Nominations for Appointment to the Grants Working Group (GWG)

NEW APPOINTMENTS
John Balchunas, MS
Workforce Director, National Institute for Innovation in Manufacturing Biopharmaceuticals

Referral: Mr. Balchunas was referred by Dr. Shyam Patel.

Expertise Relevance to CIRM GWG: Mr. Balchunas's expertise in life science and biopharma economic development, workforce development, and public private partnership will be invaluable in reviewing Infrastructure program awards.

Prior Service in CIRM Reviews: N/A

Bio:
John Balchunas is the Workforce Director for the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) where he is responsible for guiding strategy around workforce and talent development for a federally-funded public private partnership focused on transforming biopharmaceutical manufacturing. John's career has largely centered around biopharma workforce and economic development. Prior to NIIMBL, John was responsible for business development and industry partnership for the professional development program at North Carolina State University's Biomanufacturing Training and Education Center (BTEC). Prior to BTEC, John served as the Director of Workforce Development for the North Carolina Biotechnology Center (NCBiotech) for 10 years where he forged an array of partnerships with industry to understand and communicate biopharmaceutical manufacturing workforce needs. John started his career as a technical writer in the biomanufacturing and medical diagnostic industries. John holds a Master of Science in Technical Communication and a Bachelor of Science in Microbiology from North Carolina State University and was selected as a Marano Fellow in the Aspen Institute's 2012-2013 Sector Skills Academy.

Allan B. Dietz, PhD
Consultant, Mayo Clinic

Referral: Dr. Dietz was referred by Dr. Shyam Patel.

Expertise Relevance to CIRM GWG: Dr. Dietz's expertise in academic GMP facilities and workforce development will be invaluable in reviewing Infrastructure program awards.

Prior Service in CIRM Reviews: N/A

Bio:
Dr. Allan B. Dietz is a Consultant in the Division of Transfusion Medicine, Department of Laboratory Medicine and Pathology, Consultant in the Department of Immunology and Associate Professor of Laboratory Medicine and Pathology. Dr. Dietz was a founder and the Director of IMPACT (Immune, Progenitor, and Cellular Therapeutics) a GMP facility at Mayo Clinic, Rochester in the Department of Lab Medicine and Pathology for over 20 years. IMPACT was charged with identifying, translating, and implementing the use of cells as drugs. Dr. Dietz established multiple cell therapy platforms that offered physicians across the Institution an opportunity to treat patients with investigational cell therapies. As an example, the cancer vaccine (immunotherapy) platform treated patients with NHL, GBM, Melanoma, and Ovarian cancer. Data from this platform has justified NIH funding of multiple phase II studies. The stem cell (MSC) platform has been evaluated in more than 15 independent trials with multiple indications. These trials continue to enroll in peer reviewed, funded phase II trials. Across the entire effort, the lab under Dr. Dietz' management manufactured more than 500 patient products and delivered more than 1000 doses of investigational

cell products for some of the most difficult to treat diseases. The lab established one of the first Cell Therapy Fellowships, as well as developed and published a system and process to allow medical centers to manage externally manufactured products. He has more than 150 papers published, has multiple issued patents, and technology that has led to three startup companies. In 2019, Dr. Dietz was a recipient of the prestigious Mayo Clinic Team Science Award for his work on novel therapies for wound healing. Scientific efforts in his lab focus includes comprehensive approach to characterizing immunity, bio comparability studies of manufactured products, and development of closed manufacturing systems. In 2022, Dr. Dietz stepped down from this Directorship to dedicate his efforts to process and product development for next generation products. He earned his BA in Biology and Chemistry at University of Northern Iowa, his PhD in Genetics at Texas A&M University and completed his postdoctoral fellowship at the United States Department of Agriculture, Agriculture Research Service as well as at the Mayo Clinic. He has served in multiple roles at Mayo including on the Steering Committee for the Center for Individualized Medicine (CIM), Precision Cancer Therapeutics Program, the Stem Cell Research Oversight Subcommittee, and externally as an ad hoc Committee Member of the International Society for Cellular Therapy.

