Nominations for Appointment to the Grants Working Group (GWG)

Appointment of New Members

Alex Bailey, Ph.D.
Dr. Alex Bailey is currently Associate Director for Regulatory Affairs at REGENXBIO Inc, a gene therapy company developing treatments for retinal, metabolic and neurodegenerative diseases. Prior to REGENXBIO Inc, Alex spent over 5 years at FDA Center for Biologics Evaluation and Research (CBER), initially as a Pharmacology/Toxicology Reviewer and more recently as the Team Leader in the Pharmacology/Toxicology Branch in the Office of Cellular, Tissue and Gene Therapies (OCTGT). Alex received his Ph.D. in Biomedical Engineering from the University of Virginia and conducted post-doctoral research at the Fred Hutchinson Cancer Research Center in Seattle, WA.

As Team Lead at FDA CBER OCTGT, Alex provided scientific and regulatory oversight of a team of experienced Pharmacology/Toxicology reviewers responsible for the regulatory review of preclinical studies to support the safe use of investigational cell therapies, gene therapies, tissue-engineered products, and medical devices in human clinical trials. In this role, Alex was also responsible for developing consensus on regulatory strategies for preclinical, manufacturing, and clinical development of CBER-regulated biologics across broad therapeutic areas. Alex served as Subject Matter Expert on numerous committees and working groups within the FDA, as well as contributed to the development of guidance documents.

Alex completed the FDA CBER Leadership Program and is a recipient of the FDA CBER awards for Managerial Excellence and Policy Development. He was a Fellow in the FDA Commissioner's Fellowship Program (Class of 2010), where he designed a database of product development and preclinical testing strategies for cell-based regenerative medicine products to assess data quality, identify trends, and stratify products based on potential for tumor formation. Later, Alex served as a Preceptor for the Commissioner's Fellowship program. He was also a Fellow in the Excellence in Government Fellows Program. Alex is a co-chair of the External Advisory Board of the University of Virginia Department of Biomedical Engineering.

Claire Henchcliffe, M.D., D.Phil.
Claire Henchcliffe is the Vice Chair for Clinical Research in Neurology and the director of the Parkinson's and Movement Disorders Institute at Weill Cornell Medical Center in New York City. She read for her BA in Biochemistry and completed her graduate thesis at the University of Oxford in the UK. She then pursued post-doctoral training in genetics and neuroscience at the University of Cambridge, UK, and the University of California at Berkeley, California. Dr. Henchcliffe received her medical degree from the College of Physicians and Surgeons of Columbia University in New York City. She completed both her internship and residency in neurology, and subsequently a fellowship in movement disorders at Columbia Presbyterian Medical Center's Neurological Institute. Her current research focuses on developing new treatments for Parkinson's disease, and is clinical core leader of a NYSTEM-funded consortium to

develop a cell-based therapy for this disorder. Her group have also developed a robust biomarker program, intended for improvement of clinical trial outcome measures. She has been an investigator and on the steering committees for multiple clinical trials in Parkinson's disease, and is the Weill Cornell site Principal Investigator for the NIH-funded NeuroNEXT clinical trial network. Most recently, she serves as Medical Director of the Trial Innovation Unit, linking the NCATS-funded Weill Cornell Clinical and Translational Science Center to the newly formed national Trial Innovation Network. In addition to running a busy clinical practice specializing in movement disorders, she frequently teaches and writes about Parkinson's disease and other neurodegenerative disorders.

Extension of Terms of Scientific Members of the Grants Working Group

Grants Working Group Members originally appointed in 2008-10 have terms that are now expiring or just expired. We are seeking to extend the terms of two members who were reappointed from four years to six years. Their updated biographies follow.

Proposed Reappointments to GWG

Last	First	Term	Expertise
Kerr	Doug	2	Drug Development for Neurologic Disease & Injury; Motor Neuron Disease; Neural Injury
Wagner	John	2	Lympho-Hematopoietic Disorders; Bone Marrow Transplantation; Cord Blood

Douglas Kerr
Doug Kerr is the Global Neurology Development Lead for Shire. Previously Dr. Kerr served as a Senior Director for Corporate Strategy at Biogen where he assessed pipeline opportunities for the company and as Senior Medical Director, Research and Development in Neurodegeneration. Prior to joining Biogen, Dr. Kerr spent 14 years at Johns Hopkins University where he was an Associate Professor of Neurology the Johns Hopkins School of Medicine and of Molecular Microbiology and Immunology in the Johns Hopkins Bloomberg School of Public Health.

Dr. Kerr received his PhD from Thomas Jefferson University and his MD from Jefferson Medical and founded and directed the Johns Hopkins Project RESTORE, a multidisciplinary effort dedicated to advancement of treatments for autoimmune neurologic disorders. Dr. Kerr has testified before the US Congress and the UK House of Lords on stem cell prospects in neurologic disorders. He has over 110 peer-reviewed publications in the medical literature, mainly dealing with spinal cord motor neuron disorders and autoimmune neurologic disorders. Dr. Kerr currently directs clinical development programs for ALS and remains active with the spinal muscular atrophy (SMA) and transverse myelitis (TM) communities

John E. Wagner, M.D.
John E. Wagner is a Professor in the Department of Pediatrics, Director of the Blood and Marrow Transplant Program, and Co-Director of the Center for Translational Medicine at the University of Minnesota. He holds two endowed chairs—Children's Cancer Research Fund/Hageboeck Family Chair in Childhood Cancer Research, and the University of Minnesota McKnight-Presidential Chair.

Dr. Wagner's research is focused on the development of novel molecular and cellular therapeutics for treating life-threatening malignant and non-malignant diseases for which

conventional treatments are unsatisfactory. Current projects in the setting of umbilical cord blood transplantation include: ex vivo expansion of hematopoietic stem and progenitor cells, isolation and expansion of regulatory T cell populations, isolation and expansion of thymic progenitor cells and use of engineered T cells to target residual leukemia. Dr. Wagner is recognized for pioneering the use of double umbilical cord blood transplantation in adults, use of embryo selection to insure an HLA matched, healthy child ('savior sibling') for couples at high risk for a genetic disease, and use of stem cell populations to repair the skin in severely affected children with epidermolysis bullosa. The University of Minnesota has performed nearly 1100 umbilical cord blood transplants to date.