Nominations for Appointment to the Grants Working Group (GWG)

NEW APPOINTMENTS
Andrew Fesnak, MD
Assistant Professor, University of Pennsylvania

Referral: Dr. Fesnak was identified by Dr. Bruce Levine.

Expertise Relevance to CIRM GWG: Dr. Fesnak's expertise in biomanufacturing clinical grade cell therapy products in an academic laboratory and developing and overseeing workforce training programs for many different learners will be invaluable in reviewing Infrastructure, Translational, and Clinical program awards.

Prior Service in CIRM Reviews: N/A

Bio:
Dr. Andrew Fesnak is an Assistant Professor in the Division of Transfusion Medicine and Therapeutic Pathology in the Department of Pathology and Laboratory Medicine in the Perelman School of Medicine at the University of Pennsylvania. He earned his BA in Molecular Biology from Princeton University and his MD from Robert Wood Johnson Medical School. He completed Clinical Pathology residency and Transfusion Medicine fellowship at the Hospital of the University of Pennsylvania. Currently, Dr. Fesnak is the Deputy Director of Clinical Cell and Vaccine Production Facility (CVPF) and the Director of the Hematopoietic Stem Cell and Cell Processing Laboratory in the Hospital of the University of Pennsylvania. The CVPF is an academic GMP-compliant engineered cell therapy manufacturing facility. As the Deputy Director and prior as the Director of Clinical Manufacturing, Dr. Fesnak has reviewed and released more than 600 individual cell therapy products for more than 24 different clinical trials. Under Dr. Fesnak's guidance, the CVPF manufactured many of the fields pioneering agents including the world's first CRISPR-engineered, redirected T cell products used in humans. Dr. Fesnak also plays numerous roles in the area of cell therapy education and workforce development. Dr. Fesnak is the Director of Regulatory Education in the Institute for Translational Medicine and Therapeutics, overseeing the Master of Regulatory Affairs and Master of Science in Regulatory Science. He directs several graduate level courses run annually. Globally, Dr. Fesnak has served as the chair of the Association for Advancement of Blood and Biotherapies (AABB) Cell Therapy Education Committee, where he was a founding faculty member of the AABB Cell Therapy Certification Program. In 2022, he led development of a foundations level online training course for cell therapy professionals. Dr. Fesnak was a co-investigator and course moderator for the NCI Awardee Skill Development (NASDC) UE5 short-course series on Cell and Gene Therapy Translation (CGTT).

Christopher Gaiteri, PhD
Associate Professor, SUNY Upstate Medical University

Referral: Dr. Gaiteri was referred by Dr. Nathan Price.

Expertise Relevance to CIRM GWG: Dr. Gaiteri's expertise in systems biology, including its application to research Alzheimer's disease, aging, and psychiatric conditions, will be invaluable in reviewing Discovery stage program awards.

Prior Service in CIRM Reviews: Dr. Gaiteri has served as a reviewer for the Discovery stage program.

Bio:
Dr. Christopher Gaiteri is Associate Professor in the Department of Psychiatry at SUNY Upstate Medical University. His overall research goal is to advance effective treatments for Alzheimer's disease, with a theme of integrating

computational and experimental approaches. To assist in this mission, he builds methods that extract molecular networks from brain omic datasets and define molecular control points within them, then joins with experimental biologists to test the function of these molecules. However, since this hybrid style of research is isolated from neuroimaging approaches to disease, he and his collaborators have assembled brain-based omics, fMRI, MRI and cellular morphology data—all on the same set of individuals—which is allowing us them to build a Rosetta stone of how different biophysical scales in the brain interact in health and disease. Continuing with this theme of bringing siloed aspects of research together, he and his collaborators are also building collaborator recommendation systems, so that results can be repurposed across scientific fields. In summary, they are producing research and alliances to more effectively integrate approaches to Alzheimer's on multiple biophysical scales.

Dr. Gaiteri earned his PhD Neurobiology at University of Pittsburgh in 2011. The motivation for using computation to drive novel experiments led to his employment at various places, and was also generated by them. He started out at Sage Bionetworks, where he benefited from the early systems biology work of Eric Schadt/Jun Zhu/Bin Zhang, because at the time even the use of microarrays was novel, let alone taking them as a serious means to drive experiments. Subsequently, working at the Allen Institute, he was able to get a taste for audacious big data generation projects. He moved to Rush University because they had the biggest pile of Alzheimer's brain pathology data in the world, but hadn't capitalized on it with brain omics. There, he started on his usual path of trying to single-handedly be their omics person, providing support for multiple AMP-AD groups. As the rate data swelled, he benefited from hiring some of the best individuals he'd worked with previously, finding them so deeply talented and effective that increasingly he thinks his strongest contribution to Alzheimer's research is aiming and igniting other scientists. In summary, Dr. Gaiteri is an enthusiastic systems biologist focused on Alzheimer's disease who has utility in assisting with sprawling projects.

Fraser Sim, PhD
Professor of Pharmacology & Toxicology, SUNY University at Buffalo

Referral: Dr. Sim was referred by Dr. Mark Noble.

Expertise Relevance to CIRM GWG: Dr. Sim's expertise on CNS stem cells will be invaluable in reviewing Discovery stage program awards.

Prior Service in CIRM Reviews: Dr. Sim has served as a reviewer for the Discovery stage program.

