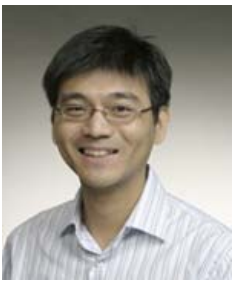
2018 CTMC Faculty

Harold Adams, MD, FAAN
Harold Adams, Jr., MD is a professor of neurology in the Carver College of Medicine at the University of Iowa. He has been active in patient care and clinical research that has focused on the diagnosis and treatment of vascular diseases of the brain. Dr. Adams was one of the developers of the NIH stroke scale and the leader in the development of the TOAST classification; two important advances in stroke research and patient care. His scholarly activities have resulted in approximately 500 publications. He initiated the writing of guidelines for the treatment of stroke and has served as chair of the Stroke Council of the American Heart Association and chair of the advisory committee of the American Stroke Association. In addition, Dr. Adams was a director of the American Board of Psychiatry and Neurology and led efforts in creating the sub-specialty of vascular neurology. Dr. Adams continues to be an active teacher to students, residents, and practitioners. He is very proud of receiving the teacher of the year award from the medical students on 14 occasions. harold-adams@uiowa.edu



Ken Cheung, PhD
Dr. Cheung is a Professor of Biostatistics in the Mailman School of Public Health at Columbia University. His research interests include adaptive designs in clinical trials in cancer, stroke, and other neurological disorders, SMART designs for adaptive intervention and behavioral intervention technologies, and the analysis of high dimensional physical activity data. Dr. Cheung is a member of the American Heart Association, American Statistical Association, the International Biometric Society, and the Society for Clinical Trials. He is an elected Fellow of the American Statistical Association. He serves as an associate editor for Biometrics and Clinical Trials. kencheung2@gmail.com

Christopher S. Coffey, PhD
Dr. Coffey is a Professor of Biostatistics and Director of the Clinical Trials Statistical and Data Management Center (CTSDMC) in the University of Iowa College of Public Health. He received his Ph.D. in biostatistics from the University of North Carolina at Chapel Hill in 1999, and has over 15 years of experience providing data management and statistical support to large randomized clinical trials. He is the principal investigator of the Data Coordinating Centers for the NIH funded Network of Excellence in Neuroscience Clinical Trials (NeuroNEXT) and Childhood and Adolescent Migraine Prevention study (CHAMP); and the Statistics Core for the Michael J. Fox Foundation funded Parkinson's Progression Markers Initiative (PPMI). Dr. Coffey is a Fellow of the Society for Clinical Trials, currently sits on the Board of Directors for the SCT, and serves on a number of data and safety monitoring boards. His research interests lie in the area of novel trial designs, particularly the use of adaptive designs. christopher-coffey@uiowa.edu

2018 CTMC Faculty

Robin Conwit, MD

Dr. Conwit is a neurologist and program director in the Office of Clinical Research with extensive experience in clinical trials, neuromuscular disease and clinical neurophysiology. She is also a NINDS project scientist for NeuroNEXT. Prior to working at NIH she was a neurology department faculty member at Johns Hopkins subspecializing in electromyography and neuromuscular disease, with clinical trials experience in ALS and diabetic neuropathy. Her prior experience also includes running an ALS Clinic at the University of Pittsburgh where she was the principal investigator for ALS clinical trials. Dr. Conwit earned a bachelor's degree from Colgate University, where she was a Phi Beta Kappa graduate, magna cum laude; attended medical school at the University of Buffalo; and completed a residency in Neurology at George Washington University, followed by a fellowship in electromyography at NIH. Her current interests include Neurological Emergencies Treatment Trials (NETT), neurologic intervention studies, adult neuromuscular diseases including ALS and neuropathies. conwitr@ninds.nih.gov

Michelle A. Detry, PhD

Dr. Detry is a Statistical Scientist for Berry Consultants, LLC with expertise in Phase I, II, and III clinical trial design and analysis/reporting in support of Data Monitoring Committees (DMCs). She received her PhD in Biometry in 2003 from the University of Texas-Houston School of Public Health. Prior to joining Berry Consultants in 2011, Dr. Detry was an Assistant Scientist in the Department of Biostatistics & Medical Informatics in the University of Wisconsin School of Medicine and Public Health. In that role, she led projects focused on the design and creation of reports prepared for independent DMCs for multicenter Phase II/III and Phase III industry sponsored clinical trials, frequently taught seminars on study design and statistical methods to postdoctoral clinical fellows, and co-developed the workshop series "Clinical Research Study Design". Prior to her position at the University of Wisconsin, Michelle was a Principal Statistical Analyst at the University of Texas M. D. Anderson Cancer where she designed clinical trials using Bayesian methods. In addition to clinical trials, Dr. Detry has experience in the analysis of data for healthcare quality improvement, Epidemiology, and basic science research. michelle@berryconsultants.net

