CIRM
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Nominations for Appointment to the Grants Working Group (GWG)

NEW APPOINTMENTS

Shirley Bartido, PhD, MBA
Director of Global Regulatory Affairs of Cell Therapy Oncology, Takeda

Referral: Dr. Bartido was identified by CIRM Therapeutics Team.

Expertise Relevance to CIRM GWG: Dr. Bartido's expertise in regulatory affairs and cell therapy oncology will be invaluable in reviewing Clinical and Infrastructure program applications.

Prior Service in CIRM Reviews: NA

Dr. Shirley Bartido is currently Takeda's Director of Global Regulatory Affairs in Cell Therapy Oncology. Dr. Bartido holds a PhD in Immunology and an MBA in Pharmaceutical Management from Rutgers University. She completed her doctoral studies at New York University elucidating an alternative Class II processing and presentation pathway utilizing a viral antigen. Her postdoctoral work at Memorial Sloan Kettering Cancer Center involved the development of DNA vaccines for the treatment of melanoma using the melanosomal antigen tyrosinase. Following her postdoctoral work, she joined the Carl Icahn Institute of Gene Therapy and Molecular Medicine as an Assistant Professor to serve as the Assistant Director of the Gene Therapy Immunology Core Laboratory. In this role, she developed several immunomonitoring tools for assaying efficacy of adenoviral directed immunotherapies using AdV-IL-12 vectors targeting metastatic liver cancer. This was followed by an 11-year role as the Senior Quality Manager of the Cell Therapy and Cell Engineering Facility at Memorial Sloan Kettering Cancer Center. In this role, she developed the QA program for the development and GMP manufacturing of autologous CD19 Chimeric Antigen Receptor T-cell therapies for several clinical trials which targeted several indications in leukemia and prostate cancer as well as gene therapy for the treatment of B-Thalassemia using lentiviral transduced CD34+ HPSCs. She was an integral member in the design and construction of a state-of-the-art GMP facility at MSKCC. She then proceeded to become the Director of Regulatory Affairs at Cellectis Inc, a French based company. The company's platform consists of incorporating gene editing TALEN based technology in the development of allogeneic CAR T-cells targeting hematological malignancies. Currently, at Takeda, she is the global regulatory lead in several cell therapy projects that seek to broaden the impact of immunotherapy in cancer treatment by focusing on mechanisms that leverage innate immunity. She has authored several peer-reviewed publications in several well cited scientific journals and has been invited as speaker in many well attended international and regional conferences.

Mari-Lynn Drainoni, MEd, PhD
Research Professor, Boston University

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

Expertise Relevance to CIRM GWG: Dr. Drainoni's expertise in implementation science will be invaluable in reviewing Infrastructure program applications.

Prior Service in CIRM Reviews: NA

Mari-Lynn Drainoni, M.Ed., Ph.D., is Research Professor in the Section of Infectious Diseases in the School of Medicine in the Chobanian and Avedisian School of Medicine and in the Department of Health Law, Policy & Management at the Boston University School of Public Health. She is also Co-Director of the Evans Center for Implementation and Improvement Sciences at Boston University. Dr. Drainoni's areas of expertise include the conduct of implementation research, qualitative research methods and mixed method studies with a focus on integrating research into practice. Her specific studies have focused on the content areas of infectious diseases, including HIV/AIDS and hepatitis C, as well as substance use, antibiotic prescribing and antibiotic stewardship, and integrating screening for social determinants of health into clinical practice. Dr. Drainoni has conducted numerous implementation studies to integrate research into practice, studies evaluating demonstration programs for at-risk populations, and mixed methods studies that include both surveys involving primary data collection and qualitative data collection and analysis. Some of her

