Nominations for Appointment to the Grants Working Group (GWG)

NEW APPOINTMENTS

Steven R. Bauer, PhD
Chief Regulatory Science Affairs Program Officer, Wake Forest Institute for Regenerative Medicine (WFIRM)

Referral: Dr. Bauer was identified by CIRM Review Team.

Expertise Relevance to CIRM GWG: Dr. Bauer's expertise in regulatory affairs and product development will be invaluable in reviewing Clinical program applications.

Prior Service in CIRM Reviews: Dr. Bauer has participated in Translational program reviews.

Steven R. Bauer, PhD, Chief Regulatory Science Affairs Program Officer. Dr. Bauer co-directs the Translational Core and participates as a regulatory science advisor in the Regenerative Medicine Hub at WFIRM. Before joining WFIRM, Dr. Bauer was Chief of the Cellular and Tissue Therapies Branch (CTTB) in the Division of Cellular and Gene Therapies at the Center for Biologics Evaluation and Research (CBER), FDA. Dr. Bauer has three decades of experience in regulatory science research, regulatory oversight, and policy development for regenerative medicine product development. As the Chief of CTTB, Dr. Bauer supervised CBER scientific staff engaged in review of cell- and gene-based biological therapies, policy development in emerging areas of cellular therapies, and research relevant to their use in clinical trials. Dr. Bauer has extensive regulatory experience with review of hundreds of regulatory submissions from all phases of product development from IND to BLAs including many novel cell, gene and tissue engineering applications. Dr. Bauer also headed FDA's multipotent stromal cell (MSC) research consortium that published over twenty papers illustrating challenges and improvement strategies for characterization of complex MSC-based cellular and tissue engineering products. Dr. Bauer received his Ph.D. in Biochemistry from the University of Maryland in 1986. From 1986 through 1991, Dr. Bauer was a scientific member of the Basel Institute for Immunology in Basel, Switzerland.

Alexandra Capela, PhD
Senior Vice President, IND and Regulatory Strategy, Vita Therapeutics

Referral: Dr. Capela was identified by Dr. Lisa Kadyk.

Expertise Relevance to CIRM GWG: Dr. Capela's expertise in nonclinical research regulatory affairs will be invaluable in reviewing Clinical and Translational program applications.

Prior Service in CIRM Reviews: Dr. Capela has participated in Translational program reviews.

Dr. Capela's background is in Neural Development and Stem Cell biology and she has been directly involved in the development of various types of stem and progenitor cell therapies for the treatment of diverse neurodegenerative diseases and muscle dystrophies. She has more than 20 years of experience in the cell therapy field including development of autologous and allogeneic iPSC-derived gene edited products. Dr. Capela worked for a number of years at StemCells Inc (STEM), a Bay Area Biotechnology company that pioneered the development of adult derived human neural stem and progenitor cell therapies for CNS diseases. At STEM she led preclinical efficacy and safety strategy on various translational programs, most of which went on to clinical trial stage (4 IND submissions, 2 in ultra rare pediatric disorders); she oversaw the retina program from its inception which reached clinical stage with a Phase I/II and a Phase II clinical trial in Age related macular degeneration with Geographic atrophy. Dr Capela was also the PI in a CIRM Disease Team Grant in collaboration with UC Irvine aimed at generating preclinical data in Alzheimer's Disease.

Dr. Capela has also served as a preclinical and regulatory consultant, advising pre-clinical stage companies and startups as well as academic groups, expanding her expertise to additional CNS indications such as Parkinson's, Huntington's and MS, as well as non-CNS disorders. In her current position at Vita Therapeutics, Dr Capela leads IND and Regulatory Strategy. She is responsible for the design of pilot and IND-enabling nonclinical studies, selection of partner CROs and for shepherding VitaTx's programs through applicable regulatory events leading to IND submission.

Bambi Grilley, RPh, RAC, CIP, CCRC, CCRP
Director, Clinical Research and Early Product Development Center for Cell and Gene Therapy, Professor of Pediatrics, Baylor College of Medicine

Referral: Dr. Grilley was identified by CIRM Review Team.

Expertise Relevance to CIRM GWG: Dr. Grilley's expertise in clinical and nonclinical research regulatory affairs will be invaluable in reviewing Clinical and Translational program applications.

Prior Service in CIRM Reviews: Dr. Grilley has participated in Clinical and Translational program reviews.

