



## Nominations for Appointment to the Grants Working Group (GWG)

### NEW APPOINTMENTS

#### **Nadya Lumelsky, PhD**

**Director, Tissue Engineering and Regenerative Medicine Program, NIDCR, NIH**  
**Chief, Integrative Biology and Infectious Diseases Branch, NIDCR, NIH**

Referral: Dr. Lumelsky was recommended by the National Academies of Sciences through a partnership with CIRM.

Expertise Relevance to CIRM GWG: Dr. Lumelsky's expertise in fundamental stem cell biology, translational research, and a broad range of tissue/organ regenerative medicine and stem cell research will be invaluable in the review of Discovery and Translational stage program awards.

Prior Service in CIRM Reviews: N/A

#### Bio:

Dr. Nadya Lumelsky is Chief of Integrative Biology and Infectious Diseases Branch and a Director of Tissue Engineering and Regenerative Medicine Program at the National Institute of Dental and Craniofacial Research (NIDCR) at NIH. She has wide-ranging expertise in stem cell and developmental biology, cell biology, and bioengineering.

Dr. Lumelsky earned her PhD in Molecular Biology at the State University of New York at Albany. Earlier in her career, Dr. Lumelsky conducted research at Yale University and the University of Wisconsin, Madison on the mechanisms of the regulation of human hemoglobin gene expression. Prior to joining NIDCR in 2006, she was an investigator at the intramural NIH Program at the National Institute of Neurological Disorders and Stroke where she conducted research on the derivation of dopaminergic neurons and insulin-producing beta-cells from mouse embryonic stem cells. Her lab at the National Institute of Diabetes & Digestive & Kidney Diseases was focused on derivation of insulin-producing cells from cultures of human primary pancreatic cells. While at NIDCR, she co-developed the Dental, Oral, and Craniofacial Tissue Regeneration Consortium (DOCTRC), an initiative designed to shepherd new therapies through pre-clinical studies and into human clinical trials. She also served as a project scientist on this initiative. Among her other activities, she contributed to the National Cell Manufacturing Consortium's technology roadmap for achieving large-scale, cost-effective manufacturing of high-quality cells. She has been a leading and senior author on publications in *Science*, *Nature*, *Diabetes*, *Stem Cells*, *Molecular and Cellular Biology*, *Tissue Engineering* and other high impact journals.

#### **Terry Magnuson, PhD**

**Professor and Vice Chancellor, The University of North Carolina Chapel Hill**

Referral: Dr. Magnuson was recommended by the National Academies of Sciences through a partnership with CIRM.

Expertise Relevance to CIRM GWG: Dr. Magnuson's expertise in mouse genetics, genomics, and stem cell differentiation will be invaluable in the review of Discovery stage program awards.

Prior Service in CIRM Reviews: Dr. Magnuson has not reviewed for CIRM; however, he served on the Institute of Medicine Committee which evaluated CIRM.

Bio:

Dr. Terry Magnuson is the Kay M. & Van L. Weatherspoon Eminent Distinguished Professor and Vice Chancellor for Research at The University of North Carolina Chapel Hill. He was the founding chair of the Department of Genetics and Director of the Genome Science Center. He leads the Cancer Genetics Program in the Lineberger Comprehensive Cancer Center. He was appointed Vice Dean for Research in the School of Medicine and then Vice Chancellor for Research for the university. His research focuses on mammalian chromatin remodeling complexes, stem cells and germ cells.

Dr. Magnuson received his PhD from Cornell University, and completed his postdoctoral fellowship at the University of California, San Francisco. Dr. Magnuson served as chair of the Jackson Laboratory Board of Scientific Overseers, as a member of the Board of Directors for the Society for Developmental Biology and also as a member of the Genetics Society of America (GSA). He was the 2019 President of the GSA. He was appointed by the National Academies to establish guidelines for human embryonic stem cells. He served as Vice Chair of a National Academy committee that evaluated the California Institute for Regenerative Medicine, and as a member of the committee reviewing the charge of the NIH Recombinant DNA Advisory Committee. Dr. Magnuson was a member of the NIH Council of Councils. He has been elected to the American Academy of Arts and Science, the National Academy of Medicine and is a fellow of the American Association for the Advancement of Science.

**Thomas Petersen MD, PhD**  
**Vice President, United Therapeutics**

Referral: Dr. Petersen was recommended by the National Academies of Sciences through a partnership with CIRM.

Expertise Relevance to CIRM GWG: Dr. Petersen's expertise in tissue engineering, lung biology/physiology, and exosome therapeutics will be invaluable in the review of Discovery, Translational and Clinical stage program awards.

Prior Service in CIRM Reviews: N/A

Bio:

Dr. Thomas Petersen is Vice President of Regenerative Medicine for United Therapeutics, based in North Carolina. He is responsible for the management of a regenerative medicine program focused on cell-based therapies and transplantable lung tissues for end-stage pulmonary diseases. He directs the scientific and technical activities of an active R&D laboratory and oversees internal scientific programs and external scientific collaborations. He oversaw the preclinical and early clinical development of an MSC-derived exosome product, which resulted in one of the first successful IND clearances and clinical trials of a therapeutic MSC-derived exosome product in the US.

Dr. Petersen earned his BSE in Electrical Engineering from Princeton University, and his MD and PhD in Biomedical Engineering from Duke University. He completed his postgraduate training in the biomedical engineering and anesthesia departments at Yale University as well as the division of pulmonary and critical care medicine at University of Washington, after which he accepted a position at United Therapeutics. Prior to joining United Therapeutics, he explored whether lung tissue can be regenerated in vitro and saw results suggesting that repopulation of lung matrix is a viable strategy for lung regeneration, an important step towards the ultimate goal of generating fully functional lungs in vitro. He holds multiple patents involving endothelial progenitor cells and mesenchymal stem cells, and has published in journals such as *Science*, *Biomaterials*, *Physical Review Letters*, and *American Journal of Physiology-Lung Cellular and Molecular Physiology*. Among many services, he has reviewed for the Annals of the American Thoracic Society, Cell Transplantation, and Tissue Engineering, and has served on an NIH study section on biomaterials and biointerfaces. He is a member of the Consortium Monitoring Board for the NIH NIDDK ReBuilding a Kidney (a consortium working on optimizing approaches for isolating, expanding and differentiating kidney cell types and their integration into complex structures replicating human kidney function), and is a member of the National Academies of Sciences, Forum on Regenerative Medicine.

**Avery Posey, PhD**  
**Assistant Professor, University of Pennsylvania**

Referral: Dr. Posey was referred by CIRM ICOC board member Dr. Larry Goldstein.

Expertise Relevance to CIRM GWG: Dr. Posey's expertise in cancer stem cell and gene therapy research will be helpful in reviewing Translational and Discovery program applications, particularly as he is tumor agnostic in scope of work. He also has interest in Education.

Prior Service in CIRM Reviews: Dr. Posey has reviewed as a specialist for the Discovery Quest awards.

Bio:

Dr. Avery Posey is an Assistant Professor at University of Pennsylvania Perelman School of Medicine, Department of Systems Pharmacology and Translational Therapeutics. He is a cancer immunologist, with training in bioinformatics, biochemistry, and genetics. His laboratory studies the development of adoptive cell therapies targeting cancer with autologous and allogeneic T cells, gene-editing, and cancer-specific glycosylation. He currently serves on the Editorial Board for *Gene Therapy* and *Cancer Immunity and Immunotherapy – Frontiers in Immunology*, and has served as a Guest Editor on special issues on CAR-T Cells for the journals *Frontiers in Immunology* and *Cancers*.

Dr. Posey earned his undergraduate degrees in Bioinformatics & Computational Biology and Biochemistry & Molecular Biology at the University of Maryland and his PhD in Developmental Genetics at the University of Chicago. He trained in the laboratory of Carl H. June as a postdoctoral fellow and investigated novel co-stimulation of chimeric antigen receptor (CAR) T cells, signaling differences between clinical versions of CAR molecules, and developed CAR T cells specific to abnormally glycosylated tumor-associated antigens in cancer. Given the mentorship and training he received in the labs of George K. Lewis (undergraduate), Elizabeth M. McNally (graduate), and Carl H. June (postdoc), he believes that it is his responsibility to provide strong mentorship to the next generation of scientists. He is affiliated with many graduate groups at the University of Pennsylvania, including Pharmacology, Bioengineering, Immunology, and Gene Therapy & Vaccines. He offers supportive training to Ph.D. students, MD/Ph.D. students, postdoctoral fellows, MD fellows, and research technicians.

As a cancer immunologist, he strongly believes that incorporating the study of tumor surface glycosylation into target identification will improve the specificity of cancer targeting from tumor-associated to tumor-specific. To this effort, he has grown collaborations with many of the world's renowned expert glycobiologists including Henrik Clausen, Ph.D. of the University of Copenhagen, Alice Yu, M.D., Ph.D. and John Yu, M.D., Ph.D. of Academia Sinica of Taiwan, Michael Pierce, PhD, Director of the UGA Cancer Center and member of the Complex Carbohydrate Research Center, Carolyn Bertozzi, PhD, National Academy of Sciences member and Professor of Chemistry at Stanford University, Richard Cummings, PhD, Director of the National Center for Functional Glycomics at Beth Israel Deaconess Medical Center, Jeffrey Esko, PhD, Professor of Cellular and Molecular Biology and Co-Director of the Glycobiology Research & Training Center at UCSD; and Gabriel Rabinovich, PhD, National Academy of Sciences member and Professor of Immunology at the University of Buenos Aires. Clinical evaluations of CAR T cells targeting the Tn glycoform of MUC1, which were initially developed during his postdoc and further optimized in his independent laboratory, were initiated in the summer of 2019 as a Phase I clinical trial NCT04025216. His long-term goal is to develop universal, safe, and effective immunotherapies through T cell engineering to promote cytotoxic inflammation and anti-tumor immunity in cancer.