Linnea Fletcher, PhD
Biotechnology Department Chair, Austin Community College

Referral: Dr. Fletcher was referred by Dr. Maria Millan.

Expertise Relevance to CIRM GWG: Dr. Fletcher's expertise in manufacturing and education through the InnovATEBIO/NSF program will be invaluable in reviewing Infrastructure and Education program awards.

Prior Service in CIRM Reviews: N/A

Bio:
Dr. Linnea Fletcher is the Chair of the Biotechnology Department at Austin Community College (ACC), the first program in Texas to formally adopt the Washington Skill Standards for Biotechnology and receive program recognition from the Texas Skill Standards Board. The Biotechnology Program at ACC works with the local bioscience industry to educate students in basic laboratory skills, math skills, genetic engineering, protein purification, cell culture, quality assurance and quality control principles, regulations, bioinformatics, computer skills, ethics, documentation, and teamwork. Dr. Fletcher is also Director of the InnovATEBIO National Biotechnology Education Center at ACC, part of a national network for biotechnology workforce innovation which develops a collaborative infrastructure to support innovation and address the needs of the biotechnology community, develops regional outreach and mentoring infrastructure to broadly engage underserved populations in biotech labs and emerging technologies, monitors and addresses biotechnology industry and technician workforce trends, and identifies opportunities to generate partnerships and collaborations that accelerate innovation in biotechnology education.

Dr. Fletcher earned her AA in Biology at El Camino Jr. College, her BS in Biology, BA in Chemistry and MS in Biochemistry at University of California, Irvine, and her PhD in Ph.D. Microbiology University of Texas at Austin. She completed a postdoctoral fellowship at Southwestern Medical School to study the cellular receptor for diptheria toxin using monoclonal antibodies and a second postdoctoral fellowship in the Biochemistry Department at University of Texas to study how the 3D structure of mRNA affects translation. She started teaching while in graduate school and when she had to choose between education and research, she chose education. She started as Chair of the Biology Department Chair at Austin Community College, NRG campus, eventually teaching every biology course offered. She became Dean of Math/Science/Technology/Business at the Cypress Creek Campus when it first opened, and then started the Biotechnology Department at ACC, working on several grant projects such as the Advanced Technological Center Grant in Biotechnology (aka Bio-Link). She also started a high school Biotechnology Program with Alice Sessions which is still in operation today with over 1,000 high school students. As a result of her involvement as South Central Regional Director of the National Science Foundation Advanced Technological program, she became more involved in NSF and completed a two-year rotation as a Program Director in the Division of Undergraduate Education.

Patrick Hanley, PhD
Chief & Director of the Cellular Therapy Program and Associate Professor, Children's National Hospital

Referral: Dr. Hanley was referred by Dr. Bruce Levine.

Expertise Relevance to CIRM GWG: Dr. Hanley's expertise in GMP regulations for cell and gene therapies will be invaluable in reviewing Infrastructure program awards.

Prior Service in CIRM Reviews: N/A

Bio:
Dr. Hanley is the Chief and Director of the Cellular Therapy Program and an associate professor of pediatrics at Children's National Hospital and the George Washington University, respectively. He oversees processing for standard of care stem cell transplantation as well as the development, manufacture, quality, and testing of novel cellular therapies and is responsible for seeking partnerships and commercialization of promising cell and gene therapies. Trained as an Immunologist, Dr. Hanley has an extensive background and interest in cellular therapy and is passionate about improving regulations for cellular therapy, training the next generation of cell therapists, and facilitating the translation of new therapeutics. Over the past 16 years he has helped to translate more than 300 products on over 25 cell therapy protocols–ranging from mesenchymal stromal cells to cord blood virus-specific T cells and tumor-associated antigen specific T cells–into the clinic.