For over 30 years, Bambi Grilley has worked primarily in the field of Clinical Research, focused predominately on oncology. She worked in and supervised the Investigational Drug Pharmacy at MD Anderson Cancer Center for 10 years and following that, she accepted a position as the Administrator of the IRB and IACUC at Baylor College of Medicine and served in that position for 2 years. For 25 years she served on the BCM IRB and for the majority of that time, as a vice-Chair. She is currently a Professor, Pediatrics at BCM and the Director of Clinical Research and Early Product Development for the Center for Cell and Gene Therapy where she is responsible for coordinating the development, implementation, and conduct of clinical research protocols for use in four affiliated hospitals and institutions. Her expertise has helped to establish the Protocol Review Committees, the Data Review Committees, the Clinical Research Quality Control Program and the Clinical Research Quality Assurance Program. In the 26 years she has been with CAGT, she has assisted investigators in conducting over 2000 clinical research studies and the submission of 113 Investigator Initiated, cell/gene therapy related INDs and over 200 protocols under those INDs. Currently, 29 of those clinical research treatment studies are active with CAGT.

Bambi is owner of QB Regulatory Consulting, LLC through which she has expanded her skillset to include support of several start-up companies, primarily in the cell and gene therapy space by providing regulatory affairs consulting and project management support. She has helped those start-up companies develop regulatory strategies, make regulatory submissions (including a company sponsored IND), and in some cases conduct clinical trials. Bambi is a very active member of the International Society for Cell & Gene Therapy (ISCT), currently serving on its Board of Directors as Chief Regulatory Officer, Chair of North America Legal and Regulatory Affairs Committee, and executive/leadership roles on several other of its committees. She is a patient advocate and works tirelessly to address the "valley of death" of academic GMCT products, most recently by joining the American Society for Transplantation and Cellular Therapy's (ASTCT) task force, ACT To Sustain (Adoptive Cell Therapy to Sustain), publishing a paper in Transplant and Cellular Therapy titled "ACT To Sustain: Adoptive Cell Therapy To Sustain access to non-commercialized genetically modified cell therapies". Bambi is the recipient of The Norton Rose Fulbright Faculty Excellence Award and the 2021 AACR Team Science Award for her work with the St. Baldrick's Foundation Pediatric Dream Team.

Gloria Huang, MD
Associate Professor, Yale School of Medicine

Referral: Dr. Huang was identified by CIRM Review Team.

Expertise Relevance to CIRM GWG: Dr. Huang's expertise in prevention and treatment of gynecologic cancer will be invaluable in reviewing Clinical and Translational program applications.

Prior Service in CIRM Reviews: Dr. Huang has participated in Clinical program reviews.

Gloria Huang MD is a gynecologic oncologist and physician-scientist at Yale School of Medicine and Yale Cancer Center. A graduate of Stanford Medical School, she completed her OBGYN residency at Stanford and her clinical fellowship in Gynecologic Oncology at Albert Einstein College of Medicine/Montefiore Medical Center. She is a nationally recognized leader in clinical and translational research in gynecologic oncology. In addition to serving on the NRG Translational Science Committee, she has experience developing and leading clinical trials and translational studies. Her current research focuses on the development of novel targeted therapies and combination treatment strategies for aggressive ovarian and uterine cancers. Through molecular and genetic analyses of normal and

malignant tissues, her research group has uncovered novel circulating and tissue biomarkers and identified biomarker-informed therapeutic vulnerabilities, including a new treatment strategy for ARID1A-mutated gynecological cancers. The goal of her life's work is to bring more effective prevention, treatment and curative strategies for all individuals at risk for or diagnosed with gynecological cancer.

Carrie Lucas, PhD
Associate Professor, Yale University School of Medicine

Referral: Dr. Lucas was identified by CIRM Review Team.

Expertise Relevance to CIRM GWG: Dr. Lucas' expertise in basic and translational immunology will be invaluable in reviewing Translational and Discovery program applications.

Prior Service in CIRM Reviews: Dr. Lucas has participated in Discovery program reviews.