Valerie Durkalski-Mauldin, PhD, MPH

Dr. Durkalski is a Professor of Biostatistics in the Department of Public Health Sciences at the Medical University of South Carolina (MUSC) and the Director of the Data Coordination Unit, an NIH-funded statistical and data coordinating center at MUSC that specializes in the design and coordination of multicenter clinical trials. The DCU serves as the Statistical and Data Coordinating Center (SDCC) for several NIH-funded large multicenter clinical trials and three clinical trial networks. As Director of the DCU, she serves as PI for the SDCC and collaborates on several large multicenter clinical trials in various therapeutic areas

and has published and presented on various topics related to the design and conduct of clinical trials. In addition to these roles, Dr. Durkalski serves on several Data and Safety Monitoring Boards as well as serving as a member of an FDA Advisory Panel. Her research interests are in non-inferiority trials and the implementation and analysis of adaptive confirmatory trial designs. durkalsv@musc.edu

Eric Foster, PhD

Dr. Foster is a Clinical Assistant Professor from the Department of Biostatistics at the University of Iowa. Since joining the faculty, he has provided data management and statistical support for clinical trials at the Iowa Clinical Trials Statistical and Data Management Center. As the NeuroNEXT design team coordinator, Eric has worked with PIs in order to enhance study design prior to grant submission. Eric has also taken over as the DCC PI for several NIH funded studies, including BrAIST (Bracing in Adolescent Idiopathic Scoliosis Trial), CAPTION (Collaboration among Pharmacists & Physicians to Improve Outcomes Now), and most recently the CITC (Clinical Islet Transplantation Consortium). eric-foster@uiowa.edu

Wendy Galpern, MD, PhD

Dr. Galpern is a Medical Director in the Neuroscience Clinical Development Group at Janssen Research and Development / Johnson and Johnson where she is involved with clinical trials in Alzheimer's disease and other neurodegenerative disorders. Prior to joining Janssen in September 2015, she was a Program Director in the Office of Clinical Research at the National Institute of Neurological Disorders and Stroke at the National Institutes of Health where she was involved with oversight and implementation of clinical research projects with a particular emphasis on clinical trials in movement disorders. Additionally, she maintained a movement disorders clinical practice at Walter Reed National Military Medical Center. Dr. Galpern earned her medical and doctoral degrees from the University of Massachusetts Medical School and conducted her doctoral research on neuroprotection and neurotransplantation in neurodegenerative disorders in the laboratory of Dr. Ole Isacson. She completed her internship in medicine at the

Massachusetts General Hospital followed by neurology residency and a clinical and basic science fellowship in movement disorders at the Massachusetts General Hospital and Brigham and Women's Hospital in Boston, MA. Subsequently, Dr. Galpern was a clinical fellow in movement disorders with Dr. Anthony Lang at the Toronto Western Hospital in Toronto, ON. wgalpern@its.jnj.com

2018 CTMC Faculty

Josh Grill, PhD

Joshua D. Grill, PhD, is the Director of the Katherine and Benjamin Kagan Alzheimer's Disease Treatment Development Program and the leader of the Recruitment and Education Core of the Mary S. Easton Center for Alzheimer's Disease Research at UCLA. He is also co-Principal Investigator of the Network for Excellence in Neuroscience Clinical Trials (NeuroNEXT) at UCLA. He is an Assistant Professor of Neurology. Dr. Grill earned his doctorate in Neuroscience in the Department of Neurobiology and Anatomy at the Wake Forest University School of Medicine. Dr. Grill's areas of expertise include neurobiological changes that accompany normal aging and disease and his current research is focused on clinical trials in Alzheimer's disease.

