

2019 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

Michael Benatar, MD



Dr. Benatar is a Professor of Neurology, and Epidemiology & Public Health. He is also the Chief of the Neuromuscular Division and the first incumbent of the Walter Bradley Chair in ALS Research. His primary clinical interest is in amyotrophic lateral sclerosis (ALS), myasthenia gravis and electromyography. His primary research focus is on ALS (including clinical trials, genetics and biomarker development), and myasthenia gravis. MBenatar@med.miami.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

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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



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



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

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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.

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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

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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



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

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Hallett, conducting IND-regulated clinical trials in patients with Essential Tremor, before returning to the NINDS for his current position in 2014.

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Fred Korley, MD, PhD

Dr. Korley has expertise in the design and conduct of clinical investigations to diagnose and treat acute brain and cardiac injury using emerging diagnostic technologies. He received doctoral training in translational science and his dissertation focused on the use of high sensitivity troponin I in the diagnosis of acute coronary syndrome. This work also examined other emerging diagnostics including CT coronary angiography and novel electrocardiographic techniques. Additionally, Dr. Korley has substantial experience in the discovery, quantification and validation of novel protein-based biomarkers using advanced proteomics techniques. He is a co-inventor of a panel of novel biomarkers for diagnosing acute traumatic brain injury (TBI). He is the PI of HeadSMART (*Head Injury Serum Markers for Assessing Response to Trauma*), a prospective cohort study examining the utility of blood-based biomarkers for acute stage TBI diagnosis and risk-stratification. korley@umich.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

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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.

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Katherine Mathews, MD

Dr. Mathews is interested in all aspects of Clinical Pediatric Neurology. Particular interests include neuromuscular disorders and the neuropsychological outcome of childhood stroke. Her research career began with using genetic linkage, then a putative mouse model, to identify the gene causing facioscapulohumeral dystrophy. She closed her laboratory in 1998 due to increasing clinical and administrative demands, and her current academic efforts have been focused on improving the quality of care for patients with neuromuscular disease. Dr. Mathews has maintained an active interest in the impact of molecular genetics on neuromuscular diseases (diagnosis, pathophysiology and treatment). She served on NIH and CDC working groups to define the direction of research on neuromuscular disease in the future. She has become increasingly involved in collaborative clinical research efforts, many of which are laying a groundwork for clinical trials. She currently is a co-PI (with Paul Romitti, PhD) on the Iowa MDSTARnet project, a CDC sponsored, multi-center Duchenne/Becker Muscular Dystrophy surveillance and epidemiology project. She's co-PI on one project of the University of Iowa's NIH funded Wellstone Center, directed by Kevin Campbell, PhD and Steve Moore, MD, PhD. Her project involves defining the phenotypes of patients with FRKP mutations and will extend nationwide. This clinical project was a key component of this successful NIH application. She is also the Iowa PI in the United Dystrophinopathy project; a

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genotype-phenotype study headed by Dr. Kevin Flanigan at the University of Utah and recently funded by the NIH. katherine-mathews@uiowa.edu



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



Mark Quigg, MD

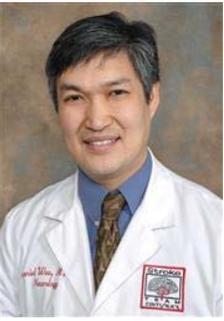
Dr. Quigg completed his neuroscience training at the Karolinska Institute in Stockholm, Sweden. He specializes in the evaluation and treatment of difficult-to-control seizures and the neurological aspects of sleep medicine. He is the medical director of the electroencephalography and intensive monitoring laboratories and is an expert in using these tools to evaluate epilepsy, sleep disorders and disorders with similar symptoms. He is nationally recognized for his clinical practice and research. He holds national offices, including on the neurology board and professional societies for neurology and epilepsy. quiggmarky@gmail.com



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

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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



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