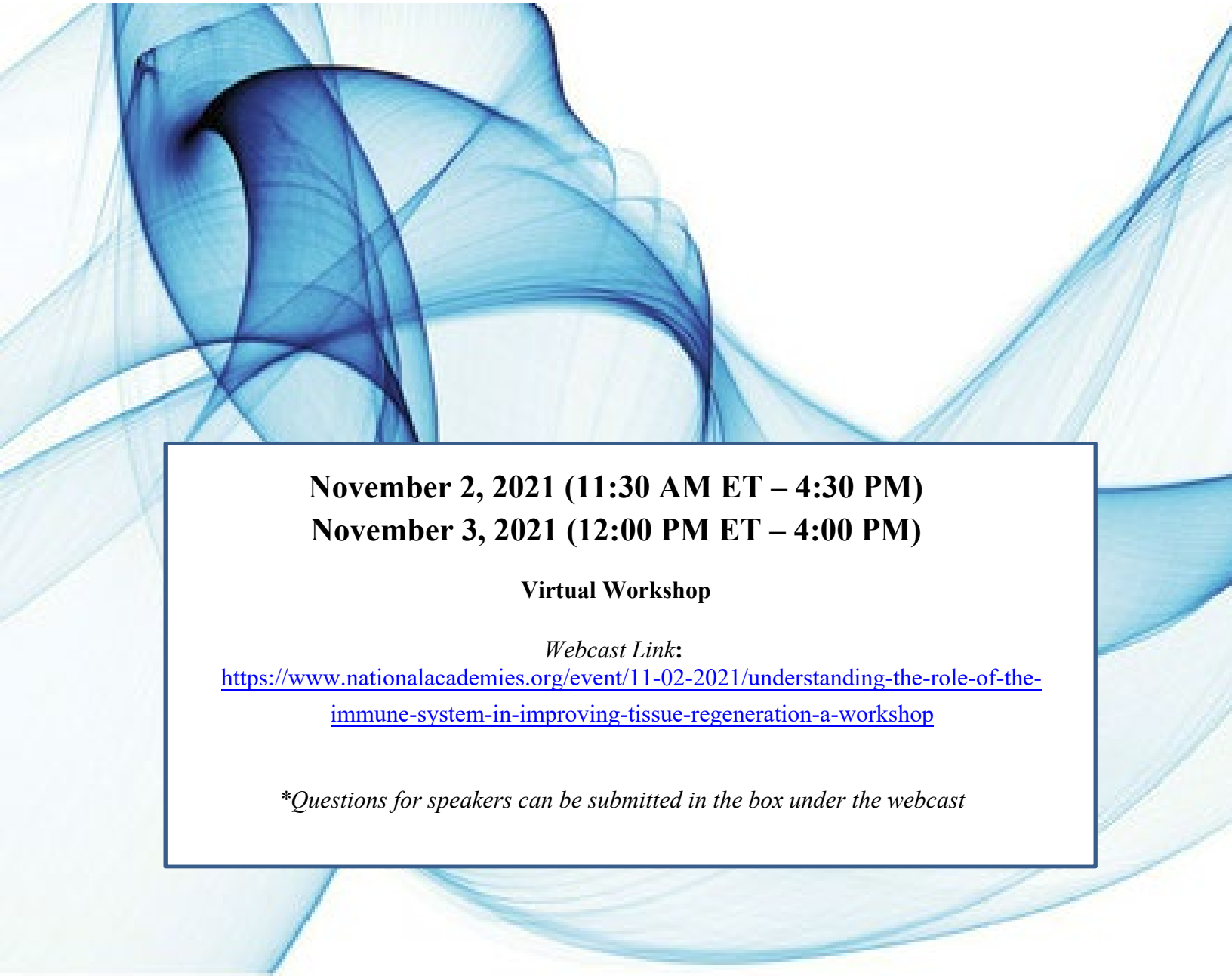
The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Board on Health Sciences Policy

Forum on Regenerative Medicine

Fall 2021 Workshop



November 2, 2021 (11:30 AM ET – 4:30 PM)
November 3, 2021 (12:00 PM ET – 4:00 PM)

Virtual Workshop

Webcast Link:
https://www.nationalacademies.org/event/11-02-2021/understanding-the-role-of-the-immune-system-in-improving-tissue-regeneration-a-workshop

**Questions for speakers can be submitted in the box under the webcast*

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Forum on Regenerative Medicine

Fall 2021 Workshop
November 2-3, 2021

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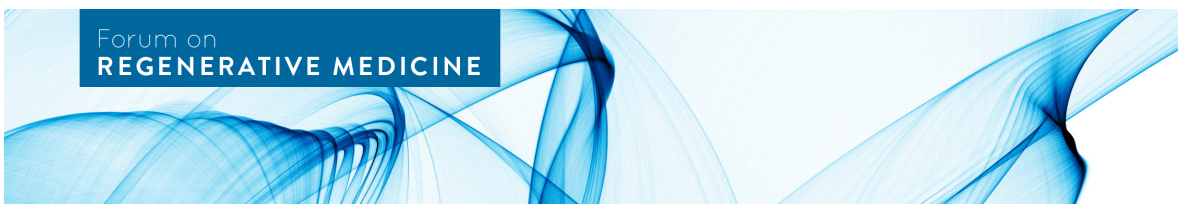

AGENDA

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

Forum on Regenerative Medicine

Understanding the Role of the Immune System in Improving Tissue Regeneration: A Workshop

November 2-3, 2021
Virtual Workshop

TIMELINE:
November 2, 2021: 11:30 AM – 4:30 PM
November 3, 2021: 12:00 PM – 4:00 PM

WEBCAST: **https://www.nationalacademies.org/event/11-02-2021/understanding-the-role-of-the-immune-system-in-improving-tissue-regeneration-a-workshop**

STATEMENT OF TASK: The Forum on Regenerative Medicine will hold a public workshop to explore potential promising approaches to modulate the immune system and/or the regenerative medicine product for improving the clinical outcomes of tissue repair and regeneration in patients.

Workshop discussions may examine:

- lessons learned from other fields (e.g. organ or bone marrow transplantation) about the role of the host's immune system in accepting a graft to inform whether manipulation of a graft can impact the acceptance or rejection of it;
- topics such as potential approaches for modulating critical immune system pathways and communication mechanisms between the immune system and damaged and/or diseased tissues;
- the application of these lessons learned to the development and use of regenerative medicine products, for example:
    - what immune factors and pathways play a role in regeneration;
    - biomarkers that may be useful for assessing a patient's immune status or response to regenerative medicine therapies;
    - scaffolds, biomaterials, and other bioengineering tools that may modify immune responses; and
    - imaging technologies to leverage immune surveillance in patients and evaluation of the results of regenerative therapies.

A planning committee of the National Academies of Sciences, Engineering, and Medicine will organize the workshop, select and invite speakers and discussants, and moderate the discussions. Proceedings of the presentations and discussions at the workshop will be prepared by a designated rapporteur in accordance with institutional guidelines.

11:30 a.m. ET **Welcome from the Forum Co-Chairs**

Tim Coetzee, *Forum Co-Chair*
Chief Advocacy, Services, and Science Officer
National Multiple Sclerosis Society

Kathy Tsokas, *Forum Co-Chair*
Vice President
Regulatory, Quality, Risk Management and Drug Safety
Janssen Inc. Canada

11:40 a.m. **Introduction and Charge to the Workshop Speakers and Participants**

Nadya Lumelsky, *Workshop Planning Committee Co-Chair*
Chief, Integrative Biology and Infectious Diseases Branch;
Program Director, Tissue Engineering and Regenerative Medicine Research Program
National Institute of Dental and Craniofacial Research (NIDCR)
National Institutes of Health (NIH)

Kimberlee Potter, *Workshop Planning Committee Co-Chair*
Scientific Program Manager
Biomedical Laboratory R&D Service
Office of Research & Development
Department of Veterans Affairs

11:50 a.m. **Keynote: Tissue Homeostasis, Inflammation, and Repair**

Ruslan Medzhitov
Sterling Professor of Immunobiology
Yale School of Medicine
Investigator, Howard Hughes Medical Institute

12:10 p.m. **Comment from the Patient Perspective**

Sherilyn George-Clinton
Leader
Multiple Sclerosis: You Are Not Alone (M.S. Y.A.N.A)

SESSION I. LESSONS LEARNED ON IMMUNE TOLERANCE AND GRAFT ACCEPTANCE

Moderator: Sohel Talib, California Institute for Regenerative Medicine

Session Objectives:

- Discuss the current state of knowledge about immune tolerance mechanisms and what lessons have been learned from other areas of research, including: transplant immunology, cancer immunotherapy, maternal-fetal interface, and the microbiome.

12:20 p.m. **Lessons Learned from Transplant Immunology**

Megan Sykes
Michael J. Friedlander Professor of Medicine and Professor of Microbiology & Immunology and Surgical Sciences (in Surgery)
Director, Columbia Center for Translational Immunology
Columbia University

12:35 p.m. **Microbiome and Immune Tolerance – If we can't Live Without it, How Best to Live with It? Lessons Learned from Allogeneic Hematopoietic Cell Transplantation**

Robert Jenq
Deputy Department Chair, Genomic Medicine
Associate Professor, Genomic Medicine
Associate Professor, Stem Cell Transplantation
MD Anderson Cancer Center

12:50 p.m. **Q&A with the Speakers and Participants**

Additional Panelist:
Ruslan Medzhitov
Sterling Professor of Immunobiology
Yale School of Medicine
Investigator, Howard Hughes Medical Institute

1:25 p.m. **Break**

SESSION II. ENGINEERING OF ALLOGENEIC DONOR CELLS FOR ACCEPTANCE BY THE HOST'S IMMUNE SYSTEM

Moderator: Rachel Salzman, American Society of Gene & Cell Therapy

Session Objectives:

- Explore recent advances in engineering of allogeneic donor cells for acceptance by the host's immune system (e.g., gene editing approaches, immune silent, universal donor cells).