Dr. Carrie L. Lucas received her PhD from Harvard Medical School and her postdoctoral training from the National Institutes of Health, NIAID. The Lucas laboratory is devoted to discovering new and translationally relevant principles of immunology by defining and studying severe pediatric immune disorders. Combining human genomics, *in vitro* studies using primary patient cells, and *in vivo* mouse modeling approaches, her team seeks to gain incisive basic and translational insights starting with patients. The lab's focus on primary immunodeficiencies has largely centered around phosphoinositide 3-kinase (PI3K) signaling and disease mechanisms and treatments in patients with mutations in PI3K subunits, including 'Activated PI3K-delta Syndrome' (APDS) and 'Inactivated PI3K-gamma Syndrome' (IPGS). More recently, the lab has added an emphasis on studying inflammatory diseases, including SARS-CoV-2-associated 'multisystem inflammatory syndrome in children' (MIS-C) and vaccine-associated myocarditis. A major current effort centers on new biology illuminated by a monogenic autoinflammatory disease the Lucas lab named 'Deficiency in ELF4, X-linked' (DEX). Each of our research projects starts with an initial focus on dissecting pediatric immune diseases and aims to leverage that knowledge for new therapies, including precision medicine approaches in monogenic diseases, which has recently been achieved with FDA approval of targeted therapy in APDS. The rare diseases studied uniquely enable elucidation of in-depth mechanistic insights into human immunology, thereby providing translational knowledge to improve understanding and treatment of a broader set of common diseases with immune involvement.

Adora Ndu, PharmD, JD
Chief Regulatory Affairs Officer, BridgeBio Pharma

Referral: Dr. Ndu was identified by Dr. Abla Creasey.

Expertise Relevance to CIRM GWG: Dr. Ndu's expertise in regulatory affairs and clinical trials will be invaluable in reviewing Clinical program applications.

Prior Service in CIRM Reviews: NA

Dr. Ndu is the Chief Regulatory Officer for BridgeBio Pharma Inc. Prior to joining BridgeBio, Dr. Ndu served as Group Vice President, Worldwide Research & Development, Strategy, Scientific Collaborations and Policy at BioMarin Pharmaceutical, Inc. She has over 15 years of experience in drug development and regulatory affairs in U.S. and international markets. Dr. Ndu was formerly Director and Head of the Division of Medical Policy Development at the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research and also a Commander in the Commissioned Corps, U.S. Public Health Service. She has been involved in the registrations of multiple products globally and is a respected thought leader in regulatory science, having played a significant role in developing and evaluating guidance, as well as shaping regulatory policy. Dr. Ndu received her doctorate in pharmacy from Howard University's College of Pharmacy and a law degree from the University of Maryland; she completed a residency at Georgetown University Hospital and a fellowship at Procter & Gamble Pharmaceuticals. She currently serves on the Board of Directors for Acadia Pharmaceuticals (ACAD) and DBV Technologies (DBVT), as well as a number of non-profit organizations.

Isaac R. Rodriguez-Chavez, PhD, MHS, MS
Independent Scientific and Regulatory Consultant Advisor

Referral: Dr. Rodriguez-Chavez was identified by CIRM Review Team.

Expertise Relevance to CIRM GWG: Dr. Rodriguez-Chavez's expertise in regulatory affairs, clinical trials and DEI will be invaluable in reviewing Clinical and Infrastructure program applications.

Prior Service in CIRM Reviews: NA

Dr. Isaac R. Rodriguez-Chavez is a distinguished scientific and regulatory expert with a 30-year career spanning Infectious Diseases, Viral Immunology, Viral Oncology, Microbiology, Vaccinology, and Rare Diseases. His experience covers the entire life cycle of medical product development from basic, preclinical, interventional clinical research (phase I – IV), non-interventional clinical research, and post-marketing studies leveraging them with standard healthcare systems and enhancing equity, diversity and inclusion (EDI). Currently an independent clinical research, regulatory affairs and digital medicine consultant, he has held influential roles, including Senior Vice President at ICON plc, where he led Decentralized Clinical Trials (DCTs) and Digital Medicine strategies. He made significant contributions as an FDA, CDER Senior Officer, leading work on modernizing clinical research through DCTs and Digital Health Technologies, fostering EDI.