Laurie Gutmann, MD

Dr. Gutmann received her BA from Oberlin College and her MD from West Virginia University. Her neurology residency and fellowship in neuromuscular diseases were at the University of Virginia. She was previously Professor of Neurology at West Virginia University. She worked for four years as a Program Officer in the NINDS/NIH Office of Clinical Research. She serves as a Director for the American Board of Psychiatry and Neurology, a member of the ACGME RRC, and on the ABMS committee addressing maintenance of certification for physician scientists. She is currently Professor and Vice Chair of Clinical Research in the University of Iowa Department of Neurology. She is currently a part of the Clinical Coordinating Center for the NeuroNEXT (NIH Network of Excellence for Neurologic Clinical Trials) in charge of site support, recruitment/retention and diversity in clinical trials, as well as part of various protocol development groups. laurie-gutmann@uiowa.edu

Adam Hartman, MD

Dr. Hartman is a Program Director in the Division of Clinical Research with a background in child neurology and epilepsy. Before joining NINDS, he was an Associate Professor of Neurology and Pediatrics at Johns Hopkins School of Medicine, with a joint appointment in the Johns Hopkins Bloomberg School of Public Health Department of Molecular Microbiology and Immunology. He also was Co- Director of the Neurosciences Intensive Care Nursery and Associate Program Director for the Child Neurology residency at Johns Hopkins. Dr. Hartman earned a bachelor's degree in Chemistry from Northwestern University and an MD from Northwestern University Medical School. After completing a residency in Pediatrics in the National Capital Uniformed Services Pediatric Residency Program, he served as a general pediatrician in the US Navy for five years (the last as Division Head of General Pediatrics at Naval Medical Center San Diego). He completed his residency in child neurology and a fellowship in clinical neurophysiology/pediatric epilepsy, both at Johns Hopkins. His current interest is in Pediatric Neurology clinical trials. adam.hartman@nih.gov

2018 CTMC Faculty

Dietrich Haubenberger, MHSc, MD

Dr. Haubenberger is Director of the Clinical Trials Unit at the NINDS Intramural Research Program and Assistant Clinical Director for Clinical Research, National Institutes of Health in Bethesda, MD. Dr. Haubenberger received his medical degree and training as neurologist at the Medical University of Vienna, Austria, followed by a tenure track position to become Associate Professor of Neurology in 2014. Dr. Haubenberger's research focuses on the area of movement disorders, where he is an expert in tremor disorders. He published in the field of clinical genetics, neurophysiology as well as outcome measures research. From 2008-2011, Dr. Haubenberger completed a research fellowship at NINDS under Dr. Mark Hallett, conducting IND-regulated clinical trials in patients with Essential Tremor, before returning to the NINDS for his current position in 2014.
haubenberger@me.com

Pooja Khatri, MD, MSc

Dr. Khatri is Professor of Neurology at the University of Cincinnati (UC) and Director of Acute Stroke for the UC Stroke Team. Her prior training includes neurology residency at the University of Pennsylvania, vascular neurology fellowship at University of Cincinnati, and an MSc in clinical epidemiology from Harvard School of Public Health. She has been awarded an NIH/NINDS K23 grant, and the American Heart Association (AHA) Robert G. Siekert Young Investigator Award for identifying that time to angiographic reperfusion predicts good clinical outcome after acute stroke. She has been part of the leadership of several trials including the IMS III and THERAPY trials of endovascular therapy for stroke, and she is lead PI of the ongoing, Phase III, PRISMS trial of tPA for mild stroke. She is co-Principal Investigator of the NIH StrokeNet National Coordinating Center (NCC). At the local level, she was PI of the Cincinnati NeuroNEXT site grant, and she is now PI of the StrokeNet regional coordinating center (RCC). Other clinical trial experience includes prior membership on the FDA Advisory Panel for neurological drugs and current membership on the UC IRB. She has over 100 peer-reviewed publications with expertise including acute stroke management, clinical trial design and implementation, and stroke systems of care. pooja.khatri@uc.edu

