# Clinical Trials Methodology Course

July 22 - 25, 2019 • The Graduate Hotel • Iowa City, Iowa

## Faculty Bios

### Harold Adams, MD

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

### Opeolu Adeoye, MD

Dr. Adeoye completed a fellowship in Neurovascular Emergencies and Neurocritical Care, joining the faculty in 2008 with dual appointments in Emergency Medicine and Neurosurgery. Dr. Adeoye's background and training allow him to ensure optimal care of patients with neurological conditions from the prehospital setting through the emergency department, into the hospital until they are ready for discharge to home or a rehab facility. Currently, Dr. Adeoye serves as the Medical Director for Telestroke Program. Academically, Dr. Adeoye's research interest is in acute stroke. He conducts research funded by the NIH and serves on national committees for the Society of Academic Emergency Medicine, American Heart Association and Neurocritical Care Society. adeoyeo@UCMAIL.UC.EDU

## Erika Augustine, MD

Erika Augustine, MD, MS, is an Associate Professor of Neurology, Pediatrics, and the Center for Health + Technology at the University of Rochester. Following residency training in Pediatrics and Pediatric Neurology at Harvard University/Boston Children's Hospital, Dr. Augustine completed dual fellowships in Pediatric Movement Disorders and Experimental Therapeutics, with a focus on clinical trial design.

Dr. Augustine specializes in the care of children with movement disorders. Her clinical research program focuses on advancing therapeutic development for rare pediatric neurological disorders, with emphasis on comprehensive clinical phenotyping and trial design. Dr. Augustine leads clinical programs developing novel therapeutics for the neuronal ceroid lipofuscinoses (Batten diseases), a group of rare pediatric neurodegenerative disorders. Erika_Augustine@URMC.Rochester.edu

## Michael Benatar, MD, PhD

Dr. Benatar is a Professor of Neurology and the Chief of the Neuromuscular Division in the Department of Neurology at the University of Miami. He is also the first incumbent of the Walter Bradley Chair in ALS Research. Dr. Benatar earned his medical degree from the University of Cape Town in South Africa and his PhD in Neuroscience at Oxford University in the United Kingdom. He also has a Masters in Science in Clinical Research, which he acquired at Emory University in Atlanta, Georgia. He completed his Neurology Residency and a Neurophysiology Fellowship at Beth Israel Deaconess Medical Center in Boston, Massachusetts. He is board certified in Neurology, Clinical Neurophysiology and Electrodiagnostic Medicine. He leads an active program of clinical and translational ALS research that encompasses clinical trials, genetics, and the development of physiological and imaging biomarkers. His research program is devoted to understanding the reasons why therapy development efforts have not been successful in the past and to development of effective treatments for patients with ALS. 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

## Christopher S. Coffey, PhD

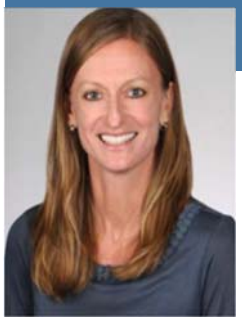
Dr. Coffey is a Professor of Biostatistics and Director of the Clinical Trials Statistical and Data Management Center (CTSDMC) in the University of Iowa College of Public Health. He received his Ph.D. in biostatistics from the University of North Carolina at Chapel Hill in 1999, and has over 15 years 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

## Colin Derdeyn, MD

Dr. Derdeyn is the Krabbenhoft Professor and Chair of the Department of Radiology at the University of Iowa Hospitals and Clinics. He is also a professor of neurology and Director of the Iowa Institute of Biomedical Imaging. He received his B.A. (Echols Scholar) from the University of Virginia in 1984, and his M.D. from the University of Virginia in 1988. He is a past president of the Society for NeuroInterventional Surgery and former Chair of the Stroke Council of the American Heart Association. Dr. Derdeyn's practice is limited to the endovascular treatment of cerebrovascular disease, including ischemic stroke. His research interests primarily relate to occlusive cerebrovascular disease and cerebral hemodynamics. He has extensive experience in stroke-related clinical trials as an executive investigator, including COSS and SAMMPRIS. He was the director of a large, NIH-funded, stroke research center (Specialized Programs for Translational Research in Acute Stroke (SPOTRIAS, P50 NS55977) at Washington University, where he was the director of the stroke and cerebrovascular center from 2007 – 2015. He was the chair of the DSMB for the ESCAPE trial. He is currently the NeuroInterventional PI for the MOST trial and chair of the StrokeNet Endovascular Advisory Group. colin-derdeyn@uiowa.edu