current research projects include: 1) an AHRQ-funded study evaluating alternative implementation strategies for antibiotic stewardship in two large inpatient hospital systems across the US; 2) a HRSA-funded study to implement and evaluate the use of community health workers to improve retention and outcomes in clinical care for persons living with HIV in 10 sites across the US; 3) a NIDA-funded study to examine police-led models of engaging people in treatment for opioid addiction in Massachusetts; 4) serving as the Implementation Science Core Director of the Healing Communities Study, a NIDA/SAMHSA-funded study in four states to implement and evaluate interventions designed to reduce overdose deaths; 5) an NHLBI-funded project to assess the implementation of a social determinants of health screening and referral intervention for children with sickle cell anemia; 6) a study of the uptake of rapid diagnostic tests for infectious disease and behavioral factors influencing use of rapid diagnostic tests; 7) an NICHD-funded study to test and implement an intervention designed to screen for social determinants of health and unmet material needs in pediatric practices across the US; 8) a VA-funded initiative to implement and evaluate a peer intervention for veterans leaving incarceration; 9) an American Cancer Society-funded study evaluating an intervention designed to improve offering the HPV vaccine in community health centers; and 10) leading the implementation science component of a PCORI-funded study to compare two brief interventions within the primary care medical home to assess the most effective strategy to improve outcomes among pregnant and postpartum women with depressive symptoms, assess the optimal time to deploy each strategy and examine the barriers to establishing these interventions. Dr. Drainoni also is the Implementation Science Lead on the Providence-Boston Center for AIDS Research (CFAR), Implementation Science Lead on the Lifespan/Brown Criminal Justice Research Program on Substance Use and HIV, and Principal Investigator on the Boston University School of Public Health NIDA-funded T32, Integrated Care for Addiction, HIV and HCV Research and Education (ICAHRE).

Kimberly Fulda, DrPH
Director, North Texas Primary Care Practice-Based Research Network

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

Expertise Relevance to CIRM GWG: Dr. Fulda's expertise in community based clinical research and health disparities will be invaluable in reviewing Infrastructure program applications.

Prior Service in CIRM Reviews: NA

Dr. Fulda is the Director of the North Texas Primary Care Practice-Based Research Network (NorTex). NorTex is a network of primary care clinics that conduct research to improve the health of our community. She primarily conducts research on health disparities; however, NorTex research covers a wide array of research topics relevant to primary care. Her research is interdisciplinary and includes investigators from many fields. Dr. Fulda also has experience in evaluation and has served as an evaluator for multiple federally funded projects. She has specific expertise in public health, health disparities, clinical research, and research design and analysis.

Anna Herland, MSc, PhD
Professor, SciLifeLab, KTH, Royal Institute of Technology

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

Expertise Relevance to CIRM GWG: Dr. Herland's expertise in metabolic and immune interactions in neurological disorders will be invaluable in reviewing Discovery program applications.

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

Dr. Herland's research group at KTH, Royal Institute of Technology, and Karolinska Institutet at Sclifelab focuses on creating advanced in vitro systems. They develop analytical and cell-based microfluidic in vitro systems that predict human outcomes. For both in vitro and in vivo applications, they develop stimuli and read-outs for realtime assessment of biological functions of mammalian cells. The focus area is neural in vitro models, where they use stem cell-derived cells and primary human and animal cells to study cellular interactions and blood-brain barrier functions. She has led collaborative projects with Pharma-industry since 2010, in industrial collaborations with AstraZeneca and other biotech companies. Her national and international academic research collaborations include microfluidics, stem cell biology, and neurodegenerative disease.

Seraphin Kuate, MSc, PhD
CMC Regulatory, Bristol Myers Squibb

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

Expertise Relevance to CIRM GWG: Dr. Kuate's expertise in CMC regulatory affairs and immune therapy will be invaluable in reviewing Translational program applications.