2:00 p.m. **Protecting Transplanted Cells from Immune Rejection is the Key to Unlocking the Potential of Regenerative Medicine**

Sonja Schrepfer
Head of Hypoimmune Platform
Sana Biotechnology
Adjunct Professor, Department of Surgery
University of California, San Francisco

2:15 p.m. **Challenges to Using Mesenchymal Stem Cells in Immunomodulatory Therapies**

Katarina Le Blanc
Professor of Clinical Stem Cell Research
Karolinska Institute

2:30 p.m. **Off-the-Shelf Engineered iPSC-derived NK and T Cells for the Treatment of Cancer**

Bob Valamehr
Chief Research and Development Officer
Fate Therapeutics

2:45 p.m. **Q&A with the Speakers and Participants**

SESSION III. ENDOGENOUS REGENERATION AND THE ROLE OF THE LOCAL ENVIRONMENT IN REPAIR

Moderator: Steven Becker, National Cancer Institute

Session Objectives:

- Examine what "proper healing" looks like at the level of the local environment, and discuss relevant research gaps.
- Consider the effects of aging, gender, and other variables and pathological changes on the local environment, endogenous repair, and wound healing.

3:10 p.m. **Reversing Aging: Proinflammatory Metabolite Prostaglandin E2 Augments Muscle Regeneration**

Helen Blau
The Donald E. and Delia B. Baxter Foundation Professor
Director, Baxter Laboratory For Stem Cell Biology
Professor, by Courtesy, of Psychiatry and Behavioral Sciences
Stanford University

3:25 p.m. **Biomaterials for Modeling Immune Mediation in Wound Healing**

Erika Moore
Rhines Rising Star Larry Hench Assistant Professor
Department of Materials Science and Engineering
University of Florida

3:40 p.m. **Endogenous Pro-Resolution and Pro-Regenerative Mechanisms in the Periodontal Tissue**

George Hajishengallis
Thomas W. Evans Centennial Professor
Department of Basic and Translational Sciences
University of Pennsylvania

3:55 p.m. **Q&A with the Speakers and Participants**

4:20 p.m. **Reflections on Day 1 and Preview of Day 2**

Nadya Lumelsky, *Workshop Planning Committee Co-Chair*
Chief, Integrative Biology and Infectious Diseases Branch;
Program Director, Tissue Engineering and Regenerative Medicine Research Program
National Institute of Dental and Craniofacial Research (NIDCR)
National Institutes of Health (NIH)

Kimberlee Potter, *Workshop Planning Committee Co-Chair*
Scientific Program Manager
Biomedical Laboratory R&D Service
Office of Research & Development
Department of Veterans Affairs

4:30 p.m. **Adjourn Workshop Day 1**

DAY 2: November 3, 2021

12:00 p.m. ET **Welcome and Overview of Day 2**

Nadya Lumelsky, *Workshop Planning Committee Co-Chair*
Chief, Integrative Biology and Infectious Diseases Branch;
Program Director, Tissue Engineering and Regenerative Medicine Research Program
National Institute of Dental and Craniofacial Research (NIDCR)
National Institutes of Health (NIH)

Kimberlee Potter, *Workshop Planning Committee Co-Chair*
Scientific Program Manager
Biomedical Laboratory R&D Service
Office of Research & Development
Department of Veterans Affairs

SESSION IV. MODULATING THE HOST IMMUNE SYSTEM TO CREATE A PRO-REGENERATION ENVIRONMENT

Moderator: Candace Kerr, National Institute on Aging

Session Objectives:

- Discuss the goal(s) of host immune modulation and consider what the correct molecular targets are for creating a pro-regenerative environment.
- Examine recent research advances of the role of innate and adaptive immunity in cell engraftment and endogenous tissue regeneration, and approaches for immunomodulation of the structure and function of stem cell niches for goals of tissue regeneration.

12:10 p.m. **Cellular Senescence, Senolytics, and Organ Regeneration and Transplantation**

James Kirkland
Director, Robert and Arlene Kogod Center on Aging
Noaber Foundation Professor of Aging Research
Mayo Clinic

12:25 p.m. **Mapping the Immune and Tissue Environment in Healing and Non-Healing Wounds**

Jennifer Elisseeff
Jules Stein Professor, Biomedical Engineering
Morton Goldberg Professor, Ophthalmology
Professor, Materials Science & Engineering, Chemical and Biomolecular Engineering
Director, Translational Tissue Engineering Center
Johns Hopkins University

12:40 p.m. **Resolution of Acute Inflammation Stimulates Tissue Regeneration**

Charles Serhan
Endowed Distinguished Scientist & Director of the Center for Experimental Therapeutics and Reperfusion Injury
Brigham Women's Hospital
Professor of Anaesthesia
Harvard Medical School

12:55 p.m. **Q&A with the Speakers and Participants**

1:20 p.m. **Break**

SESSION V. DEVELOPING TOOLS AND PRECLINICAL MODELS FOR MONITORING AND OPTIMIZING THE HOST'S PRO-REGENERATIVE ENVIRONMENT

Moderator: Sadik Kassim, Vor Biopharma

Session Objectives:

- Explore recent advances in monitoring and imaging of the immune system as well as the potential implications of these new approaches for clinical translation of regenerative medicines.
- Discuss challenges and opportunities with regard to preclinical models for studying the immune system involvement in response to regenerative medicine.

1:40 p.m. **Tools for Immune Profiling and Monitoring**

Garry Nolan
Rachford and Carlota Harris Professor
Department of Pathology
Stanford University

1:55 p.m. **Engineered Immunity as a Model for Regenerative Medicine**

Michel Sadelain
Stephen and Barbara Friedman Chair
Director, Center for Cell Engineering
Memorial Sloan Kettering Cancer Center

2:10 p.m. **Basic Immunology to Guide Regenerative Therapeutic Design**

Kaitlyn Sadtler
Earl Stadtman Tenure-Track Investigator
Chief of Section on Immunoengineering
National Institute of Biomedical Imaging and Bioengineering

2:25 p.m. **Q&A with the Speakers and Participants**

2:50 p.m. **Break**

SESSION VI. FINAL PANEL: WHAT ARE SOME POSSIBILITIES TO HARNESS THE IMMUNE SYSTEM TO IMPROVE OUTCOMES FOR PATIENTS?

Session Objectives:

- Explore areas of clinical therapeutic need amenable to being clinical trial candidates that could demonstrate not only proof of principle of a specific therapeutic for a clinical indication but also ways to address the immune system's role in improving tissue regeneration.

3:05 p.m. **Panel Discussion**

Moderator: Richard McFarland, Advanced Regenerative Manufacturing Institute

Speakers:

Sherilyn George-Clinton
Leader
Multiple Sclerosis: You Are Not Alone (M.S. Y.A.N.A)

Thomas Wynn
Vice President, Discovery
Pfizer

Edward Botchwey
Associate Professor
Department of Biomedical Engineering
Georgia Tech

Sonja Schrepfer
Head of Hypoimmune Platform
Sana Biotechnology
Adjunct Professor, Department of Surgery
University of California, San Francisco

Danielle Brooks
Biologist
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Division of Clinical Evaluation and Pharmacology/Toxicology
Center for Biologics Evaluation and Research
Food and Drug Administration

Jennifer Elisseeff
Jules Stein Professor, Biomedical Engineering
Morton Goldberg Professor, Ophthalmology
Professor, Materials Science & Engineering, Chemical and Biomolecular Engineering
Director, Translational Tissue Engineering Center
Johns Hopkins University

3:35 p.m. **Summary of Key Points from Discussion**

Richard McFarland
Chief Regulatory Officer
Advanced Regenerative Manufacturing Institute

3:45 p.m. **Reflections from the Workshop and Final Comments**

Nadya Lumelsky, *Workshop Planning Committee Co-Chair*
Chief, Integrative Biology and Infectious Diseases Branch;
Program Director, Tissue Engineering and Regenerative Medicine Research Program
National Institute of Dental and Craniofacial Research (NIDCR)
National Institutes of Health (NIH)

Kimberlee Potter, *Workshop Planning Committee Co-Chair*
Scientific Program Manager
Biomedical Laboratory R&D Service
Office of Research & Development
Department of Veterans Affairs

4:00 p.m. **Adjourn Workshop Day 2**

FORUM
INFORMATION

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Forum on Regenerative Medicine

The National Academies of Sciences, Engineering, and Medicine's Forum on Regenerative Medicine provides a convening mechanism for interested parties from academia, industry, government, patient and provider organizations, regulators, foundations, and others to meet and discuss sensitive and difficult issues in a neutral setting in order to engage in dialogue and discussions that address the challenges facing the application of, and the opportunities for, regenerative medicine to improve health through the development of effective new therapies. The Forum identifies existing and potential barriers to scientific and therapeutic advances; identifies and discusses opportunities to assist in facilitating more effective partnerships among key stakeholders; examines the impact that current policies have on the discovery, development, and translation of regenerative medicine therapies; examines the unique challenges of identifying, validating, and bringing regenerative medicine applications to market; and explores the ethical, legal, and social issues posed by regenerative medicine advances.

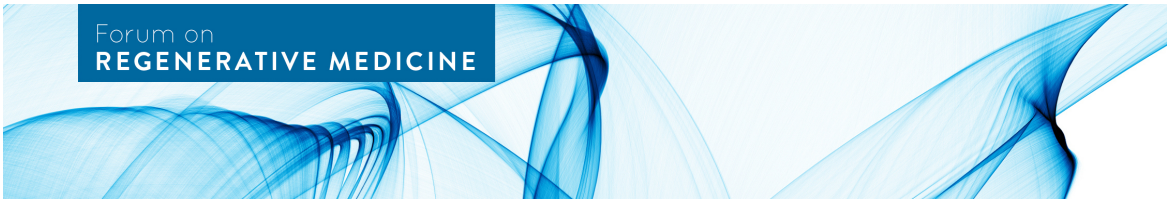
Regenerative medicine holds the potential to create living, functional tissues which can be used to repair or replace those that have suffered irreparable damage due to disease, age, traumatic injury, or congenital defects. Whether through tissue-engineering, synthetic constructs, or cellular therapies, the field holds the promise of providing relief to those suffering from traumatic injuries to neurodegenerative diseases. However, the enormous potential health and economic benefits this relatively new field could potentiate upon society must be balanced by the enactment of the proper policies and procedures to assure these therapies are safe and effective for use.

