

Memorandum

To: Members of the ICOC
From: Gil Sambrano, Vice President, Portfolio Development and Review
Re: Nominations for Appointment of Scientific Members to the Grants Working Group
Date: March 26, 2026

Background

The purpose of the Grants Working Group (GWG) is to provide recommendations to the ICOC regarding the merit and funding of grant and loan applications. The GWG evaluates the merit of applications across all five of CIRM's funding pillars in Discovery, Preclinical, Clinical, Education and Infrastructure. The scope of proposals we receive is very broad ranging from fundamental biology projects to advanced clinical trials across numerous disease areas and fields of study that use stem cell-based approaches, gene therapy and regenerative medicine.

To cover this breadth of expertise, CIRM maintains a large pool of Board-appointed GWG members (**currently 265 members**) with expertise in many areas including education, fundamental biology, translational research, medicine, product manufacturing, drug development, regulatory affairs, and clinical trials. The pool of Board-appointed GWG members allows us to compose and tailor each review panel to the needs of a specific set of applications.

Appointments to the GWG follow a set of requirements prescribed in Prop 71 and Prop 14 including specific durations (terms) of service. The pool of GWG members is in constant flux due to variable terms of service, changes in members' availability, and also changing expertise needs as scientific fields evolve. As such, we regularly bring for your consideration nominations for the appointment and/or re-appointment of GWG members to maintain a consistently active and relevant pool of experts on hand.

This quarter, we propose to appoint one new GWG member. We also have six GWG members whose appointment term is expiring and propose to reappoint. We have provided a brief bio of each member that provides a summary of their research interests, scientific training, and salient accomplishments. Additionally, we'd like to share some figures related to the notable increase over the last few years in the fraction of GWG scientific members who are women and their increased participation in GWG panels.

Requested Action: CIRM requests ICOC approval of the proposed new appointment and reappointments to the GWG.

New Appointment

CIRM is seeking the appointment of the individual listed below so that they may join the pool of members drawn upon to serve as panelists on GWG reviews. This appointment will strengthen the GWG's expertise across several areas as briefly summarized in the following description.

Dr. Fitzgerald is a pediatric epileptologist with expertise in novel therapies for genetically based epilepsies. We have seen an increase in CLIN2 applications for gene therapy projects in pediatric neurological indications, with epilepsy in particular.

Mark P. Fitzgerald, MD, PhD, FAES
Associate Professor of Neurology
Perelman School of Medicine, University of Pennsylvania

Referral: Mark was identified by CIRM Review Team.

Expertise Relevance to CIRM GWG: Mark Fitzgerald's expertise in epilepsy and gene therapy will be invaluable in reviewing Clinical program applications.

Prior Service in CIRM Reviews: Mark has participated as a specialist for Clinical program reviews.

Mark P. Fitzgerald, MD PhD is an Associate Professor of Clinical Neurology at the Perelman School of Medicine at the University of Pennsylvania and an attending pediatric epileptologist in the Division of Neurology and the Medical Director of the Epilepsy Neurogenetics Initiative (ENGIN) at Children's Hospital of Philadelphia (CHOP). He has a special interest in treating infants and very young children with epilepsy. He focuses on neurodevelopmental and epilepsy outcomes in children with a variety of genetic epilepsies. He has also served as the PI for multiple industry sponsored clinical trials of novel therapies for genetically based epilepsies, including small molecule and ASO/gene therapy trials.

Re-appointments

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
Guest	James	3	6	Neurotherapeutics, Clinical Trial Design, Spinal Cord Injury
Krasnodembskaya	Anna	2	6	MSC-based Therapies for Lung Diseases, MSC Extracellular Vesicles, Lung-resident MSC, Lung Organoid Models
O’Kane	Cecilia	2	6	ARDS; Biologic and Cell Therapies for Lung Infection and Inflammation
Reeves	R. Keith	2	2	Innate Immune Response to Infectious Disease
Thomas	Paul G.	2	4	Immunology, Influenza, T Cell Receptor Repertoires
Williams	Michelle LeRoux	3	6	Clinical and Nonclinical Research Regulatory Affairs

James Guest, MD, PhD, FAANS

James D. Guest, MD, PhD, FAANS, is a Professor of Neurological Surgery at the University of Miami Miller School of Medicine and a senior investigator at The Miami Project to Cure Paralysis. He is an internationally recognized neurosurgeon-scientist with more than three decades of experience spanning basic neurobiology, translational therapeutics, and multicenter clinical trials in spinal cord injury and related neurological disorders.