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

Dr. Kuate is an accomplished, strategy-focused, and US FDA-trained Regulatory Affairs Professional with over 24 years of experience in the development, manufacturing and regulation of biotechnology-based products including more than 12 years of unique combined experience as CMC reviewer at the Center for Biologics Evaluation and Research (CBER) and as CMC regulatory at several biopharmaceutical companies supporting the development, manufacturing and life cycle management of biologics/biotechnological-based drug products including biologics (NBRs and biosimilars), biologics and small molecule conjugates (e,g, ADC), immunoglobin intravenous (IVIGs), and gene/cell therapy products. Strong analytical skills and solid scientific background understanding and addressing regulatory CMC requirements through all phases of product development. More than 12 years of experience as research scientist in biotechnology product development with 23 scientific peer-reviewed publications and a book chapter. Experience communicating with regulatory authorities, leading regulatory advice meetings, and filing clinical and marketing applications with major regulatory authorities/regions including among others: US, EU, Canada, and Japan.

Dr. Kuate has a Master's of Science degree in Biochemistry from the University of Yaoundé I, Cameroon, a PhD in molecular Virology/Immunology from Ruhr-University Bochum, Germany, a Master's of Science degree in Epidemiology/Biostatistics from the University of Bielefeld, Germany, and a dual degree Master's degree in International Management (MIM) / Masters of Business administration (MBA) from the University of Maryland University College (UMUC), Maryland, USA. Dr. Kuate also has several professional certifications including the Regulatory Affairs Certification (RAC) and the Certified Clinical Research Professional (CCRP) certification.

Anthony Lubinecki, ScD
CMC Consultant, AL Associates LLC

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

Expertise Relevance to CIRM GWG: Dr. Lubinecki's expertise in CMC will be invaluable in reviewing Clinical program applications.

Prior Service in CIRM Reviews: NA

Anthony S. Lubiniecki, Sc.D. is a member of AL Associates LLC, a consulting firm for biopharmaceutical development and CMC issues of biotechnology products. He retired from Janssen R&D in 2017 as Senior Scientific Director & Fellow, CMC Strategy, Pharmaceutical Development & Manufacturing Sciences at Janssen R&D, LLC. During his 43 years in industry, he worked on development of over 50 recombinant derived investigational products using both microbial and eukaryotic expression systems, of which fourteen have become marketed products, including Simponi, Stelara, Sylvant, Darzalez, and Tremfya during his 13 years at Janssen R&D LLC. He also led CMC strategy for 4 cell and gene therapy products which went to clinical trials for Janssen. At Janssen, he served as CMC Strategist on a number of large molecule projects including daratumumab, and as Vice President of Cell Culture and Tech Transfer. At GlaxoSmithKline and predecessor firms, he was vice president of biopharmaceutical development for 16 years. At Genentech, he was Director, Cell Culture Process Development for 6 years, leading to the global licensure of tissue plasminogen activator, the first recombinant DNA-derived biological prepared in cell culture. He has also provided review and/or scientific approval for over 80 IND, BLA, and supplemental BLA regulatory filings to FDA and international counterparts. Tony also has been active in shaping regulatory policy by serving as a Pharmaceutical Research & Manufacturers of America representative to the International Conferences on Harmonization (ICH) Expert Working Groups for 6 Q5-Q7 guidance documents and served as Rapporteur for two of them (ICH Q5D & Q5E). He was a member of the HHS Secretary's Advisory Committee on Xenotransplantation, a member of the Department of Commerce Material Technical Advisory Committee, and advisor to the Department of Defense biodefense measures program through the National Research Council/National Academy of Sciences. He earned his Doctor of Science degree in Public Health Microbiology from the University of Pittsburgh in 1972, and his Bachelor of Science degree in Biological Sciences from Carnegie Mellon University in 1968. He was also Adjunct Professor of Chemical & Biochemical Engineering at University of Maryland Baltimore County from 1991 to 2023.

Guo-li Ming, MD, PhD
Perelman Professor of Neuroscience and Associate Director of Institute of Regenerative Medicine, University of Pennsylvania

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

Expertise Relevance to CIRM GWG: Dr. Ming's expertise in neurodevelopment and neurological disease will be invaluable in reviewing Discovery program applications.