There are a number of key issues that must be explored and illuminated in order to realize the full potential of regenerative medicine. Ethical, legal, and social issues pose potential challenges with much debate still taking place around the use of adult, embryonic, and induced pluripotent stem cells for research and therapy. Additionally, many prospective advances, while developed for disease treatment, have the potential to be used for enhancement of physical attributes or anti-aging therapy. There is also a concern about possible unanticipated consequences of these treatments and products and the potential for stockpiling of and unequal access to organs. Ensuring the ethical application of regenerative medicine advances will be critical to not only progress the field but also to improve the health of individuals and the public.

Scientific and technical hurdles also exist for which a better fundamental understanding of the underlying cell biology is necessary. This knowledge will allow for more specific engineering of tissues and organs and will diminish the chance of transplant rejection by ensuring biocompatibility with the host tissue. Similarly, it is necessary to understand the cellular response to biomaterials and scaffolds to ensure that the desired biological function is developed and retained. While great advances have been realized to date, to take full advantage of regenerative medicine, the barriers to scientific advance will need to be delineated and potential solutions discussed.

Guidelines for the safe and proper use of regenerative medicine advances will need to be developed, translational barriers identified, and the regulatory environment clearly defined. Commercial aspects will need to be addressed including: the development of cost-effectiveness strategies for growing cells and organs at an industrial capacity; assessments of effectiveness, quality, and biosafety developed; and products certified. Greater dialogue and coordination of efforts between the public and private sectors will enable regenerative medicine products to be brought to market in a safe, effective, and swift manner.

Forum sponsors include federal agencies, medical and scientific associations, foundations, research organizations, patient groups, and industry representatives. For more information about the Forum on Regenerative Medicine, please visit our website at nas.edu/RegenMedForum or contact Sarah Beachy at 202-334-2217, or by email at sbeachy@nas.edu.



Forum on Regenerative Medicine

Membership

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Katherine Tsokas, J.D. (Janssen Inc. Canada)

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Forum on Regenerative Medicine

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Claudia Zylberberg, Ph.D.
Founder and CEO
Akron Biotech

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Board on Health Sciences Policy
Forum on Regenerative Medicine

Member Biographies

Timothy Coetzee, Ph.D. (*Co-Chair*)
Dr. Coetzee is the chief advocacy, services and science officer at the National Multiple Sclerosis Society (NMMS) in New York. Dr. Coetzee has been engaged in multiple sclerosis advocacy work throughout his career. He leads the society's federal and state activism programs and manages its investment in basic, clinical and commercial research. He has also helped launch and served as president of Fast Forward, an initiative of the NMMS to speed the commercial development of new treatments for multiple sclerosis. He earned his Ph.D. at Albany Medical College in New York.

Katherine Tsokas, J.D. (*Co-Chair*)
Katherine Tsokas has almost 30 years of progressive global regulatory experience in small and large sized Pharma companies. She has worked on products at various stages of development, from early through to filing, approval and commercialization. Currently, Katherine is the Janssen Regulatory Head of Regenerative Medicine & Advanced Therapy (RMAT), and the Johnson & Johnson Director of the RMAT Network. In these roles, she ensures global regulatory policy strategies contribute to and support development plans for RMAT products across several therapeutic areas, and facilitates J&J enterprise wide efforts to enhance awareness and connectivity for the development of process that enable assessing, partnering, and developing safe and effective advanced therapies globally. In addition, she represents Global Regulatory Affairs (GRA) on the J&J First in Human Committee, and she leads the Real World Evidence (RWE) Regulatory team and represents GRA on the cross-functional RWE Leadership team. Katherine received her Bachelor of Science Biology from Temple University, Juris Doctorate from Widener University Law School, and is admitted to the practice of law in Pennsylvania and New Jersey.

Raeka Aiyar, Ph.D. (*for Susan Soloman*)
Dr. Aiyar is Associate Vice President at The New York Stem Cell Foundation Research Institute, and an experienced molecular biologist turned science communicator. Trained in genomics and bioinformatics at the University of Waterloo, she received her PhD at the European Molecular Biology Laboratory in Germany, where she investigated new therapeutic strategies for mitochondrial diseases. Since then, Dr. Aiyar has dedicated her career to science communication, engaging a variety of audiences through writing, training, and outreach. As Director of Communications and Development at the Stanford Genome Technology Center and the Chronic Fatigue Syndrome Research Center at Stanford for 3 years, she led the Center's scientific communications, including fundraising, scientific strategy, program management, and collaboration building. In her current role at NYSCF, she oversees communications materials and initiatives, grant proposal development, and scientific event programming.

Rachael Anatol, Ph.D. *(for Celia Witten)*
Rachael Anatol is Deputy Director of the Office of Tissues and Advanced Therapies (previously the Office of Cellular, Tissue, and Gene Therapies)/Center for Biologics Evaluation and Research. Dr. Anatol graduated from the University of Maryland, College Park, with a Doctor of Philosophy in Molecular and Cell Biology and conducted her post-doctoral training at the National Heart, Lung, and Blood Institute /National Institutes of Health. Prior to her current role, Dr. Anatol served for 7 years as the Associate Director of Policy-New Legislation in the Office of Cellular, Tissue, and Gene Therapies.

Sangeeta Bhatia, M.D., Ph.D. (NAS, NAE, NAM)
Dr. Bhatia is a Howard Hughes Medical Institute Investigator and the John J. and Dorothy Wilson Professor at MIT's Institute for Medical Engineering and Science and Electrical Engineering and Computer Science (EECS). She is a member of the Koch Institute for Integrative Cancer Research, the Ludwig Center for Molecular Oncology, and the Harvard Stem Cell Institute, an Institute Member of the Broad Institute, and a Biomedical Engineer at the Brigham & Women's Hospital. Trained as both a physician and engineer, Bhatia's laboratory is dedicated to leveraging miniaturization tools from the world of semiconductor manufacturing to impact human health. She has pioneered technologies for interfacing living cells with synthetic systems, enabling new applications in tissue regeneration, stem cell differentiation, medical diagnostics and drug delivery. Her multidisciplinary team has developed a broad and impactful range of inventions, including human micro livers which model human drug metabolism, liver disease, and interaction with pathogens. Her group also develops nanoparticles and nanoporous materials that can be designed to assemble and communicate to study, diagnose, and treat a variety of diseases, including cancer. Her work has been profiled broadly such as in Scientific American, the Boston Globe, Popular Science, Forbes, PBS's NOVA scienceNOW, the Economist and MSNBC.

Dr. Bhatia trained at Brown, MIT, Harvard, and MGH. She is an elected member of the National Academy of Engineering, the American Academy of Arts & Sciences, and a fellow of the Massachusetts Academy of Sciences, Biomedical Engineering Society, American Institute for Medical and Biological Engineering, and American Society for Clinical Investigation. She has been awarded the 2014 Lemelson-MIT Prize; the 20th Heinz Award for Technology, the Economy, and Employment; the David and Lucile Packard Fellowship given to "the nation's most promising young professors in science and engineering;" the NSF CAREER Award; the Y.C. Fung Young Investigator Award of the American Society of Mechanical Engineers; the Young Investigator Award of the American College of Clinical Pharmacology; the Brown Engineering Alumni Medal; and was named a Merkin Fellow of the Broad Institute. As a passionate mentor and advocate for diversity in science and engineering, she has been the recipient of the Harvard Medical School Diversity Award and the Harvard-MIT Thomas McMahon Mentoring Award. She co-authored the first undergraduate textbook on tissue engineering and is a frequent advisor to governmental organizations on nanobiotechnology, biomedical microsystems, and tissue engineering. She and her over 150 trainees have contributed to more than 40 issued or pending patents and launched 10 biotechnology companies with 70+ commercial products at the intersection of medicine and miniaturization. She has published more than 170 manuscripts which have been cited a total of over 16,000 times. Prior to her position at MIT, she held a tenured position at UCSD, and has worked in industry at Pfizer, Genetics Institute, ICI Pharmaceuticals, and Organogenesis.

Philip John Brooks, Ph.D.
Philip John (P.J.) Brooks joined the NCATS Office of Rare Diseases Research as a program director in August 2018. Prior to that time, he was in the NCATS Division of Clinical Innovation, where he was the lead program director for the Clinical and Translational Science Awards (CTSA) Program Collaborative Innovation Awards, designed to fund projects that will result in novel and creative approaches to overcoming roadblocks in translational science (PAR-18-244(link is external) and PAR-18-245(link is external)). Brooks represents NCATS on the Trans-NIH Microbiome Working Group and Gene Therapy Working Groups. He is also the Working Group Coordinator for the NIH Common Fund program on Somatic Cell Genome Editing (link is external).

Brooks received his Ph.D. in neurobiology from the University of North Carolina at Chapel Hill. After completing a postdoctoral fellowship at the Rockefeller University, Brooks became an investigator in the intramural program of the National Institute on Alcohol Abuse and Alcoholism. He developed an internationally recognized research program focused on two distinct areas: the molecular basis of alcohol-related cancer, and rare neurologic diseases resulting from defective DNA repair, including xeroderma pigmentosum, Cockanye syndrome and Fanconi anemia.

George Q. Daley, M.D., Ph.D. (NAM)
Dr. Daley seeks to translate insights in stem cell biology into improved therapies for genetic and malignant diseases. Important research contributions from his laboratory include the creation of customized stem cells to treat genetic immune deficiency in a mouse model (together with Rudolf Jaenisch), the differentiation of germ cells from embryonic stem cells (cited as a "Top Ten Breakthrough" by Science magazine in 2003), and the generation of disease-specific pluripotent stem cells by direct reprogramming of human fibroblasts (cited in the "Breakthrough of the Year" issue of Science magazine in 2008). As a graduate student working with Nobelist Dr. David Baltimore, Dr. Daley demonstrated that the BCR/ABL oncogene induces chronic myeloid leukemia (CML) in a mouse model, which validated BCR/ABL as a target for drug blockade and encouraged the development of imatinib (GleevecTM; Novartis), a revolutionary magic-bullet chemotherapy that induces remissions in virtually every CML patient. Dr. Daley's recent studies have clarified mechanisms of Gleevec resistance and informed novel combination chemotherapeutic regimens.

