

Nominations for Appointment to the Grants Working Group (GWG)

Zhiqiang An, PhD

Dr. Zhiqiang An is Professor of Molecular Medicine, the Robert A. Welch Distinguished University Chair in Chemistry, and Director of the Texas Therapeutics Institute at the University of Texas Health Science Center at Houston. His laboratory focuses on antibody drug resistance mechanisms, biomarkers for therapeutic antibodies, and antibody drug discovery targeting human diseases. Dr. An also directs the Therapeutic Monoclonal Antibody Lead Optimization and Development Core Facility funded by the Cancer Prevention and Research Institute of Texas (CPRIT). Previously, he served as Chief Scientific Officer at Epitomics, Inc. and was Director of Biologics Research at Merck Research Laboratories. He started his biotech career at Millennium Pharmaceuticals. Dr. An received his Ph.D. degree from the University of Kentucky and his postdoctoral training at the University of Wisconsin-Madison. He is an elected fellow of Society for Industrial Microbiology and Biotechnology (SIMB), an elected fellow of the American Academy of Microbiology (ASM), and elected fellow of American Association for the Advancement of Science (AAAS).

Dean Lee, MD, PhD

Dean Lee is Professor of Pediatrics and DiMarco Family Endowed Chair in Cell Based Therapy at Nationwide Children's Hospital. He is the founding Director of the Cellular Therapy and Cancer Immunotherapy Program, a joint program between NCH and The Ohio State University James Cancer Hospital. Dr. Lee conducts clinical and translational research on natural killer (NK) cells and their potential for cancer immunotherapy. His laboratory identified a crucial role for IL-21 and STAT3 signaling in NK cell function and proliferation, which has enabled a method for large-scale propagation of clinical-grade NK cells for adoptive transfer. NK cells expanded with this approach have been infused into adult and pediatric patients with leukemia, brain tumors, and solid tumors in investigator-initiated Phase I trials. Dr. Lee is chair of the Cellular Therapy Strategy Group for the Pediatric Blood and Marrow Transplant Consortium, member of the NIH Novel and Exceptional Technology and Research Advisory Committee and member of the Cell Therapy Steering Committee of the Children's Oncology Group. His work in cancer immunotherapy and cellular therapy has been supported by NIH, DOD and numerous foundation research grants, and has led to over 100 peer-reviewed publications, patents, and commercial licenses. Dr. Lee practices clinically in the area of bone marrow transplantation, with a particular interest in haplotransplantation and cellular therapy.

Reappointment of Scientific Members to the Grants Working Group

We are seeking the reappointment of the individuals listed in the table below. Their updated biographies follow. In accordance with the rules set forth by Proposition 71, reappointments should be staggered into thirds, each with a 2, 4, or 6-year term.

Last	First	Term	Expertise
Arbab	Ali	6	Imaging; Cell Tracking; Radiology; Oncology
Atassi	Nazem	6	Translational Research and Clinical trials in Neurodegenerative Disorders
Brayman	Kenneth	4	Diabetes; Kidney & Islet Transplantation; Peripheral Vascualar Disease
Burdick	Jason	2	Development of Hydrogels for Biologic Application

Proposed Reappointments to GWG

AGENDA ITEM #4 ICOC MEETING July 22, 2020

Crowley	John	2	Design & Analysis of Cancer Clinical Trials
Damaser	Margot	2	Female Pelvic Dysfunction; Urinary & Fecal Incontinence; Pelvic Organ Prolapse
Danielson	Carol	4	Clinical Regulatory; CMC Regulatory; Cell Therapy, Biologics, & Small Molecule Therapeutics
Gernert	Manuela	2	Pathophysiology of Epilepsies; Neural Transplantation; Drug Delivery in Epilepsy
Hacker	Timothy	6	Animal Models of Disease for Preclinical Testing
Larkindale	Jane	4	Neuromuscular Disease; Patient Outreach; Venture Philanthropy

Ali Syed Arbab, MD, PhD

Dr. Arbab is a professor in the Department of Biochemistry and Molecular Biology and College of Graduate Studies and Leader of the Tumor Angiogenesis Initiative at Georgia Regents University. Previously, he was the Senior Scientist and Director of the Cellular and Molecular Imaging Laboratory (CMIL), Department of Radiology, at Henry Ford Hospital in Detroit. Prior to Henry Ford, Dr. Arbab oversaw the Nuclear Medicine Division at Yamanashi Medical University in Japan.

He received his MD from the Institute of Post-graduate Medicine and Research in Bangladesh and his PhD in Radiological Science from Yamanashi Medical University, Japan. His postdoctoral training in Cellular MR Imaging was at The National Institutes of Health. Dr. Arbab's research interests include: Involvement of bone marrow progenitor cells in resistance to anti-angiogenic treatments, differentiation of glioma from radiation injury, cell mediated gene therapy, changes in tumor vascular permeability, SPECT technology, stem cell biology, and optical imaging.

