CIRM Scientific and Medical Research Funding Working Group
Biographical information of candidates nominated to serve as Scientific Members of the Working Group

John J. Crowley, PhD
Dr. Crowley is the President and CEO of Cancer Research And Biostatistics (CRAB), where he oversees the study design, protocol development, data management, quality control, data analysis, and statistical research of more than 100 active multi-site clinical cancer trials, and manages a staff of 75 high-level statisticians, data coordinators and other professionals dedicated to conquering cancer through large-scale clinical trials. He received his master's and doctorate degrees (in 1970 and 1973, respectively) in Biomathematics from the University of Washington. He served as a Postdoctoral Fellow at Stanford University and then moved on to an Assistant Professorship in 1974, followed by an Associate Professorship in 1979, at the University of Wisconsin Departments of Human Oncology and Statistics. In 1982 Dr. Crowley accepted an appointment as Associate Member at the Fred Hutchinson Cancer Research Center (FHCRC) along with an Associate Professorship in Biostatistics at the University of Washington. He was subsequently promoted to Full Professor at the University and Full Member at FHCRC in 1984.

Dr. Crowley was the Director of the Statistical Center for the SWOG, co-located at CRAB and the Fred Hutchinson Cancer Research Center from 1984 to 2012. He served as Head of the Biostatistics Program at the Fred Hutchinson Cancer Research Center from 1983 until 1993, during which time he was honored with a Mortimer Spiegelman Award, given every year by the American Public Health Association to an outstanding young biostatistician. Dr. Crowley's credentials also include prestigious fellowships from the American Statistical Association and the American Association for the Advancement of Science. In 2013 he was honored with the Marvin Zelen Leadership Award in Statistical Science. To date he has authored over 400 professional papers and books.

Dr. Crowley's research interests focus on the design and analysis of cancer clinical and translation trials. His more recent research focuses on analytical methods for utilizing microarray data to determine predictive and prognostic groups; the design of targeted therapy trials; and methods for describing staging systems for lung cancer and myeloma. His longstanding interest in developing exploratory tools for survival data has produced widely used statistical applications in these areas. Dr. Crowley also educates cancer clinicians and biostatisticians here and abroad in the principles and pitfalls of cancer clinical trials.

Adrian Gee, PhD
Dr. Gee is Professor in the Departments of Medicine and Pediatrics Section of Hematology-Oncology at Baylor College of Medicine. He received his bachelor's degree from the University of Birmingham, England, and his Ph.D. from the University of Edinburgh, Scotland. He did his postdoctoral training at the National

Institutes of Health, and the University of Toronto, before taking a faculty position at the University of Florida. There he performed some of the first applications of immunomagnetic tumor purging in the United States, and his laboratory became a central cell processing facility for this procedure. He joined Baxter Healthcare in 1987, where he worked on the development of the MaxSep and Isolex magnetic cell separators. Dr. Gee co-founded the International Society for Hematotherapy and Graft Engineering (ISHAGE, now ISCT), and the Journal of Hematotherapy (nowCytotherapy) in 1992. From 1992 to 1997 he helped establish the stem cell transplantation program at the University of South Carolina. He then directed the Cell Processing Laboratory at the University of Texas MD Anderson Cancer Center until 1999, when he joined the Center for Cell and Gene Therapy (CAGT) at Baylor College of Medicine in Houston.

The CAGT houses GMP manufacturing facilities for vectors and cell therapy products, and has been selected as one of the 5 national somatic cell therapy processing centers by the National Heart, Lung & Blood Institute. He was involved in the development of standards for the collection processing and transplantation of hematopoietic stem cells for the Foundation for the Accreditation of Cell Therapy (FACT), the American Association of Blood Banks and the National Marrow Donor Program. He has written more than 180 scientific articles and has authored and edited a number of books on graft engineering and stem cell processing.

James D. Guest, MD, PhD

Dr. Guest is a clinician-scientist whose work focuses on spinal cord injury (SCI) at the Miami Project to Cure Paralysis. He completed his MD with honors in research at the University of Alberta and his neurosurgical residency at the University of British Columbia. His PhD in Neuroscience was completed at the University of Miami under the direction of Drs. Richard and Mary Bunge, pioneers in the biology and translation of Schwann cell transplantation to the central nervous system. He also completed a fellowship in spinal surgery at the Barrow Neurological Institute under the direction of Dr. Volker Sonntag. Post-doctoral training occurred during the last two years of residency in cooperation with Drs. John Steeves and Wolfram Tetzlaff, founding faculty of ICORD (International Collaboration on Research Discoveries) in Vancouver, Canada.

Dr. Guest spent 11 years as chief of spinal neurosurgery at the Miami Veteran's hospital and is now fully devoted to translational and clinical research within the Miami Project to Cure Paralysis. His laboratory studies cellular and neuroprosthetic treatments for SCI emphasizing the use of large animal models. He is a principal investigator on clinical trials of neuroprotection and cellular therapy for SCI. He is a consultant to the Food and Drug Administration (FDA) and an investigator in the North American Clinical Trials Network (NACTN). He serves on the editorial board of the Journal of Neurotrauma and several other SCI-devoted organizations. He previously served on the board of the American Spinal Cord Injury Association and

is a member of the translational research steering committee of the Rick Hansen Institute.

Dr. Guest has trained more than 25 post-doctoral fellows, medical and undergraduate students. The research training emphasizes acquisition of skills in research translation and in the development and validation of new technologies and devices.