## Valerie Durkalski-Mauldin, PhD, MPH

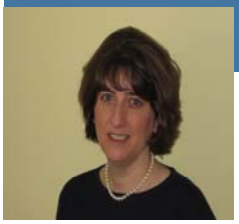
Dr. Durkalski is a Professor of Biostatistics in the Department of Public Health Sciences at the Medical University of South Carolina (MUSC) and the Director of the Data Coordination Unit, an NIH-funded statistical and data coordinating center at MUSC that specializes in the design and coordination of 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

## Dixie Ecklund, RN, MSN, MBA

Ms. Ecklund is Director of Operations of the CTSDMC. She has over 30 years of combined experience in conducting clinical trials through the CTSDMC and in her previous role as Nurse Manager of the General Clinic Research Center (GCRC). She has been involved in various capacities in hundreds of clinical trials, ranging from small Phase 1 studies to multi-center Phase 3 studies. Ms. Ecklund has served as an IRB member for 25 years and was appointed an IRB chair in 2009. She has administrative experience with responsibilities including protocol implementation, protocol compliance, resource allocation, budgetary implications, and collaboration with many partners. Ms. Ecklund is responsible for overseeing all day-to-day activities of the DCC. She participates in all of the NeuroNEXT study team meetings and all of the operational meetings. She functionally supervises all DCC team leaders, monitors their progress, and provides guidance for operational questions. Ms. Ecklund serves as the direct liaison from the DCC Leadership to the CCC Leadership. She serves on the Site Support team and is a direct contact to the NeuroNEXT PIs and Coordinators. She serves as the DCC liaison for many of the Committees and is an ad-hoc member of NEC. Ms. Ecklund serves as the liaison to the NINDS DSMB on behalf of all of the NeuroNEXT investigators. She also serves on the Protocol Steering Committees as the blinded DCC member. dixie-ecklund@uiowa.edu

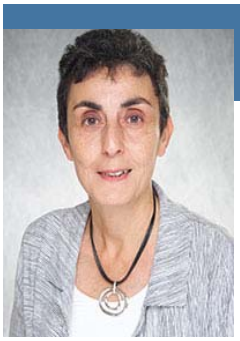
## Eric Foster, PhD

Dr. Foster is a Project Statistician from Ferring Pharmaceuticals. He has provided data management and statistical support for both NIH-sponsored and industry-sponsored clinical trials. These trails have ranged from Phase I through Phase IV studies in multiple therapeutic areas such as stroke, neurological diseases, diabetes, devices, and reproductive health. eric.foster@ferring.com



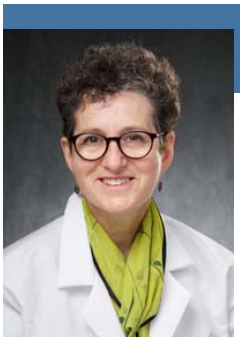
## Wendy Galpern, MD, PhD

Dr. Galpern is 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 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



## Corinne Griguer, PhD

Dr. Griguer is an Associate Professor of the Department of Radiation Oncology at the University of Iowa. Her laboratory research program focuses on mechanistic studies of glioma initiation and progression, especially the contributions from the mitochondria. Over the past 10 years, as PI on several university- and NIH-funded grants, she's laid the ground work in the understanding on how mitochondria play an essential role in tumor chemo-resistance and survival in glioma. Her research efforts have helped to delineate how these processes are regulated at the molecular level, and have identified Cytochrome c Oxidase as a main player in the regulation of chemo-resistance through a bioenergetic switch from glycolysis to oxidative phosphorylation. Currently, she is the PI on an ongoing NINDS funded prospective and prognostic biomarker trial which has enrolled 152 glioblastoma patients undergoing standard of care (19 clinical sites) from which cytochrome c oxidase activity is currently assayed against the standard biomarker O6-methylguanine–DNA methyltransferase. corinne-griguer@uiowa.edu

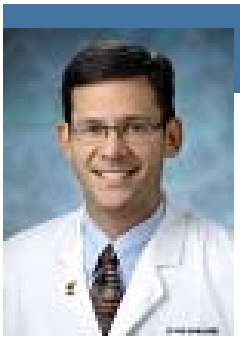


## Laurie Gutmann, MD

Dr. Gutmann has had long-standing clinical trials experience beginning at WVU, enhanced by her four years of experience in the extramural clinical trials program at NINDS/NIH. She served there as program officer for several U01 trials, was a consultant for Coriell Repository, and was actively involved in the Office of Clinical Research activities. She is currently a member of the University of Iowa neuromuscular research division and director of the Myotonic Dystrophy Clinic. She is coPI of the CTMC and Associate Director of Workforce Development for the University of Iowa Institute of Clinical and Translational Studies. She is vice chair of the AAN Education committee, chair of the ACGME Residency Review Committee and serves as a director for the American Board of Psychiatry and Neurology. laurie-gutmann@uiowa.edu