Dr. Daley received his bachelor's degree magna cum laude from Harvard University (1982), a Ph.D. in biology from MIT (1989), and the M.D. from Harvard Medical School, where he was only the twelfth individual in the school's history to be awarded the degree summa cum laude (1991). He served as Chief Resident in Internal Medicine at the Massachusetts General Hospital (94-95) and is currently a staff physician in Hematology/Oncology at the Children's Hospital and the Dana Farber Cancer Institute, and a member of the Hematology Division of the Brigham and Women's Hospital in Boston. He has been elected to the National Academy of Medicine of the National Academies of Sciences, Engineering, and Medicine, the American Society for Clinical Investigation, the American Association of Physicians, and the American Pediatric Societies, and is a fellow of the American Academy of Arts and Sciences and the American Association for the Advancement of Science. Dr. Daley was an inaugural winner of the NIH Director's Pioneer Award for highly innovative research and has received the Judson Daland Prize from the American Philosophical Society for achievement in patient-oriented research, the E. Mead Johnson Award from the American Pediatric Society for contributions to stem cell research, and the E. Donnall Thomas Prize of the American Society for Hematology for advances in human induced pluripotent stem cells.

Dr. Daley is the Samuel E. Lux IV Professor of Hematology/Oncology and Director of the Stem Cell Transplantation Program at Boston Children's Hospital. He is also Professor of Biological Chemistry and Molecular Pharmacology, Medicine, and Pediatrics at Harvard Medical School, an investigator of the Howard Hughes Medical Institute, Associate Director of Children's Stem Cell Program, founding member of the Executive Committee of the Harvard Stem Cell Institute, and past-President of the International Society for Stem Cell Research (2007-2008).

Rena N. D'Souza, Ph.D.
Dr. Rena D'Souza is the Director of the National Institute of Dental and Craniofacial Research, National Institutes of Health. She is deeply committed to the organization's mission — to improve dental, oral and craniofacial health — and believes the institute plays a key role in how oral health care is delivered. Prior to becoming NIDCR's director, Dr. D'Souza served in the position of Associate Vice Provost for Research for the University of Utah and as Assistant Vice President for Academic Affairs and Education for the Health Sciences. She held the Ole and Marty Jensen endowed chair in the School of Dentistry where she served as inaugural dean. As a clinician-scientist, D'Souza has been strongly committed to discovery and mentoring throughout her academic career. She is a past president of the American Association for Dental Research (AADR) and the International Association for Dental Research (IADR). She has authored over 150 publications and book chapters in the areas of craniofacial development, matrix biology and tissue regeneration for over 30 years. She is a Fellow of AAAS and also of AADR. Dr. D'Souza received the Presidential Award for Research Excellence from the Texas A&M Health Science Center in 2010 and was inducted into the German National Academy of Sciences in 2012. She

was recognized as the Columbia University College of Dental Medicine's Birnberg Research Medal in 2016 and received the Irwin D. Mandel Distinguished National Mentoring Award in 2017.
Dr. D'Souza will maintain an active research laboratory in the National Institute of Child Health and Human Development (NICHD), NIH.

Brian Fiske, Ph.D.
Dr. Fiske joined The Michael J. Fox Foundation in 2004. As Senior Vice President, Research Programs, Dr. Fiske co-manages a team of professionals who stay closely linked to the Parkinson's community in order to develop an aggressive and innovative agenda for accelerating research and drug development for Parkinson's disease. This ensures that MJFF priorities reflect and best serve the ultimate needs of patients. Brian regularly meets with academic and industry scientists around the world to identify promising ideas to support, providing troubleshooting and ongoing management of projects. He currently oversees the teams focused on MJFF's strategies for developing disease-modifying and symptomatic therapies for Parkinson's patients.

Dr. Fiske earned an undergraduate degree in biology from Texas A&M University and a PhD in Neuroscience from the University of Virginia. After completing postdoctoral research at Columbia University, he spent several years as an editor for the scientific journal, Nature Neuroscience. He brings this broad experience and knowledge to the Foundation to help bring new treatments to people with Parkinson's.

Lawrence Goldstein, Ph.D.
My primary goal is to understand the molecular and neuronal defects in Alzheimer's disease and Niemann Pick Type C disease. Our lab studies induced pluripotent stem cell lines that contain known mutations that cause hereditary Alzheimer's disease, genomes that contribute to sporadic Alzheimer's disease, embryonic stem cell lines in which expression of the gene that causes Niemann Pick Type C disease is reduced as in true human disease, and induced pluripotent stem cell lines carrying Niemann Pick Type C mutations. This latter disease is of interest because it directly ties cholesterol trafficking and transport to what appears to be a pediatric form of Alzheimer type dementia. We are also using these cell lines and neurons from animal models to probe basic mechanisms of vesicle movement and sorting in neurons, and how such mechanisms inter-relate with disease development. Finally, we are probing how genetic variation predisposes to different neuronal and liver phenotypes and disease by developing pluripotent stem cell lines carrying genomes of people who developed sporadic Alzheimer's disease or in one case carry susceptibility elements (from Craig Venter whose diploid genome is completely sequenced and which is known to harbor Alzheimer susceptibility variants). To study these problems, we have developed new quantitative methods for generating and purifying neurons made from human embryonic stem cells and induced pluripotent stem cells, as well as methods for evaluating a range of normal and disease phenotypes in these cells.

My teaching interests are primarily focused on graduate, postdoctoral, and physician-scientist education in the lab. I have also done some formal medical student teaching since coming to UCSD, for which I have received highly enthusiastic comments from medical students. My graduate students and postdocs over the years have been very successful both in my lab and upon leaving my lab and secured independent faculty positions at major research institutions including Harvard Medical School, University of Chicago, Johns Hopkins University, University of Utah, University of Maryland, Albert Einstein College of Medicine, UCSD, and equivalent institutions in other nations around the world. Recently I have become interested in the training of physician-scientists and have in the past several years trained two young physician-scientists both of whom have recently achieved independent faculty status. I have also been involved in the development of several new training programs for graduate students, postdocs, and physician scientists in and around UCSD.

Thomas Greenwell, Ph.D. (*for Michael Steinmetz*)
Thomas Greenwell, Ph.D. is a Health Scientist Administrator with over 12 years of experience in science administration and portfolio management at NIH. He specializes in knowledge and administration of grants in cellular neuroscience and technology applications, especially related to vision. He has experience in behavioral models of addiction and stress, fetal alcohol syndrome, and opioid peptides. His interests remain in furthering the public health of the nation, new health science technologies, and government collaborations with pharma and medical device companies.

Patrick Hanley, Ph.D. *(for Daniel Weiss)*
Patrick Hanley, Ph.D., is an assistant professor of pediatrics and Chief & Director of the Cellular Therapy Program at Children's National Hospital. He oversees process development; translation; and manufacturing of cellular therapy products as well as follow up testing of patients enrolled on cellular therapy clinical trials. 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 fifteen years he has helped to translate more than 20 cellular 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 serves on the Board of Directors of FACT and as the commissioning editor of the journal Cytotherapy. He is also active in ISCT; co-chairing the Immuno-Gene Therapy Committee; co-founding the Early Stage Professionals Committee; and he was recently elected Vice President-elect; North America. He; along with colleagues Drs. Catherine Bollard and Russell Cruz; co-founded Mana Therapeutics; a biotech company with the mission of educating immune cells and curing cancer.

Candace Kerr, M.S., Ph.D.
Candace Kerr is the program officer for the Stem Cell Program in the Aging Physiology Branch of the Division of Aging Biology at the National Institute on Aging. NIA's Stem Cell Program has supported major findings on the genetics regulating stem cell lifespan and genomic stability, the relationships between stem cell survival and aged health, and the discovery of molecules that facilitate stem cell depletion and cellular senescence.

Before joining the NIA in 2017, Dr. Kerr was on the faculty of the University of Maryland School of Medicine researching human adult and cancer stem cells, and earlier on the faculty at Johns Hopkins University School of Medicine where her laboratory studied human pluripotent stem cells and the translation of these cells to treat reproductive and neurological conditions.

Dr. Kerr received her M.S. in molecular genetics at the University of Maine and her Ph.D. in quantitative genetics and biochemistry from Pennsylvania State University. As a postdoctoral fellow at Johns Hopkins University School of Public Health, she also studied the glycobiological interactions in receptor binding and endocrine functions in mice fertility and reproduction

Dr. Kerr is the author of 35 peer-reviewed research papers and 14 review articles, textbook chapters, and commentaries. She has also shared her expertise as editor for several journals related to the stem cell biology field.

Walter Koroshetz, M.D. (*for Timothy LaVaute*)
Walter J. Koroshetz, M.D., was selected Director of NINDS on June 11, 2015. Dr. Koroshetz joined NINDS in 2007 as Deputy Director, and he served as Acting Director from October 2014 through June 2015. Previously, he served as Deputy Director of NINDS under Dr. Story Landis. Together, they directed program planning and budgeting, and oversaw the scientific and administrative functions of the Institute. He has held leadership roles in a number of NIH and NINDS programs including the NIH's BRAIN Initiative, the Traumatic Brain Injury Center collaborative effort between the NIH intramural

program and the Uniformed Health Services University, and the multi-year work to develop and establish the NIH Office of Emergency Care Research to coordinate NIH emergency care research and research training.

Robert S. Langer, Sc.D. (NAS, NAE, NAM)
Robert S. Langer is the David H. Koch Institute Professor at the Massachusetts Institute of Technology. He completed his undergraduate studies in Chemical Engineering at Cornell University and obtained his Sc.D. in Chemical Engineering at MIT. He joined MIT as Assistant Professor of Nutritional Biochemistry in 1978. Dr. Langer has written over 1,250 articles and also has nearly 1,050 patents worldwide. Dr. Langer's patents have been licensed or sublicensed to over 250 pharmaceutical, chemical, biotechnology and medical device companies.