**Michael V. Sefton, ScD**  
**Professor, University of Toronto**

Referral: Dr. Sefton was recommended by the National Academies of Sciences through a partnership with CIRM.

Expertise Relevance to CIRM GWG: Dr. Sefton's expertise in tissue engineering, biomaterials, and vascularization will be invaluable in the review of Discovery and Translational stage program awards.

Prior Service in CIRM Reviews: N/A

Bio:

Dr. Michael Sefton is University Professor in the Department of Chemical Engineering and Applied Chemistry and the Institute of Biomedical Engineering, University of Toronto. He is also currently Executive Director of Medicine by Design, <http://mbd.utoronto.ca/>. He has been active in the preparation of blood compatible materials through heparinization, the microencapsulation of mammalian cells in synthetic polymers and various strategies for vascularizing tissue constructs.

Dr. Sefton has degrees in Chemical Engineering from the University of Toronto (1971) and MIT (1974) and has been at the University of Toronto since 1974. He was Director of the Institute of Biomedical Engineering at the University of Toronto from 1999-2005 and President of the US Society for Biomaterials in 2006. He received the Acta Biomaterialia Gold award in 2011 and the Terumo Global Science prize in 2016 (among others). He was elected an international member of the US National Academy of Medicine in 2014 and the US National Academy of Engineering in 2020. He was made an Officer of the Order of Canada in 2018.

**Ilyas Singec, MD, PhD**  
**Director, Stem Cell Translation Laboratory, NCATS, NIH**

Referral: Dr. Singec was recommended by the National Academies of Sciences through a partnership with CIRM.

Expertise Relevance to CIRM GWG: Dr. Singec's expertise in fundamental stem cell biology, translational research, drug development, neuroscience, regenerative medicine will be invaluable in the review of Discovery and Translational stage program awards.

Prior Service in CIRM Reviews: N/A

Bio:

Dr. Ilyas Singec is the inaugural Director of the Stem Cell Translation Laboratory (SCTL) in the Division of Preclinical Innovation at the National Center for Advancing Translational Sciences (NCATS), NIH. SCTL aims to bring iPSC technology into the clinic and drug discovery by addressing the key scientific challenges in the stem cell field and providing researchers access to innovative protocols and resources to advance the translation of regenerative medicine applications. Dr. Singec's current research focuses on industrial-scale cell engineering and high-throughput screening, next-generation cell differentiation methods, and deep cell characterization of normal and diseased states with relevance to neurological and psychiatric diseases.

Dr. Singec earned his MD and doctorate (summa cum laude) from the Universities of Bonn and Freiburg (Germany). He completed his residency in clinical neuropathology and neuroanatomy in Freiburg followed by postdoctoral training at the National Institute of Neurological Disorders and Stroke (NINDS/NIH), and the Sanford Burnham Prebys Medical Discovery Institute in La Jolla, CA. Prior to joining NCATS, Dr. Singec worked in the pharmaceutical industry and founded a consulting company for stem cells and drug development.

**Rohini Sharma, MBBS, PhD, FRACP, FRCP**  
**Medical Oncologist & Clinical Pharmacologist, Imperial College London**

Referral: Dr. Sharma was identified by the Review team's Senior Science Officer based on assessment of expertise through publications.

Expertise Relevance to CIRM GWG: Primary liver cancer is the fourth most common cause of cancer-related death worldwide and unlike other cancer types, mortality rates continue to rise. Dr. Sharma's clinical and research expertise in liver cancer continue to be invaluable in the review of Clinical stage program awards.

Prior Service in CIRM Reviews: Dr. Sharma has reviewed as a specialist on Clinical program reviews.

Bio:

Dr. Rohini Sharma is a Reader in Clinical Pharmacology and Medical Oncology and lead of the Liver Cancer Study Group at Imperial College, London. She is also the Medical Oncology lead for Liver Cancer and Neuroendocrine Cancers at the Hammersmith Hospital, Imperial College Healthcare NHS Trust. Her expertise includes liver, pancreas and biliary cancer, neuroendocrine tumours, and paragangliomas. Her current research interests include early phase clinical trials, drug development and PET imaging. Her research group is involved in the discovery and validation of novel diagnostics as well as novel targeted therapies for the management of hepatocellular carcinoma and neuroendocrine tumors. Clinically, she is a lead practitioner in the delivery of Selective Internal Radiotherapy Treatment for the management of liver cancer and peptide receptor radiotherapy treatment for the management of neuroendocrine tumors.

Dr. Sharma completed her medical training at the University of Adelaide, Australia, completed her specialist oncology training at the Royal Prince Alfred Hospital, Sydney, and completed her clinical pharmacology training at Westmead Hospital, Sydney. She was awarded a NHMRC Fellowship to complete her PhD at the Westmead Millennium Institute, University of Sydney, Australia. Following the completion of her PhD, she was awarded the prestigious Higher Education Funding Council for England Clinical Senior Lecturer position at Imperial College, London. In her role as oncology lead for the specialist hepato-oncology clinic at Hammersmith Hospital, she and her team help ensure that new discoveries are rapidly translated into the clinic for the benefit of patients. The liver cancer service she co-leads is the UK's only specialized service that provides a hepatologist and a medical oncologist co-managing patients with a suspected, current, or previous diagnosis of primary liver cancer, with a view to improving clinical outcomes and promoting research. She has authored over 100 publications published in journals such as *Frontiers in Immunology*, *Liver Cancer*, *The Journal of Nuclear Medicine*, *Neuroendocrinology*, and *Journal of Hepatology*.

**Nathaniel Smilowitz, MD**  
**Assistant Professor, New York University School of Medicine**

Referral: Dr. Smilowitz was identified by the Review team's Senior Science Officer based on assessment of expertise through publications.

Expertise Relevance to CIRM GWG: Dr. Smilowitz's clinical and research expertise in interventional cardiology will continue to be helpful in reviewing Clinical program applications. His extensive knowledge of the therapies, tools, and techniques in the field are essential in assessing the needs of

Prior Service in CIRM Reviews: Dr. Smilowitz has reviewed as a specialist for the Clinical program.

Bio:

Dr. Nathaniel Smilowitz is an Assistant Professor in the Department of Medicine at New York University Grossman School of Medicine and an interventional cardiologist at NYU Langone Health. Clinically, he focuses on the treatment of ischemic heart disease and acute coronary syndromes. His research focuses on myocardial infarction, coronary artery disease, percutaneous coronary intervention, and postoperative cardiovascular complications following non-cardiac surgery. His current research efforts include serving as the Principal Investigator for an NIH/NHLBI-funded study on coronary microvascular disease, and as a co-investigator for the AHA Go Red for Women Strategically Focused Research Network-funded Heart Attack Research Program to study mechanisms of myocardial infarction with non-obstructive coronary arteries. He is a site investigator for a clinical trial assessing the efficacy of cell therapy for patients with heart failure and a clinical trial on percutaneously inserted left ventricular assist device in myocardial infarction.

Dr. Smilowitz earned his MD from New York University, completed his residency in Internal Medicine at New York Presbyterian - Columbia University Medical Center, and completed fellowships in Cardiovascular Disease and Interventional Cardiology at NYU Langone Health. He subsequently earned a Masters degree in Clinical Investigation from New York University. He is a Fellow of the American College of Cardiology and the Society for Cardiovascular Angiography and Interventions, and he serves on the research and publications committee for the American College of Cardiology NCDR Chest Pain-MI Registry. He has published over 100 articles in journals such as the *Journal of the American Medical Association*, *JAMA Cardiology*, *Circulation*, *the European Heart Journal*, *the American Heart Journal*, and the *American Journal of Medicine*.

**Vernon K. Sondak, MD**  
**Chair, H. Lee Moffitt Cancer Center**

Referral: Dr. Sondak was identified by the Review team's Senior Science Officer based on assessment of expertise through publications.

Expertise Relevance to CIRM GWG: Dr. Sondak's clinical and research expertise in melanoma will continue to be helpful in reviewing Clinical program applications, particularly given the sharp rise in melanoma diagnoses in the past three decades, increasing incidence of melanoma in young adults (particularly young women), and in melanoma causing a large majority of skin cancer deaths.

Prior Service in CIRM Reviews: Dr. Sondak has reviewed as a specialist for the Clinical program.

Bio:

Dr. Vernon Sondak is Chair of the Department of Cutaneous Oncology at the H. Lee Moffitt Cancer Center and Research Institute in Tampa, Florida. He holds the Richard M. Schulze Family Foundation Distinguished Endowed Chair in Cutaneous Oncology, and is also a Professor in the Departments of Oncologic Sciences and Surgery at the University of South Florida Morsani College of Medicine. Since 2004, when he came to Tampa, the Cutaneous Oncology Clinic at Moffitt has grown into one of the largest multidisciplinary treatment centers for adult and pediatric melanoma and related conditions in the world. Dr. Sondak has been a leader in studies of surgical treatment of melanoma and other cutaneous malignancies, particularly in the application of sentinel lymph node biopsy and lymph node dissection to the staging and treatment of melanoma, and has been instrumental in training many surgical oncologists in these techniques over the years. Dr. Sondak also has a strong research background: he served as Principal Investigator of the Moffitt Skin SPORE, a major NCI-funded "team science" grant conducting translational research in melanoma and other cutaneous malignancies. His research interests include surgical treatment of melanoma in adults and children; adjuvant (postoperative) and neoadjuvant (preoperative) therapy of melanoma; and evaluation of new therapies for patients with localized or disseminated melanoma.