Dr. Rodriguez-Chavez is a board member of BlueCloud by HealthCarePoint offering EDI plans for industry's clinical trials, and a board member of the Hypertrophic Cardiomyopathy Association (HCMA), advising on regulatory matters for a rare, genetic disease. He serves as a Regulatory Science Editor at the DIA Global Forum Magazine. He is a co-chair for the IEEE-SA Clinical Trial Technology Modernization Network, shaping the development of technical standards for the industry to modernize clinical research using digital health technologies and maintaining diversity plans. His academic background includes a PhD in Virology and Immunology, an MS in Microbiology, an MHS in Clinical Research, and a BS in Biology. With post-doctoral specialty training in Infectious Diseases, Viral Immunology, Viral Oncology, and Clinical Research, he has authored 60+ scientific and technical publications and presented at over 157 global conferences.

REAPPOINTMENTS

CIRM is seeking the reappointment of the individuals listed in the table below. Their updated biographies follow.

Proposed Reappointments to GWG

Last	First	Term	Years	Expertise
Baker	Andrew	2	2	Gene & Cell Therapy for Cardiovascular Disease
Barrett	Julia	3	6	Clinical Research Regulatory Affairs
Bauer	Daniel	2	4	Pediatric Hematology-Oncology; Therapeutic Genome Editing
Bersenev	Alexey	2	6	Manufacturing, Hematopoietic Stem Cells & Immunotherapy
Brayman	Kenneth	3	6	Islet, Pancreas & Kidney Transplantation
Cutler	Corey	2	2	Hematology-Oncology; Cancer Immunology; Stem Cell Transplantation
Gibson	Rachel	2	2	Chemotherapy-Induced Mucositis; Gut Microbiome
Kassim	Sadik	2	6	Genomic Medicines & Immune Therapies
Larkindale	Jane	3	6	Neuromuscular Disease, Patient Outreach & Venture Philanthropy
Nielsen	Ulrik	2	6	Cancer Immunotherapy; Adoptive T Cell Therapy
Truskey	George A.	2	4	Cardiovascular Tissue Engineering; Stem Cells; Cell Mechanics
Tullius	Stefan G.	2	6	Regenerative Approaches in Transplantation Surgery
Weiss	Mitchell J.	2	4	Hematology; Genome Editing; Developmental Hematopoiesis; Hemaglobinopathies

Andrew Baker, BSc, PhD, FAHA, FESC, FRSE, FMedSci
Dr. Baker is a Professor of Translational Cardiovascular Sciences at The University of Edinburgh. His research focuses on the mechanisms that control vascular damage and how to influence repair and regeneration of the vascular system using innovative therapies, including gene-, cell- and RNA-based approaches.

Andrew graduated from the University of London in 1990 with a First Class BSc (Joint Honours) in pharmacology and toxicology and then studied for his PhD with the Leukaemia Research Fund at the University of Wales College Of Medicine, graduating in 1994. He then joined the group led by Professor Andrew Newby for his post-doctoral work in Cardiff and developed adenoviral vectors for gene delivery studies in the cardiovascular system. He then transferred to a lectureship at the University of Bristol (Bristol Heart Institute) to continue studies on adenovirus-mediated gene transfer to assess vascular function and gene therapy. In 1999, Dr. Baker joined Professor Anna Dominiczak at the University of Glasgow as a Senior Lecturer in Molecular Medicine, then as Reader and in 2005 as Professor of Molecular Medicine.

Andrew was awarded the Blandsford Prize (1990) in pharmacology and the “Update in Thrombolysis Research” (Berlin, 1998) for his publication entitled “Divergent effects of tissue inhibitor of metalloproteinase-1, -2 or -3 overexpression on rat vascular smooth muscle cell invasion, proliferation and death in vitro: TIMP-3 promotes apoptosis” which was published in the Journal of Clinical Investigation. In 1999, he was awarded the British Cardiac Society Young Investigator Research Prize for his work “Gene therapy for vein grafting: Tissue inhibitor of metalloproteinases-3 (TIMP-3) inhibits neointima formation in vitro and in vivo in part by promoting apoptosis”. He was awarded the MakDougall-Brisbane prize from the Royal Society of Edinburgh in 2008 and a fellowship from the Society in 2010. Also, in 2010 he was awarded an Outstanding Achievement Award from the European Society of Cardiology and in 2011 received a Royal Society Wolfson Research Merit Award. From August 2010 to November 2011, he was Acting Director of the Institute for Cardiovascular and Medical Sciences at the University of Glasgow and in 2011 he was awarded a British Heart Foundation Chair of Translational Cardiovascular Medicine. In 2015, he was awarded a Fellowship of the Academy of Medical Sciences. As of October 2015, Andrew relocated his BHF Chair to the Centre for Cardiovascular Science at the Queen’s Medical Research Institute, University of Edinburgh, UK.