## Adrianne Haggins, MD

Dr. Haggins is an Associate Professor of Emergency Medicine at the University of Michigan. Dr. Haggins' primary research interests are related to health disparities in access to care, designing socio-cultural educational curriculum, and increasing diversity in the health care workforce. She also has interests in mentorship and professional development, particularly for underrepresented minority and first generation in college pre-med students. ahaggins@med.umich.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 the Medical Director of Early Clinical Development for Neurocrine Biosciences Inc. He's the former Director of the Clinical Trials Unit and Assistant Clinical Director for Clinical Research at the NINDS Intramural Research Program, National Institutes of Health. Dr. Haubenberger received his medical degree and training as a neurologist at the Medical University of Vienna, Austria, followed by a tenure trach position to become an Associate Professor of Neurology in 2014. Dr. Haubenberger's research focuses on the area of movement disorders, where he conducted clinical trials and outcome measure development projects in tremor disorders. He, furthermore, published in the field of clinical genetics, neurophysiology, as well as outcome measures development. At Neurocrine, Dr. Haubenberger is leading clinical development programs as well as a translational biomarkers team. dhaubenberger@neurocrine.com

## Michelle Jones-London, PhD

Dr. Michelle D. Jones-London serves as Chief, Office of Programs to Enhance Neuroscience Workforce Diversity (OPEN-WD). In this position, she plays a critical role in guiding the Institute's diversity efforts and chairs the NINDS Diversity Working Group. Dr. Jones-London joined NINDS as a Program Director in July, 2006. Dr. Jones-London earned her Ph.D. in Neuroscience from the Department of Neuroscience and Anatomy at Pennsylvania State University College of Medicine. She then received postdoctoral training as a research fellow at University of Pennsylvania in the Department of Psychiatry. Dr. Jones-London came to the NIH in July 2004 as an Emerging Leader Fellow; she performed duties across the Department of Health and Human Services including the Center for Scientific Review, FDA Office of Women's Health Science Program, and the Immediate Office of the Secretary, Intergovernmental/Tribal Affairs Office. Dr. Jones-London directs the diversity training and workforce development programs at NINDS which include Diversity and Re-Entry Supplements, Predoctoral Fellowships to Promote Diversity in Health-Related Research (F31), Career Development Awards to Promote Diversity (K22 and K01) and Diversity Research Education Grants (R25) (including the Neuroscience Scholars Program with SfN). She also provides oversight for the Institute's diversity outreach initiatives at several other national scientific conferences. Her trans-NIH efforts include oversight for the NIH Blueprint ENDURE and DSPAN (F99/K00) programs, the BRAIN Initiative Diversity K99/R00, and former Project Scientist for the NIH National Research Mentoring Network (NRMN). Her research interests have focused on understanding monoaminergic neurotransmitter regulation and mechanisms of behavioral psychopharmacology in animal models of disorders such as ADHD, Tourette Syndrome, and depression.

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## Marianne Kearney-Chase

Ms. Chase is the Director of Research Operations at Neurological Clinical Research Institute (NCRI). She has over 25 years of experience working in both industry and academia on investigator-initiated trials, including with NIH, various foundations, and industry-sponsored. Ms. Chase has a wide variety of experience with study coordination, site management, protocol development, regulatory compliance, and project management. She currently oversees 25+ protocol managers and administrative staff in her role at NCRI, providing regulatory and site management expertise as well as overseeing all ongoing clinical research trials managed by the group.

Ms. Chase is responsible for overall Network operations of the NeuroNEXT Clinical Coordination Center, ensuring that all aspects of the planned clinical trials are conducted in full compliance with DHHS, NIH, NINDS and FDA policies and regulations. She collaborates with the Clinical Sites, the NEC and DCC to ensure that all trials are conducted with the highest quality and managed efficiently. mchase@mgh.harvard.edu

## 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 TBI. He is the PI of HeadSMART (***Head*** Injury ***S***erum ***M***arkers for ***A***ssessing ***R***esponse to ***T***rauma), a prospective cohort study examining the utility of blood-based biomarkers for acute stage TBI diagnosis and risk-stratification. korley@umich.edu

## Stephen Korn, PhD

Dr. Korn came to NINDS as Director of the Office of Training, Career Development and Workforce Diversity (now the Office of Training & Workforce Development) in January, 2006. He received his Ph.D. in Pharmacology from the University of North Carolina- Chapel Hill, and received postdoctoral training at NIH (as a PRAT Fellow of NIGMS) and at the Roche Institute of Molecular Biology (with financial support from NRSA postdoctoral fellowships). He then spent 15 years on the faculty of the University of Connecticut at Storrs, where he was a Full Professor. His area of scientific specialty is the molecular basis of ion channel gating and permeation, but he has also conducted electrophysiological and imaging research on calcium and pH transport/buffering, and synaptic transmission in the hippocampal slice. korns@ninds.nih.gov