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

Dr. Ming is the Perelman Professor of Neuroscience and Associate Director of Institute of Regenerative Medicine at University of Pennsylvania. She received MD on Child and Maternal Care from Tongji Medical University in China in 1994 and Ph.D. from UCSD in 2002. After her postdoctoral training at the Salk Institute for Biological Studies, she became an Assistant Professor at Johns Hopkins University in 2003 and Professor in 2011. Her research centers on understanding molecular mechanisms underlying neurodevelopment and its dysregulation using patient-derived induced pluripotent stem cells. She has received Alfred P. Sloan Research Fellowship, Young Investigator Award from Society for Neuroscience, A. E. Bennett Research Award from Society of Biological Psychiatry, and Herman and Walter Samuelson Stem Cell Research Award. She serves on the ACNP Women's committee and as a member for BBRF council and AAAS council. She became a member of the National Academy of Medicine in 2019 and a member of AAAS in 2022.

Renato Polimanti, PhD
Associate Professor of Psychiatry, of Biomedical Informatics and Data Science, and of Chronic Disease Epidemiology, Yale University Schools of Medicine and of Public Health Wu Tsai Institute

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

Expertise Relevance to CIRM GWG: Dr. Polimanti's expertise in psychiatric disorders and pharmacogenomics will be invaluable in reviewing Discovery program applications.

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

Dr. Polimanti is an Associate Professor at Yale University with a primary appointment in Psychiatry and secondary appointments in Chronic Disease Epidemiology and in Biomedical Informatics and Data Science. His main areas of research are molecular epidemiology and biological psychiatry. Specifically, his studies are focused on the investigation of the pathogenic mechanisms of psychiatric disorders and behavioral traits using genomic data. Their final aim is to find molecular mechanisms that can be used to implement precision medicine tools such as accurate disease biomarkers and/or personalized therapies. Dr. Polimanti has reported his findings in over 200 peer-reviewed publications (44 as first author, 67 as last author; Google Scholar h-index=44 i10-index=138). These include publications in high-impact journals such as Nature, Science, Nature Neuroscience, Nature Genetics, JAMA Psychiatry, Lancet Psychiatry, Psychological Medicine, Biological Psychiatry Molecular Psychiatry, and the American Journal of Psychiatry. His ongoing projects are funded bythe National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), the Department of Veterans Affairs, and One Mind. Dr. Polimanti's group is also part of large collaborative efforts such as the Psychiatric Genomics Consortium, the Million Veteran Program, and the COVID-19 Host Genetics Initiative. Because of his recognized expertise, Dr. Polimanti served as a reviewer for grant applications submitted to national and international organizations such as the Alzheimer's Association, the Dutch Research Council, the Estonian Research Council, the National Institutes of Health, the National Science Foundation, and The Wellcome Trust/DBT India Alliance.

Heidi Russell, MD, PhD
Professor in the Department of Management, Policy and Community Health, University of Texas School of Public Health in Houston

Referral: Dr. Russell was identified by GWG member, Dr. Rayne Rouce.

Expertise Relevance to CIRM GWG: Dr. Russell's expertise in pediatric oncology, clinical research and health economics will be invaluable in reviewing Discovery, Clinical and Infrastructure program applications.

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

Dr. Russell is a Professor in the Department of Management, Policy and Community Health at the University of Texas School of Public Health in Houston. She has been in this position for two years, and prior to her current position she was a faculty member at Baylor College of Medicine in the Texas Children's Cancer and Hematology Centers for 28

years. She received her undergraduate degree from The Georgia Institute of Technology, her medical degree from the University of Alabama School of Medicine and completed her pediatrics residency and pediatric hematology-oncology fellowship at Baylor College of Medicine. After a decade of medical practice and clinical research, Dr Russell returned to school to receive her PhD in Public Health from the University of Texas School of Public Health.

In addition to pediatric oncology, Dr Russell's training includes health care systems, health economics and clinical research. She has published 67 peer reviewed manuscripts across these fields. She has served as co-investigator on NIH and foundational grants. Her current research direction is using large administrative and claims data to untangle how the medical delivery system affects clinical outcomes in pediatrics.