Dr. Hanley was elected Vice President, North America of the International Society for Cell and Gene Therapy (ISCT) where he also serves on the board of directors, on the Immuno-Gene Therapy Committee (and former co-chair), and co-founded and served as the inaugural co-chair of the Early Stage Professionals committee which focuses on workforce development and training. He also serves on the board of directors and as the chair of the education committee of the Foundation for the Accreditation of Cellular Therapy (FACT) and is an active cellular therapy and cord blood inspector. Dr. Hanley has actively participated in the Cell Therapy Liaison Meeting with the Food and Drug Administration since 2018 and he is the commissioning editor of the journal Cytotherapy. In 2017, along with Drs Catherine Bollard and Russell Cruz, he founded Mana Therapeutics, a biotech company aimed at educating immune cells and eliminating cancer. In his free time he enjoys tweeting with fellow scientists and Bills fans, playing soccer, cycling, cooking, and traveling.

Robert Kutner
Senior Consultant, Biologics Consulting

Referral: Mr. Kutner was referred by Dr. Chris Scull.

Expertise Relevance to CIRM GWG: Mr. Kutner's expertise directing a vector core facility at an academic medical center as well as industry experience will be invaluable in reviewing Infrastructure program awards and his expertise in chemistry, manufacturing and controls will be invaluable in reviewing Clinical and Translational program awards.

Prior Service in CIRM Reviews: N/A

Bio:
Robert H. Kutner is currently a Senior Consultant at Biologics Consulting Group. He became a consultant following over a decade in industry where he led Process and Analytical Development activities at Avrobio, Inc., Rocket Pharmaceuticals and bluebird bio Inc.. Robert joined industry after a decade of work and research at Louisiana State University Medical School where he left as the Director of the Vector Core facility. He is a practitioner in cell and gene therapy where he has contributed as a researcher with publications on production, concentration, and testing of recombinant adenovirus, adeno-associated virus, lentivirus, fowl pox, and modified vaccinia.

Prior to becoming a Senior Consultant, Robert was the Senior Director and Head of Process and Analytical Development at Avrobio Inc.. While at Avrobio, he built out process and analytical development laboratory systems and teams. Primary activities focused on comparability studies for investigator sponsored trials and establishing representative systems for external procedures. Programs advanced were autologous ex vivo CD34+ gene therapy treatments for Cystinosis, Fabry, Gaucher, Pompe, and Hunter diseases.

Before leading development at Avrobio, Mr. Kutner was the Associate Vice-President and Head of Human Gene Therapy at Rocket Pharmaceuticals. He led clinical translation and comparability efforts for industrialized GMP production of recombinant lentivirus for ex vivo based hematological trials in Fanconi Anemia, Leukocyte Adhesion Deficiency-I, Infantile Malignant Osteopetrosis, and Pyruvate Kinase Deficiency. While leading development at Rocket Pharm., he oversaw the CMC strategy for the in vivo AAV based Danon disease program.

Robert came to Rocket Pharma. from bluebird bio Inc. where he was Director and Head of Process Development and Process Research. He was responsible for core CMC lentiviral vector manufacturing activities which included process characterization and preparations for process validation of the Zynteglo, Skysona, and Abecma drug substances. Activities also included translating preclinical and academic studies for facile development. Robert was also responsible for broadening the horizontal strategic platform with the build-out of process research laboratories focused on mRNA production.

He joined bluebird bio as a Senior Scientist and Head of Process Development where he was lead scientists with a primary focus on development of ex vivo applications using lentiviral vectors for Phase I/II and Phase II/III autologous cell therapy-based programs.

Prior to his transition into industry, Robert was the Director of the Vector Core in the Gene Therapy Program at Louisiana State University Medical School. There he led technical and administrative activities for the government funded Gene Therapy Program's Vector Core. The academic Vector Core he oversaw had a portfolio of services around recombinant plasmids, adenovirus, adeno-associated virus, alphavirus, Fowl Pox, Modified Vaccinia Ankara, retrovirus, and lentivirus-based vectors for use in elucidating mechanisms, R&D of therapeutics, or prime and boost vaccination studies.