Dr. Guest’s research expertise encompasses cell-based and extracellular vesicle therapies, gene and biologic approaches, invasive and non-invasive neuromodulation technologies, neurophysiology, and systems-level rehabilitation strategies. He has authored more than 250 peer-reviewed publications and book chapters and has played a central role in defining international standards, outcome measures, and trial methodology for spinal cord injury research. His work emphasizes rigorous mechanistic rationale, appropriate preclinical validation, and realistic pathways to clinical translation.

He is the Co-Chair and Principal Investigator of the North American Clinical Trials Network (NACTN) for the Treatment of Spinal Cord Injury, a multicenter consortium that has conducted pivotal acute and chronic interventional studies and developed prospective registries used to inform trial design and care standards. Through this role, Dr. Guest has extensive experience evaluating trial readiness, endpoint selection, safety monitoring, and go/no-go decisions for translational programs. He has also served on data safety monitoring boards and scientific advisory boards for academic, foundation, and industry-sponsored studies.

Anna Krasnodembskaya, PhD

Professor Anna Krasnodembskaya (PI) is Chair of Cell-based Therapies and Regenerative Medicine at Queen's University of Belfast in the United Kingdom. She earned a PhD at St. Petersburg State University, Russia and completed postdoctoral training at the Cardiovascular Research Institute at UCSF after which she was appointed as a Lecturer and Research Group Leader at Queen's University Belfast, UK in 2013. She was promoted to Reader in 2019, followed by promotion to Professor in 2025.

Our studies are focused on understanding the mechanisms of respiratory diseases and development of regenerative therapies. In particular, we are interested in the development of Mesenchymal Stem Cells (MSC) - based therapies, investigation of the mechanisms of action of MSCs and MSC extracellular vesicles in the injured lung and the role of lung-resident MSCs in lung repair and regeneration. We also have strong interest in physiologically relevant models of the human lung tissue such as organoids, lung-on-chip and decel-recel approach. We have recently established a novel organoid model of the distal lung based on primary human cells.

Ongoing work is investigating the ability of MSC-derived extracellular vesicles to alleviate lung injury through transfer of healthy mitochondria, the role of epithelial senescence in ARDS, and the role of endogenous lung MSCs in regulation of endothelial and epithelial cells using an organoid model of the distal lung.

Cecilia O'Kane, MRCP, PhD

Dr. O'Kane is a physician-scientist and holds the position of Clinical Professor at the School of Medicine, Dentistry and Biomedical Sciences at Queen's University Belfast in the United Kingdom. She trained as a physician in respiratory medicine at Queen's University and earned a PhD at Imperial College London studying tuberculosis.

Dr. O'Kane's research interests include respiratory failure in the critically ill, particularly the Acute Respiratory Distress Syndrome (ARDS), mechanisms of tissue damage and repair in the lung, mycobacterial infection including Tuberculosis and Non-Tuberculous Mycobacterial infection, and novel therapies including biological and cellular therapies to treat infection and inflammation in the lung. Her group works in both wet lab and clinical research, and has a particular focus on human models of the lung environment. She is involved in the REALIST clinical trial, a Wellcome Trust HICF-funded trial of umbilical cord-derived mesenchymal stromal cells in patients with moderate-severe ARDS to test the safety and efficacy of novel MSCs in reducing inflammation and promoting repair in ARDS.

Dr. O'Kane has contributed over 90 scientific publications, was elected to the Royal College of Physicians of Edinburgh, and the Association of Physicians of Great Britain and Ireland. She is co Editor-in-Chief of the journal Thorax.