Dr. Baker has served on the GWG for 6 years. He has reviewed for Clinical program.

Julia Barrett, MD, MPH
Julia Barrett is Executive VP of Drug and Biological Products at Greenleaf Health. She was previously a Senior Clinical Consultant with Biologics Consulting. She received her BA in biology from Smith College, her MD from Northwestern University School of Medicine, and a MPH from George Washington University. Dr. Barrett completed an internship and residency in Internal Medicine at the University of Minnesota, and a fellowship in General Internal Medicine at George Washington University before joining the Food and Drug Administration (FDA) as a senior clinical reviewer. After leaving the FDA, Dr. Barrett initially consulted independently while practicing internal medicine.

Dr. Barrett was a clinical reviewer at the Center for Biologics Evaluation and Research (CBER), FDA from 1992 to 1997 in the Office of Vaccines Research and Review. While at FDA, she was responsible for providing comprehensive clinical review of Investigational New Drug (IND) applications and Biologics License Applications (BLAs). Dr. Barrett’s regulatory expertise, coupled with her clinical experience, provides her with a unique perspective on FDA requirements for the design, preparation and implementation of Phase 1, 2, and 3 clinical protocols, as well as overall clinical development strategy. Dr. Barrett assists her clients with designing and conducting clinical programs for a variety of investigational products (biologics, drugs, combination products) and clinical indications. She has planned and participated in many FDA meetings and is involved in the preparation of FDA submissions, including pre-INDs, INDs, briefing packages, BLAs and New Drug Applications (NDAs).

Dr. Barrett has served on the GWG for 12 years. She has reviewed for Clinical program.

Daniel E. Bauer, MD, PhD
Daniel Bauer is a physician-scientist whose research utilizes genome editing to understand the causes of blood disorders and to develop innovative therapeutic strategies. His clinical work in pediatric hematology focuses on the care of patients with hemoglobin disorders.

Daniel Bauer received a B.S. in Biology from Brown University and obtained his M.D. and Ph.D. from the University of Pennsylvania. His graduate thesis in Cell and Molecular Biology was under the mentorship of Craig Thompson, M.D., investigating mechanisms of growth factor regulation of hematopoietic cell metabolism. He Bauer trained in pediatrics and pediatric hematology/oncology at Boston Children's Hospital and Dana-Farber Cancer Institute. His postdoctoral

work was in the laboratory of Stuart Orkin, M.D., where he studied the role of common genetic variation in the regulation of fetal hemoglobin.

Bauer is a Principal Investigator and Staff Physician at Dana-Farber/Boston Children's Cancer and Blood Disorders Center, Assistant Professor of Pediatrics at Harvard Medical School, Principal Faculty at the Harvard Stem Cell Institute, and Associate Member of the Broad Institute of MIT and Harvard. His honors have included the American Society of Clinical Investigation Young Physician-Scientist Award (2014), NIH Director's New Innovator Award (2016), Society for Pediatric Research's Young Investigator Award (2017), and Foundation for the National Institutes of Health Trailblazer Prize for Clinician-Scientists Finalist (2018).

Dr. Bauer has served on the GWG for 6 years. He has reviewed for Clinical and Discovery program.

Alexey Bersenev, MD, PhD
Dr. Alexey Bersenev is a Co-founder and Chief Technology Officer (CTO) at Cell BioEngines and oversees company's CGT process development programs, CMC operations and bio-manufacturing. In addition to his position at Cell BioEngines, he serves as a Director of the Advanced Cell Therapy Lab at Yale-New Haven Hospital and is an Assistant Professor of Clinical Laboratory Medicine at the Department of Laboratory Medicine at Yale University.

Prior to joining Yale, Dr. Bersenev worked as a cell manufacturing specialist at the University of Pennsylvania and trained in clinical cell processing in a GMP cell manufacturing facility and was involved in the manufacture of first CAR T-cell products for clinical trials and technology transfer to Novartis. He has expertise in clinical manufacturing of cellular products for clinical trials, including product and process development, cell processing and culture, operations of academic GMP facility and compliance with regulations. His research interests include optimization of T-cell manufacturing, automation of cell processing, cell separation and sorting, regulatory challenges and analysis of clinical trials and industry trends in cell therapy.

