CALIFORNIA'S STEM CELL AGENCY

Nominations for Appointment to the Grants Working Group (GWG)

Appointment of New Members

Nicholas D. Andersen, MD
Nicholas D. Andersen is an Assistant Professor of Pediatric Cardiac Surgery and Director of Pediatric Cardiac Transplantation and Mechanical Circulatory Support at Duke University Medical Center. Dr. Andersen is an academic surgeon-scientist who specializes in congenital cardiac surgery, with a clinical focus on corrective surgery for single ventricle heart disease. He attended medical school at Harvard and performed his general surgery and cardiothoracic surgery training at Duke University. He then performed a sub-specialty fellowship in pediatric cardiac surgery at Boston Children's Hospital.

Dr. Andersen's research aims to improve the care of children with congenital heart disease through focused translational research that can be applied to the care of surgical patients. He is versatile with surgical experimentation using a variety of model organisms, and has performed experiments with bacteria, yeast, nematodes (C. elegans), zebrafish, rat, rabbit, canine, rabbit, pig, and human tissues in experimental model systems. He is experienced with clinical research using small and large database repositories, and has performed numerous clinical and laboratory studies related to pediatric cardiology and pediatric cardiac surgery over the course of his training through the support of various research grants and fellowships. Dr. Andersen has served on the Editorial Board for the Journal of Thoracic and Cardiovascular Surgery beginning in 2015.

Rebecca Buckley, MD
Rebecca Hatcher Buckley graduated with an A.B. degree from Duke University in 1954, an MD degree from the University of North Carolina School of Medicine in 1958 and received housestaff training in Pediatrics at Duke. Dr. Buckley was a fellow in Allergy under Dr. Susan C. Dees and a fellow in Immunology under Dr. Richard S. Metzgar, all at Duke. She then became a faculty member in the Department of Pediatrics, served as Chief of the Division of Allergy and Immunology from 1974 to 2003 and has been the James Buren Sidbury Distinguished Professor of Pediatrics and Professor of Immunology at Duke since 1979.

Dr. Buckley's research interests have been in the fundamental causes of genetically-determined immunodeficiency diseases. For the past 37 years her research has been on the syndrome of severe combined immunodeficiency (SCID) and the longterm clinical and immunologic outcomes of nonablative T cell-depleted haploidentical parental bone marrow transplants. This treatment can be provided to all SCID infants, regardless of whether or not they have a matched sibling donor. For the past two decades she has advocated newborn screening for SCID, and the Secretary of HHS officially recommended that this be implemented in May of 2010. The North Carolina legislature and Governor approved this in 2015. Dr. Buckley is the author or co-author of 363 scientific publications.

She trained more than 80 post-doctoral fellows during her 29 year tenure as Chief of the Division of Allergy and Immunology at Duke. Dr. Buckley has been a member of over 30 national committees and councils. She was president of The American Academy of Allergy, Asthma and Immunology (AAAAI) from 1979-80. She is an elected member of the Society for Pediatric Research, the American Pediatric Society (Council 1991-2001; President 1999-2000), American Association for the Advancement of Science, Fellow (2000); Chairman Section on Medical Sciences (2001-2003), American Association of Immunologists (Chairman, Clinical Immunology Committee 1984-87), and American Academy of Pediatrics (Section on Allergy & Immunology; Executive Committee 1981-84). She served two terms as a

Director of the American Board of Allergy and Immunology. Dr. Buckley has also served on a number of editorial boards including the Journal of Immunology, the Journal of Allergy and Clinical Immunology and the Journal of Clinical Immunology, where she was Associate Editor. She chaired the NIH Immunological Sciences Study Section and was a member of NIAID's Board of Scientific Counselors.