Nazem Atassi, MD

Nazem Atassi is Associate Director of the Neurological Clinical Research Institute at Massachusetts General Hospital, and Associate Professor of Neurology at Harvard Medical School. He has completed Neurology training at Boston University Medical Center and Fellowship in Neuromuscular Disorders and Clinical Trials at MGH.

Dr. Atassi received his Masters of Medical Science in 2010 from Harvard Medical School. He serves on the executive committee of the Northeast ALS Consortium (NEALS), and he is the founder and Co-Chair of the Upper Motor Neuron and the Imaging committees at NEALS.

Dr. Atassi received several awards including the MIT 100K Life Science Award from Massachusetts Institute of Technology, the Anne B. Young Translational Neuroscience Fellowship, and NIH K23 Career Development Award. He is completing Masters in Business Administration (MBA class 2019) at Sloan, Massachusetts Institute of Technology. He has hands-on industry experience in designing and running multicenter clinical trials through his work as a medical monitor for Pfizer and Fellow at Biogen.

Dr. Atassi is the Primary Investigator for several research projects focusing on Amyotrophic Lateral Sclerosis clinical trials, neuroimaging, and outcomes measures. His research is funded by the National Institute of Health, ALS Association, ALS Finding a Cure, ALS One Foundation, Muscular Dystrophy Association, and Harvard NeuroDiscovery Center.

Dr. Atassi directs the NCRI Imaging core which leverages a world-class research imaging infrastructure available at Mass General and apply these technologies to develop new ALS therapies. This Core is laser-focused on building novel imaging platforms that can measure the biological activity of experimental treatments in people living with ALS, leading to efficient clinical trial designs and accelerated pace of drug discovery.

Kenneth L. Brayman, MD, PhD, FACS

Kenneth Brayman is the director of UVA's kidney, pancreas and islet transplant programs and the director of the Center for Cellular Therapy and Biologic Therapeutics. He's also the Nabi Professor of Transplantation.Dr. Brayman received his medical and doctorate degrees from the University of Pennsylvania School of Medicine. He completed his internship and residency in general surgery at the Hospital of the University of Pennsylvania and fellowships in transplantation surgery and surgical endoscopy at the University of Minnesota Hospital.

He is board certified by the American Board of Surgery and the National Board of Medical Examiners. He serves on numerous committees and is a member of professional and scientific societies including American Association of

Kidney Patients, American Pancreatic Association and American Society of Transplant Physicians. Dr. Brayman is also a founding member of the International Pancreas and Islet Transplant Association. He is widely published in scientific and professional journals on topics related to his research and clinical experience.

Dr. Brayman has over twenty years of experience as a principal investigator in basic and translational research and clinical trials. His research interests include transplant immunosuppression, chronic allograft nephropathy, solid organ transplantation in patients with HIV, islet cell transplantation, transplantation tolerance, gene therapy and xenotransplantation. He was responsible for developing and establishing the Islet Isolation GMP Facility at UVA, and he has overseen the allo- and auto-transplantation of islets in more than 20 recipients. The Islet Transplant Program, headed by Dr. Brayman, uses an FDA-approved Human Islet Isolation class 10,000 GMP Facility at UVA for the isolation of clinical-grade pancreatic islets for transplants and currently participates with the NIH-sponsored Collaborative Islet Transplant Registry (CITR).

Jason A. Burdick, Ph.D.

Jason A. Burdick is the Robert D. Bent Professor of Bioengineering at the University of Pennsylvania. Dr. Burdick's research involves the development of hydrogels through techniques such as photocrosslinking and self-assembly and their processing using approaches such as electrospinning and 3D printing. The applications of his research range from controlling stem cell differentiation through material cues to fabricating scaffolding for regenerative medicine and tissue repair.

Jason currently has over 220 peer-reviewed publications and has been awarded a K22 Scholar Development and Career Transition Award through the National Institutes of Health, an Early Career Award through the Coulter Foundation, a National Science Foundation CAREER award, a Packard Fellowship in Science and Engineering, and an American Heart Association Established Investigator Award. He was recently awarded the Clemson Award through the Society for Biomaterials and the George H. Heilmeier Faculty Award for Excellence in Research. He is on the editorial boards of Tissue Engineering, Biofabrication, and Journal of Biomedical Materials Research A, and is an Associate Editor for ACS Biomaterials Science & Engineering.