Robert Kutner graduated from the University of Oklahoma with a Bachelor of Science in Chemistry with a biological emphasis. Following his undergraduate studies, he started his career at Dow Chemical where he supported operations as a Lab Analyst for industrial scale GMP production of plasticizers used in the manufacture of cell-culture bags and other plastics used in biologics.

Anne Plant, PhD
Fellow, National Institute of Standards and Technology

Referral: Dr. Plant was referred by Dr. Sohel Talib.

Expertise Relevance to CIRM GWG: Dr. Plant's expertise in quality and analytics will be invaluable in reviewing Infrastructure program awards.

Prior Service in CIRM Reviews: N/A

Bio:
Dr. Anne Plant is a Fellow at the National Institute of Standards and Technology (NIST), where her current research focuses on single-cell measurements from live cell microscopy, and development of theoretical approaches that lead to predictive understanding of complex cellular systems. She aims to provide a thermodynamic basis for understanding which cellular measurands are the most important for controlling a particular phenotype. Her current work is motivated by a critical challenge in characterizing cell-based therapies, namely what should be measured that will provide predictive information about the cell product to assure desirable functionality in order to allow predictive understanding of complex biological processes and help make the manufacturing of advanced therapy products more efficient and reliable.

Dr. Plant received a PhD in Biochemistry from Baylor College of Medicine. She has conducted research at the Biomolecular Engineering Branch of the Naval Research Laboratory, assisted in developing new program initiatives for the Chemical Science and Technology Laboratory at NIST, served on the National Science and Technology Council by advice and technical background to the NSTC and the White House on issues such as tissue engineering, stem cell technology, and the interface of the life and physical sciences, served as a group leader in Cell Systems Science at NIST where she initiated a program in measurements for tissue engineering that focused on robust extracellular matrix preparations, and served as the first Chief of the Division of the Biosystems and Biomaterials Division at NIST. She is an ex-officio member of the NIBIB National Advisory Council, a member of the NASEM Forum on Regenerative Medicine, a Fellow of the AIMBE, an AAAS Fellow, and an advisor to the NHLBI-led In-Depth Cell Characterization Hub of the Regenerative Medicine Innovation Project established by the 21st Century Cures Act.

Jerome Ritz, MD
Executive Director of the Connell-O'Reilly Cell Manipulation Core Facility and Professor, Harvard Medical School

Referral: Dr. Ritz was referred by Dr. Sarah Nikiforow.

Expertise Relevance to CIRM GWG: Dr. Ritz's experience directing a cell manipulation core facility which assists in developing new cell-based therapies for patients will be invaluable in reviewing Infrastructure program awards and his expertise in hematologic malignancies, bone marrow transplantation and cancer immunology will be invaluable in reviewing Clinical program awards.

Prior Service in CIRM Reviews: N/A

Bio:
Dr. Jerome Ritz established the Connell-O'Reilly Cell Manipulation Core Facility (CMCF) at Dana-Farber Cancer Institute (DCFI) in 1997 and is currently its Executive Director. The CMCF is a core facility of the Dana-Farber/Harvard Cancer Center and supports the adult and pediatric stem cell transplant programs at DFCI, BWH and Boston Children's Hospital. The CMCF is a GMP processing facility that provides manufactured cellular products of various types for patients enrolled on clinical trials evaluating novel cellular therapies for cancer and other diseases. These manufactured products include cellular vaccines, immune cells for adoptive cell therapy, CAR T cells, genetically modified hematopoietic stem cells and induced pluripotent stem cells.

A graduate of Northwestern University in Evanston Illinois, Dr. Ritz received his MD from Chicago Medical School followed by residency training in Internal Medicine at the University of Wisconsin Hospitals. Dr. Ritz subsequently completed a clinical fellowship in Hematology and Oncology at Boston's Beth Israel Hospital and a research fellowship in Tumor Immunology at the Dana-Farber Cancer Institute. He joined the DFCI faculty after completing his fellowship training and is currently Professor of Medicine at the Dana-Farber Cancer Institute, Brigham and Women's Hospital and Harvard Medical School.

