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

Lauren E. Black, Ph.D

Dr. Black is Senior Scientific Advisor with Navigator Services at Charles River Laboratories (CRL), a global clinical and preclinical research organization (CRO). Navigators provide a center of expertise to assist drug sponsors with achieving regulatory and clinical objectives through all stages of nonclinical and clinical development. Dr. Black provides expert toxicologic data analysis, clinical strategic development planning, tailored nonclinical program designs, and regulatory communications advice. Dr. Black's practice is focused on pharmacologic toxicity, biotechnology products, immunopharmacology, and expedited development for high risk indications. She also serves as the program director at CRL for immunology/immunotoxicology related issues. Prior to joining CRL, Dr. Black served at the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) for 11 years and left in 2002 to consult to the pharmaceutical industry.

Dr. Black joined the FDA/CDER in 1991 as a Reviewing Pharmacologist with the Division of Antiviral Drug Products, assigned primarily to the Investigational New Drug applications (INDs) for immunosuppressants and transplantation including Prograf, CellCept, and Rapamune. Additionally, she reviewed ~30 other INDs and New Drug Applications (NDAs) for antiviral drugs and antisense oligonucleotides. She performed key pharmacodynamic studies for early files for intravenous oligonucleotides and published Agency guidance on the safety studies needed to initiate trials with these drugs. These efforts accelerated development of 2nd generation oligonucleotides with improved safety profiles.

In 1995, Dr. Black transferred to the FDA CBER, and reviewed ~400 INDs for biologic proteins, cell therapies, and immunomodulators. She served on the review committees for Remicade, Simulect, Amevive, Raptiva, and Tysabri. Dr. Black helped establish standards for toxicity programs for chronic biotherapies as use of these drugs approached broad clinical use. She co-led the committee to set standards for clinical dose estimates, and generated algorithms, terminology, and safety margin approaches for the *Guidance to Industry* on human starting doses.

Dr. Black also contributed to working groups on biotechnology safety, immunotoxicology, tissue engineering, xenotransplantation, as well as rheumatoid arthritis and osteoarthritis and she contributed to four *Guidances to Industry*. Dr. Black briefed FDA Advisory Committees on Dermatologic Products and Xenotransplantation and received a number of CDER and CBER awards for review and policy initiatives. These included awards for strategic design of nonclinical safety programs. Her invited lectures include those for the Society of Toxicology (SOT) (where she is a full member), Summer School on Immunotoxicology, the Society of Toxicologic Pathology (STP), the American College of Toxicology (ACT), universities, CPA, and the Pharmaceutical Education and Research

Institute (PERI). She is a co-organizer of the annual meeting, the CRL Symposium on Biotechnologic Products and Immunomodulation.

Robert J. Deans, Ph.D.
Dr. Deans is Senior Vice President of Regenerative Medicine at Athersys, Inc. He received a B.Sc. from the Massachusetts Institute of Technology, a Ph.D. from the University of Michigan, Ann Arbor, and postdoctoral training in molecular immunology at the University of California Los Angeles.

Dr. Deans is responsible for regenerative medicine technology development at Athersys Inc. and its European subsidiary, ReGenesys. Athersys is developing cell therapeutics based on adherent stem cells isolated from adult bone marrow. Athersys has completed accrual in a Phase I clinical study for treatment of acute myocardial infarct, is currently enrolling patients for adjunctive therapy of allogeneic bone marrow transplant to manage acute graft versus host disease morbidity, and has an approved IND for stem cell treatment of ischemic stroke with site enrollment underway.

Athersys has also formed development collaborations for the MultiStem® platform with Angiotech Pharmaceuticals (Cardiovascular) and Pfizer Regenerative Medicine (Inflammatory Bowel Disorder). An IND has been approved for a Phase II study using MultiStem in ulcerative colitis patients. Athersys has also formed a co-development agreement with Regenerative Technologies Inc for use of adherent stem cell progenitors in combination with matrix for treatment of spinal fusion. The MultiStem clinical development program is active in both the US and Europe, and the technology platform has received regulatory approval in Belgium and Germany, with other reviews underway.

Dr. Deans has more than 17 years experience in stem cell therapeutics, having previously served at Osiris Therapeutics as VP of Research. At Osiris, his group developed the clinical manufacturing platform for mesenchymal stem cells currently in clinical approval trials. His group demonstrated proof of concept for use of MSC as universal donor products, and provided the technology framework for Phase I and Phase II trials in allogeneic bone marrow transplant, a Phase I study in bone formation, and filing a Phase I study for use of MSC in acute myocardial infarct. Before joining Osiris in 1998, Dr. Deans was Director of R&D at the Immunotherapy Division of Baxter Healthcare (Nexell Therapeutics), where he developed the biological components of the Isolex300i hematopoietic stem cell purification platform. In addition, Dr. Deans served on the faculty of the Norris Cancer Center at University of Southern California (USC) Medical School from 1984 to 1992.