Roger Lewis, MD, PhD

Dr. Lewis received his PhD in Biophysics and MD from Stanford University. He is a Professor at the David Geffen School of Medicine at UCLA and Chair of the Department of Emergency Medicine at Harbor-UCLA Medical Center. Dr. Lewis's expertise centers on adaptive and Bayesian clinical trials, including platform trials; translational, clinical, health services and outcomes research; interim data analysis; data monitoring committees; and informed consent in emergency research studies. In 2009, Dr. Lewis was elected to membership in the National Academy of Medicine (formerly the Institute of Medicine). He is a Past President of the Society

for Academic Emergency Medicine (SAEM), currently a member of the Board of Directors for the Society for Clinical Trials, and the Senior Medical Scientist at Berry Consultants, LLC, a group that specializes in adaptive clinical trials. Dr. Lewis has served as a grant reviewer for the Agency for Healthcare Research and Quality (AHRQ), the Canadian Institutes of Health Research (CIHR), the Centers for Disease Control and Prevention (CDC), the National Cancer Institute of France, the National Institutes of Health (NIH), the Patient Centered Outcomes Research Institute (PCORI) and foundations. He is also a member of the Medicare Evidence Development & Coverage Advisory Committee of the Centers for Medicare & Medicaid Services. Dr. Lewis serves as the chair of data and safety monitoring boards (DSMB) for both federally-funded and industry-sponsored clinical trials, including international trials. He is a research methodology reviewer for JAMA and an editor of the JAMA series entitled "JAMA Guides to Statistics and Methods." He has served as a content reviewer for many other peer reviewed journals. He has authored or coauthored over 200 original research publications, reviews, editorials, and chapters. roger@emedharbor.edu

Renee Martin, PhD

Dr. Martin is an Associate Professor of Biostatistics in the Department of Public Health Sciences and the Biostatistics Section Head for the Data Coordination Unit. She has extensive experience and expertise in the planning, implementation and analysis of Phase I-III clinical trials. With emphasis in stroke therapies and aneurysm repair, she serves or has served as an unblinded statistician for several NINDS-sponsored and industry-sponsored. Dr. Martin has served as the primary statistician and statistical PI for the ALISAH, LARGE, ENACT trials and the Phase I trial of N-acetylcysteine in maternal chorioamnionitis to decrease inflammation in the fetal brain and improve neurologic outcomes (CHORIO). Dr. Martin also serves as the primary statistician for the Characterization of Intracranial Atherosclerotic Stenosis using High-resolution MRI (CHIASM) Study and the CTA Spot Sign Score in Acute Cerebral Hemorrhage (SCORE-IT) Study which focus on MRI and/or brain imaging for prediction of clinical outcomes rather than therapeutic interventions, and she has participated as a statistical member of the NINDS-appointed DSMB for the ARUBA trial of arteriovenous malformation and currently serves on the Core DSMB for the NINDS NeuroNEXT projects. Dr. Martin also works collaboratively with DCU faculty/students to publish on methodological issues in clinical trials, such as covariate imbalance and adaptive randomization in clinical trial designs and statistical aspects of interim analysis.
hebertrl@musc.edu

2018 CTMC Faculty

William Meurer, MD, MS

Dr. Meurer is an Assistant Professor of Emergency Medicine and Neurology with fellowship training in Stroke and Cerebrovascular Disease, along with a Master's degree in Clinical Research Design and Statistical Analysis. His specific clinical and research focus is on adaptive trial design the treatment of acute neurological illness. He has extensive experience in the design and conduct of clinical trials and provides expertise from the entire spectrum of trial development from idea, design, enrollment, analysis and interpretation. wmeurer@med.umich.edu

Charity Patterson, PhD, MSPH

Charity G. (Moore) Patterson is a professor in the Department of Physical Therapy at the University of Pittsburgh. She is the founding Director of the Physical Therapy Data Center. Her primary area of research expertise is biostatistics, clinical trials and data coordination for exercise, rehabilitation, and physical therapy studies. Patterson has collaborated on studies funded by the National Institutes of Health, Patient Centered Outcomes Research Institute (PCORI), and the Department of Defense. She has more than 150 peer-reviewed publications in journals of high impact. She also serves as a reviewer for peer-reviewed scientific journals and national funding agencies. cgp22@pitt.edu

Melanie Quintana, PhD

Dr. Quintana is a Statistical Scientist at Berry Consultants, LLC. Her research interests include Bayesian model uncertainty and prior specification with applications to genetic association studies. She has a PhD in Statistics from Duke University. melanie@berryconsultants.net

Jeff Saver, MD

Dr. Saver is a professor of clinical neurology and the director of the stroke unit at the David Geffen School of Medicine of UCLA. Saver has been the global or site principal investigator for more than 50 clinical trials. One of the most ambitious and groundbreaking was FAST-MAG, a first-of-its-kind study showing that paramedics can safely give intravenous medication to stroke patients in the ambulance. jsaver@mednet.ucla.edu