Amy Ryan, PhD
Associate Professor, Anatomy and Cell Biology and Associate Director, Center for Gene Therapy, University of Iowa

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

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

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

Amy Ryan is currently a tenured Associate Professor in the Department of Anatomy and Cell biology at the University of Iowa and Associate Director of the Center for Gene Therapy. She was recently awarded the title of Stead Family Scholar. Her research career to date has focused on mechanisms of airway regeneration with pioneering work on the use of induced pluripotent stem cells as models of the airway epithelium. She has published over 98 peer-reviewed research articles, with an H-index of 31 and has continued funding from the NIH, NSF, FDA, and the Cystic Fibrosis Foundation. She has an active role in the scientific community as chair of the biennial conference on Stem Cells, Cell Therapy, and Bioengineering in Lung Biology and Disease, Chair of the Respiratory & GI Tract Gene & Cell Therapy Committee for the American Society of Cell and Gene Therapy and will join the Women in Physiology Committee at the American Physiological Society in 2024.

Erica Shelton, MD, MPH, MHS
Senior Clinical Program Officer, Comparative Clinical Effectiveness Research, Patient-Centered Outcomes Research Institute (PCORI)

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

Expertise Relevance to CIRM GWG: Dr. Shelton's expertise in health services research focused on vulnerable populations will be invaluable to Infrastructure program applications.

Prior Service in CIRM Reviews: NA

Erica Shelton facilitates the oversight of several funded studies and initiatives focused on vulnerable populations and populations of color experiencing barriers or limited access to health care. She is responsible for strategic decision-making and planning, management, and monitoring of program portfolio and programmatic activities (e.g., topic development, advisory panels, workgroup meetings) to enhance and accelerate PCORI's patient-centered research agenda.

Prior to joining PCORI, Shelton conducted health services research focusing on optimization of health care access for vulnerable populations to decrease health disparities and enhance value and efficiency of emergency care. She has published in multiple peer reviewed journals and her research interests include increasing patient and community engagement in the health care system, especially among urban populations and communities of color, to overcome linkage barriers to follow-up care. She also completed a four-year term appointed by former Governor Larry Hogan as 1 of 11 Commissioners on the Maryland Community Health Resources Commission.

In addition to her work at PCORI, Shelton is also a practicing emergency medicine physician and an Assistant Professor in the Department of Emergency Medicine at Johns Hopkins University. Shelton earned her medical degree from UCLA/CDU and her Master of Public Health and Master of Health Sciences degrees from the Johns Hopkins University Bloomberg School of Public Health. She also holds an undergraduate degree in chemical engineering with a minor in African and African Diaspora studies from the Massachusetts Institute of Technology.

Julia Skapik, MD, MPH, FAMIA
Chief Medical Information Officer, National Association of Community Health Centers

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

Expertise Relevance to CIRM GWG: Dr. Skapik's expertise in dissemination and implementation science will be invaluable to Infrastructure program applications.

Prior Service in CIRM Reviews: NA

Julia Skapik is the Chief Medical Information Officer for the National Association of Community Health Centers (NACHC) and a board-certified Internist and Clinical Informaticist. At NACHC she heads the development of technology-enabled public health and quality improvement projects, a next-generation HIT data infrastructure and warehouse, a unified data dictionary for community health, and a curriculum for informatics and human-centered design. Dr. Skapik is an industry leader as the board chair of HealthLevel7 International and is currently a practicing community health primary care provider with Neighborhood Health of Virginia.