John Crowley, PhD

John Crowley is Chief of Strategic Alliances at Cancer Research And Biostatistics (CRAB). Dr. Crowley founded CRAB in 1997, and served as President and CEO until 2014. Dr. Crowley was the Director of the Statistical Center for SWOG, co-located at CRAB and the Fred Hutchinson Cancer Research Center from 1984 to 2012. Building on that expertise, under Dr. Crowley's leadership CRAB also serves as the Statistical Center for the University of Arkansas for Medical Sciences Myeloma Center and is an advisor to the International Association for the Study of Lung Cancer, the International Myeloma Foundation and Sarcoma Alliance Research Through Collaboration.

Dr. Crowley's research interests focus on the design and analysis of cancer clinical and translation trials. His more recent research focuses on analytical methods for utilizing microarray data to determine predictive and prognostic groups; the design of targeted therapy trials; and methods for describing staging systems for lung cancer and myeloma. His longstanding interest in developing exploratory tools for survival data has produced widely used statistical applications in these areas. Dr. Crowley also educates cancer clinicians and biostatisticians nationally and locally in the principles and pitfalls of cancer clinical trials.

Since Dr. Crowley's research career began in 1974, he has had numerous significant accomplishments. He served as Head of the Biostatistics Program at the Fred Hutchinson Cancer Research Center from 1983 until 1993, during which time he was honored with a Mortimer Spiegelman Award, given every year by the American Public Health Association to an outstanding young biostatistician. Dr. Crowley's credentials also include prestigious fellowships from the American Statistical Association and the American Association for the Advancement of Science, the Marvin Zelen Award for Leadership in Statistical Science, and the Breslow Lectureship. To date Dr. Crowley has authored over 400 professional papers and books.

Dr. Crowley received his master's and doctorate degrees in Biomathematics from the University of Washington. He served as a Postdoctoral Fellow at Stanford University. Moving to the University of Wisconsin, Dr. Crowley was appointed Assistant Professorship, followed by an Associate Professorship in the Departments of Human Oncology and Statistics. In 1982 Dr. Crowley accepted an appointment as Associate Member at the Fred Hutchinson Cancer Research Center along with an Associate Professorship in Biostatistics at the University of Washington. He was subsequently promoted to Full Professor at the University and Full Member at Fred Hutch. Dr. Crowley's academic base is now at CRAB.

Margot Damaser, PhD

Margot Damaser is Professor of Molecular Medicine in the Cleveland Clinic Lerner College of Medicine at Case Western Reserve University, Cleveland, OH and has joint appointments as Full Staff in the Biomedical Engineering Department of the Lerner Research Institute and the Glickman Urological and Kidney Institute at Cleveland Clinic, Cleveland, OH. She also is a Senior Research Career Scientist in the Advanced Platform Technology Center of the Louis Stokes Cleveland VA Medical Center, Cleveland, OH. For over 20 years, she has lead a research lab conducting research on the causes of and treatments for pelvic floor disorders, including stress urinary incontinence, pelvic organ prolapse, and fecal incontinence. She has developed and used animal models to test novel therapies with a focus on applying techniques from regenerative medicine to pelvic floor disorders. She uses the animal models to investigate the effects of comorbidities such as diabetes, obesity, age, and other pelvic floor disorders, on urinary incontinence and the response to regenerative therapies. Dr. Damaser is also developing several novel devices for improved diagnosis and treatment of incontinence. She holds one issued US Patent and has 5 pending US Patent applications.

Dr. Damaser has over 140 scientific peer-reviewed publications and has had continuous research funding from VA and NIH for 20 years in addition to collaborative research grants from private foundations and several companies. She is widely regarded as an international expert on urodynamics, models for studying female pelvic floor disorders, and new technologies in female urology and pelvic floor disorders. As such, she serves on NIH, VA, DOD, and private foundation study sections and as an editorial board member of the journals Neurourology & Urodynamics, PLoS ONE, Scientific Reports, and Nature Reviews Urology. She is also one of the founders of the Society for Pelvic Research. She is a member of the American Urological Association Research Education Conferences and Communications Committee. Most recently, she has joined the NIH NIDDK Advisory Board (Council) as a member of the NIDDK Kidney, Hematology, and Urology (KUH) Sub-Council.

Dr. Damaser has won a number of awards for her high quality research. In 2000 Dr. Damaser was awarded the Presidential Early Career Award for Scientists and Engineers, for outstanding research on the human urinary bladder using mathematical modeling along with physiological and neurological studies. This is the highest honor bestowed by the U.S. Government on young professionals at the outset of their independent research careers. In 2012 she was awarded the American Medical Women's Association Gender Equity Award by the Case Western Reserve University School of Medicine, which is given to a member of the faculty who exemplifies the principle of gender equality in teaching and who promotes a gender-fair training environment. In 2014 she was elected to the American Institute for Medical and Biological Engineering (AIMBE) College of Fellows, representing the top 2% of medical and biological engineers.