Dr. Langer has received over 220 major awards. He is one of 5 living individuals to have received both the United States National Medal of Science (2006) and the United States National Medal of Technology and Innovation (2011). He also received the 2002 Charles Stark Draper Prize, considered the equivalent of the Nobel Prize for engineers, the 2008 Millennium Prize, the world's largest technology prize, the 2012 Priestley Medal, the highest award of the American Chemical Society, the 2013 Wolf Prize in Chemistry, the 2014 Breakthrough Prize in Life Sciences and the 2014 Kyoto Prize. He is the also the only engineer to receive the Gairdner Foundation International Award; 82 recipients of this award have subsequently received a Nobel Prize. Among numerous other awards Langer has received are the Dickson Prize for Science (2002), Heinz Award for Technology, Economy and Employment (2003), the Harvey Prize (2003), the John Fritz Award (2003) (given previously to inventors such as Thomas Edison and Orville Wright), the General Motors Kettering Prize for Cancer Research (2004), the Dan David Prize in Materials Science (2005), the Albany Medical Center Prize in Medicine and Biomedical Research (2005), the largest prize in the U.S. for medical research, induction into the National Inventors Hall of Fame (2006), the Max Planck Research Award (2008), the Prince of Asturias Award for Technical and Scientific Research (2008), the Warren Alpert Foundation Prize (2011) and the Terumo International Prize (2012). In 1998, he received the Lemelson-MIT prize, the world's largest prize for invention for being "one of history's most prolific inventors in medicine." In 1989 Dr. Langer was elected to the National Academy of Medicine of the National Academies of Sciences, Engineering, and Medicine, and in 1992 he was elected to both the National Academy of Engineering and to the National Academy of Sciences, and in 2012 he was elected to the National Academy of Inventors.

Cato T. Laurencin, M.D., Ph.D. (NAE, NAM, NAS)
Cato T. Laurencin is the University Professor and Albert and Wilda Van Dusen Distinguished Endowed Professor of Orthopaedic Surgery at the University of Connecticut. He is Professor of Chemical Engineering, Professor of Materials Science and Engineering and Professor of Biomedical Engineering at the school. He serves as the Chief Executive Officer of The Connecticut Convergence Institute for Translation in Regenerative Engineering and the Director of the Raymond and Beverly Sackler Center for Biomedical, Biological, Physical and Engineering Sciences at UConn.
Dr. Laurencin earned a B.S.E. in Chemical Engineering from Princeton University, and his M.D., Magna Cum Laude, from the Harvard Medical School, and received the Robinson Award for Surgery. He earned his Ph.D. in Biochemical Engineering/Biotechnology from the Massachusetts Institute of Technology where he was named a Hugh Hampton Young Fellow. A practicing sports medicine and shoulder surgeon, Dr. Laurencin has been named to America's Top Doctors for over fifteen years. He is a Fellow of the American Academy of Orthopaedic Surgeons, a Fellow of the American Orthopaedic Association, a Fellow of the American College of Surgeons and a member of the American Surgical Association. He received the Nicolas Andry Award, the highest honor of the Association of Bone and Joint Surgeons. Dr. Laurencin served as Dean of the Medical School and Vice President for Health Affairs at the University of Connecticut.

Dr. Laurencin is a pioneer of the new field, Regenerative Engineering. He is an expert in biomaterials science, stem cell technology and nanotechnology and was named one of the 100 Engineers of the Modern Era by the American Institute of Chemical Engineers. He received the Founder's Award (highest award) from the Society for Biomaterials, the Von Hipple Award (highest award) from the Materials Research Society and the James Bailey Award (highest award) from the Society for Biological Engineering. He received the NIH Director's Pioneer Award, NIH's highest and most prestigious research award, for his new field of Regenerative Engineering and the National Science Foundation's Emerging Frontiers in Research and Innovation Grant Award. Dr. Laurencin is the Editor-in-Chief of Regenerative Engineering and Translational Medicine, published by Springer Nature, and is the Founder of the Regenerative Engineering Society. He is a Fellow of the American Chemical Society, a Fellow of the American Institute of Chemical Engineers, a Fellow of the Biomedical Engineering Society, a Fellow of the Materials Research Society and a AAAS Fellow. The American Association for the Advancement of Science awarded Dr. Laurencin the Philip Hauge Abelson Prize given 'for signal contributions to the advancement of science in the United States'.

Dr. Laurencin is active in mentoring, especially underrepresented minority students. He received the American Association for the Advancement of Science (AAAS) Mentor Award, the Beckman Award for Mentoring, and the Presidential Award for Excellence in Science, Math and Engineering Mentoring in ceremonies at the White House. The Society for Biomaterials established The Cato T. Laurencin, M.D., Ph.D. Travel Fellowship in his honor, awarded to underrepresented minority students pursuing research.

Dr. Laurencin is also active in addressing Health Disparities. Dr. Laurencin completed the Program in African-American Studies at Princeton University. He is a core faculty member of the Africana Studies Institute at the University of Connecticut, and is Editor-in-Chief of the Journal of Racial and Ethnic Health Disparities, published by Springer Nature. He co-Founded the W. Montague Cobb/NMA Health Institute, dedicated to addressing Health Disparities, and served as its Founding Chair. The W. Montague Cobb/NMA Health Institute and the National Medical Association established the Cato T. Laurencin Lifetime Research Achievement Award, given during the opening ceremonies of the National Medical Association Meeting. He is a recipient of the Herbert W. Nickens Award from the Association of American Medical Colleges recognizing his work advancing social justice and equity.

Dr. Laurencin is an elected member of the National Academy of Sciences, the National Academy of Engineering, the National Academy of Medicine, and an elected fellow of the National Academy of Inventors. He is the first surgeon in history elected to all four of these academies. He is an elected fellow of the American Academy of Arts and Sciences and an elected fellow of the American Association for the Advancement of Science. Active internationally, he is an elected fellow of the Indian National Academy of Sciences, the Indian National Academy of Engineering, the African Academy of Sciences, The World Academy of Sciences, and is an Academician of the Chinese Academy of Engineering.

Dr. Laurencin is the recipient of the National Medal of Technology and Innovation, America's highest honor for technological achievement, awarded by President Barack Obama in ceremonies at the White House. He is the first individual in history to receive the oldest/highest award of the National Academy of Medicine (the Walsh McDermott Medal) and the oldest/highest award of the National Academy of Engineering (the Simon Ramo Founder's Award).

Timothy LaVaute, Ph.D.
Dr. LaVaute is a Program Director in Division of Neuroscience at National Institute of Neurological Disorders and Stroke (NINDS) where he manages a portfolio of grants and cooperative agreements in the research areas of neural stem cells, developmental neuroscience, neurogenesis, and gliogenesis. Dr. LaVaute oversees the NINDS P30 Neuroscience Cores Grant Program, is the NINDS point of contact for the NIH's Regenerative Medicine Innovation Project, and the NIH Common Fund's Somatic Cell Genome

Editing Program. He serves as the point of contact at the NINDS for NIH policy on research utilizing human fetal tissue, and human embryonic stem cells. Dr. LaVaute received his Ph.D. from the University of Wisconsin-Madison, where he developed methods for directed differentiation of human embryonic stems cells, for the generation of specific subtypes of neurons and glia.

Sheng Lin-Gibson, Ph.D. *(for Anne Plant)*
Dr. Sheng Lin-Gibson is the chief of the NIST Biomaterials Group and the Director of Regenerative Medicine Biomanufacturing Programs. She serves as the Convenor of ISO/TC 276: Biotechnology Working Group 3: Analytical Methods, where international experts develop measurement science-based standards to advance biotechnology, including cellular and gene therapy. She also serves as the Chairperson for the U.S. Mirror Committee to ISO/TC276 that coordinates US positions with input from government, industry, and professional organizations. Dr. Lin-Gibson is currently leading and contributing to the development of several international standards on cell measurements and bioprocessing particularly relevant to the cellular and gene therapy industry as well as a NIST laboratory program supporting these efforts. She is the NIST Liaison to Standards Coordination Body (SCB) through a NIST-SCB MOU aimed to jointly identify standardization needs and gaps as well as measurement science underpinning standards development. Dr. Lin-Gibson serves as the Program Director and a Principle Investigator on a NIDCR/NIST Interagency Agreement to develop measurements and standards to advance dental research and oral health since 2007. Her research portfolio includes the measurement of cells, microbial systems, and biomaterials. She has coauthored over 60 peer-reviewed publications, served on numerous NSF, NIH, NAS, and NIST expert panels, and is a recipient of two Department of Commerce Bronze Medals.

Sara Lin, Ph.D. (*for Amy Patterson*)
Dr. Lin is the program director for the Division of Lung Diseases at the National Heart, Lung, and Blood Institute (NHLBI) where she guides international research efforts to study mechanisms of lung development and regeneration. Her work is part of a coordinated approach to identify therapies for conditions that affect the airways and lungs – from rare ones, like bronchopulmonary dysplasia (BPD), to more common ones, including asthma, the seasonal flu, and COVID-19.

Nadya Lumelsky, Ph.D. (*for Rena D'Souza*)
Dr. Lumelsky is a Chief of Integrative Biology and Infectious Diseases Branch and a Director of Tissue Engineering and Regenerative Medicine Program at the National Institute of Dental and Craniofacial Research (NIDCR) at the National Institutes of Health (NIH). Prior to joining NIDCR in 2006, she was an investigator at the intramural NIH Program at the National Institute of Neurological Disorders and Stroke and a Section Chief at the National Institute of Diabetes & Digestive & and Kidney Diseases. Earlier in her career, Dr. Lumelsky conducted research at the University of Wisconsin/Madison and Yale University. She has a wide-ranging expertise in stem cell and developmental biology, cell biology, and bioengineering, and has been a leading and senior author on publications in *Science, Nature, Diabetes, Stem Cells, Molecular and Cellular Biology, Tissue Engineering* and other high impact Journals.

Terry Magnuson, Ph.D.
Dr. Magnuson was recruited to Carolina in 2000 as founding chair of the Department of Genetics and Director of the newly established Carolina Center for Genome Sciences. He also created the Cancer Genetics Program in the UNC Lineberger Comprehensive Cancer Center. He was appointed Vice Dean for Research in the School of Medicine in July 2010.

A founding member of the International Mammalian Genome Society, Dr. Magnuson also served on the external advisory committee for the Mouse Genome Database at the Jackson Laboratory (2001-2004) and was Chair of the Jackson Laboratory Board of Scientific Overseers (2005-2010). He has served on the Board of Directors of the Society for Developmental Biology (2000-2006), the Genetics Society of

America (2004-2006), and he was a Board Member of the publically traded CRO Company, PPD (2001-2011).

He was appointed by the National Academies to establish guidelines for work with human embryonic stem cells (2004-2009), and also served as vice chair of an Institute of Medicine committee evaluating the California Institute for Regenerative Medicine (2011-2012), and served as a member of the Institute of Medicine's committee reviewing the NIH Recombinant DNA Advisory Committee.