Bio:
Dr. Fraser Sim is Professor of Pharmacology & Toxicology and Director of the Neuroscience Program at SUNY University at Buffalo Jacobs School of Medicine and Biomedical Sciences. His research focuses on neurobiology, neurodegenerative disorders, and genomics and proteomics. His lab investigates the molecular control of cell fate and homeostasis of resident stem and progenitor cells in the human brain. Using a combination of multicolor cell sorting techniques and whole genome analysis, they are characterizing the signaling pathways which regulate the formation and fate of human oligodendrocyte progenitor cells and testing the functional significance of these pathways using both pharmacological and viral methods in culture and animal-based models of myelination and demyelination.

Dr. Fraser Sim earned his MA in Natural Sciences and PhD in Molecular Neurobiology from Pembroke College at Cambridge University. He holds 4 patents including identification of tumor stem cell markers for use as a diagnostic and therapeutic target in primary neural and glial tumors of the brain, optimized cell preparation for myelin disorders, and has published over 40 journal articles. Among other commitments, he is a member of the New York State Spinal Cord Injury Research Board, has served as a grant reviewer on for the NIH (most recently serving on the study sections for Neurological Sciences and Disorders, Cellular and Molecular Biology of Glia, Neuronal Vulnerability to Proteinopathies in ADRD), has served as a panel member for the Department of Defense Congressionally Directed Medical Research Programs in Multiple Sclerosis study sections, has served as a National Science Foundation and hoc merit reviewer, has reviewed for the Biomedical Research Committee of the National Multiple Sclerosis Society and reviewed for various awards overseen by the Wellcome Trust in the UK. In addition to having served as an ad hoc reviewer for over 50 journals, he serves as an editorial board member of *GLIA*, and has served as guest editor for *Frontiers in Neuroscience* and *Neurotherapeutics.*

REAPPOINTMENTS

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

Proposed Reappointments to GWG

Last	First	Term	Years	Expertise
Bailey	Alex	2	2	Non-clinical Regulatory; Clinical Regulatory; Pharmacology/Toxicology; Cell and Gene Therapy; Tissue engineering
Vallier	Ludovic	3	6	Pluripotent Stem Cell Biology; Endoderm; iPSC Modeling of Liver & Metabolic Disease

Alex Bailey, PhD
Dr. Alex Bailey is the Head of Early Program & Platform Development at REGENXBIO Inc, a gene therapy company developing treatments for retinal, metabolic and neurodegenerative diseases. During his tenure at REGENXBIO, he has also served as Product Development Lead and Global Regulatory Lead for numerous preclinical and clinical-stage programs, primarily in rare disease. Prior to REGENXBIO Inc, Alex spent over five years at the FDA Center for Biologics Evaluation and Research (CBER), initially as a Pharmacology/Toxicology Reviewer and subsequently as the Team Leader in the Pharmacology/Toxicology Branch in the Office of Cellular, Tissue and Gene Therapies (OCTGT).

Dr. Bailey received his PhD in Biomedical Engineering from the University of Virginia and conducted post-doctoral research at the Fred Hutchinson Cancer Research Center in Seattle, WA. While he was Team Lead at FDA CBER OCTGT (office since renamed to OTP), he provided scientific and regulatory oversight of a team of experienced Pharmacology/Toxicology reviewers responsible for the regulatory review of preclinical studies to support the safe use of investigational cell therapies, gene therapies, tissue engineered products, and medical devices in human clinical trials. In this role, he was also responsible for developing consensus on regulatory strategies for preclinical, manufacturing, and clinical development of CBER-regulated biologics across broad therapeutic areas. Dr. Bailey served as Subject Matter Expert on numerous committees and working groups within the FDA, as well as contributed to the development of guidance documents. He completed the FDA CBER Leadership Program and was a recipient of the FDA CBER awards for Managerial Excellence and Policy Development. He was a Fellow in the FDA Commissioner's Fellowship Program (Class of 2010), where he designed a database of product development and preclinical testing strategies for cell-based regenerative medicine products to assess data quality, identify trends, and stratify products based on potential for tumor formation. Later, he served as a Preceptor for the Commissioner's Fellowship program.

Dr. Bailey has served on the GWG for almost 6 years. He has reviewed for Clinical and Translational stage programs.

Ludovic Vallier, PhD
Dr. Ludovic Vallier is Einstein Professor for Stem Cells in Regenerative Therapies at the Berlin Institute of Health (BIH) and Max Planck Fellow at the Max Plank Institute for Molecular Genetics (MPIMG). He received his PhD from Ecole Normale Superieure of Lyon /University Claude Bernard in 2001 where he studied the function of cell cycle regulators in pluripotency. He then joined the group of Prof. Roger Pedersen at the University of Cambridge, Department of Surgery, where he uncovered the mechanisms by which TGFβ signaling controls self-renewal and differentiation of human pluripotent stem cells. He became an independent investigator in 2008 after receiving a MRC non clinical senior fellowship and was named Professor of Regenerative Medicine in 2015. He was the manager of the NIHR Cambridge Biomedical Research Centre human Induced Pluripotent Stem Cells core facility between 2009-2022 and was co-deputy director of the Wellcome and MRC Cambridge Stem Cell Institute until 2022. His group based at the BIH Center for Regenerative Therapy (BCRT) and MPIMG takes advantage of human pluripotent stem cells and primary organoids to generate liver cells with a clinical interest for disease modelling and cell-based therapy. More precisely, they investigate the molecular mechanisms controlling cell fate decisions during human liver development and exploit the resulting knowledge to produce hepatocytes and cholangiocytes. The resulting cells are currently used to study metabolic disorders and to develop regenerative medicine applications against liver diseases.

Dr. Vallier has served as a GWG member for 10 years. He has reviewed for Discovery and Translational stage programs as well as COVID-19, tissue collection for disease modeling, and hispc derivation offerings.