Carol H. Danielson, DrPH, MS, RAC

Carol Danielson is the President of Regulatory Advantage International, LLC. She has provided regulatory expertise and strategy for more than twenty five years for drugs, biologics, and combination products from discovery through post-marketing. She is experienced in regulatory affairs, clinical affairs, quality assurance and compliance.

Dr. Danielson has an MS in Biology from Samford University and a Doctorate in Public Health from the University of Alabama. She previously served on the Board of Directors for the Arizona Biotechnology Organization, is currently on the Advisory Board for the Clinical Research Program at Pima College and is an adjunct professor in clinical and regulatory affairs. She serves as instructor and chairperson of the Editorial Board for the Drug Information Association's Regulatory Affairs training courses and was the recipient of DIA's 2011 award for contributions to Science and Medicine.

Dr. Danielson focuses on regulatory strategy for novel products and applications, products intended to meet unmet healthcare needs, and projects involving vulnerable populations. Her areas of specialization include global strategy, regulatory submissions, GxP audits, focused in-house training, and advice and milestone meetings with regulatory agencies. She serves as US Agent for a number of IND development campaigns.

Manuela Gernert, PhD

Dr. Gernert is Professor at the Department of Pharmacology, Toxicology, and Pharmacy (Director: Prof. Dr. Wolfgang Löscher) at the University of Veterinary Medicine Hannover, Germany. She was born in Bad Wildungen, Germany, and graduated from the University of Kassel with a degree in Biology. She pursued postgraduate training and specialization in Neurosciences and Pharmacology, particularly Neuropharmacology in Germany and the United States including the Brain Research Institute at UCLA. She has held posts in academic institutions and was appointed to the Department of Pharmacology, Toxicology, and Pharmacy in Hannover in 1995. Her research interests are in the pathophysiology of epilepsies with the aim to find new targets for treatments. Here, she focuses on localized treatment approaches such as neural transplantation and intracerebral drug delivery in epilepsy research.

Timothy Hacker, PhD

Timothy Hacker is the Director of Cardiovascular Physiology Core Facility, which is designed to create and analyze animal models of disease for basic science and pre-clinical testing of cell and other therapeutics. Tim Hacker completed his PhD at the University of Wisconsin-Madison in 1996 in Exercise Physiology under the direction of A. James Liedtke developing swine models of cardiac hibernation and stunning. He then joined the faculty at Concordia University in Wisconsin to help create a new school of Physical Therapy. He returned to UW-Madison in 2000 to join the Cardiovascular Research Core Lab.

His work at the Cardiovascular Research Core Lab facility provides researchers with surgical models of disease as well as non-invasive imaging and invasive physiologic monitoring of the disease process. Dr. Hacker has established cardiac disease models in mice, rats, rabbits, pigs, dogs and primates. Currently, the facility is conducting studies focusing on cell delivery devices and targeting, cell tracking, heart failure, arrhythmias, gene, drug and cell therapy and other cardiovascular diseases. His work examining defects in the lamin protein have led to a phase I clinical trial starting in 2014 to test a drug which slows or even reverses heart failure associated with lamin mutations.

Jane Larkindale, DPhil

Jane Larkindale is the Executive Director for both the Duchenne Regulatory Sciences Consortium (D-RSC) and the Rare Disease Cures Accelerator-Data and Analytics Platform (RDCA-DAP) at the Critical Path Institute in Tucson, Arizona. Larkindale was a key leader in launching RDCA-DAP in September 2019. She launched D-RSC in 2005 and has been its leader since inception. She is a molecular biologist by training, having completed her D.Phil. (Ph.D.) in the department of plant sciences at Oxford University in 2001, which she attended on a Rhodes Scholarship. In the laboratory, she did research in areas as diverse as molecular biology, biochemistry, genomics, plant science, medical physics, marine biology, and industrial chemistry. In the course of this research, she published numerous original research papers and review articles in several disciplines. Her experience in drug development and neuromuscular diseases started at the Muscular Dystrophy Association, an international non-profit covering over forty neuromuscular diseases, where she ended as Vice President for Research. Dr. Larkindale was instrumental in the start-up of MDA Venture Philanthropy (MDA's drug development arm), which invested in 21 drug development projects, of which 10 entered clinical trials, and several of which have been licensed by large pharmaceutical companies. After leaving MDA, Dr. Larkindale started a consulting company in the area of drug development for rare neuromuscular diseases and worked for the Friedreich's Ataxia Research Alliance, developing biomarker and patient reported outcomes programs and working on a new patient registry.