Dr. Ritz's major research interests have been in cancer immunology and stem cell transplantation. Studies in his laboratory have focused on immune reconstitution after hematopoietic stem cell transplantation. In this setting, donor immune cells play a critical role in the recognition and elimination of residual leukemia cells (graft versus leukemia – GVL) but immunologic targeting of normal recipient cells also leads to graft versus host disease (GVHD) and damage to normal tissues. His studies of immune reconstitution have demonstrated that donor B cells and regulatory T cells play important roles in the development of GVL and GVHD and the establishment of immune tolerance after stem cell transplantation. These observations have led to new strategies to selectively modulate immune reconstitution to improve patient outcomes after transplant. Current projects in his lab now also focus on the detailed analysis of CAR T cell products with the goal of understanding mechanisms of expansion and persistence of CAR T cells after infusion.

Isabelle Rivière, PhD
Director, Cell Therapy and Cell Engineering Laboratory at Memorial Sloan Kettering Cancer Center

Referral: Dr. Plant was referred by Dr. Sohel Talib.

Expertise Relevance to CIRM GWG: Dr. Riviere's expertise at an academic GMP facility will be invaluable in reviewing Infrastructure program awards.

Prior Service in CIRM Reviews: N/A

Bio:
Dr. Isabelle Rivière is director of the cell therapy and cell engineering laboratory at Memorial Sloan Kettering Cancer Center, where she investigates novel strategies for cell therapies and immunotherapies to increase or retarget the immune response against tumors and treat hematological disorders. She is a leader in cell therapy and cell engineering with 25+ years of experience in developing and advancing cell therapy drug candidates (including CAR T cells, CD34+ HPS-, embryonic stem- and iPS- derived products) from pre-clinical stage to phase I/II clinical trials and in building strong collaborations between academia and industry partners. Her experience encompasses process development and clinical cell manufacturing, quality control/analytics, manufacturing of vectors and gene editing tools, quality assurance and compliance, CMC and technology transfer.

She earned her PhD in Cellular and Molecular Biology (Cell Therapy, Cell Engineering and Immunotherapy) from the University of Paris and conducted her postdoctoral studies at MIT, Cambridge, MA and at NUY Medical Center, New York, NY, in Dan Littman's lab. In addition to her work at MSKCC, she serves as Scientific Advisor at Mnemo Therapeutics, serves on the Advisory Board of the Center for Commercialization of Cancer Immunotherapy C3i (Canada) and the National Science Foundation (NSF) Engineering Research Center (ERC) for Cell Manufacturing Technologies (CMaT), and is elected as the Secretary of the American Society of Gene and Cell Therapy.

Beth Shaz, MD, MBA
Deputy Director, Duke University

Referral: Dr. Shaz was identified by a member of the CIRM Review team based on literature reviews.

Expertise Relevance to CIRM GWG: Dr. Shaz's experience in academic GMP facilities will be invaluable in reviewing Infrastructure program awards.

Prior Service in CIRM Reviews: N/A

Bio:
Dr. Beth Shaz is the Deputy Director of Marcus Center for Cellular Cures (MC3) at Duke University. Dr. Shaz has 20+ years of experience in transfusion medicine and cellular therapies. Dr. Shaz oversees the Robertson cGMP Laboratory as well as the Molecular Products and Cellular Therapies (MPACT) cGMP Facility in the Brain Tumor Center, Department of Neurosurgery. In addition, she is the Co-Director of Duke's Stem Cell Lab, Associate Director of the Carolinas Cord Blood Bank (CCBB), and supervises MC3's clinical trials in adult populations. Dr. Shaz holds a primary appointment with the Department of Pathology as Professor. Her goals are to improve the health of our community and ensure equal access to safe and efficacious blood and biotherapies.