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
Breuer	Christopher	3	4	Cardiovascular Tissue Engineering
Broeckel	Ulrich	3	6	(Pharmaco)genetics & iPSC Modeling, Cardiovascular Disease
Robins	Allan	2	2	Stem Cell Manufacturing; Pluripotent Stem Cells

Christopher Breuer, MD
Christopher Breuer is Professor of Surgery and Director of Tissue Engineering Program at Nationwide Children's Hospital/ The Ohio State University. Dr. Breuer received his BA in Biology from College of the Holy Cross and his MD from Brown/Dartmouth. He completed an internship and residency in general surgery, a junior residency in pediatric surgery, a postdoctoral fellowship in surgical research, and was Chief Resident in both general surgery and pediatric surgery. Dr. Breuer is board certified in pediatric surgery.

Dr Breuer's research interests focus on the development of improved vascular grafts for use in congenital heart surgery where complications arising from currently used vascular grafts are a leading cause of morbidity and mortality. He runs an NIH funded laboratory investigating the cellular and molecular mechanisms underlying vascular neotissue formation in tissue engineered vascular grafts. He is the principal investigator on the first FDA approved trial investigating the use of tissue engineered vascular grafts in humans. Dr. Breuer's clinical interests include congenital heart disease and Fontan physiology.

Dr. Breuer has served on the GWG for 12 years. He has reviewed for Clinical and Translational programs.

Ulrich Broeckel, MD
Ulrich Broeckel is a Professor of Pediatrics, Adjunct Professor of Medicine and Physiology and the School of Pharmacy. He is the Chief of the Section of Genomics Pediatrics, at the Medical College of Wisconsin. He earned his MD from the University of Heidelberg and residency training in the Department of Internal Medicine at the University of Regensburg. Dr. Broeckel was a Research Fellow at the University of Ulm before moving to the Medical College of Wisconsin, initially as a postdoctoral fellow in the Laboratory of Genetics Research.

Dr. Broeckel's laboratory specializes in human genetics, pharmacogenetics, and the functional evaluation of genes and their variants involved in complex diseases. His research interest includes cardiovascular disease, in particular left ventricular hypertrophy, heart failure and the underlying risk factors with projects based on large epidemiological studies in clinical cohorts. Dr. Broeckel's laboratory utilizes patient-derived human induced pluripotent stem cells (hiPSC) for the study of complex disease function and genome annotation. In addition, he is the technical director of a CAP certified clinical diagnostic laboratory focused on chromosomal abnormality testing. Dr. Broeckel is a member of

the American Heart Association (AHA), the American Association for the Advancement of Science (AAAS), the American Society of Human Genetics, the European Society of Human Genetics and the International Society of Stem Cell Research (ISSCR). His research is supported by grants from the National Institutes of Health (NIH). He is also the founder and CEO of RPRD Diagnostics, a pharmacogenetics and precision medicine company based in Milwaukee, WI.

Dr. Broeckel has served on the GWG for 12 years. He has reviewed for Clinical, Discovery and Translational programs.

Allan Robins, PhD
Allan Robins is currently an Independent Consultant in the area of cell therapy manufacturing, process development and manufacturing scale up. He was previously Senior Vice President, Science and Technology at ViaCyte from June 2012 until June 2017. Dr. Robins was Acting CEO of ViaCyte from May 2011 until June 2012 and Vice President and Chief Technology Officer from 2004 until 2011. He oversaw company-wide cell manufacturing and process development activities along with research operations in Athens, Georgia. Prior to ViaCyte, Dr. Robins served as Senior Vice President and Chief Scientific Officer of BresaGen, Inc., the United States subsidiary of BresaGen Limited, an Australian biotechnology company that has since been acquired by Hospira, Inc. Under Dr. Robins' leadership, BresaGen, Inc. was awarded significant support for its stem cell research from the National Institutes of Health. BresaGen merged with ViaCyte's predecessor companies in 2004. Prior to BresaGen, Inc., Dr. Robins was Vice President and Chief Scientific Officer of BresaGen Limited, where he helped raise over $30 million and developed a proprietary expression system which continues to be used in the production of protein pharmaceuticals. Dr. Robins received a B.S. with honors in biochemistry and a Ph.D. in molecular biology from the University of Adelaide in Australia. He followed his studies with postdoctoral work at Cambridge University in England.

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