Robin Jenkins, MBA
Robin Jenkins is the Senior Director of Medical Affairs Innovation at Sanofi US. Robin brings over 20 years of experience in the pharmaceutical industry, including Generics and Large Pharma. During Robin's tenure, she has held various roles within the Global Development & Medical Affairs organizations. Her broad experience includes strategic resourcing and brand planning, long range strategic planning , budget management at the organizational level, strategic global allocation of clinical trials, development of training programs, and extensive systems development. In addition, Robin is highly experienced project head that has led several large-scale strategic, cross-divisional projects, some of which include The *Project Data Sphere* initiative, Clinical Transparency, and Clinical Trial Disclosure.

Kathleen McCarthy Kirby
Kathleen is Principal at Viridian Strategies, a clinical consulting company focused on providing support, including Clinical Operations and Program Management to start up clinical stage biopharmaceutical companies. Kathleen is a deeply experienced leader, manager and advisor on many topics relating to clinical development, has been in the biotech / biopharma industry for over 25 years, and is a senior leader in Clinical Operations. During her career, Kathleen has worked with and consulted to some of the most established companies in the biotechnology industry, including Biogen, Genzyme, and Shire HGT.

Most recently, Kathleen held the position of Vice President, Clinical Operations at bluebird bio, a Cambridge-based gene therapy company. Her small but highly experienced team was responsible for the conduct of extremely complex clinical trials using ex vivo gene therapy delivered by stem cell transplantation. Kathleen's expertise also includes global clinical program management, both strategic and tactical implementation, personnel and team development, vendor out-sourcing, contract negotiation and regulatory interactions.

Kathleen was a key contributor on the initial release of the DIA TMF Reference Model. Kathleen's interest is primarily focused on supporting start up companies using novel therapies to treat rare diseases, with strong attention towards patient recruitment and process optimization. Kathleen has returned to consulting, which is what she did prior to joining Bluebird Bio. She has consulted for Shire HGT, Altus, Stromedix and other small start up companies.

Jay H. Traverse, MD
Dr. Traverse is a senior cardiology associate at the Minneapolis Heart Institute at Abbott Northwestern Hospital and an associate professor of medicine in the Department of Cardiology at the University of Minnesota. He is also currently the Acting Director of Research at the Minneapolis Heart Institute Foundation and recently completed a 6-year term as Chairman of the CV division of the Medical Staff of Abbott Northwestern Hospital. Dr. Traverse graduated from Case Western Reserve University School of Medicine in 1989 and completed his Internal Medicine, Cardiology and Interventional Cardiology Fellowships at the University of Minnesota.

Dr. Traverse has a long-standing interest in cardiovascular cell therapy. He received an Investigational New Drug (IND) application and designed the first trial in the United States using bone marrow mononuclear stem cells in the setting of acute myocardial infarction. His institution was selected as one of the original sites for the NHLBI Cardiovascular Cell Therapy Research Network (CCTRN) of which he is a Co-Principal Investigator. Dr. Traverse was the Principal Investigator for the CCTRN's *TIME* and *LateTIME* trials that investigated the role of timing of cell delivery in the setting of acute myocardial infarction. He has been involved in multiple clinical stem cell trials at the Minneapolis Heart Institute that evaluated a variety of stem cells including, skeletal myoblasts, CD34+ stem cells, MSCs, BMCs, adipose-derived stem cells and cardiac stem cells as well as studies involving gene therapy and biomaterials. Dr. Traverse's group has performed the largest number of cardiovascular stem cell deliveries in the United States.

Dr. Traverse's other research interests focus on Ischemia / Reperfusion injury and identification of factors that influence infarct size including circadian effects of infarct size and the protective role of pre-infarction angina. He is currently Principal Investigator of an NHLBI study at his Institution examining the potential benefits of postconditiong in the setting of acute myocardial infarction to reduce reperfusion injury.

Michelle LeRoux Williams, Ph.D.
Dr. Williams is a fellow in the American Institute for Medical and Biological Engineering (AIMBE) and is an internationally recognized expert in biologics and cell therapy. Most recently, Dr. Williams served as Chief Scientific Officer of Osiris Therapeutics (NASDAQ-OSIR), where she led the development of five stem cell products; Prochymal®, Osteocel®, Grafix®, Cartiform® and Ovation®, which account for more than $300 million in annual sales.

Dr. Williams is the inventor of the world's first commercially available stem cell product (Osteocel®/Trinity®), comprising primary mesenchymal stem cells and allogenic bone matrix used for the repair and reconstruction of osseous defects. Dr. Williams also led the team that obtained regulatory approval of the world's first approved stem cell drug, Prochymal® (remestemcel-L) for the treatment of severe graft-versus-host disease in children, a life-threatening complication of

hematopoietic stem cell transplantation for which Prochymal is now the most frequently used treatment.

Dr. Williams led the diligence, contracting and asset transfer efforts for multiple agreements including major deals with Genzyme Corporation ($130 million), Nuvasive ($89 million) and Mesoblast (up to $100 million).

Dr. Williams has led 15 multi-center GCP cell therapy clinical trials from phase I through phase IV. In 2005, Dr. Williams' team secured the first Fast Track and Orphan Drug designations from FDA for a stem cell product and in 2008 Osiris received the first FDA expanded access approval for a stem cell drug.

Dr. Williams earned a Bachelor's degree in mechanical engineering from Rice University and a Ph.D. in biomedical engineering from Duke University. Dr. Williams completed an NIH postdoctoral fellowship in tissue engineering at Columbia University. She serves on the editorial board of Stem Cells Translational Medicine.