Currently, he is a member of the NIH stem cell working group (2009 – date) and the NIH Council of Councils (2014-date). He was elected to the American Academy of Arts and Sciences (2007), a fellow of the AAAS (2009), and to the Institute of Medicine (2012). He served on the International Selection Committee for the Franklin Institute's Bower Prize in Genomics (2010) and is a Senior Editor for Genetics (2009-date) and a member of the Board of Reviewing Editors for Science Signaling (2010-date).

The work in the Magnuson lab focuses on the role of mammalian genes in unique epigenetic phenomena such as genomic imprinting, X-chromosome inactivation and stem cell pluripotency. The lab also studies the tumor suppressor role of the BAF/PBAF chromatin remodeling complexes and has developed a novel genome-wide mutagenesis strategy. Dr. Magnuson received his Ph.D. from Cornell University and was a postdoctoral fellow at UCSF.

Michael May, Ph.D.
Michael May is President and Chief Executive Officer of the Centre for Commercialization of Regenerative Medicine (CCRM), a Canadian, not-for-profit that develops technologies and launches new companies by supporting both academic and industry activities in the field of regenerative medicine, including cell and gene therapy. With a staff of 70, a network of academic members, 50+ industry partners, dedicated funding and facilities to develop technologies, manufacture cell product and incubate companies, CCRM is generating health and economic benefits for its stakeholders. Prior to CCRM, Michael was the President, and co-founder, of Rimon Therapeutics Ltd., a Toronto-based tissue engineering company developing novel medical polymers that possess drug-like activity.

Michael sits on a number of boards and advisory committees including: the Centre for the Commercialization of Antibodies and Biologics (CCAB); the Entrepreneurship Leadership Council at the University of Toronto; the TO Health! Human & Science Steering Committee; the Cell and Gene Therapy Insights, Editorial Advisory Board; the Industry Committee of the International Society for Stem Cell Research (ISSCR); and the Executive Committee, Alliance for Regenerative Medicine (ARM). He is the Chairman of the start-up company: ExCellThera Ltd.

Dr. May completed his PhD in Chemical Engineering at the University of Toronto in 1998 as an NSERC Scholar and was awarded the Martin Walmsley Fellowship for Technological Entrepreneurship

Richard McFarland, Ph.D., M.D.
Richard McFarland, Ph.D., M.D. joined ARMI as its Chief Regulatory Officer on May 1, 2017. Dr. McFarland comes to ARMI from the Food and Drug Administration's Center for Biologics Evaluation and Research (FDA/CBER) where his career spanning 16 years involved review over an extensive range of products and policy development in numerous areas both inside FDA, across the federal government, and internationally. He spent more than a decade as Associate Director of Policy for FDA/CBER's Office of Tissues and Advanced Therapies and its predecessor office, the Office of Cellular, Tissue and Gene Therapies. In this position, he was heavily involved in policy development for tissue engineering, regenerative medicine, and alternatives to animal use in regulatory decision making. In addition to development of risk-based regulatory oversight paradigms within FDA, his interests included broader efforts to create an interlocking network of interagency efforts to foster growth of basic and translational

science to support maturation of the overlapping fields of tissue engineering and regenerative medicine from primarily discovery science toward a stage of commercial development.

His position at ARMI will allow him to apply the knowledge and experiences gained over the last decade and half in the field to ARMI's efforts to establish an industrial common, in the form of a Manufacturing Innovation Institute within the Manufacturing USA network, with the aims to coalesce the field and provide a route for nascent product concepts to reach the marketplace. Bringing these products to the market will benefit critical U.S. public health needs and will provide the economic drivers needed to create new highly-skilled jobs.

Dr. McFarland received his B.S., Ph.D., and M.D. from the University of North Carolina at Chapel Hill, and completed his anatomic/clinical pathology residency and immunopathology fellowship training at UT Southwestern in Dallas. Immediately prior to joining the FDA, he was on the faculty of the Pathology Department of the University of Texas Southwestern in Dallas. In addition to FDA policy documents he has co-authored over 25 articles in peer-reviewed articles journals including Nature, the Proceedings of the National Academy of Science (PNAS), and Blood.

Jack Mosher, Ph.D.
Jack Mosher, Ph.D. is the Senior Manager of Scientific Affairs for the International Society for Stem Cell Research (ISSCR). Jack, who joined the ISSCR in 2015, works closely with ISSCR committees, leadership and staff to provide scientific oversight for the public and professional educational, policy and communication programs.

Jack earned his Ph.D. in Neurobiology at UNC Chapel Hill and was a postdoctoral fellow in the laboratory of Dr. Sean Morrison at the University of Michigan. Jack's research interests have been focused on the development of the nervous system. As a graduate student, Jack studied the genetic regulation of early nervous system development in *Drosophila* and as a postdoctoral fellow he investigated the basic biology of neural crest stem cells and their contribution to the development and disease of the peripheral nervous system (PNS). This research included the role of stem cells in PNS tumors and the pathology and potential treatment of aganglionic megacolon.

Prior to joining the ISSCR, Jack was an Assistant Research Scientist at the University of Michigan where he became involved in scientific educational outreach efforts around the 2008 Michigan ballot initiative, Proposal 2, designed to protect legal forms of human embryonic stem cell research. This process reinforced the importance and need for clear and accurate information and education on stem cell research.

Amy Patterson, M.D.
Dr. Patterson is the Chief Science Advisor and Director of Scientific Research Programs, Policy, and Strategic Initiatives in the Immediate Office of the Director (IOD) of the National Heart, Lung, and Blood Institute (NHLBI), part of the National Institutes of Health (NIH). In this role, she provides leadership and strategic coordination of trans-NHLBI efforts and manages a broad portfolio of issues germane to the conduct of clinical research, research oversight, policy development, major new scientific initiatives, and relationships with organizations within and external to the Institute.

Prior to joining the NHLBI in 2015, Dr. Patterson served as the NIH Associate Director for Science Policy and as the NIH Associate Director for Biosecurity and Biosafety Policy. Her responsibilities encompassed areas such as human subjects protections; the organization and oversight of clinical trials; scientific, social, and ethical considerations in genetics research and human gene transfer trials; and safety and security implications of emerging new technologies.

Prior to coming to the NIH Office of the Director, she served as the Deputy Director of the Division of Cellular and Gene Therapies and Medical Officer in the Division of Clinical Trial Design and Analysis at the FDA Center for Biologics Evaluation and Research. Dr. Patterson received her B.A. (Cum Laude) in biology from Harvard University and her M.D. (Alpha Omega Alpha) from Albert Einstein College of Medicine. She conducted her internship and residency in internal medicine at New York Hospital and Memorial Sloan Kettering and completed her post-doctoral clinical research fellowships in adult and pediatric endocrinology and metabolism at the NIH.

Duanqing Pei, Ph.D.
Dr. Pei is Professor of stem cell biology and also serves as the Director General (President) at the Guangzhou Institutes of Biomedicine and Health (GIBH), Chinese Academy of Sciences, in Guangzhou, China. He obtained his PhD from the University of Pennsylvania in 1991 and trained as a postdoctoral fellow at the University of Michigan before becoming a faculty member at the University of Minnesota School of Medicine in 1996. He joined the Medical Faculty at Tsinghua University in Beijing China in 2002 and moved to the newly formed GIBH in 2004.

Dr. Pei studied the transcription regulation of hepatitis B virus (HBV) for his Ph.D. thesis by identifying C/EBP as a repressor for HBV transcription and dissecting the transactivation domains in C/EBP. Then he shifted his research interest into the field of extracellular matrix remodeling by studying the structure and function of matrix metalloproteinases (MMPs). He cloned several novel members of the MMP family, uncovered the unique intracellular activation mechanism of MMPs with the proprotein convertase system, and the intracellular trafficking of membrane-bound MMPs. Upon returning to China, he once again changed his field of study and started working on pluripotency first and then reprogramming. The Pei lab in Tsinghua began to publish in the stem cell field on the structure and function of Oct4, Sox2, FoxD3, Essrb, and Nanog, and their interdependent relationship towards pluripotency. Based the understanding of these factors, the Pei lab was the first in China to create mouse iPSCs using a non-selective system, and then improved the iPS process systematically. The Pei lab subsequently disseminated the iPS technology in China by providing not only resources, but also training workshops. Recent publications from the Pei lab includes the discovery of vitamin C as a potent booster for iPSC generation and a mesenchymal to epithelial transition initiates the reprogramming process of mouse fibroblasts. Now, his lab continues to explore new ways to improve iPS technology, dissect the reprogramming mechanisms driven by Oct4/Sox2/Klf4 or fewer factors, and employ iPSCs to model human diseases in vitro.

Anne Plant, Ph.D.
Anne Plant received her Ph.D. from Baylor College of Medicine in Houston, TX in Biochemistry. She is Chief of the Biosystems and Biomaterials Division at NIST. She served for a year in the White House Office of Science and Technology Policy and is currently the NIST Representative to the NSTC Life Science Sub-Committee. She serves on the NIBIB National Advisory Council for Biomedical Imaging and Bioengineering, co-chairs ASTM International Committee F04.46 on Standards for Cell Signaling, and is on the Editorial Advisory Board of the journal, Biointerphases. She is a Fellow of the American Institute for Medical and Biological Engineering. Her research has recently been focused on robust quantification of cell response through quantitative cell imaging, and theoretical approaches for prediction of complex biological response.

Kimberlee Potter, Ph.D.
Dr. Potter is the Portfolio Manager of Surgery, Trauma, and Restorative Medicine in the Office of Research and Development at the Department of Veterans Affairs where she serves as the VA representative on the National Academies of Sciences, Engineering, and Medicine (NASEM) Forum for Regenerative Medicine, the Armed Forces Institute of Regenerative Medicine IIPT, and the Congressionally Directed Medical Research Program for the Reconstructive Transplantation Research

Program. She is also a member of the Veterans Health Administration NASEM Strategic Workgroup. Prior to joining VA, Dr. Potter worked at Armed Forces Institute of Pathology as the Technical Director of the Magnetic Resonance Microscopy Facility where she applied non-invasive imaging techniques to the study of forensic, pathologic, and engineered tissues. She worked with the Office of the Armed Forces Medical Examiners on blast-induced traumatic brain injury and the application of medical imaging for virtual autopsies. Prior to joining AFIP, she was a visiting scientist at National Institutes of Health at the National Institute on Aging and then at the National Institute on Child Health and Human Development. She received her post-doctoral training at the University of California at Santa Barbara in the Department of Chemical & Nuclear Engineering. Dr. Potter received her B.S. degree in Engineering Chemistry from Queen's University (Canada) and her Ph.D. from Cambridge University (England).