Dr. Bersenev received his medical education and certification as a general surgeon in Russia. He holds a PhD in transplantation/ pathology. He gained expertise in immunology, hematology, stem cell biology and published scientific papers during post-doctoral training in the US in Philadelphia at the Thomas Jefferson University and the Children’s Hospital of Philadelphia.

Dr. Bersenev has served on the GWG for 6 years. He has reviewed for Clinical, Translational and Infrastructure programs.

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).

Dr. Brayman has served on the GWG for 10 years. He has reviewed for Clinical, Translational, Discovery and Infrastructure programs.

Corey Cutler, MD, MPH, FRCP(C)
Dr. Corey Cutler is a Professor of Medicine at Harvard Medical School, and an institute physician in the Division of Hematologic Oncology, Department of Medical Oncology at the Dana-Farber Cancer Institute and Brigham and

Women's Hospital, Boston, MA. He is the Director of the Stem Cell Transplantation Program at Dana-Farber. He is also an affiliate faculty Member of the Harvard Stem Cell Institute, Cambridge, MA. Dr. Cutler graduated from McGill University's Faculty of Medicine, completed a residency in Internal Medicine at the McGill University Health Science Center, and completed fellowship training in hematology, medical oncology, and stem cell transplantation at the Dana-Farber Cancer Institute. Dr. Cutler earned an MPH degree at the Harvard School of Public Health.

Dr. Cutler is the President of the American American Society for Blood and Marrow Transplantation (2024-2025) and is the Co-Chair of the Clinical Trials Working Group of the NIH Consensus Conference on Chronic GVHD. He previously was the Co-Chair of the CIBMTR GVHD Working Committee, and a member of the Clinical Trials Advisory Committee of the CIBMTR. Dr. Cutler is on the editorial boards for the journal, "Transplantation and Cellular Therapy." He has been a contributing author on more than 300 peer-reviewed publications and 25 reviews and book chapters. His research focuses on development of novel methods of acute and chronic graft-vs.-host disease prophylaxis and therapy, and decision theory in stem cell transplantation.

Dr. Cutler has served on the GWG for 6 years. He has reviewed for Clinical program.

Rachel Gibson, PhD
Professor Rachel Gibson graduated with a PhD in Medicine at the University of Adelaide in December 2004 having focused on a new aspect of supportive care in cancer. Following the completion of her PhD she was awarded a Cancer Council South Australia Post-Doctoral Research Fellowship (2004-2009) to continue her research into gut toxicity at the Royal Adelaide Hospital. In 2008 Professor Gibson took up an academic position within the School of Medical Sciences at the University of Adelaide. In 2016 she was appointed as the inaugural Dean: Academic at the University of South Australia. Professor Gibson returned to the University of Adelaide in 2019 to take up the role of Director, Allied Health. She is currently the Head of School, Allied Health Science and Practice.

Professor Gibson has held significant leadership roles within the Multinational Association of Supportive Care in Cancer (MASCC) Professor Gibson is currently a Board Member of the Multinational Association for Supportive Care in Cancer (MASCC). She has previously been a member of the MASCC Executive Committee (Secretary 2014-2016; Treasurer 2016-2018) as well as the Scientific Chair of the Annual MASCC Meeting (2017-2018). Her role as Scientific Chair involved extensive external stakeholder relationships which needed to be managed in conjunction with the delivery of the meeting. Key relationships were also fostered with clinicians, MASCC staff, commercial pharmaceutical companies, the MASCC Board and many service suppliers.

A key project for Professor Gibson was as the leader for producing the updated Clinical Practice Guidelines for Gastrointestinal Mucositis. Her role was to lead an international team of clinicians, allied health professionals and scientists to produce evidence-based clinical practice guidelines through data collation, analysis, international presentations and finally Clinical Practice Guidelines dissemination. These current guidelines provide clinicians from around the world with tools to effectively manage cancer patients with gastrointestinal mucositis.

Professor Gibson has developed extensive international collaborations with a variety of large pharmaceutical companies. These collaborations have resulted in her appointment as an advisory board member specifically looking at gastrointestinal toxicity following cancer treatment with multiple companies. Professor Gibson has also successfully negotiated and delivered-on-time contract research projects for commercial pharmaceutical companies. Through this exposure to commissioned contract project delivery, she is very accustomed to key elements of project management such as schedule management, delivery risk management, budget management and communication with stakeholders.