A graduate of Boston University School of Medicine, Dr. Sondak did his surgical training at the University of California Los Angeles. Prior to joining Moffitt in 2004, Dr. Sondak was a Professor of Surgery in the Division of Surgical Oncology at the University of Michigan. Dr. Sondak has received numerous awards, including the Golden Scalpel Award (Outstanding Chief Resident) from the UCLA Division of General Surgery, a Distinguished Alumnus Award from Boston University School of Medicine, the William W. Coon Award for Outstanding Faculty Teaching from the University of Michigan Section of General Surgery, and the Rays of Hope Leadership Award from the Shade Foundation of America, devoted to skin cancer education and prevention for children. He is a member of the National Cancer Institute's Board of Scientific Counselors for Clinical Sciences and Epidemiology, the group responsible for peer review and oversight of the NCI's intramural research program. He is also an Executive Board member of the Melanoma World Society, and a member of the Lancet Oncology International Advisory Board, as well as an external advisor to several SPORÉ grants at other US institutions. Dr. Sondak is the author or coauthor of over 435 articles in peer-reviewed publications and 238 abstracts, in addition to 8 books and 82 book chapters. He has served as a peer reviewer for manuscripts in over 50 different journals, including virtually all of the most prestigious surgery, oncology and dermatology journals.

**Allen M. Spiegel, MD**  
**Professor and Dean Emeritus, Albert Einstein College of Medicine**

Referral: Dr. Spiegel was recommended by the National Academies of Sciences through a partnership with CIRM.

Expertise Relevance to CIRM GWG: Dr. Spiegel's expertise in Type 1 diabetes and beta cell biology will be invaluable in the review of Translational and Clinical stage program awards.

Prior Service in CIRM Reviews: Dr. Spiegel has not reviewed for CIRM; however, he served on the Institute of Medicine Committee which evaluated CIRM.

Bio:

Dr. Allen Spiegel is the Marilyn & Stanley M. Katz Dean Emeritus, Professor of Medicine (Endocrinology) and Professor of Molecular Pharmacology at Albert Einstein College of Medicine in the Bronx, New York. He is a widely renowned physician-scientist and endocrinologist with extensive experience in translational research programs. His research has centered on G-protein-regulated signaling dysfunction in human disease, and his work on signal transduction helped to clarify the genetic basis of several endocrine diseases.

Dr. Spiegel earned his MD at Harvard Medical School and completed his internship and residency at Massachusetts General Hospital. He began his career at the NIH in 1973 as a Clinical Associate in its Endocrinology Training program. He then served as a Senior Investigator in the Metabolic Disease Branch from 1977 to 1984. In 1985, he was appointed Chief of Molecular Pathophysiology, and then Chief of the Metabolic Diseases Branch. In 1990, he was appointed Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Division of Intramural Research. He served in these various capacities until his appointment as Director of the NIDDK in 1999. He served on the 15-member NIH Stem Cell Task Force which implemented new programs such as a stem cell bank, centers of excellence, research resource infrastructure enhancement awards and short courses. Following his distinguished career at NIH, he accepted the position of Dean at Einstein where he established the Stem Cell Institute. He continues to work with NIH, serving as a special volunteer for the Metabolic Diseases Branch at NIDDK. He has testified before the US Senate and House at multiple hearings focused on stem cell research. A member of the National Academy of Medicine, he has published extensively, with more than 250 peer-reviewed papers and 100 reviews and book chapters to his name, as well as two books on G proteins.

**Edmund Waller, MD, PhD**  
**Professor, Emory University**

Referral: Dr. Waller was referred by Dr. Sohel Talib, Director of Therapeutic Development and member of Business Development at CIRM.

Expertise Relevance to CIRM GWG: Dr. Waller's clinical and research expertise in hematology, medical oncology, and stem cell transplantation continue to be invaluable in the review of Translational and Clinical stage program awards.

Prior Service in CIRM Reviews: Dr. Waller has reviewed as a specialist for Clinical stage programs.

**Bio:**

Dr. Edmund Waller is a Professor in the Departments of Medicine, Pathology, and Hematology and Medical Oncology at Emory University School of Medicine, Director of the Bone Marrow and Stem Cell Transplant Program, Medical Director of the Center for Stem Cell Processing and Apheresis at Emory University Hospital, and Director of the Center for Regenerative Engineering and Medicine (a collaboration among Emory University, Georgia Tech, and the University of Georgia). He also holds the Rein Saral, MD Professorship in Cancer Medicine at the Winship Cancer Institute of Emory University. His primary research focuses on optimizing antitumor immunity in cancer patients. His clinical and research focus has been to improve the efficacy of hematopoietic stem cell transplantation, and he has built a translational research program at Emory focused on developing novel technologies to improve transplant outcomes (e.g., development of small molecules and innovative methods of graft engineering). Clinically, he specializes in bone marrow transplants for acute leukemia, myelodysplastic syndrome, myeloproliferative neoplasms, lymphoma, aplastic anemia, sickle cell disease and in the management of graft-versus-host disease (GVHD). He is also an expert in CAR T-cell therapy.

Dr. Waller earned his BA in Biology from Harvard University, his MD from Cornell University Medical College, and his PhD in Chemical Biology from Rockefeller University in New York. He completed his residency in Internal Medicine, clinical fellowship in Medical Oncology, and a research fellowship in Experimental Pathology at Stanford University. He is board certified in medical oncology, and internal medicine. He is a member of the American College of Physicians, American Society for Blood and Marrow Transplantation, American Society of Clinical Oncology, American Society of Hematology, and International Society for Experimental Hematology. He has published over 340 articles in journals such as *The New England Journal*, *Science*, *The Journal of Clinical Oncology*, *Blood* and *Lancet Oncology*. He has founded two biotech start-ups: Cambium Medical Technologies, a clinical stage company developing platelet lysate as treatment for dry eyes, and Cambium Oncology, a preclinical company developing small molecule antagonists to a novel immune checkpoint pathway to treat cancer patients.

**Letisha Wyatt, PhD**  
**Assistant Professor, Oregon Health & Science University**

Referral: Dr. Wyatt was referred by Dr. Shyam Patel, Director of Business Development at CIRM.

Expertise Relevance to CIRM GWG: Dr. Wyatt's expertise in neuroscience and data science, as well as strong commitment to open science, and diversity, will be invaluable to assessing the quality and impact data sharing plans and DEI plans across the various programs. Her extensive experience in education and mentorship will also be invaluable in reviewing Education program applications.

Prior Service in CIRM Reviews: N/A

Bio:

Dr. Letisha Wyatt is an Assistant Professor in the Department of Neurology, Director of Diversity in Research, and Director of Innovative Policy for the Racial Equity and Inclusion Center at the Vollum Institute at Oregon Health & Science University (OHSU). Part of her work at OHSU involves supporting efforts for enhancing inclusivity in laboratories and graduate education, as well as building operational plans and internal systems to achieve organizational effectiveness in progressive workplace policies that advance racial equity. Her research focuses on neuropharmacology and the pathology of neurodegenerative diseases.

Dr. Wyatt earned her BS in Neurobiology, Physiology & Behavior from University of California, Davis, and her PhD in Molecular Pharmacology & Toxicology from the University of Southern California. She completed her postdoctoral fellowship at Legacy Health Research Institute, where she continued her graduate research on purinergic signaling in the central nervous system as a molecular target for new treatments for alcohol abuse and stroke. In addition to her neuroscience research, she served as a Biomedical Research & Data Specialist, collaborating with the OHSU Library and the Center for Cancer Early Detection Advanced Research (CEDAR) to support open science practices, data literacy, and data stewardship needs. Dr. Wyatt has a strong commitment to education and mentorship, having instructed high school through graduate students in the laboratory and the classroom on their academic and professional development. She has a strong commitment to diversity, equity and inclusion in science, engineering, technology, math, and medicine, working hard to engage trainees from underrepresented backgrounds throughout their high school, undergraduate, postbaccalaureate, graduate, and postdoctoral career development.

**REAPPOINTMENTS**

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

**Proposed Reappointments to GWG**

<b>Last</b>	<b>First</b>	<b>Term</b>	<b>Years</b>	<b>Expertise</b>
Bonner-Weir	Susan	3	6	Diabetes; Stem Cell Biology
Brivanlou	Ali	3	6	Developmental Biology
Custer	Linda	2	4	Clinical Operations; Biostatistics; Clinical Trial Design
Ellis	James	3	6	Vector Development; Reprogramming; iPSC Banking; Rett Syndrome; Neurodevelopmental Disorders, Cardiomyopathies, and Post-transcriptional Regulation
Evans	Todd	3	6	Developmental & Molecular Biology
Freeman	Thomas	3	6	Neural Transplantation; Neurodegenerative Disorders; Spine Surgery
Gregory-Evans	Kevin	3	6	Ophthalmology; Tissue Engineering; Molecular Genetics
Griffith	May	3	6	Biomaterials; Cornea Regeneration and Transplantation
Isacson	Ole	3	6	Neurodegenerative Disease (PD, HD); Neuroregeneration
Kung	Andrew	3	6	Pediatric Cancers; Cancer Genomics, Precision Medicine; Tumor Biology
Lorson	Christian	3	6	Alternative Splicing; Spinal Muscular Atrophy; Gene Therapy
Mao	Hai-Quan	3	6	Biomaterials; Nanotechnology; Drug/Gene Delivery; Regenerative Engineering; Stem Cell Delivery
McKenna	David	3	6	Development of Cellular-Based Therapies; GMP Manufacturing of Adult and Induced Pluripotent Stem Cells and Immune Cells
Mendez	Ivar	3	6	Neurotransplantation; Neurosurgery; Robotic Surgery
Murphy	Michael	2	6	Vascular Surgery; Cardiovascular Cell Therapy
Niklason	Laura	3	6	Cardiovascular & Pulmonary Tissue Engineering; Blood Vessels
Raja	Rajiv	2	4	Biomarker Development, Translational Genomics
Sagen	Jacqueline	3	6	Neural Transplantation; Axonal Regrowth; Chronic Pain Syndromes
Schöler	Hans	3	6	Stem Cell Pluripotency & Germline Development
Schwob	James	3	6	Neural Development; Olfactory Projection; Neurogenesis
Traverse	Jay	2	2	Stem Cell Therapy for Cardiovascular Disease
Weber	Darin	2	6	Regulatory (CMC; Device; Cell Therapy)