Dr. Buckley has received numerous awards and honors for her contributions to medicine from organizations such as the National Institutes of Health, the Immune Deficiency Foundation, the American Society for Microbiology and the American Academy of Allergy, Asthma and Immunology where she was named an Honorary Fellow in 1999. She is a member of Alpha Omega Alpha. In October of 2003 she was elected to the Institute of Medicine of the National Academy of Sciences. On September 30, 2007 she was appointed by the U.S. Secretary of HHS to a 4 year term as a member of the HRSA Advisory Committee on Heritable Disorders of Newborns and Children. On April 29, 2012 she was inducted into the National Academy of Sciences. On October 13, 2013, she was the recipient of the Thomas A. Waldmann Award from the Foundation for Primary Immunodeficiency Diseases, and on March 26, 2014, she was the recipient of the March of Dimes Colonel Harlan Sanders Lifetime Achievement Award in Genetics from the American College of Medical Genetics. She was elected a member of the Association of American Physicians on April 26, 2014, and on May 4, 2014, she was the recipient of the John Howland Award from the American Pediatric Society. On May 12, 2019 she will receive an Honorary Degree of Doctor of Science from the University of North Carolina and On May 9-13, 2019 she will be selected as the *2019 Distinguished Fellow of the American Association of Immunologists*. Dr. Buckley currently serves as Chairman of the Medical Advisory Committee of the Immune Deficiency Foundation. She remains actively involved in clinical and scientific research, teaching and patient care.

Troy Lund, MD, PhD
Dr. Troy Lund is a Associate Professor in the Department of Pediatrics at the University of Minnesota where he serves as a physician faculty member and pediatric bone marrow transplant specialist. Dr. Lund is interested in the use of blood and marrow transplantation primarily for patients with inherited metabolic disorders, like adrenoleukodystrophy (ALD) and Hurler syndrome. His work both in his laboratory and with his patients has created many new approaches to treatment, which will ultimately make transplant safer and more effective.

Dr. Lund's research focuses on improving the outcomes for all patients undergoing blood and marrow transplantation by increasing the speed at which hematopoietic stem cells reconstitute the immune system after transplant. He also works to increase our understanding the pathophysiological processes underlying inherited metabolic diseases. One area Dr. Lund is exploring is how an autoimmune reaction may trigger the cerebral form of adrenoleukodystrophy (cALD), the most serious form of ALD. This study represents the largest screening for immune-reactivity in cALD ever performed, and further research could help identify ALD patients with immune-reactivity prior to the onset of cALD.

Dr. Lund earned his PhD in cancer biology at the University of South Florida and his medical degree at the University of Minnesota Medical School where he also completed a residency and fellowship in hemotology/oncology and blood and marrow transplantation. He has received several awards during his time at the University of Minnesota including a Team Science Award. Basic Science Paper of the Year, and Butterfly Award for Outstanding Medical Research.

Reappointment of Scientific Members to the Grants Working Group

We are seeking the reappointment of the individuals listed in the table below. Their updated biographies follow. In accordance with the rules set forth by Proposition 71, reappointments should be staggered into thirds, each with a 2, 4, or 6-year term.

Proposed Reappointments to GWG

Last	First	Term	Expertise
Andrews	Brenda	4	Genomics; Phenomics; Cell Cycle Regulated Transcription

Centanni	John	6	Clinical Product Development for Cellular Therapeutics; Regulatory Strategy & Communication
Miller	Andra	4	Regulatory Strategy for Cellular & Gene Therapy Products; RAC; CMC
Otto	Kelly	2	Clinical Drug Development & Clinical Operations

Brenda Andrews, PhD
Brenda Andrews is Professor and Chair of the Banting & Best Department of Medical Research within the Faculty of Medicine at the University of Toronto, where she holds the Charles H Best Chair in Medical Research. She is also Director of the Terrence Donnelly Center for Cellular and Biomolecular Research (the Donnelly Centre), an interdisciplinary biomedical research institute with a focus on technology development for post-genome biology, functional genomics, systems & computational biology and bioengineering.