Dr. Gibson has served on the GWG for 6 years. She has reviewed for Clinical, Translational and Discovery programs.

Sadik Kassim, PhD
Sadik Kassim, Ph.D. is a scientist and executive with extensive experience in the biotechnology industry with a specific focus on cell and gene therapy bioprocessing and translational research. Currently, he serves as Chief Scientific and Technology Officer of Genomic Medicines for the Life Sciences companies at Danaher Corporation. Most recently, he was Chief Technology Officer at Vor Bio where he built the technical operations team responsible for process development, analytical development, supply chain and manufacturing support of a CRISPR gene-edited HSPC product and oversaw the company's CAR-T efforts. Prior to Vor, Sadik served as Executive Director at Kite Pharma and led the development of manufacturing processes for autologous CAR-T and TCR-based cell therapies. As the Chief Scientific Officer at Mustang Bio, Sadik managed the foundational build-out of the company's preclinical and manufacturing activities. Earlier in his career, he was Head of Early Analytical Development for Novartis' Cell and Gene Therapies Unit and worked on research teams at the National Cancer Institute with Dr. Steven Rosenberg, the University of Pennsylvania Gene Therapy Program with Dr. Jim Wilson, and Johnson and Johnson's Immunology

Discovery group. Sadik and his teams have contributed to the successful BLA and MAA applications for three of the commercially available CAR-T therapies: Kymriah, Yescarta, and Tecartus.

Dr. Kassim has served on the GWG for 6 years. He has reviewed for Clinical, Translational, Discovery and Infrastructure programs.

Jane Larkindale, DPhil
Jane Larkindale is the Vice President of Clinical Science at PepGen, a company developing enhanced delivery oligonucleotide therapeutics with programs in Duchenne muscular dystrophy and myotonic dystrophy. She has dedicated the past 15 years of her career to accelerating therapy development for rare diseases, with a focus on neuromuscular diseases. She launched and ran international consortia and programs focused on data standardization and aggregation, and use of that data to support regulatory acceptance of disease models, outcome assessments and biomarkers to accelerate drug development. She has worked with world leaders in the rare disease space, including the Critical Path Institute, the Muscular Dystrophy Association and the Friedreich's Ataxia Research Alliance.

Dr. Larkindale has served on the GWG for 10 years. She has reviewed for CIRM Alpha Stem Cell Clinics (CASC) Network Initiative.

Ulrik B. Nielsen, PhD
Ulrik Nielsen is an experienced entrepreneur, executive and scientist. Dr. Nielsen was most recently a founder of Torque Therapeutics where he served as the President and CEO until 2018. Torque is developing an entirely new class of cell therapy for cancer using its proprietary Deep Priming technology. Previously, he was a founder and CSO of Merrimack (NASDAQ: MACK). At Merrimack, the team put six novel anti-cancer therapeutics into clinical development and got the drug Onivyde approved for pancreatic cancer. At Merrimack, Ulrik also led the spinout of Silver Creek Pharmaceuticals (private) where he continues to serve as a board member. Silver Creek is focused on targeting growth factors to specific tissues and cell types to promote their survival and regeneration. The first targeted growth factor is poised to enter clinical development in 2018. He received his M.S. and Ph.D. degrees from the University of Copenhagen in molecular biology and trained at the University of California, San Francisco.

Dr. Nielsen has served on the GWG for 6 years. He has reviewed for Clinical, Translational and Discovery programs.

George A. Truskey, PhD
George A. Truskey is the former Associate Vice President for Research & Innovation and the R. Eugene and Susie E. Goodson Professor of Biomedical Engineering at Duke University. He received a BS degree in bioengineering from the University of Pennsylvania and a PhD in Chemical Engineering from MIT.

He served as the Chair of the Department of Biomedical Engineering at Duke from 2003-2011 during which he led efforts to obtain the endowment for the Coulter-Duke Translational Partnership. From 2011-2020, he was Senior Associate Dean for the Pratt School of Engineering and facilitated the expansion in research and faculty and development of new educational programs. He was president of the Biomedical Engineering Society from 2008-2010. He is the Editor-in-Chief of Current Opinion in Biomedical Engineering and is a Fellow of the American Association for the Advancement of Science (AAAS), Biomedical Engineering Society (BMES), the American Institute of Medical and Biological Engineering, the American Heart Association and the International Academy of Medical & Biological Engineering (IAMBE).