**Susan Bonner-Weir, PhD**

Dr. Susan Bonner-Weir is the Diabetes Research and Wellness Foundation Chair and Senior Investigator in the Section on Islet Cell and Regenerative Biology at Joslin Diabetes Center and Professor of Medicine at Harvard Medical School. She is a cell biologist who has focused on the islets of Langerhans: their architecture, their postnatal growth, and their function. She has defined the islet vasculature and the organization and polarity of the beta cells within the islet using scanning and transmission electron microscopy. Using stereological methods to assess islet cell mass and methods to determine the determinants of the beta cell mass replication, neogenesis, apoptosis and cell volume, she has built the case that beta cell mass is dynamic and can change with demand. Prior to these studies, adult beta-cells were thought to be a static population and without active growth, but Dr. Bonner-Weir's models provided compelling evidence that adult pancreatic beta-cell mass increases in response to a metabolic need; this concept of beta cell mass compensation has now been accepted by the field. Additionally, she has built the case for neogenesis or the differentiation of new beta cells from progenitors after birth and in adults. Another area of her research has been understanding the phenotypic basis of functional heterogeneity among beta cells whether normal, immature or dysfunctional due to glucose toxicity. In a series of papers, she and her team showed that the neonatal immature beta cell have a very different phenotype than an adult beta cell and that the transcription factor MafA is key to their functional maturation. More recent work focuses on the life stages of the beta cell from immaturity to senescence.

Dr. Bonner-Weir earned her PhD in Biology at Case Western Reserve University and completed her postdoctoral training in Islet Morphology at Harvard Medical School. She serves or has served on the editorial boards of the *American Journal of Physiology*, *Journal of Biological Chemistry*, *Endocrinology*, *Cell Transplantation*, and *Diabetes*. She has been a member of grant review panels for the National Institutes of Health, the Juvenile Diabetes Research Foundation, the American Diabetes Association and the European Union Research Council. She has published over 210 peer reviewed papers and 80 chapters, perspectives and reviews on various aspects of the biology of the islets of Langerhans, their growth and function and how they do after transplantation. Among many honors, she has received the Global Achievement Award at Joslin Diabetes Center, the William Silen Lifetime Achievement Award for Mentoring at Harvard Medical School, and has been elected as a Fellow of the American Association for the Advancement of Science.

Dr. Bonner-Weir served as a GWG member for 12 years. She has reviewed for Discovery programs, Leadership Awards, and Disease Team Awards.

**Ali Brivanlou, PhD**

Dr. Ali Brivanlou is the Robert and Harriet Heilbrunn Professor and Head of the Laboratory of Synthetic Embryology at Rockefeller at The Rockefeller University in New York.

Dr. Brivanlou's laboratory aims to decipher the molecular circuitry that underlies the establishment of discrete cell fates during early human embryogenesis with a special emphasis on the development of the embryonic germ layers and the brain. His group discovered the molecular basis of embryonic induction for each germ layer and demonstrated that the human brain is induced by default based on an evolutionarily conserved molecular mechanism. In addition, his lab derived and characterized both human embryonic stem cell (hESC) and induced pluripotent stem cell (iPSC) lines from both normal as well as diseased (Huntington) individuals. Three of his lines (RUES1, 2, and 3) became part of the NIH registry and are distributed nationally and internationally. In collaboration with Rockefeller physicist, Eric Siggia, he developed micropattern technology to standardize quantitative measurement of fate determination in hESCs and hiPSCs, and discovered that a simple confinement of colony architecture was sufficient to unveil a surprising self-organizing activity of human pluripotent cells. Dr. Brivanlou is currently using this platform to screen for compounds that can revert the aberrant signature back to normal and has identified several hits currently under validation. His group has also applied their expertise in tissue engineering to the creation of 3D organoids, gastruloids, and neuruloids that represent highly reproducible in vitro models for the study of disease mechanisms during early development. In collaboration with Rockefeller virologist, Charles Rice, Dr. Brivanlou has used his robust micropattern technology to infect organoids with CMV, Rubella, and Zika virus, and more recently, the SARS-CoV-2 virus responsible for COVID-19.

Dr. Brivanlou earned his Maîtrise in Biochemistry at the Université des Sciences et Techniques du Languedoc and his PhD in Molecular Biology at University of California, Berkeley. He joined The Rockefeller University in 1994 as Assistant Professor after postdoctoral work in Douglas Melton's lab at Harvard University. He holds nearly a dozen patents, and his research has been published widely in peer-reviewed journals, including *Developmental Biology*, *Nature*, *Nature Biotechnology*, *Nature Cell Biology*, and *Molecular and Cellular Biology*. Among his many awards are

the Irma T. Hirschl/Monique Weill-Caulier Trusts Career Scientist Award, the Searle Scholar Award, the James A. Shannon Director's Award from the NIH, and the Presidential Early Career Award for Scientists and Engineers.

Dr. Brivanlou served as a GWG member for 12 years. He reviewed for the Discovery stage (Basic Biology) program awards, Leadership Awards, and Genomics Centers of Excellence awards.

#### **Linda Custer, PhD**

Dr. Linda Custer is a consultant in the regenerative medicine, cell therapy, and biologics areas. She was most recently VP of Clinical Research at Avania, a clinical research organization in Marlborough MA with additional offices across the US as well as Australia and the Netherlands. She supervised more than two dozen professionals in the areas of clinical project management, clinical trial monitoring, clinical operations, and clinical safety monitoring and reporting. She worked closely with clients in developing investigational new drug applications (INDs), building strategic therapy development plans, and overseeing the conduct of clinical trials from start to finish. Her clients were developed products in fields including regenerative medicine, cell therapies, biologics, orthopedics.

Prior to her work at Avania, Dr. Custer held senior clinical operations roles at Tarveda Therapeutics (previously Blend Therapeutics), Biogen (previously Biogen Idec), and Osiris Therapeutics. While at Tarveda, she oversaw the submission of separate IND applications for three novel oncology therapies and initiated and oversaw trials for each of them. At Biogen, she led multidisciplinary clinical development teams for therapies in multiple sclerosis, amyotrophic lateral sclerosis, and Sjögren's syndrome. During 10 years at Osiris, Dr. Custer initiated and led the clinical development of Prochymal remestemcel-L (culture-expanded allogeneic human mesenchymal stromal cells) for treatment of Crohn's disease and contributed to programs developing Prochymal for treatment of graft-versus-host disease, juvenile diabetes, idiopathic pulmonary fibrosis, and primary myocardial infarction.

Earlier in her career, Dr. Custer led research teams at Viacell, Sontra Medical, Circe Biomedical, and W.R. Grace in various health technology research and development projects. At Viacell, she explored expansion of human cord blood cells for therapeutic indications. At Sontra Biomedical, she conducted and analyzed clinical research in the use of dermal ultrasound both to deliver transdermal relatively impermeable therapies and to monitor continuously blood glucose levels without finger sticks. At Circe Biomedical and W.R. Grace, she designed and tested cell and biologics therapies including bioengineered kidney, liver, and pancreas systems.

Dr. Custer holds SB degrees in both life sciences and chemical engineering from MIT and a PhD degree in chemical engineering from UC Berkeley.

Dr. Custer served as a GWG member for 6 years. She reviewed for Clinical stage program awards, Accelerating Center awards and Alpha Stem Cell Clinics Network Expansion awards.

#### **James Ellis, PhD**

James Ellis is a Professor in the Department of Molecular Genetics at the University of Toronto, a Senior Scientist in Developmental & Stem Cell Biology at the Hospital for Sick Children, and the Research Integrity Advisor at the Hospital for Sick Children. Dr. Ellis is a pioneer in developing induced Pluripotent Stem Cell (iPSC) differentiation methods, reprogramming patient cells, and modeling childhood disease for drug testing. His research theme is to define disease mechanisms using gene delivery to reprogram and manipulate human stem cells, and his team uses these cells to study post-transcriptional regulation of gene expression. They develop vectors with reporter genes that mark specific cell types, such as our EOS vectors that express highly in pluripotent stem cells but extinguish during differentiation. His lab currently uses iPSC cells in collaborative research teams to model Rett syndrome, Autism Spectrum Disorders, Williams Beuren syndrome and cardiomyopathies. They phenotype the affected cells in vitro and interrogate potential disease pathways using chemical compound screens to identify candidate drugs that may have therapeutic utility. A new research direction concentrates on post-transcriptional regulation during human neurodevelopment.

Dr. Ellis completed his BSc in Microbiology at McGill University and his PhD in Medical Genetics at the University of Toronto with Dr. Alan Bernstein developing retrovirus vectors for gene targeting. His postdoctoral fellowship studying the beta-globin Locus Control Region was mentored by Dr. Frank Grosveld in London UK. Dr. Ellis established his own research team at the Hospital for Sick Children in Toronto in 1994 with a focus on gene therapy for Sickle Cell Anemia. He subsequently developed MECP2 vectors for Rett syndrome, and vectors with reporter genes that mark specific cell types. Among other honors, he has received the Janet Rossant Research Innovation Award for interdisciplinary collaboration. He has served on an NIH panel on the development and validation of novel tools to probe cell-specific and circuit-specific processes in the brain and he serves on the TriAgency Panel for Responsible Conduct of Research.

Dr. Ellis served as a GWG member for 10 years. He reviewed for Discovery stage (Basic Biology) program awards and Translational stage programs.