Derek Robertson, M.B.A, J.D., CHC
Derek Robertson is, along with his wife Shantá, co-founder of the Maryland Sickle Cell Disease Association (MSCDA). Derek and Shantá have three sons, two of whom have sickle cell disease (SCD). As President of MSCDA, Derek oversees the overall direction of the organization. Derek has served on various SCD related committees. He was appointed by the US Secretary of Health and Human Services to serve on the Secretary's Advisory Committee on Heritable Disorders from 2004 – 2007 and the federal Maternal and Child Health Bureau's Newborn Screening Expert Panel from 2001 – 2004. He currently serves as a member of the National Institute of Health's National Heart, Lung, and Blood Institute's Sickle Cell Disease Advisory Committee.

Professionally, Derek is a healthcare attorney/ consultant who brings with him a vast experience in government pricing programs with a particular specialty in the Public Health Service Section 340B Drug Pricing Discount Program (the "340B Program"). Derek also has extensive experience in Medicare and Medicaid reimbursement as well as the federal Medicaid Drug Rebate Program. As a Managing Director in the Consulting firm, Apogenics, Inc., Derek advises his clients on how to stay in compliance with various federal laws and regulations including anti-kickback laws and various guidance related to federal drug pricing discount programs. Derek has worked extensively with hospitals and universities on federal grants management and, program income calculation and reporting. He presents nationally at conferences on government pricing programs, specialty pharmacy trends and conflicts of interest in healthcare.

Prior to joining the Apogenics team, Derek helped establish and served as a contracted Executive Director and General Counsel to the Hemophilia Alliance, Inc., an organization representing Hemophilia Treatment Centers (HTCs) that participate in the 340B Program. He also served as General Counsel for the Hemophilia Alliance Group Purchasing Organization. While representing the Alliance, Derek spent two years as an associate attorney at the law firm of Powers, Pyles, Sutter and Verville, PC in Washington DC.

Derek holds an MBA from City University of New York - Baruch College and his Doctor of Jurisprudence from the University of Houston Law Center. He is licensed to practice law in both Texas and Washington, DC. He certified in Health Care Compliance by the Health Care Compliance Association.

Kelly Rose, Ph.D.
Dr. Rose is a program officer with the Burroughs Wellcome Fund, where she oversees the Interfaces in Science and the Regulatory Science Programs. Prior to Burroughs Wellcome, Dr. Rose was the executive director for the Research Triangle Material Research Science and Engineering Center (RT-MRSEC), which conducts research and education at four partner universities in the Research Triangle: Duke University, North Carolina State University, North Carolina Central University, and University of North Carolina-Chapel Hill. Prior to RT-MRSEC, Dr. Rose was the program coordinator for the California Institute of Regenerative Medicine Bridges Program in Berkeley, CA. Dr. Rose earned her Ph.D. in

Biomedical Sciences from the University of New Mexico. She was awarded a National Institute of Health Institutional Research and Academic Career Development Award (IRACDA) postdoctoral fellowship at the University of California-San Francisco, where she worked on a joint project in the Departments of Bioengineering and Craniofacial Biology.

Krishnendu Roy, Ph.D.
Dr. Krishnendu (Krish) Roy received his undergraduate degree from the Indian Institute of Technology (India) followed by his MS from Boston University and his PhD in Biomedical Engineering from Johns Hopkins University. Following his PhD, he joined Zycos Inc., a start-up biotechnology company where he served first as a Scientist and then as a Senior Scientist in the Drug Delivery Research group. Dr. Roy left his industrial position to join The University of Texas at Austin in 2002, where he was most recently Professor and Fellow of the Cockrell Chair in Engineering Excellence. He left UT-Austin in July of 2013 to move to Georgia Tech. where he is currently the Robert A. Milton Chair. At Georgia Tech, he also serves as the Director of the newly established Marcus Center for Cell-Therapy Characterization and Manufacturing as well as the Director of the Center for ImmunoEngineering, a consortium of 30+ faculty focused on using engineering tools and methodologies to understand and modulate the immune system in health and disease. He is also the Technical Lead of the NIST/AMTech National Cell Manufacturing Consortium (NCMC), a national public-private partnership, focused on addressing the challenges and solutions for large scale manufacturing of therapeutic cells. Dr. Roy's research interests are in the areas of controlled drug and vaccine delivery technologies, Immuno-engineering, stem-cell engineering and cell manufacturing, with particular focus in biomedical materials in cancer and immunotherapies. In recognition of his seminal contribution to these fields, Dr. Roy has been elected Fellow of the American Institute for Medical and Biological Engineering (AIMBE) and Fellow of the Biomedical Engineering Society (BMES). In addition, Dr. Roy has received numerous awards and honors including Young Investigator Awards from both the Controlled Release Society (CRS) and The Society for Biomaterials (SFB), the Young Scientist Award from HSEMB, NSF CAREER award, Global Indus Technovator Award from MIT, the CRS Cygnus Award etc. He serves as a member of the Editorial Boards of the Journal of Controlled Release and the European Journal of Pharmaceutics and Biopharmaceutics.

Krishanu Saha, Ph.D.
Dr. Krishanu Saha is an Assistant Professor, Departments of Biomedical Engineering and Medical History & Bioethics at the University of Wisconsin-Madison. His interests lie in using human stem cells together with emerging engineering methods in material science and synthetic biology to make smarter therapeutics, model human disease, and advance personalized medicine. As a Society in Science-Branco Weiss Fellow, he worked with Sheila Jasanoff at Harvard University on "The Constitutional Foundations of Bioethics: A Cross-National Comparison" from September 2010 to December 2011. He is also affliated with Robert F. and Jean E. Holtz Center for Science & Technology Studies at the University of Wisconsin-Madison. Saha received his B.S. in Chemical Engineering and Chemistry from Cornell University (2001), his M.Phil in Biotechnology (Biological Sciences) from the University of Cambridge (2002) and his Ph.D. in Chemical Engineering from the University of California-Berkeley (2007).

Rachel Salzman, D.V.M.
Dr. Salzman serves as Chief Scientific Officer of The Stop ALD Foundation (SALD), and has held this position since 2001. SALD is a non-profit Medical Research Organization dedicated to employing entrepreneurial approaches and innovative methodology towards effective therapies, cures, and prevention of x-linked adrenoleukodystrophy (ALD), an often fatal neurodegenerative disease. The biomedical interests of the Foundation include gene therapy, hematopoietic stem cells and other adult stem cells, genomics, and small molecules. In this context SALD made critical contributions to the groundbreaking ex vivo lenti trial conducted in pediatric patients in France, which is now a pivotal clinical study sponsored by a publicly owned US-based biotech. Rachel also consults for large pharma and biotech in the field of drug development, including preclinical and clinical analysis in a variety of

therapeutic areas including oncology, metabolic disease, CNS disorders, and orphan indications. As an active member of The American Society of Gene and Cell Therapy (ASGCT) Dr. Salzman is an elected member of the Board of Directors and also serves as ASGCT's Chairperson of the Government Relations Committee. Prior to these roles, Rachel worked in private veterinary practice in both large and small animal medicine. She has a D.V.M. from Oklahoma State University and a B.S. from Rutgers University.

Ivonne Schulman, M.D.
Dr. Schulman is a program director at the National Institute of Diabetes and Digestive and Kidney Diseases at the National Institutes of Health.

Jay Siegel, M.D.
Dr. Jay Siegel is retired from Johnson & Johnson, where he was Chief Biotechnology Officer and Head of Scientific Strategy and Policy. He also currently serves on the Executive Committees and the Boards of the Biotechnology Industry Organization and the Alliance for Regenerative Medicine.

Dr. Siegel joined Johnson & Johnson in 2003 as President of Centocor R&D, and subsequently served as Group President of R&D, as Head of Global Regulatory Affairs and Head of the Biotechnology Center of Excellence.

Before joining Johnson & Johnson, Dr. Siegel spent 20 years at the FDA Center for Biologics Evaluation & Research in positions of increasing responsibility regulating the biotechnology industry.

Dr. Siegel received a B.S. in Biology from the California Institute of Technology and an M.D. from Stanford University.

Ilyas Singeç, M.D., Ph.D. (*for Philip John Brooks*)
Ilyas Singeç joined NCATS in 2015 as the director of Stem Cell Translation Laboratory in the Division of Pre-Clinical Innovation. Singeç translates stem cell discoveries into clinical applications, focusing on the development of new assays (tests), drugs and cell therapies.

Prior to joining NCATS, Singeç carried out postdoctoral work first at the National Institute of Neurological Disorders and Stroke and then at the Sanford Burnham Prebys Medical Discovery Institute in La Jolla, California, where he also served as staff scientist and director of cell reprogramming. Most recently, Singeç worked in the pharmaceutical and entrepreneurial industries.

Singeç earned his M.D. and Ph.D. summa cum laude in Germany at the Universities of Bonn and Freiburg, completing his residency in clinical neuropathology and neuroanatomy in Freiburg.

Mitchel Sivilotti, M.Sc. *(for Michael May)*
Prior to joining CCRM, Mitch led operations, manufacturing, development, and commercial departments at Cesca Therapeutics, Inc. (Nasdaq: KOOL), located in Rancho Cordova, California. While at Cesca, Mitch managed a global employee base (U.S., EU, India, China) involved in all aspects of regenerative medicine-based software, controlled electromechanical devices and companion disposables for therapeutic use in Intraoperative Orthopedics (Spine & Non-Unions) & Hematology/Oncology Markets (BMT, Cord Blood). Cesca Therapeutics was the result of a $80M USD merger between Thermogenesis Corp. and TotipotentRX Corporation, which Mitch co-founded in 2007 in Los Angeles, California.