His current research interests include the response of cells to physical forces, cardiovascular and skeletal muscle tissue engineering, and the development of human microphysiological systems for disease modeling and drug and toxicity testing.

Dr. Truskey has served on the GWG for 6 years. He has reviewed for Infrastructure, Education and Discovery programs.

Stefan G. Tullius, MD, PhD, FACS
Stefan G. Tullius, MD, PhD, is the Joseph E. Murray, MD Distinguished Chair in Transplant Surgery, Professor of Surgery at Harvard Medical School, Chief of Transplant Surgery and Director of the Transplant Surgery Research Laboratory at Brigham and Women's Hospital in Boston. He is an internationally recognized clinician/scientist, a frequent invited speaker and visiting Professor, and has published more than 330 scientific manuscripts in addition to several book chapters. Work originating from his laboratory on the effects of organ quality, transplant outcome, organ preservation, immunosenescence and composite tissue transplantation has been widely recognized and changed clinical practice.

He is an Executive Editor of *Transplantation*, an Associate Editor of *Transplant International,* and has served as Associate Editor of the *American Journal of Transplantation*. Dr. Tullius was Senior Treasurer of The Transplantation Society (TTS), and is currently Vice President of TTS and Vice President of The International Society of Uterus Transplantation (ISUTx). He was on the Board of the European Society of Organ Transplantation (ESOT) and has been on the Board of the National Kidney Registry. Dr. Tullius has also served as Region I Councilor of the United Network of Organ Sharing (UNOS). Dr. Tullius is a member of numerous professional societies, including the American Surgical Association, and has organized several international clinical and basic science meetings.

In recognition of his contributions, Dr. Tullius has received several awards including the Clinical Science Investigator Award of the AST, The award for Outstanding Achievements in Transplantation by TTS, the Excellence in Transplantation Award from the National Kidney Foundation, the Pichlmayr Award of the German Transplant Society, the Fritz Lindner Award of the German Surgical Association, and the Joseph E. Murray/Simon J. Simonian Award at his home institution for his excellence in mentoring.

Dr. Tullius has served on the GWG for 6 years. He has reviewed for Clinical program.

Mitchell J. Weiss, MD, PhD
Mitchell Weiss is a physician-scientist who cares for pediatric patients with classical blood disorders and performs related laboratory research. He received his MD and PhD degrees at the University of Pennsylvania School of Medicine, followed by training in pediatrics and pediatric hematology/oncology at Boston Children's Hospital, The Dana Farber Cancer Institute and Harvard University. For 15 years, he was a faculty member at The University of Pennsylvania School of Medicine (UPENN) and Children's Hospital of Philadelphia (CHOP) where he rose to the rank of Professor of Pediatrics with Tenure. He was Director for the Pediatric Physician-Scientist Development Program at CHOP (2007-2011) and Associate Director for the Combined Degree and Physician Scholar Program at UPENN (2001-2014). He has mentored numerous fellows and young faculty, 5 of whom received NIH career development awards and most of whom have gone on to successful careers in academia or industry. In 2014, he became Chairman of the Hematology Department at St. Jude Children's Research Hospital, where he oversees the Divisions of Experimental Hematology and Clinical Hematology.

Dr. Weiss' research focuses on understanding the biology of blood cell development, particularly red blood cells. Since moving to St. Jude, his work has placed a greater emphasis on translational studies aimed at developing new treatments for hemoglobinopathies, particularly sickle disease and beta-thalassemia. Dr. Weiss has published over 170 original research papers in journals including Blood, Journal of Clinical Investigation, Nature, Nature Genetics, Nature Medicine and Proceedings of the National Academy of Science. He has been funded continually by the National Institutes of Health (NIH) since 2002. He is a member of The American Society for Clinical Investigation and The Association of American Physicians. Dr. Weiss' mission as Hematology Chairman at St. Jude Children's Research Hospital is to facilitate cutting edge basic, translational and clinical research, foster faculty development and promote outstanding clinical care for patients with non-malignant blood disorders.

Dr. Weiss has served on the GWG for 6 years. He has reviewed for Clinical program.