**Todd Evans, PhD**

Dr. Todd Evans is the Peter I Pressman, MD, Professor of Surgery, Vice Chair for Research and Chief of the Division of Research in Surgery, and the Associate Dean for Research at Weill Cornell Medicine (WCM). Dr. Evans grew up in Indiana, and earned his BA at Northwestern University (Biology) and his PhD at Columbia University (Molecular Genetics). He carried out a postdoctoral fellowship at the National Institutes of Health, during which time he discovered a critical gene (*Gata1*) that controls red blood cell development and differentiation. This led to his appointment in 1990 as an Assistant Professor at the University of Pittsburgh, followed by a move to the Albert Einstein College of Medicine in 1995, where he rose through the ranks to become a tenured Professor and also served as the Dean of the Graduate Program.

Dr. Evans was recruited to WCM in 2009, to establish a new Research Division in the Department of Surgery and the Program in Stem Cell Biology and Regenerative Medicine in Surgery. He has published over 170 peer-reviewed papers including in the highest impact research journals. His work has been funded by many agencies, including continuously for 30 years by the National Institutes of Health, and by the New York State Department of Health (NYSTEM). Dr. Evans has received numerous honors, including a MERIT award and an Outstanding Investigator Award from the NHLBI, and leadership posts on multiple NIH advisory committees. He has also served on review committees for the American Heart Association and American Cancer Society. The overall focus of research in the Evans Laboratory is to understand the molecular regulation of organogenesis, and discover the underlying genetic and epigenetic programs that, when deregulated, cause developmental defects and organ-based diseases. Pluripotent stem cell models and the zebrafish animal model are used to model human disease and for the discovery and development of new therapeutics, especially tailored for precision medicine. In 2020 the laboratory helped forge a New York City research consortium, and pivoted toward COVID-19 research using human pluripotent stem cells to discover FDA-approved drugs that block SARS-CoV-2 infection of various tissues including lung, gut, and heart. Dr. Evans has 6 patents related to novel protocols and small molecules that promote progenitor cell fate and regeneration. He recently co-founded a WCM-based company called OncoBeat, LLC, focused on the discovery of drugs that can protect the heart from damage caused by cancer therapeutics.

Dr. Evans served as a GWG member for 10 years. He reviewed for Discovery stage program awards and Research Leadership awards.

**Thomas Freeman, MD, FAANS, FACS**

Dr. Thomas Freeman is Professor and Director of Clinical Research in the Department of Neurosurgery and Brain Repair, as well as the Medical Director of the Center of Excellence for Aging and Brain Repair at the University of South Florida. His clinical specialty is complex spine surgery including surgery of the sacroiliac joint. In addition to providing treatment to patients at Tampa General Hospital and James A. Haley Veterans Hospital, he is often invited to speak at conferences throughout the US, as well as Canada, Puerto Rico, and Russia, on spine surgery practices and surgical management. His research interests are in cellular therapies for treatment of neurodegenerative disorders, particularly Parkinson's and Huntington's disease, and other neurological injuries such as stroke and spinal cord injuries.

Dr. Freeman earned his BS from Massachusetts Institute of Technology and MD from Johns Hopkins University School of Medicine. He completed his internship in the Department of Surgery at Columbia Presbyterian Medical Center, served as an Honorary Registrar in the Department of Neurology at the National Hospital at Queens Square, London, England, and completed his residency in the Department of Neurosurgery at New York University Medical Center. He holds 10 patents and 18 provisional patents for tools such as grid arrays for use in the transplantation of materials into the brain, prosthesis for spine discs, and trajectory guides. He served as a special government employee for the FDA Center for Biologics Evaluation and Research and he has served, and continues to serve, as a consultant, medical director, and/or scientific advisory board member for companies focused on regenerative medicine or biologics. He has reviewed for NIH study sections, the Medical Research Council of Canada, and served on the editorial board of the journal *Cell Transplantation*. He is the past president of SIMEG, the Sacroiliac Medical Expert Group. Among many honors, he has often been recognized as one of the Best Doctors in America and was awarded the Molly & Bernard Sanberg Memorial Award for Brain Repair by the American Society of Neural Therapy and Repair for his significant contributions to the field of brain repair.

Dr. Freeman has served as a GWG member for almost 10 years. He reviewed for Strategic Partnership awards and Disease Team Research awards.

**Kevin Gregory-Evans, MD, PhD, FRCS, FRCOphth**

Dr. Kevin Gregory-Evans is Professor of Ophthalmology in the Faculty of Medicine Department of Ophthalmology and Visual Sciences at the University of British Columbia (UBC) and the Julia Levy BC Leadership Chair in Macular Research. The overall theme of his research is to identify new ways of treating common retinal diseases, such as macular degeneration and retinitis pigmentosa, focusing on novel cell-based therapeutic strategies in model systems and clinical trials. He reported one of the first localizations for a retinal disease gene and has reported on another 15 retinal disease genes since. His lab is undertaking several projects to look at how cells can be used to replace damaged retinal tissue and new ways that cells can be used to deliver and secrete drugs long-term into the diseased retina to prevent further decline of vision. Recently he published a paper on a novel small molecule (PKX-001) that improves transplanted photoreceptor precursor cell survival in vivo. His clinic specializes in treating patients with macular degeneration, retinitis pigmentosa, glaucoma, aniridia and other diseases of the retina.

Dr. Gregory-Evans achieved an MBBS at St. Bartholomew's Medical School, University of London; was awarded FRCS, Royal College of Surgeons and Physicians, Glasgow; was awarded FRCOphth, Royal College of Ophthalmologists, London; and was awarded a MD in molecular biology and a PhD in cell biology at the University of London. He completed his clinical ophthalmology training at Moorfields Eye Hospital, London, and basic science research training at the Institute of Ophthalmology, London, and at Oregon Health Sciences University Casey Eye Institute. Prior to accepting a position at UBC, he was elected to the Macular Disease Advisory Group at the Royal College of Ophthalmologists, UK, to advise on setting up retinal disease treatment clinics throughout the UK. He has published 91 original research papers in journals such as *Journal of Tissue Engineering and Regenerative Medicine*, *Human Genetics*, and *Cell Transplantation*, and over 35 book chapters or review articles. Among many services, he served as Director for the Foundation for Fighting Blindness whereupon he was awarded with the 'Recognition of Leadership' Award. He serves as a member of the Pfizer Pharmaceuticals Stem Cell Advisory Panel and the Novartis Luxturna Advisory Committee (Canada). He regularly reviews grants for the Canadian Institute of Health Research. Among many honors, he was awarded the Lang Medal by the Royal Society of Medicine for work on translational therapeutics for retinal diseases.

Dr. Gregory-Evans served as a GWG member for 8 years. He reviewed for Translational and Discovery stage program awards.

**May Griffith, PhD**

May Griffith is a Professor in the Department of Ophthalmology at the University of Montreal, affiliated to the Biomedical Engineering program, and CHUM Research Centre. She is internationally recognized as an expert in cell biology and biomaterials who achieved the world's first successful regeneration of the human cornea, a tissue that does not regenerate itself. With her unique expertise spanning cell biology, biomaterials and translational biomedicine, she and her team have developed bioresponsive implants mimicking the corneal extracellular matrix that stimulated the patients' endogenous cells to regenerate fully functional, innervated neo-corneas as alternatives to allograft transplantation, and have successfully advanced my novel therapeutic implants from the laboratory into clinical trials. She continues to innovate and develop novel biomaterials and test these for clinical use in regenerative medicine, by bridging the translational gap between bench and bedside through first-in-human clinical trials.

Dr. Griffith earned her BSc in Zoology and Human Biology, MSc in Zoology and PhD in Cellular & Developmental Biology at University of Toronto. She completed her postdoctoral fellowships at the University of Alberta and Harvard Medical School. Following her tenure at Linköping University in Sweden, she was recruited back to Canada for her internationally recognized expertise in translational regenerative medicine, having achieved two successful bench-to-bedside, first-in-human clinical trials with unique biomaterials developed in her laboratory. She led two multinational, interdisciplinary teams in both clinical trials using biosynthetic implants to stimulate endogenous cells to regenerate neo-corneas. Biomaterials-based programs designed to promote corneal and other endogenous regeneration worldwide have since evolved around her initial successful clinical trial. Her scientific output includes 127 peer-reviewed papers including papers in high impact journals, e.g. *Science*, *Science Transl. Med.*, *Science Advances*. She has written over 50 book chapters and reviews in influential textbooks, including "Principles of Regenerative Medicine" and "Cornea", the "bibles" in these areas.

Among many distinctions, Dr. Griffith is a Canada Research Chair, Tier 1, in Biomaterials and Stem Cells in Ophthalmology. The Canada Research Chairs Program stands at the centre of a national strategy to make Canada one of the world's top countries in research and development, and chairholders improve Canada's depth of knowledge and quality of life, strengthen Canada's international competitiveness, and help train the next generation of highly skilled people through student supervision, teaching, and the coordination of other researchers' work. Dr. Griffith has a commitment to mentorship and training. She has trained over 60 graduate students and post-doctoral fellows from biology, chemistry, and engineering, providing an environment for interdisciplinary exposure and

collaboration. Her former trainees include several award-winning scientists generating high quality research outputs and hold senior research positions in academia and industry, while several work on regulatory issues at Health Canada and in patent law.

Dr. Griffith served as a GWG member for 8 years. She reviewed for New Faculty Physician Scientist awards and Tools and Technologies awards.

### **Ole Isacson, MD, PhD**

Dr. Ole Isacson is currently Professor of Neurology (Neuroscience) at Harvard Medical School and the founding director of the Neuroregeneration Research Institute at McLean Hospital (MGB). After completion of his MD-PhD and research at University of Lund, Sweden, and a post-doctoral fellowship at University of Cambridge, UK, Dr. Isacson was recruited as faculty to Harvard University and Massachusetts General Hospital, Department of Neurology, to establish an independent laboratory.