After receiving her PhD in Medical Biophysics from the University of Toronto, Dr. Andrews obtained her early training in genetics with the late Dr. Ira Herskowitz at the University of California San Francisco. In 1991, Dr. Andrews was recruited to the Department of Medical Genetics (now Molecular Genetics) at the University of Toronto. She became Chair of the Department in 1999, a position she held for 5 years before assuming her current positions. Dr. Andrews' current research interests analysis of genetic interaction networks in budding yeast, using automated genetics platforms that include high content microscopy for systematic analysis of cell biological phenotypes. Specific interests in the Andrews lab include mechanisms of cell cycle control, control of cell function by kinases and other enzymes and the regulation of cell polarity and morphogenesis. Her research is currently funded by the CIHR, the National Institutes of Health, the Ontario Research Fund, the Canadian Foundation for Innovation and the Canadian Institute for Advanced Research (CIFAR).

Dr. Andrews is a Fellow of the Royal Society of Canada, Fellow of the American Association for the Advancement of Science, a Fellow of the American Academy of Microbiology and Director of the Genetic Networks Program of the CIFAR.

John Centanni, MS
John Centanni is head of Regulatory Affairs at Neurona Therapeutics. He has demonstrated success in managing translational and clinical research from early stage research to human clinical trials both in academic and industry environments. Most recently, Mr. Centanni led the regulatory efforts of AxoGen Corporation in the development of biological products. Previous to this effort, Mr. Centanni was a faculty member of the University of Wisconsin, Masters in Biotechnology Program teaching the importance and application of regulatory, clinical, and quality functions in the biotechnology industry. During his tenure at the University of Wisconsin, Mr. Centanni provided FDA regulatory support across campus to facilitate the success of numerous investigational new drug (IND) applications and associated IND-enabling studies leading to active early phase clinical trials for new therapies. One primary area of regulatory focus included the clinical development of cellular and gene therapy products. Mr. Centanni is an accomplished scientist leading federally-funded multi-million dollar clinical and translational research projects at the capacity of Principal Investigator while at Stratatech Corporation. He has an established track record as it relates to scientific publications and generation of intellectual property with an extensive patent portfolio. Mr. Centanni received a Bachelor of Science degree from the University of Wisconsin-Oshkosh in Oshkosh, Wisconsin and a Master of Science degree in Biomedical Science from Hood College in Frederick, Maryland.

Andra Miller, PhD
Andra Miller, President VectorCell Bio Consulting provides regulatory consulting and product development strategy to early and late phase companies and academic investigators worldwide who are targeting the US market in the fields of gene therapy, cell therapy, and other advanced/regenerative medicines. Her consultation includes the development of regulatory strategies to facilitate rapid development of cell, gene and regenerative therapies using a science based approach, interpretation of FDA and NIH/RAC guidelines, pre-IND, IND and BLA preparation, phase I, II and III product development strategies and assessment of cGMP, cGTP and quality system compliance. Until November 2016, she

was the Director of Cell and Gene Therapies at Biologics Consulting Group and from 1993-2000 Dr. Miller was an expert microbiologist and gene therapy group leader in the Division of Cellular and Gene Therapies at the Center for Biologics Evaluation and Research for the FDA where she was responsible for IND review, policy issues, and development of industry guidance and regulation for cellular and gene therapies and related products. Dr. Miller's experience includes cell and stem cell products (including embryonic and induced pluripotent stem cells), viral and non-viral vectors, combination products, tissue products, *ex vivo* modified cells such as CAR-T cells and review of product jurisdiction issues.

Kelly Otto, MS
Kelly Otto is currently the Vice President, Clinical Development Operations at Avalyn Pharmaceuticals. Previously she was the Director of Biostatistics and Clinical Data Management and Systems Operations at the Cystic Fibrosis Therapeutics Development Network. She was formerly Vice President of Clinical Development Operations at Corus Pharma where her responsibilities included representing the company to the FDA in pre-NDA negotiations and presenting and discussing strategy and progress to the Board of Directors and Venture Capitalists. She holds a MS in Statistics and has over 25 years of experience in clinical trials and drug development. In addition, she has been responsible for CRO selection and management in many companies. Ms. Otto has experience with several electronic data management systems including selection, setup, reporting and form and edit check design. She has frequently authored, reviewed, and edited study documents, SOPs, manuscripts, abstracts and regulatory documents.