## Roger Lewis, MD, PhD

Dr. Lewis 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. Dr. Lewis is a member of the National Academy of Medicine. He is a Past President of the Society for Academic Emergency Medicine, 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. He has served as a grant reviewer for the Agency for Healthcare Research and Quality, the Canadian Institutes of Health Research, the Centers for Disease Control and Prevention, the National Cancer Institute of France, the National Institutes of Health, the Patient Centered Outcomes Research Institute and foundations. He is also a member of the Medicare Evidence Development & Coverage Advisory Committee of the Centers for Medicare & Medicaid Services. He serves as the chair of data and safety monitoring boards 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, "JAMA Guides to Statistics and Methods." 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

## 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, multicenter 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 genotype-phenotype study headed by Dr. Kevin Flanigan at the University of Utah and recently funded by the NIH.

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## 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

## Peggy Nopoulos, MD

Dr. Nopoulos is Professor of Psychiatry, Pediatrics and Neurology, and Interim Chair & DEO of the Department of Psychiatry at the University of Iowa Hospitals in Iowa City, Iowa. Dr. Nopoulos' research focuses on the study of brain and behavior. Specifically, she studies aspects of understanding normal healthy brain such as differences in brain structure and function between the sexes as well as understanding how the brain changes with development through adolescence. In regard to the study of disease, her lab focuses on research into brain structure and function in two main areas: prematurity, and neurogenetics with focus on triplet repeat disorders (Huntington's Disease and Myotonic Dystrophy). This is done using state of the art neuroimaging techniques, specifically Magnetic Resonance Imaging (MRI) which includes structural imaging, Diffusion Tensor Imaging, resting state fMRI, and novel sequences such as T1rho (pH imaging). A large part of Dr. Nopoulos' career has been in the mentorship of research careers for clinicians. She developed and directed the Iowa Medical Student Research Program (IMSRP) from 2001-2013 and directed the Iowa Doris Duke Clinical Research Fellowship also from 2001-2013. She developed the Masters in Translational Biomedicine (TBM) program through the Institute for Clinical and Translational Science (ICTS), designed to train fellows and junior faculty. She is director of the T32 post-doctoral fellowship in the department of psychiatry, and currently is primary mentor on three junior faculty with NIH K-23 awards.
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## 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.

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## Jordan Schultz, PharmD

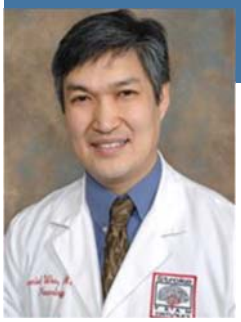
Jordan Schultz, PharmD, graduated from the University of Iowa College of Pharmacy in 2013. After completing a 2 year residency, he worked as a Clinical Pharmacy Specialist in Neurology at the University of Iowa. Dr. Schultz completed the CTMC course in 2017 and joined the faculty of the Carver College of Medicine at the University of Iowa as an Assistant Professor of Psychiatry, Neurology, and Pharmacy Practice in 2018. His lab engages in clinical and translational research involving patients with neurodegenerative diseases, with a focus on Huntington's disease and Parkinson's Disease. The Schultz Lab take an epidemiological approach to identify environmental factors, including medications, that may have an effect on disease progression. Using this information, he uses novel neuroimaging techniques to test specific hypotheses to better understand the mechanisms underlying neurodegeneration. The Schultz Lab is also well-positioned to perform clinical trials on identified interventions. jordan-schultz@uiowa.edu

## Michael Shy, MD

Dr. Shy is the Director of the Division of Neuromuscular Medicine in the Department of Neurology at the University of Iowa. Dr. Shy's professional interests involve translational research to develop rational therapies for patients with inherited peripheral neuropathies and related neurodegenerative diseases. Because genetic neuropathies have known causes, research can concentrate on specific mechanisms and intracellular pathways by which mutant genes and proteins cause demyelination, axonal degeneration or impaired glial-axonal interactions. Careful evaluation of patients as well as animal or tissue culture models of inherited neuropathies or other genetic neuromuscular diseases are essential for a translational approach; accordingly, his research has involved all of these areas ranging from tissue culture to authentic murine models to material from patients with genetic neuropathies. The combination of molecular biology, clinical expertise and human genomics offer patients the best chance to have rationally based therapies to improve their quality of life. Dr. Shy is the PI of the INC consortium (2U54NS065712) of the Rare Disease Clinical Research Network (RDCRN). Goals of the INC are to develop natural history data, develop outcome measures, train new investigators, identify modifier genes and develop standards of care for CMT. He is particularly interested in developing and accessing Clinical Outcome Assessments (COA) and biomarkers to be used to detect progression of CMT that can also be used to determine potential efficacy in clinical trials. michael-shy@uiowa.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

## 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. 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. She 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. She 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