Professor Isacson's laboratory has elucidated critical biological processes, mechanisms and treatments of neuronal vulnerability in several neurodegenerative diseases. To reverse the effects of subsequent brain cell death, his work has pioneered and patented new biotechnology platforms for specific and targeted restorative treatments using molecular, gene therapy and cell replacement methods, including stem cell derived patient derived neurons. The dual goals of his work are to prevent brain degeneration and loss of neuronal function in PD/AD related pathologies; and repair any irreversible brain damage by micro-restoration of new neurons and glia in the brain. Recently, he and his collaborators have found several key components in pathways of lysosomal and lipid function to be defective in Parkinson's disease cells and tissues. New research in his laboratory have resolved lipid-induced problem in PD disease and dementia pre-clinical animal models. In addition, he and his team have established models and published extensively on the nexus of inflammatory disarray and neurodegenerative diseases.

Professor Isacson is Principal Faculty of the Harvard Stem Cell Institute, since it was founded in 2005. He is a member of the Scientific Advisory Board of the Michael J. Fox Foundation and served as a member of the Executive Scientific Advisory Board (2014-2016). He has received several international prizes, research awards and lectureships, including The Royal Swedish Academy of Sciences: The Lindahl Young Investigator Award and the Bernard Sanberg Memorial Prize for Brain Repair. Professor Isacson served as the President of the International Cell Transplant Society (TTS), (2007-2008). He served as a US government federal advisory committee member for the FDA Center for Biologics Evaluation and Research (CBER) (2014-2016) and the CSO of Pfizer's Neuroscience Division (2016-2017). He is the author or co-author of ~ 400 scientific research articles and 3 books in his field. He was the Editor-in-Chief of *Molecular and Cellular Neuroscience* from 2010-2016. Professor Isacson was elected fellow of the American Association for the Advancement of Science (AAAS) in 2013.

Professor Isacson has served as a GWG member for 8 years.

### **Andrew Kung, MD PhD**

Dr. Andrew Kung is the Lila Acheson Wallace Chair for Pediatric Research at Memorial Sloan Kettering Cancer Center. As Chair of the Department of Pediatrics—which is the largest pediatric oncology program in the country and is a tertiary and quaternary referral center for children with cancer and those requiring stem cell transplantation—he oversees the clinical, research and training missions of the department comprised of 76 faculty and 24 fellows. His clinical practice is focused on stem cell transplantation, cancer genomics and precision cancer medicine. The overarching goal of his research program is to translate laboratory-based discoveries into clinical testing to advance the treatment of patients with cancer. The translational oncology research in his laboratory is powered by the integration of diverse experimental approaches including genomics, molecular biology, bioinformatics, experimental therapeutics and human clinical studies. They use this platform of translational methodologies to identify cancer-causing drivers, credential new cancer therapeutic targets, identify inhibitory compounds, and achieve in vivo and in-human proof-of-concept for utility in the treatment of cancer. They have advanced a number of novel therapeutic strategies to the clinic for hematologic malignancies, solid tumors, and brain tumors.

Dr. Kung earned his MD and PhD in Cancer Biology at Stanford University. He completed his residency in Pediatrics at Boston Children's Hospital, his fellowship in Pediatric Hematology/Oncology at Dana-Farber Cancer Institute and Boston Children's Hospital, and his post-doctoral fellowship in Cancer Biology at the Dana-Farber Cancer Institute. He serves on the Board of Scientific Advisors for the National Cancer Institute's Childhood Cancer Data Initiative Working Group, serves on the Scientific Advisory Board for Emendo Biotherapeutics and Karyopharm Therapeutics, is the Co-Founder of Isabl Technologies, and is a Scientific Advisor for the Children's Tumor Foundation and CureSearch's BRIDGE Initiative.

Dr. Kung served as a GWG member for 10 years. He reviewed for the Discovery and Translational stage program awards and New Faculty awards.

#### **Christian Lorson, PhD**

Dr. Christian Lorson is a Professor in the Department of Veterinary Pathology, Director of the Spinal Cord Injury Disease and Repair Program, Associate Vice Chancellor for Research, and Associate Dean for Research and Graduate Studies at the College of Veterinary Medicine at the University of Missouri School of Medicine. His research interests include molecular genetics, gene therapy, RNA processing, neurodegeneration, and animal models of disease. His lab focuses on spinal muscular atrophy (SMA), the leading genetic cause of infantile deaths. Dr. Lorson's lab discovered a relationship between SMA and cardiac problems, which suggests that SMA is a multi-system disease and not confined to the nervous system. They are collaborating with several groups to develop new drugs that will encourage the body to produce more SMN protein, with a goal of moving closer toward clinical trial.

Dr. Lorson earned his BA in Biology from Colorado College in Colorado Springs and his PhD in Molecular Microbiology and Immunology, initially studying papillomavirus gene expression and latency then transitioning into pediatric neurodegenerative disease spinal muscular atrophy, at the University of Missouri Medical School. He completed a fellowship in Molecular Biology and Microbiology at the New England Medical Center at Tufts University School of Medicine. He was subsequently named Assistant Research Professor before moving to Arizona State University where he was Assistant Professor in Biology and then Assistant Professor in Veterinary Pathobiology. He then moved to the University of Missouri as an Assistant Professor where he moved up through the ranks to his current positions. In addition to his academic roles, he has served as the Scientific Director for FightSMA, and he continues to serve on a variety of research advisory councils, including the Muscular Dystrophy Association, and SMA Trust. He is a member of the numerous professional societies, serves as an ad hoc reviewer for several scientific journals and funding agencies including the NIH, and has served as an industry consultant for SMA-related therapy development. He is also Co-founder and Chief Scientific Officer of Shift Pharmaceuticals, a biotechnology company based upon the intellectual property that Dr. Lorson generated at MU, with the goal of testing the clinical effectiveness of a molecule that may help improve the outcomes of people with SMA. The company received a Technology and Therapeutic Development Grant from the U.S. Department of Defense to help move the compound closer to the clinic.

Dr. Lorson served as a GWG member for 10 years. He reviewed for Discovery stage program awards (Basic Biology) and Targeted Clinical Development awards.

#### **Hai-Quan Mao, PhD**

Dr. Hai-Quan Mao is the associate director of the Institute of NanoBioTechnology (INBT) and a professor of Materials Science and Engineering at Johns Hopkins University. He holds a joint appointment in the Translational Tissue Engineering Center and the Department of Biomedical Engineering at the School of Medicine. Dr. Mao's research focuses on engineering novel nanomaterials for regenerative medicine and therapy delivery applications. He has developed nanofiber scaffolds from synthetic and natural biomaterials for tissue regeneration, stem cell expansion and differentiation, particularly on the proliferation and differentiation of human hematopoietic stem/progenitor cells and neural stem cells, and for soft tissue engineering and nerve regeneration. His contributions in therapeutic engineering include understanding the kinetic assembly mechanism of nanoparticles for the scalable production of nanotherapeutics, and their applications in local and systemic delivery of macromolecular therapeutics and vaccines.

Dr. Mao received his BS degree in chemistry and a PhD in polymer chemistry from Wuhan University in China in 1988 and 1993, respectively. From 1995 to 1998, he completed his postdoctoral training in the Department of Biomedical Engineering at Johns Hopkins University School of Medicine. He was a co-principal investigator at Johns Hopkins in Singapore from 1999 to 2003, prior to joining the faculty of Whiting School of Engineering at Johns Hopkins University. Dr. Mao is a handling editor for *Biomaterials*, and serves on the editorial boards of *ACS Biomaterials Science & Engineering* and *Journal of Materials Chemistry B*. He has been a standing or ad hoc member for several NIH Study Sections. He holds 28 U.S. patents and has published more than 190 peer-reviewed research manuscripts. He has been elected a Fellow of the American Institute for Medical and Biological Engineering and the Royal Society of Chemistry, and a Senior Member of the National Academy of Inventors. He was the recipient of the Young Investigator Award at the National University of Singapore in 2002 and the National Science Foundation faculty CAREER Award in 2008.

Dr. Mao served as a GWG member for 8 years. He reviewed for Discovery stage programs awards (Basic Biology) and Tools and Technology awards.

**David McKenna, Jr., MD**

Dr. David McKenna is a Professor and the American Red Cross Chair in Transfusion Medicine in the Department of Laboratory Medicine and Pathology at the University of Minnesota Medical School. He also serves as the Medical Director of Molecular and Cellular Therapeutics (MCT), the University's cGMP facility which provides full-service development and manufacturing of cell- and tissue-based products, monoclonal antibodies, other therapeutic proteins, and active pharmaceutical ingredients, for use in Phase I or II clinical trials. He is also the Laboratory and Medical Director of the University of Minnesota Medical Center Clinical Cell Therapy Laboratory, and he serves as the director of the fellowship program in Transfusion Medicine/Blood Banking. His research interests include umbilical cord blood research, quality assurance/quality control in cellular therapy, and translational research/clinical scale-up of biotherapeutics. His current projects include identifying solutions for the preservation of cell therapy products, conducting preclinical studies to enable a first-in-human study of iPSC-derived muscle cells for Duchenne muscular dystrophy, and providing cells for several clinical trials under IND, including iPSC-derived NK cells for leukemia and other cancers, MSCs for acute lung injury, and CRISPR/cas9 modified TIL for GI cancers.

Dr. McKenna earned his BS in Biological Sciences and Philosophy from the University of Notre Dame and his MD from Saint Louis University School of Medicine. He completed a residency in Anatomic and Clinical Pathology as well as a fellowship in Transfusion Medicine with an emphasis on cellular therapy at the University of Minnesota. Dr. McKenna is a board-certified physician in Anatomic Pathology, Clinical Pathology and Transfusion Medicine/Blood Banking. He has published over 90 articles in such journals as *Bone Marrow Transplant*, *Journal of Clinical Investigation*, *Journal of Immunotherapy*, *Cytotherapy*, and *Transfusion*. He is a member of the American Association of Blood Banks (AABB), serving on the board of directors for four years and also chairing their Cellular Therapies Section Coordinating Committee. He is also a scientific member and team leader of the Biomedical Excellence for Safer Transfusion (BEST) Cellular Therapy Team, a member of the editorial board of *Cytotherapy*, and he is the PI of the University of Minnesota's Production Assistance for Cell Therapy (PACT) contract with the National Heart, Lung, & Blood Institute (NHLBI).