Dr. Deans has been influential in stem cell and therapeutic societies in guiding standardization of adherent stem cell practices and characterization. He serves as chair of the International Society for Cell Therapy (ISCT) Commercialization Committee and has served on the International Society for Stem Cell Research (ISSCR) industry committee as well.

James Ellis, Ph.D.
Dr. Ellis is Professor at the University of Toronto, Senior Scientist at the Hospital for Sick Children in Toronto, and Scientific Co-Director of the Ontario Human iPS Cell Facility. He completed his Ph.D. on gene targeting using retrovirus vectors with Dr. Alan Bernstein at Mt. Sinai Hospital / University of Toronto in 1990. A post-doctoral fellowship with Dr. Frank Grosveld at the National Institute for Medical Research in London, UK led to identification of Locus Control Region (LCR) elements that drive high-level expression from β-globin transgenes in mice for blood gene therapy. He has been a Scientist and Senior Scientist at the Hospital for Sick Children in Toronto since 1994 and has pursued viral gene therapy of stem cells and technology for reprogramming into iPS cells.

Dr. Ellis' current research interests include the development of iPS cell models of human disease including Rett syndrome, autism, schizophrenia, cystic fibrosis and cardiac disorders. Dr. Ellis developed the first pluripotency reporter that functions in human cells as they reprogram (*Nature Methods* 2009). He has a strong interest in developing standard criteria for iPS cells (*Cell Stem Cell* 2009), the development of integrating viral vectors that resist transgene silencing in pluripotent cells to use for delivery of suicide vectors to enhance the safety of regenerative medicine, and in improving patient consent as it relates to reprogramming. His research is funded by the Canadian Institutes for Health Research (CIHR) and the National Institute of Health (NIH).

As a Full Professor at the University of Toronto, Dr. Ellis has mentored many trainees at all levels. He is a member the American Society of Gene & Cell Therapy (ASGCT) Embryonic Stem Cell Committee and a member of the International Society for Stem Cell Research (ISSCR). He has reviewed grants for CIRM, NIH, CIHR and other agencies, is a member of the editorial panel for *Stem Cells* and a *F1000* Member contributor, and is a frequent reviewer for the *Nature* and *Cell* family of journals among others. In 2010, he has given international invited talks in the US, Canada, Japan, Brazil, and Italy.

Joyce L. Frey-Vasconcells, Ph.D.
Dr. Frey-Vasconcells is Executive Director for Cellular Therapies, Tissues, Gene Therapies, Tissue Engineered products and Tumor Vaccines at the Consulting Division of PharmaNet where she provides strategic planning to industry. She received her B.S. and her Ph.D. degrees from Kansas State University and completed a postdoctoral fellowship at the National Cancer Institute - Frederick Cancer Research and Development Center (NCI/FCRDC) in Fort Detrick, Maryland.

Prior to joining Pharmanet, Dr. Frey-Vasconcells served as the Deputy Director, Office of Cellular, Tissue, and Gene Therapies (OCTGT) with the Center for Biologics Evaluation and Research (CBER) at the US Food and Drug Administration (FDA). During her tenure at the FDA, she was instrumental in developing many of CBER's science and public health policies regarding the regulation of cells, tissues, gene therapies, tumor vaccines, and combination products (tissue engineered products). In 2001, the FDA recognized her as the FDA regulatory expert in the regulation of cell therapies. She fostered unique innovations to the regulation of these areas and was instrumental in the strategic thinking in the regulations

for cell therapies including stem cells, pancreatic islet cells, and cord blood. She made significant contributions to the development of the newly published tissue rules, which outline the regulatory requirements for cellular and tissue based products. In addition, Dr. Frey-Vasconcells' ability to think outside the box has led to regulatory developments in areas of tissue engineered products and gene therapy.

After nearly 13 years of experience at the FDA, Dr. Frey-Vasconcell recently left FDA and joined PharmNet Consulting, where she has continued working with industry on an individual basis and with organizations whose mission is to foster product development in the areas of cell therapy, tissues, gene therapy, and tissue engineered products. She is clearly considered one of the foremost regulatory experts regarding tissues, cell therapies, combination products, gene therapies, and tumor vaccines. Dr. Frey-Vasconcell brings extensive regulatory expertise and experience for this unique group of products.