R. Keith Reeves, PhD

Dr. Reeves obtained his Ph.D. at the University of Alabama-Birmingham studying dendritic cell biology in lentivirus infections, then completed his postdoctoral training in lentivirus vaccinology, natural killer cells, and innate immunity at Massachusetts General Hospital, and Harvard Medical School (HMS). He later became faculty at HMS and Beth Israel Deaconess Medical Center through the rank of Associate Professor. Upon being recruited to Duke University in 2021, Dr. Reeves became a tenured Professor in the Department of Surgery and the Department of Pathology, Director in the Duke Center for Human Systems Immunology and Co-Director of the Center Excellence for Multiscale Immune Systems Modeling. He currently

serves as Editor-in-Chief of the journal *AIDS Research and Human Retroviruses* and is past chair of the NIH HIV Immunopathogenesis and Vaccine Development study section. Dr. Reeves' research has been continuously supported by NIH for well over 15 years, having served as PI on multiple R and P grants in addition to participating in consortia grants such as the HIV Vaccine Trials Network and BEAT-HIV Delaney Cure Collaboratory. Considered a global expert in natural killer cell biology, his research has provided some of the most detailed characterizations of NK cell responses against viruses, and his team was the first to identify memory and memory-like NK cells in humans and nonhuman primates. With over 120 publications in the field Dr. Reeves' group continues to focus on cutting-edge approaches to harness NK cells in the context of vaccines and immunotherapeutics for HIV, CMV, HCV, influenza, congenital CMV, and cancer.

Paul G. Thomas, PhD

Paul Thomas obtained his undergraduate degree in Biology and Philosophy at Wake Forest University. He did his PhD training at Harvard University, working on the innate immune response to Schistosoma-associated carbohydrates and their role in promoting Th2 responses. From there, he moved to St. Jude Children's Research Hospital for a postdoctoral fellowship with Peter Doherty on T cell responses in the influenza model. In 2009, he started his own lab at St. Jude, where his lab studied innate and adaptive immunity to viral infections. Subsequently he became the Bezos Family Distinguished Scholar in Viruses and Vaccines and the Immunology and Vaccine Development Program Director at Fred Hutchinson Cancer Center in Seattle, WA. His work covers various topics, including decoding the specificity of the T cell receptor repertoire in infections and tumors, understanding the immunological basis of severe respiratory disease, and the interactions between innate and adaptive immune responses during various viral infections.

Michelle LeRoux Williams, PhD

Michelle LeRoux Williams, Ph.D. was formally the Chief Scientific Officer of Elutia. Prior to joining Elutia, Dr. Williams served as Chief Operating Officer for Tissue Banks International, where she was responsible for its musculoskeletal business. Previously, Dr. Williams served as Chief Scientific Officer of Osiris Therapeutics, where she invented Osteocel®, the world's first commercially available stem cell product; led the team that obtained regulatory approval of the world's first FDA-approved stem cell drug, Prochymal® (remestemcel-L) for the treatment of severe graft-versus-host disease in children; and oversaw the development of three additional stem cell products, Grafix®, Cartiform® and Ovation®.

Dr. Williams is a fellow in the American Institute for Medical and Biological Engineering (AIMBE) and an internationally recognized expert in biologics and cell therapy. She earned a PhD in biomedical engineering from Duke University and a Bachelor's degree in mechanical engineering from Rice University. Dr. Williams completed an NIH postdoctoral fellowship in tissue engineering at Columbia University.

Representation of Women Scientific Members on the Grants Working Group

Over the last 5 to 6 years, CIRM has strived to increase the breadth of the GWG membership to better represent the community of scientists in the field of cell and gene therapy and ultimately the diversity of people we serve. The figure below shows the percentage of women GWG members and the percentage of women actively participating in GWG panel reviews each year between 2020 and 2025. Membership on the GWG has nearly doubled over this timespan and participation has increased about 178 percent.