Dr. McKenna served as a GWG member for 8 years. He reviewed for Translational stage programs awards and Tools and Technology awards.

**Ivar Mendez, MD, PhD, FRCSC, FACS**

Dr. Ivar Mendez is the Fred H. Wigmore Professor and Provincial Head of the Department of Surgery at the University of Saskatchewan and Saskatchewan Health Authority. Prior to his arrival in Saskatoon in 2013, he served for many years as Chairman and Founding Member of the Halifax Brain Repair Centre, the most comprehensive neuroscience research institute in Atlantic Canada. He was also Head of the Division of Neurosurgery at Dalhousie University and the QEII Health Sciences Centre for more than a decade.

As a Clinician/Scientist, Dr. Mendez' research focus is in functional neurosurgery, brain repair, stem cells, virtual care and remote presence robotic technology. His research has been supported by peer-reviewed funding from a number of sources including the Canada National Centers of Excellence, Canadian Institutes of Health Research, and Canada Foundation for Innovation.

In 2002, Dr. Mendez and his team performed the world's first long distance telementoring neurosurgery. He also established the first remote-presence robotics program serving the inhabitants of remote communities in northern Saskatchewan. Dr. Mendez has given over 200 presentations on a national and international level and has 180 peer-reviewed publications. He was the President of the Canadian Neuromodulation Society (CNS) from 2009– 2012 and in that role promoted access of neuromodulation therapy to all citizens of Canada.

Among numerous other honours and awards, Dr. Mendez was the recipient of the Royal College Medal Award in Surgery, the 2010 Canadian Red Cross Humanitarian of the Year award. He was inducted as a fellow in to the Canadian Academy of Health Sciences. In 2016 he received the Government of Canada Public Service Award of Excellence for his research on brain repair and the use of Remote Presence Robotic Technology.

Dr. Mendez served as a GWG member for 10 years. He reviewed for Discovery and Translational stage programs as well as Research Leadership awards, Tools and Technology awards, Disease Team Research awards and Targeted Clinical Development awards.

**Michael Murphy, MD**

Dr. Michael Murphy is the Cryptic Mason Medical Research Foundation Chair of Vascular Biology Research and Professor of Surgery, Cellular & Integrative Physiology, at Indiana University School of Medicine. He is also Director of the Indiana Center for Vascular Biology and Medicine, Director of the Veterans Administration Center for

Regenerative Medicine, Director of the Veterans Administration Center for Molecular and Cellular Therapeutics for Cardiovascular Disease, and Adjunct Professor of Cardiology at Indiana University School of Medicine. The majority of his research career has focused on the utility of cell-based therapy in preventing amputations in poor option/no-option Critical Limb Threatening Ischemia, an end-stage of peripheral arterial disease that is a major health concern in the Veterans Administration medical system given the amputations required when there are poor options or no-options for revascularization. His research efforts led to the first FDA approved clinical trial using intra-muscular administration of autologous bone marrow cells (ABMC) that culminated in the multi-center Phase II MOBILE Trial that treated 155 patients with the primary endpoint of amputation-free survival (AFS).

Dr. Murphy earned his BS in Biochemistry and his MD from Columbia University. He completed a research fellowship at Harvard Medical School and a residency in general surgery at Brigham and Women's Hospital, Harvard Medical School. He then completed a vascular surgery fellowship at Duke University. Among many honors, he has received awards for basic science research and translational research from the American College of Surgeons. He has served on multiple study sections for the NIH related to peripheral arterial disease, cardiovascular cell therapy, clinical and integrative cardiovascular sciences, and bioengineering. He currently serves as the Co-Chair of the NIH Bioengineering, Technology, and Surgical Sciences study section and Associate Editor of *Circulation Research*.

Dr. Murphy has served as a GWG member for almost 6 years. He reviewed for the Clinical and Translational program awards and serves on a Translational Advisory Panel.

#### **Laura Niklason, MD, PhD**

Dr. Laura Niklason is the Founder and CEO of Humacyte Inc and an Adjunct Professor at Yale University. Prior to joining Humacyte as CEO in November 2020, Niklason served as the Nicholas M. Greene Professor of Anesthesia and Biomedical Engineering at Yale University. Her research focuses primarily on regenerative strategies for cardiovascular and lung tissues, in order to find new ways to treat patients, including those with kidney failure or heart disease, or those in need of certain organ transplants. Her engineered blood vessels are currently in clinical trials and are the first life-sustaining engineered tissue to be studied in any Phase III trial.

Dr. Niklason earned her PhD in Biophysics from the University of Chicago, and her MD from the University of Michigan, Ann Arbor. She completed her residency training in Anesthesia and her fellowship in Critical Care Medicine at the Massachusetts General Hospital in Boston. She completed her post-doctoral training at Massachusetts Institute of Technology, where she developed techniques for the tissue engineering of autologous arteries. Following her postdoctoral fellowship, she joined the faculty at Duke University, where she continued her work in cardiovascular tissue engineering, and founded a biotechnology company, Humacyte, designed to bring tissue engineered cardiovascular products to the clinic. She then accepted a position at Yale University, where she expanded her research program in tissue engineering of blood vessels and the lung, as well as understanding the basic aspects of cellular aging. Dr. Niklason has received national and international recognition for her work in tissue engineering. She was one of the first to describe the engineering of whole lung tissue that could exchange gas in vivo, and this work was cited in 2010 as one of the top 50 most important inventions of the year by Time Magazine. She was inducted into the National Academy of Inventors in 2014 and was elected to the National Academy of Medicine in 2015. In 2020, she was elected to the National Academy of Engineering for her contributions to research in cardiovascular tissue engineering, lung regeneration, and biomedical imaging.

Dr. Niklason served as a GWG member for 10 years. She reviewed for Translational stage program awards.

#### **Rajiv Raja, PhD**

Dr. Rajiv Raja is the Senior Director of Diagnostics at Precision Medicine and Senior Director, Translational Medicine Lead for Immuno-Oncology at AstraZeneca. In this role, he is responsible for setting biomarker strategies for late-stage programs in immunotherapy of lung cancer. He also serves as the head of the genomics group in developing and implementing cutting-edge technologies, such as high-sensitivity RNAseq and single-cell RNAseq. Recently, Dr. Raja has been leading the development of a blood-based tumor mutational burden (bTMB) assay in collaboration with Guardant Health, and the development of blood-based minimal residual disease (MRD) assays for early-stage lung and bladder cancers.

Dr. Raja earned his PhD in Molecular Genetics from Oklahoma State University and completed his postdoctoral fellowship at the University of Illinois at Urbana-Champaign. He has over twenty years of experience developing, validating and implementing molecular diagnostic assays and technologies for clinical studies, including the development of biomarker assessment strategies for limited/degraded clinical samples. Following his postdoctoral training, he worked as a biomedical scientist at UCSF and Lawrence Livermore National Laboratory before transitioning to industry to become Director of Molecular Diagnostics at Arcturus Bioscience and then Director of



Molecular Biology at MDS Analytical Technologies. Prior to his tenure at AstraZeneca, he served as Biomarker Lead and Head of Clinical Assays and Technologies at Genentech, where he developed novel genomic technologies and companion diagnostic tests to support clinical development programs in oncology.

Dr. Raja has served as a GWG member for almost 6 years. He has reviewed for Translational stage program awards.

#### **Jacqueline Sagen, PhD**

Dr. Jacqueline Sagen is Professor of Neurosurgery at The Miami Project to Cure Paralysis within the University of Miami School of Medicine. Research in her laboratory over the past 30 years has been focused on exploring novel therapeutic strategies for chronic pain management that have the potential to provide sustained relief on a long-term or permanent basis. Early work led to initial clinical trials for cancer pain management using donor-derived adrenal chromaffin cells; however, availability of donor tissue and immunological concerns limited large-scale feasibility so her work pivoted to developing alternative cell sources, improved delivery strategies, and enhanced novel analgesic peptides with distinct targets using engineered viral vectors. Her lab has utilized and validated a wide variety of acute, inflammatory, peripheral neuropathic, and central pain models. Her current research involves using gene therapy for the prevention of phantom limb pain following extremity injuries, developing gene therapies targeting for treating chronic spinal cord injury pain, and alleviating chronic pain by engineered neural progenitors and induced human pluripotent stem cell transplants.

Dr. Sagen earned her BA in Neuroscience at Northwestern University and her PhD in Pharmacology at the University of Illinois Medical Center. She completed her MBA and her postdoctoral fellowship in Neuroscience at the University of Illinois at Chicago. She has published over 130 articles in journals such as *Experimental Neurology*, *Neuropharmacology*, *Neurotrauma*, *Pain*, and *Pharmacology Biochemistry and Behavior*. Among many commitments, she serves or has served as a member of the Education and Training Committee and as Council of the American Society for Neural Therapy and Repair, and as a representative for the University of Miami for the Federal Demonstration Partnership. She has also served on review panels for the NIH, Department of Defense, and VA for sessions on spinal cord injury, neuropathic pain, orthopedic research, chronic pain management, sensory and motor neuroscience, and small business drug discovery.

Dr. Sagen has served as a GWG member for about 10 years. She reviewed for Discovery and Translational programs stage program awards, and New Faculty Awards.

#### **Hans Schöler, PhD**

Dr. Hans Schöler is Director at the Max Planck Institute for Molecular Biomedicine in Münster, Germany; Full Professor of the Medical Faculty at the Westphalian Wilhelms University in Münster, Germany; Adjunct Professor at Hannover Medical School in Hanover, Germany; Distinguished Professor at Konkuk University in Seoul, Korea; and Adjunct Professor of Biochemistry at the University of Pennsylvania's Center for Animal Transgenesis and Germ Cell Research. His research focuses on the molecular biology of cells of the germline (pluripotent cells and germ cells) and how various somatic cells and germline cells can be reprogrammed into pluripotent cells.