Dr. Shaz was most recently the Executive Vice President, Chief Medical and Scientific Officer of the New York Blood Center enterprises. In that role, Dr. Shaz directed all medical activities, including medical oversight of blood donation, hemophilia services, transfusion services, cellular therapy laboratory, perioperative autologous services, and apheresis services. Dr. Shaz created and led Comprehensive Cell Solutions, whose goal was to develop cellular therapies. Prior to joining the New York Blood Center, Dr. Shaz was an Associate Professor at Emory University and directed the transfusion service at Grady Memorial Hospital, and before that, she was an Instructor at Harvard Medical School and Assistant Medical Director of the transfusion service and Medical Director of the transfusion/apheresis unit at Beth Israel Deaconess Medical Center.

Dr. Shaz is Past-President of AABB, a member of the Board of Directors of the Cord Blood Association, and has been a board member, committee chair and active committee member of the American Society for Apheresis. Dr. Shaz has published more than 185 peer-reviewed articles and has co-edited eight books (and has started her ninth). She is an Associate Editor of the journal *Transfusion* and was on the editorial board of the journal *Blood*. Dr. Shaz received her BS with Distinction in Chemical Engineering from Cornell University, her MD at University of Michigan Medical School, and her MBA in Healthcare Leadership at Empire State College, State University of New York. She completed her surgical internship at Georgetown University, and her pathology residency and blood banking / transfusion medicine Fellowship at Harvard Medical School.

Karen Walker
Chief Technology Officer, Kyverna Therapeutics

Referral: Ms. Walker was referred by Dr. Shyam Patel.

Expertise Relevance to CIRM GWG: Ms. Walker's expertise from working in a contract development and manufacturing organization will be invaluable in reviewing Infrastructure program awards.

Prior Service in CIRM Reviews: N/A

Bio:
Karen Walker is Chief Technology Officer of Kyverna Therapeutics. Karen brings >30 years' experience in the biotech industry, holding positions in Technical Development, Regulatory Affairs and Quality. She has worked in a number of companies including Roche/Genentech, Seattle Genetics, Novartis, Amgen, Bayer, and several other small to mid-sized biotech companies.

Her experience with Cell and Gene Therapies includes serving in the role of Senior Advisor for Cell and Gene Therapy at Roche/Genentech from 2019- Aug 2021 at which time she joined Kyvernta Therapeutics. As Sr. Advisor, Karen advised the RGNE community on aspects of development and industrialization of cell-base and gene-based therapies (ATMPs) across the development lifecycle including topics important for patient engagement, supply management, control strategy development and linking the data across the different areas of research, clinical development and CMC to gain insight into how the products perform with respect to safety, efficacy and durability of benefit. Prior experience included serving as VP and Global Head of Technical Development and Manufacturing for Novartis' Cell and Gene Therapy Unit where she led the CMC teams through the formation of the strategies and the execution of those strategies to develop Kymriah through the pivotal trial stage and to filing of the first CAR-T BLA in Pediatric ALL.

Karen's years of experience in Biopharma Technical Development, Quality, Regulatory CMC, and Manufacturing (including Cell and Gene Therapy), both within the US and Europe have contributed to honing a mind-set and

approach that is strategic, forward looking and adaptive. The challenges that are present in the development of ATMPs, including shortened development time, complex supply chains including supply security for single patient delivery, largely poorly characterized and poorly understood product mechanism of action, rapidly evolving technology and changes to the way we work, are all inspiring and energizing as the field of ATMPs emerges and evolves.

