2017 CTMC Faculty

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Dr. Augustine is Associate Director of the Center for Human Experimental Therapeutics at the University of Rochester Medical Center. She completed Pediatrics and Child Neurology residency training at Children's Hospital Boston, followed by fellowship training in Pediatric Movement Disorders and Experimental Therapeutics at the University of Rochester. Dr. Augustine now serves as Assistant Program Director for the NINDS-funded Experimental Therapeutics training program at the University of Rochester. Her research interests include methodology of clinical research and experimental therapeutics in rare pediatric neurological disorders. Current work focuses on therapeutics in Juvenile Neuronal Ceroid Lipofuscinosis.
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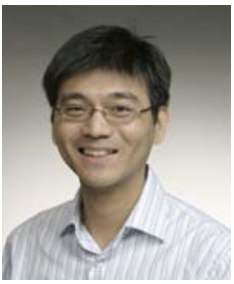
Kristine Broglio

Kristine Broglio is a Statistical Scientist at Berry Consultants with interests in adaptive clinical trials, Bayesian statistics, and survival analysis. Training first as an economist, she worked for two years in health economics research at RTI International, involved primarily in CDC sponsored studies related to diabetes. She earned an MS in Biostatistics from the University of Washington and joined the University of Texas M.D. Anderson Cancer Center where she specialized in applied statistical analysis relating to the diagnosis, treatment, and long-term outcomes of breast cancer. Since joining Berry Consultants, she has led the design and execution of numerous Bayesian adaptive clinical trials, as well as Bayesian analyses synthesizing evidence for the purpose of addressing comparative effectiveness questions. Ms. Broglio has contributed over 100 papers to the medical and statistical literature. kristine@berryconsultants.net



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

2017 CTMC Faculty

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

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

2017 CTMC Faculty

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.
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Jordan Elm, PhD

Dr. Elm is an Associate Professor of Biostatistics in the Department of Public Health Sciences (DPHS) at the Medical University of South Carolina (MUSC). She is also a faculty member of the Data Coordination Unit (DCU), an academic CRO that specializes in the design, conduct, and analysis of multicenter clinical trials. Her research is primarily collaborative and applied to clinical trials. She has been involved in clinical trials since 2001, and she is the lead statistician for several clinical trials in the following areas: Parkinson's disease, stroke, and status epilepticus. Dr. Elm is currently a co-Investigator for the Statistical Center for three NIH-funded clinical trial networks: NET-PD, NETT-SDMC, and StrokeNet-NDMC (NINDS- U01NS043127, U01NS059041, and U01NS087748). For the NET-PD network, she was the lead statistician for the FS-ZONE trial (phase II trial of pioglitazone in Parkinson's disease funded by U01NS043127). For the NETT network, she is the PI of the Statistical and Data Management Center (SDMC) for the POINT trial (NINDS - U01NS062835) a randomized, double-blind, multicenter trial of 5900 patients with TIA or minor ischemic stroke. She is the PI of the Statistical and Data Management Center (SDMC) for the ESETT trial, an adaptive comparative effectiveness clinical trial of Status Epilepticus (NINDS U01NS088023), which was developed in collaboration with the NETT and Berry Consultants. She is also the lead statistician for a clinical trial of transcranial direct current stimulation for the treatment of aphasia in chronic stroke patients (NIDCD - U01DC011739). Dr. Elm has been invited to serve on DSMBs, NIH Special Emphasis Panels, the NINDS Common Data Elements Steering Committee, the Parkinson Study Group Scientific Review Committee, NINDS PD Planning Meeting, and several other panels. She also teaches Biostatistics courses to graduate students in her department at MUSC. elmj@musc.edu

2017 CTMC Faculty

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

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,

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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 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

Brett Kissela, MD, MS

Dr. Kissela is Professor and Chair of the Department of Neurology and Rehabilitation Medicine at the University Of Cincinnati College Of Medicine. Since 2008, he has been Co-Director of the Stroke Recovery Center at Drake and a member of the University of Cincinnati Stroke team since 2000. He is fellowship trained in Vascular Neurology and has extensive clinical trial experience in acute stroke treatment, prevention, and recovery trials. He is an internationally recognized expert on causes, outcomes, and recovery of stroke, with a special interest in the impact of diabetes on stroke and factors that influence stroke outcomes. He also participates in a variety of stroke recovery projects which look to improve recovery with the use of innovative techniques and devices. Honors and awards include the Cincinnati Business Courier's Forty under 40 Award, Michael S. Pessin Stroke Leadership Prize from the American Academy of Neurology, Alpha Omega Alpha membership, National Medical Honor Society, Phi Beta Kappa, UC Faculty Senate Award and has continuously been named as one of the Best Doctors in America (National Surveys – Woodward-White and Best Doctors, Inc.).
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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

2017 CTMC Faculty

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

Anna McGlothlin, PhD

Dr. McGlothlin is a Statistical Scientist for Berry Consultants, where she works closely with collaborators in the pharmaceutical and medical device industries to design and implement clinical trials that are tailored to address specific goals. This experience covers a broad spectrum of disease areas and phases of clinical development. She earned her Ph.D. in Statistics from Baylor University, with research focused on Bayesian methodology and measurement error. Prior to joining Berry Consultants in 2012, she was a Senior Research Scientist in the early phase oncology group at Eli Lilly and Company. Dr. McGlothlin has expertise in adaptive designs, Bayesian methodology, clinical trial simulation, and in the use of interactive graphics. anna@berryconsultants.net

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

Jeremy M. Shefner, MD, PhD

Dr. Jeremy Shefner is the Kemper and Ethel Marley Professor and Chair of Neurology and Associate Director of the Barrow Neurological Institute. He is also Executive Chair of Neurology at the University of Arizona Phoenix. He received his PhD in sensory physiology in 1976, and his MD with Distinction from Northwestern University Medical School in 1983. After completing residency training at the Harvard Longwood Neurology Training Program, he was a fellow in Neuromuscular Disease at the Brigham and Women's Hospital from 1988-1990. He joined the faculty at BWH in 1990, and moved to Upstate Medical University in Syracuse, NY in 1996, becoming Chair of Neurology in 2004. In October, 2014, Dr. Shefner moved to the Barrow Neurological Institute.
Dr. Shefner has been active in designing clinical trials in ALS for many years. He co-founded the Northeast ALS Clinical Trials Consortium (NEALS) in 1996, and was co-chair of the Consortium until stepping down in 2013. During that time, NEALS grew from 9 New England ALS sites to more than 120 sites committed to performing high

quality, efficient, and innovative clinical trials in ALS. In addition to clinical trials, NEALS has vigorous educational programs for investigators, coordinators, evaluators, patients, and caregivers. Dr. Shefner has been principal investigator for many clinical trials in ALS, including those testing creatine, talampanel, lithium, and tirasemtiv. He has also held leadership positions in many other trials. A major focus has been the study of outcome measures for ALS trials, He has developed numerous outcome measures for clinical trials, including motor unit number estimation, quantitative muscle strength testing using hand held dynamometry, and electrical impedance myography, and has explored their utility in both patients and animal models. In 2014, he was awarded the Sheila Essey Award for ALS Research by the American Academy of Neurology and the ALS Association. Dr. Shefner is Neuromuscular Section Editor for Up-to-date, and is on the Editorial Boards of the ALS Journal and Neurotherapeutics.
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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

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