He earned his Diploma in Biology and his PhD in Molecular Biology at Heidelberg University. Prior to his current position, Hans Schöler served as Staff Scientist at the Max Planck Institute for Biophysical Chemistry in Göttingen, Germany; Head of Research Group at Boehringer Mannheim (now Roche) in Tübingen, Germany; Head of Research Group at the European Molecular Biology Laboratory (EMBL) Heidelberg, Germany and as Professor of Reproductive Physiology of the School of Veterinary Medicine at the University of Pennsylvania, USA.

One of his major scientific achievements was the groundbreaking differentiation of germ cells from mouse embryonic stem cells. As a respected pioneer of stem cell research, he is member in the "Zentrale Ethik-Kommission für Stammzellenforschung (ZES)" (central ethics committee for stem cell research) in Berlin. He has been a member of the editorial boards of several international journals including *Cell*; *Cell Stem Cell*; *Stem Cells*; *Cellular Reprogramming*; *Stem Cells Reviews and Reports*; *Molecular Reproduction and Development*. He is a member of many academies of science, including the German Academy of Sciences Leopoldina. Among many awards, he received—together with Irving Weissman and Shinya Yamanaka—the Robert Koch prize for his groundbreaking research in the field of stem cell biology. He has also received the Kazemi Prize for outstanding contribution to biological sciences and health promotion. He was elected as a board member of the ISSCR and the German Stem Cell Network (and as its President 2021-22) and is a member of the European Molecular Biology Organization in recognition of his outstanding research achievements.

Dr. Schöler served as a GWG member for 10 years. He reviewed for Discovery stage (Basic Biology) program awards and Leadership Awards.

**James E. Schwob, MD, PhD**

Dr. James Schwob is the George A. Bates Professor of Histology, Professor in the Department of Developmental, Molecular, and Chemical Biology, and Professor in the Department of Neuroscience at Tufts University School of Medicine. He is the co-founder of Rejuvenos Therapeutics, Ltd. and Mirodia Therapeutics, Inc. His research focuses on the mechanisms regulating neural development. A near-term goal of his lab is the exploitation of the olfactory stem cells for therapeutic use.

Dr. Schwob earned his BS in Psychology from the University of Iowa and his MD/PhD in Neural Sciences from Washington University in St. Louis. Following an internship and residency in Anatomic Pathology, and postdoctoral fellowship in the Department of Anatomy and Neurobiology at Washington University School of Medicine and Barnes Hospital, Dr. Schwob was Assistant Professor at SUNY Health Science Center, Syracuse; ultimately he became Professor and Chair of the Department of Cell and Developmental Biology prior to departing for Tufts University School of Medicine. He has published over 180 journal articles, abstracts, book chapters, reviews, and symposia proceedings and has been invited to speak at seminars located across the US, as well as the UK, Japan, and India. In addition to serving as a manuscript reviewer for many journals—such as the *Journal of Neuroscience*, *Journal of Cell Biology*, *Journal of Chemical Neurotransmission*, and *Journal of Comparative Neurology*—he has served on the Editorial Board of the *Journal of Histochemistry and Cytochemistry*, and served on the Board of Directors for University of Massachusetts Medical School's Center for Stem Cell Biology and Regenerative Medicine. He has served as a chartered member of many NIH study sections related to sensory disorders and neuroscience, as well as an ad hoc reviewer for the National Science Foundation and the NIH on communication disorders. For NIH, he has also served on the Advisory Council, National Institute on Deafness and other Communication Disorders and served on the Council of Councils for the Office of the Director and the Division of Program Coordination, Planning, and Strategic initiatives.

In addition to his research efforts and other professional accomplishments, Dr. Schwob has demonstrated a commitment to training and mentorship throughout his tenure at SUNY and Tufts. He has provided mentorship to high school students, undergraduates researchers, medical student research fellows, graduate students and postdoctoral fellows. He is a member of the Association of American Medical Colleges Group on Graduate Research, Education and Training (GREAT), which provides professional development to, and fosters the exchange of information and ideas among the faculty and administrative leaders of biomedical doctoral, postdoctoral and physician scientist programs.

Dr. Schwob served as a GWG member for 10 years. He reviewed for Discovery stage (Basic Biology) and Education program awards, as well as Leadership Awards, and Genomics Centers of Excellence Awards.

**Jay Traverse, MD**

Dr. Jay Traverse received a BS in chemical engineering from the University of Notre Dame and a M.E in Biomedical Engineering from The University of Virginia. He graduated from Case Western Reserve University School of Medicine and completed his residency and cardiology fellowship at the University of Minnesota. During his fellowship he worked in the laboratory of Dr. Robert Bache studying the regulation of coronary blood flow during exercise in the failing heart and was a recipient of a Scientist Development Grant from the American Heart Association. He is currently an Interventional cardiologist and Director of Research at the Minneapolis Heart Institute Foundation at Abbott Northwestern Hospital and an Associate Professor of Medicine in the Cardiovascular Division at the University of Minnesota. His current research interest involves the mitigation of infarct size and reperfusion injury, the role of microvascular obstruction (MVO) and the delivery of biomaterials and stem cells following myocardial infarction and in heart failure.

For the past 15 years he has been significantly involved in the development of clinical trials and delivery of cardiovascular stem cell therapy in the setting of acute MI, CHF or refractory angina. In 2005, He obtained an IND to begin the first stem cell trial in the United States at the Minneapolis Heart Institute using bone marrow mononuclear cells (BMCs) in the setting of acute myocardial infarction (AMI). That trial and their selection to the NHLBI Cardiovascular Cell Therapy Research Network (CCTRN) led to the development of the TIME and LateTIME STEMI Trials of which he was the Principal Investigator. He have been involved as an Investigator in nearly every important cell therapy trial for the United States for STEMI (TIME, LateTIME, CADUCEUS), heart failure including FOCUS-CCTRN, CONCERT-HF, DREAM-HF (Mesoblast), ATHENA (Cytori), Ixmyelocel-T (Aastrom) and the Baxter trials for refractory angina using autologous CD34+ stem cells. He has served on the task forces of the AABB and FACT to develop clinical standards for cell therapy in the cardiovascular field.

In addition to participating in several CV gene therapy trials (AC-6, SDF-1, I1-c) they were the leading enrollers in North America in the recently completed PRESERVATION Trial (Bellerophon, Inc.) that investigated the benefit of

biomaterials (alginate) in the setting of AMI and in the Phase I trial delivering a porcine-derived cardiac extracellular matrix following acute myocardial infarction (Ventrix, Inc). They currently have an IND to expand this therapy to patients undergoing CABG who cannot be completely revascularized.

Dr. Traverse served as a GWG member for 6 years. He reviewed for Coordinating and Information Management Center awards.

**Darin Weber, PhD**

Dr. Darin Weber is Senior Vice President of Regulatory Development for ProKidney, headquartered in Washington, responsible for leading the development and implementation of global regulatory strategy, and Principal Consultant for Advanced Therapies Regulatory Advisors LLC. Dr. Weber has been working in the field of cell and gene advanced therapies for more than 20 years. He is a leading regulatory expert for cellular and tissue based regenerative medicine products, with the proven ability to develop and implement regulatory strategies that shorten the time of entry of ground-breaking medical products into clinical trials.

Dr. Weber earned his BS from Evergreen State College and PhD in Biochemistry and Biophysics from Oregon State University. Prior to joining industry, he spent over seven years at the U.S. Food and Drug Administration, Center for Biologics Evaluation and Research, working as a regulatory project manager, regulatory review officer and most notably as Chief, Cellular Therapy Branch in the then newly created Office of Cellular, Tissue and Gene Therapies. During his time at the FDA, Dr. Weber was actively involved in the development of policies and guidance documents for cellular and tissue-based products. Following his tenure at the FDA, he served as a Senior Consultant on cellular and gene therapies at the Biologics Consulting Group LLC, then Executive Vice President of Global Regulatory Affairs & Quality Management at Mesoblast, and then Senior Vice President of Regulatory Affairs & Quality Assurance at Medeor Therapeutics. Dr. Weber is a long serving member of national and international expert committees—such as the U.S. Pharmacopeia (USP) Expert Committee responsible for cellular and tissue-based products as well as committees within the International Society for Cellular Therapy (ISCT)—seeking to standardize global practices for medical therapies.

Dr. Weber served as a GWG member for 6 years. He reviewed for Translational stage program awards, Disease Team Therapy awards, and Infrastructure Translating Center awards. He has also served on multiple Clinical Advisory Panels and Translational Advisory Panels.

Fred Fisher  
Patient Advocate, ALS

#### Board Member Appointment

Fred Fisher is the President and CEO of The ALS Association Golden West Chapter, an organization focused on finding an effective treatments and cures for amyotrophic lateral sclerosis (ALS, also known as Lou Gehrig's Disease). The Golden West Chapter provides services, develops and funds ALS research programs and advances state and federal public policy initiatives for the benefit of those living with ALS. The Chapter's geographic scope reaches throughout most of California and Hawaii and is funded largely through philanthropic efforts. The Golden West Chapter provides funding to the three other Chapters in California, as well as to eight Certified Treatment Centers of Excellence. As such, the Chapter's Wraparound System of Care provides service and support to everyone living with ALS in CA.

Fred has been the Chapter's President and CEO since 2003, placing him among the longest tenured and most productive ALS executives in the United States. He has more than 35 years of experience leading non-profit social service and health organizations, including those serving children, families, the frail elderly, high-risk youth and the mentally ill. As a Licensed Clinical Social Worker, he has the experience, commitment and vision to execute creative and innovative programs that have an important and meaningful impact. His commitment to evidence-based initiatives and outcomes-based service delivery, results in the identification and integration of best practices which result in higher quality and greater impact.