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
Cavagnaro	Joy	3	6	Regulatory; Preclinical Development; Cell & Gene Therapy
Cicchetti	Francesca	2	2	Neurodegenerative Disorders, Animal Models, Biomarkers, Immunology, Cell Transplantation
Roach	Jared	3	6	Systems Biology
Zimmermann	Wolfram-Hubertus	3	6	Stem Cells, Tissue Engineering, Genome Editing

Joy Cavagnaro, PhD, DABT, ATS, RAC, FRAPS
Dr. Joy Cavagnaro is the founder and president of Access BIO, L.C., a Virginia-based consultancy specializing in science-based regulatory strategies and development services to facilitate translation of biomedical research, emerging technologies and product development. Her company provides consultation for product classes such as vaccines, cellular and gene therapies, animal-based and plant-based bio-therapeutics, biotechnology-derived and tissue engineered products as well as novel small molecule chemical entities. Her areas of focus include due diligence assessments of preclinical data and preclinical design and development strategies to support translation to the clinic.

Dr. Cavagnaro earned her PhD in Biochemistry from University of North Carolina, Chapel Hill, and completed her postgraduate work at Duke and Boston University Medical Centers. Prior to establishing Access BIO, she was Vice President of Regulatory Affairs and Integrated Compliance at Human Genome Sciences, Inc., where she established the Regulatory Affairs Department. She spent nearly ten years at the FDA Center for Biologics Evaluation and Research in various roles in the Office of Biologics Research, Office of Therapeutics Research and Review and Office of the Center Director, taking on increasingly more senior roles in toxicology, pharmacology and quality assurance. During her tenure at the FDA, she was appointed to the Senior Biomedical Research Service, she served as the FDA's safety topic lead for the International Conference on Harmonization of Technical requirements for Pharmaceuticals, and rapporteur for international policy guidance for the preclinical development and safety assessment of biological products. Among other commitments, she serves as a board member of the Advarra IRB, serves on the scientific advisory committees including Friedreich's Ataxia Research Alliance and Odylia Therapeutics, a nonprofit focused on developing therapies for people with rare genetics disorders. Among many honors, she has received the American College of Toxicology Distinguished Scientist Award in Toxicology (which recognizes an individual who has made outstanding contributions to toxicology and improvement of public health and/or the environment), the Society of Toxicology's Arnold J. Lehman Award for her major contributions to risk assessment and the regulation of pharmaceuticals and was the first recipient of the Society of Toxicology's Biotechnology Specialty Section Career Achievement Award.

Dr. Cavagnaro has served as a GWG member for almost 12 years. She has reviewed for Clinical, Translational, Infrastructure and Education program awards and served on the COVID-19 panels. She has also served on a Clinical Advisory Panel and Preclinical Development Panel.

Francesca Cicchetti, PhD
Dr. Francesca Cicchetti is a professor in the department of psychiatry and neurosciences at the Faculty of Medicine at Université Laval, a researcher at the CRCHU de Québec and a fellow of the Canadian Academy of Health Sciences. Dr.

Cicchetti's research work aims to understand the cellular and molecular mechanisms underlying the development of neurodegenerative diseases with the goal to identify novel therapeutic targets. Her interests combine fundamental and clinical research and as such, a number of her discoveries have led to patents and are now being considered for clinical trials. Aware of the societal impact of these disorders, Dr. Cicchetti is actively involved in disseminating scientific breakthroughs to the general public via various media whom solicit her expertise, in organizing patient outreach activities or by participating to fundraising events.

Dr. Cicchetti obtained her PhD in neurobiology at Université Laval in Québec (Canada) in 1998. In 2002, she completed a postdoctoral fellowship at Harvard Medical School in the field of cell replacement therapy for neurodegenerative disorders. She is now professor at the department of Psychiatry & Neurosciences, Faculty of Medicine of Université Laval in Québec. Dr. Cicchetti has published over 130 manuscripts in various high impact journals including in PNAS, Annals of Neurology, Acta Neuropathologica, Trends in Pharmacology, Brain. She has received numerous awards and distinctions including the Canadian Institute of Health Research New Investigator Award (2007-2012), the Fonds de Recherche en Santé du Québec (FRSQ) Junior Research Award (2003-2006 and 2006-2007), Young Investigator Award from NARSAD (2006) and Parkinson Society Canada (2002), the National Researcher award from FRQS (2014-2017) more recently followed by an FRQS research Chair (2017-2021). Three of her publications (2014, 2015, 2016) have been awarded most influential papers in the field of Huntington's disease. She is an active member of several scientific committees and editorial boards.