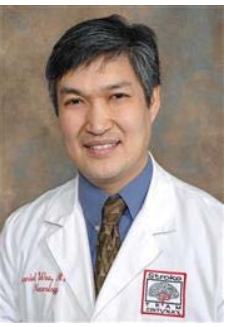
2018 CTMC Faculty

Robert Silbergleit, MD

Dr. Silbergleit has expertise in organizing and conducting clinical trials in the acute care setting. He has substantial past experience as a translational researcher, working on laboratory animal models of brain injury, and participating in clinical trials in stroke as a site PI and sub-investigator. For the past seven years, he has been a leading co-investigator in the formation and organization of the Neurological Emergencies Treatment Trials network, where he contributed to the oversight and management of all NETT trials. In the NETT he has developed specific expertise and experience in investigating initial interventions in patients with status epilepticus and neurotrauma. In multiple trials, he has developed operational and academic expertise in Exception from Informed Consent (EFIC) for Emergency Research and its conduct under FDA regulations. He is also PI of a just-funded NIH empirical ethics project to study the review of local context by local and central IRB's. robie@umich.edu

Kert Viele, PhD

Dr. Viele is a Director and Senior Statistical Scientist with Berry Consultants, LLC. His research interests involve Bayesian computational methods applied to adaptive clinical trials, functional data analysis, mixture modeling, and model selection. Dr. Viele received his Ph.D. from Carnegie Mellon University and prior to joining Berry Consultants in 2010, he was an Assistant and Associate Professor at the University of Kentucky. He has been a principal investigator (or co-PI) on NIH and NSF funded grants and has led statistical collaborations in proteomics, biology, medicine, psychology, and engineering. He has received University teaching awards, served as chair for data safety monitoring boards, and chaired numerous university committees. Dr. Viele has contributed more than 30 papers to the literature and is a former editor of the journal Bayesian Analysis. Dr. Viele was a software architect for FACTS (Fixed and Adaptive Clinical Trial Simulator), a Bayesian adaptive design software product currently licensed to several of the top 20 Pharmaceutical companies in the United States. kert@berryconsultants.net



Dan Woo, MD

Daniel Woo, MD, has been a neurologist with the University of Cincinnati Neuroscience Institute and UC Health since 1998. Dr. Woo trained at the Cleveland Clinic Foundation prior to his fellowship in Cerebrovascular Disease at the University of Cincinnati. Dr. Woo has been as a member of the UC Institutional Review Board (IRB) including serving as the vice-Chair of the IRB as well as the development and medical directorship of the University of Cincinnati's Post-Approval Monitoring Program. As a neurologist, Dr. Woo specializes in the treatment of stroke and a wide variety of neurologic problems in his general neurology clinic. woodl@ucmail.uc.edu

2018 CTMC Faculty

Sharon Yeatts, PhD

Dr. Yeatts is an Associate Professor of Biostatistics in the Department of Public Health Sciences at the Medical University of South Carolina. She is also a faculty member with the Data Coordination Unit (DCU), an NIH-funded statistical and data coordinating center that specializes in the design and coordination of multicenter clinical trials. Since he began with the DCU in 2006, Dr. Yeatts has a strong background in biostatistics, with specific training and experience in the planning, implementation and analysis of Phase I- III clinical trials. As the PI of the Statistics and Data Management Center for the phase I and II trials of deferoxamine in ICH, Dr. Yeatts is responsible for the design of the trial and the implementation of the statistical and data/project management work scope. Dr. Yeatts is the PI of the National Data Management Center for DEFUSE 3, a multicenter clinical trial using an adaptive design to assess the efficacy of endovascular therapy following imaging evaluation in ischemic stroke. In addition, Dr. Yeatts was the primary unblinded statistician for the large Phase III trials of the Interventional Management of Stroke (IMS-III) and progesterone in traumatic brain injury (ProTECT). As a co- investigator on these grants, she was responsible for the statistical monitoring of data and the implementation of interim and final efficacy and safety analyses. Dr. Yeatts serves on Data and Safety Monitoring Boards and as a grant reviewer for several funding agencies. Her primary research interests include the development and implementation of efficient early phase trial designs and novel trial outcomes. yeatts@musc.edu