevention, polypharmacy, and some aspects of comparative effectiveness. He 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. From 1990-1995, he was a senior investigator in the Laboratory of Epidemiology, Demography, and Biometry in the NIA intramural program.

Subsequently he has held leadership positions in the Centers for Medicare and Medicaid Services (CMS), National Heart, Lung, and Blood Institute, and the Food and Drug Administration. From 2003-2010, he served as Director of the Division of Medical and Surgical Services within the Coverage and Analysis Group of CMS and was responsible for developing and maintaining national coverage decisions for Medicare beneficiaries using a rigorous and open evidence-based process. His work in developing Medicare coverage of new and innovative services was recognized with the PHS Meritorious Service Medal in 2010. Dr. Salive has developed and led research initiatives in several areas including outcomes research, Alzheimer disease etiology, vaccine safety, and translation of clinical research into primary care practice. He is a Captain in the U.S. Public Health Service Commissioned Corps and serves on the PHS-2 rapid deployment force.

Leah Tuzzio, MPH

Kaiser Permanente Washington Health Research Institute

Ms. Tuzzio's research focuses on improving patient experience, reducing health care costs, and improving the health of populations. She is currently working with teams at KPWHRI's MacColl Center for Health Care Innovation and the Center for Community Health and Evaluation on projects related to quality improvement in primary care, patient-centered care, community-based research, and translating evidence into practice. One of her main projects is Healthy Hearts Northwest, an Agency for Healthcare Research and Quality-funded project to implement and evaluate quality improvement approaches in primary care. In addition, she is working with the National Institutes of Health (NIH) Collaboratory's Health Care Systems Interactions core to report on lessons learned from implementing pragmatic trials.
Ms. Tuzzio's other projects include writing manuscripts from the Robert Wood Johnson Foundation-funded Learning from Effective Ambulatory Practices (LEAP) project, studying the primary care workforce and the role of lay health workers, providing technical assistance to the Patient-Centered Outcomes Research Institute's first Evidence-to-Action Network focused on asthma research, and studying the use and adaptation of the Decision-to-Implement toolkit funded by the University of Washington's Institute of Translational Health Sciences.

She has co-led Kaiser Permanente Washington's patient-centered care interest group since 2012, and she is a member of the Health Care Research Systems Network (HCSRN) Patient Engagement in Research Workgroup. She earned a Master of Public Health (MPH) at the Emory University Rollins School of Public Health in the Behavioral Sciences and Health Education program. Her master's thesis was about the quality of life of people with dementia and their caregiver's burden. While at Emory she helped disseminate the Center for Disease Control and Prevention's Healthy Days quality of life measure across the United States and edited consumer books at the American Cancer Society's national office.

Wendy J. Weber, ND, PhD, MPH

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

Dr. Weber is Acting Deputy Director at the National Center for Complementary and Integrative Health (NCCIH) at NIH. She also serves as Branch Chief for the Clinical Research in Complementary and Integrative Health Branch in the Division of Extramural Research at NCCIH. 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 all 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 Professor of Psychiatry and Behavioral Science at Duke University Medical Center and a faculty member of the Duke Clinical Research Institute; Professor of Psychology and Neuroscience; and Faculty Associate of the Trent Center for the Study of Medical Humanities 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 serves as the President of the PROMIS Health Organization, is co-chair of the coordinating center for the NIH Health Systems Research Collaboratory, and co-chair of NIDDK's Symptoms of Lower Urinary Tract Dysfunction Research Network. 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's research has been featured on NPR Marketplace, Business Week, ABC News, and U.S. News & World Report. 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. Dr. Weinfurt conducts research on measuring patient-reported outcomes, medical decision making, and bioethics.