Dr. Cicchetti has served as a GWG member for almost 6 years. She has reviewed for Clinical and Discovery stage program awards.

Jared Roach, MD, PhD
Dr. Jared Roach is a Senior Research Scientist at the Institute for Systems Biology (ISB) in Seattle, Washington. His expertise lies in genomics and medicine, with specific expertise in multimodal clinical trials, molecular phylogenetics, computational biology, and systems biology. He is interested in basic and translational analyses and applications of high-throughput systems-biology data. He is currently focusing on understanding the genetics of complex neurodegenerative diseases, accelerating knowledge extraction from biomedical data sets, and applying systems analysis to clinical trials (particularly for Alzheimer's disease and related disorders). The translational impact of his research has contributed to clinical areas such as neurodegeneration, autoimmunity, rare genetic diseases, diabetes, inflammation, and vaccine development.

Dr. Roach earned his BS in Biochemistry from Cornell University and an MD and a PhD in Immunology at the University of Washington. He completed his residency in Internal Medicine at University of Utah. During the Human Genome Project, which he worked on from its early days through its conclusion, he was instrumental in the development of the pairwise end-sequencing strategy. At ISB, he directed the first team to sequence the genomes of a full pedigree in humans and subsequently led teams to study the genetics of complex diseases by whole-genome sequencing. One ISB effort he led in whole genome sequencing not only identified the cause of Miller syndrome, but also produced the first complete whole-chromosomal haplotypes in humans and established a new paradigm for medical genetics, with their approach becoming one of the fastest technologies to ever move from research proof-of-principle to worldwide clinical adoption as a standard of practice for diagnosing rare diseases, becoming commonplace less than five years after initial publication. Currently, he leads the Alzheimer's Translational Pillar, a system-wide initiative of Providence St. Joseph Health which initiates and drives translational projects that bridge basic science in systems biology with translational studies. Among other commitments, he serves as Specialty Chief Editor for *Frontiers in Genetics: Human and Medical Genomics*.

Dr. Roach has served as a GWG member for almost 10 years. He has reviewed for Discovery, Clinical, and Education program awards as well as the Genomics Centers of Excellence and COVID-19 awards.

Wolfram-Hubertus Zimmermann, MD
Dr. Wolfram-Hubertus Zimmermann is Professor and Director of the Institute of Pharmacology and Toxicology at the University Medical Center in Göttingen, Germany. His research interests include stem cell-based tissue engineered therapeutics for organ repair (heart, skeletal muscle, brain); therapeutic genome editing; human organoids and disease modelling for preclinical screens and evaluations of innovative drugs; and development and validation of approaches to enhance endogenous regeneration with a particular focus on the cellular diversity of the heart and other organs. He also serves as a clinical consultant in pharmacology and toxicology.

Dr. Zimmermann attended medical school at the University of Hamburg and took clinical electives at Duke University School of Medicine, Harvard Medical School, and University of Cape Town. He earned a diploma in Molecular Biology from the Center for Molecular Neurobiology, Hamburg, while completing his residency in Clinical

Pharmacology at University Erlangen-Nuremberg. He has published over 200 articles and holds 13 patents, 7 of which have been granted to date. The research developments in his laboratory have resulted in the spin out of several biotech companies with a focus on drug development and tissue engineered organ repair. He serves on the editorial board of several journals, *Basic Research in Cardiology, Der Kardiologe, Circulation Research, Regenerative Therap*y, is associate editor of the journals *Cardiovascular Research* and *Journal of Molecular and Cellular Cardiology*, and has served as an ad hoc reviewer for other journals as well as national and international granting agencies.

Dr. Zimmermann has served as a GWG member for almost 12 years. He has reviewed for Discovery and Translational stage awards as well as Preclinical Development, Research Leadership, and Disease Team Research awards.