While at TotipotentRX, Mitch served as Chief Executive Officer and Director from 2008 to 2012 and as President and Director from 2012 to 2013. From 2003 to 2007, Mitch served in various key technical and business leadership roles at Pall Corporation (now Danaher Corporation NYSE:DHR), completing his tenure as Global Marketing Manager, Regenerative Medicine. Mitch holds a graduate degree in Cellular

and Molecular Biology from the Université Laval (Quebec, Canada) and a graduate degree in Finance from Queen's University (Kingston, Canada).

Lana Skirboll, Ph.D., M.S.
Lana R. Skirboll is Vice President of Academic and Scientific Affairs at Sanofi, where she works on policy issues of importance to innovation. She formerly served as Director of Science Policy at the National Institutes of Health (NIH), where she was responsible for identifying policy issues relevant to the support and conduct of research, analyzing and recommending and creating new policies that advance the interest of the Agency. These included human subject protections, the privacy and confidentiality of research records, conflicts of interest, human embryo research, cloning and fetal tissue research, genetics, health, and society, dual use research, gene therapy and nanotechnology, comparative effectiveness research, personalized medicine, among others.Dr. Skirboll played a leadership role in NIH's organizational strategic planning and evaluation, where, for example, she developed NIH's efforts to measure and report on Agency performance. She also worked with the NIH Director, Elias Zerhouni, to design and implement the "Roadmap for Medical Research." She initiated the development of a new program on Return on Investment to explore NIH's impact on local economies and national competitiveness. She was responsible for developing and coordinating the NIH Public-Private partnership program, which leveraged NIH investments by working with industry. In addition, her team ran a small, but highly creative, science education program that worked nation-wide to develop materials for students and teachers on behalf of national science literacy and the pipeline of new young scientists, as well as creating opportunities with local students to learn about careers in science. As Acting Director of the NIH Division of Program Coordination, Planning, and Strategic Initiatives, she led national efforts to identify and address emerging scientific opportunities and rising public health challenges that cut across institutes, including the management of nearly 0.75 billion dollars in research funds. In addition, Dr. Skirboll was also responsible for NIH offices that coordinate research and activities related to research on AIDS, behavioral and social sciences, women's health, disease prevention, rare diseases, and dietary supplements. She also led NIH's burgeoning efforts to design and implement a program in Portfolio Analysis to inform Agency investments.Dr. Skirboll was trained in Pharmacology and Neuroscience. She completed her Ph.D. at Georgetown University Medical School, followed by post-doctoral work and research positions at Yale University, the Karolinska Institute (Sweden), and the National Institute of Mental Health. She is the author of more than 70 peer reviewed scientific publications.

Robert Star, M.D. (*for Ivonne Schulman*)
As director of the Division of Kidney, Urologic, and Hematologic Diseases, Dr. Star is responsible for managing a research portfolio on basic, translational, and clinical studies of the kidney, urinary tract, and disorders of the blood and blood-forming organs. The Division supports research on important health problems, including chronic kidney disease, end-stage renal disease, diabetic nephropathy, acute kidney injury, urinary incontinence, urinary tract infections, urologic chronic pelvic pain syndromes, hematopoiesis, hemoglobin disorders, sickle cell disease, and iron deficiency. The Division provides researchers with resources that advance the study of the kidney, urinary tract, and blood—for example, databases, registries, repositories, and scientific tools. Dr. Star's responsibilities also include oversight of programs that support the training and career development of individuals committed to academic and clinical research in these areas. As senior investigator and chief of the Renal Diagnostics and Therapeutics Unit, he leads a team that studies sepsis and acute kidney injury (AKI)—both are associated with high rates of illness and death. The team focuses on identifying markers to detect and therapies to treat or prevent sepsis and AKI. Our recent research findings include: models of sepsis and sepsis-AKI that better mimic human disease; how chronic kidney disease amplifies sepsis mortality and changes the mechanisms of sepsis; demonstrations of individual and combination agents that show promise for inhibiting sepsis and renal injury; and development of several imaging methods that could serve as noninvasive diagnostic tools to detect renal dysfunction.

Michael Steinmetz, Ph.D.
Dr. Steinmetz is the Director of the Division of Extramural Science Programs. He oversees the extramural grant portfolio including Retinal Diseases, Corneal Diseases, Lens and Cataract, Glaucoma, Strabismus, Amblyopia, and Visual Processing, Low Vision and Blindness Rehabilitation, and Collaborative Clinical Research. He also has a lead role in the NEI Audacious Goals Initiative to restore vision through the regeneration of visual neurons and their connections. Dr. Steinmetz serves on numerous trans-NIH and government-wide committees including the NIH Director's Pioneer Award and New Innovator Award, the NIH Brain and Blueprint coordinating committees, and the program committee of Department of Defense Vision Research Program.

Dr. Steinmetz joined the neuroscience department at the Johns Hopkins School of Medicine in 1985 following a postdoctoral fellowship in the laboratory of Vernon Mountcastle. He helped establish the Johns Hopkins Zanvyl Krieger Mind/Brain Institute in 1994 and served as a senior scientist there studying visual processing in awake, behaving monkeys. In 2003, Dr. Steinmetz came to the NIH as a Referral Officer and Scientific Review Officer for the Central Visual Processing and the Cognitive Neuroscience Study Sections in the Center for Scientific Review. Dr. Steinmetz joined the NEI Division of Extramural Research in 2007 as the Director of the Strabismus, Amblyopia, and Visual Processing Program. He was named director of that division in 2014, and served as Acting Deputy Director of NEI in 2017-2018.

Susan Solomon, J.D.
Susan L. Solomon is Founder and Chief Executive Officer of The New York Stem Cell Foundation Research Institute, the world's leading independent non-profit research institute dedicated to translating cutting- edge stem cell research into clinical breakthroughs and cures for patients.

A veteran healthcare advocate, Ms. Solomon serves on the boards of a number of prominent diabetes and regenerative medicine organizations including the College Diabetes Network and the Global Alliance for IPSC Therapies. She also serves on the Board of Directors of the Regional Plan Association. Ms. Solomon has received numerous awards for her work with NYSCF, including the New York State Women of Excellence Award from the Governor of New York, the Triumph Award from the Brooke Ellison Foundation, and recognition as a Living Landmark from the New York Landmarks Conservancy.

A lawyer by training and a chief executive and entrepreneur by experience, Ms. Solomon has decades of leadership experience in starting and building effective and focused organizations. Ms. Solomon started her career as an attorney at Debevoise & Plimpton, then held executive positions at MacAndrews and Forbes and APAX (formerly MMG Patricof and Co.). She was the founder and President of Sony Worldwide Networks, the Chairman and CEO of Lancit Media Productions, an Emmy award-winning television production company, and then served as the founding CEO of Sothebys.com, prior to starting her own strategic management consulting firm Solomon Partners LLC in 2000.

Sohel Talib, Ph.D.
Sohel Talib is Senior Science offer and Director, Therapeutics at California Institute for Regenerative Medicine (CIRM). He is responsible for developing and implementing CIRM's scientific programs and managing portfolio of clinical stage grants utilizing hematopoietic stem cell gene therapy approaches for the treatment of Hemoglobinopathies, Primary Immune Deficiency diseases (PID), HIV AIDS and Cancer. His scientific background is in the Stem Cell and Gene Therapy and has spent 20 years in the biotech industry. Before joining CIRM he was the Director of Product Development at Geron Corporation, Menlo Park, California. At Geron Corporation, Sohel directed immune-oncology program on the development of an autologous dendritic cell vaccine for cancer (Geron VAC-1). Prior to Geron Corporation, Sohel Talib, served as the Director of Immunology at Cerus Corporation, a biotech company developing novel allogeneic stem cell therapy for the hematological malignancies. He was a cofounder of Applied Immune Sciences (AIS), which was acquired by Rhone Poulenc Rorer (RPR, currently Sanofi).

AT RPR Gen Cell, he directed the development and execution of adoptive immunotherapy programs. Dr. Talib received his post-doctoral training at Stanford University, University of California, Berkeley and Roche Institute of Molecular Biology, Nutley. He obtained his Ph.D. in Biochemistry from Aligarh University, India and International DANIDA fellowship from Danish Institute of Protein Chemistry, Copenhagen.

Daniel Weiss, M.D., Ph.D.
Dr. Weiss is Professor of Medicine at the University of Vermont. He received his PhD in Pharmacology in 1987 from the City University of New York and MD from the Mt. Sinai School of Medicine in 1988. Following internship and residency in internal medicine at the University of Michigan and subsequent fellowship training in pulmonary and critical care medicine at the University of Washington, Dr. Weiss was recruited to the University of Vermont in 2001. Dr. Weiss has a longstanding interest in lung repair and regeneration after injury, notably gene and cell therapy approaches for lung diseases. In particular this has included developing novel techniques with which to investigate and enhance lung gene and cell therapies. Recent published work in cell therapy approaches for lung diseases has included several benchmark publications that have included the first ever trial of cell therapy for emphysema and that have helped define whether exogenous cells can engraft in the lung. As such, Dr. Weiss is a translational scientist whose work spans from benchtop to clinical trials. Dr. Weiss has also instituted a biennial meeting held at the University of Vermont, Stem Cells and Cell Therapies in Lung Biology and Diseases, that is widely viewed by the NIH, FDA, and non-profit Respiratory Disease Foundations as the major meeting in the field. Dr. Weiss' overall goal is to provide a firm scientific basis for clinical application of cell therapies in lung diseases. He has been funded by the NIH, DOD, non-profit Respiratory Disease Foundations, and by industry sources since 1995 and has over 100 current publications. Current work in the laboratory is focused in three major areas: 1) Bioengineering approaches for development of functional lung tissue ex vivo; 2) Immunomodulation of lung inflammation by mesenchymal stromal cells (MSCs); 3) Development of cell therapy-based approaches for lung disease.

Dr. Weiss has been involved with the ISCT for the past 10 years and currently serves as Chief Scientific Officer. A central goal of Dr. Weiss' activities with the ISCT is to promote education and actions against stem cell medical tourism.

Michael Werner, J.D.
Michael Werner has almost three decades of healthcare law, lobbying, regulatory, reimbursement and policy development experience in Washington. He focuses on issues affecting biotechnology and pharmaceutical companies, medical research and research institutions, physicians and patients. His specific areas of knowledge include legislation and FDA regulations regarding drug/biological product review, approval, and distribution; public and private payer reimbursement strategy; NIH funding programs; regulation of cell therapy, gene therapy, tissue engineering and regenerative medicine products; and bioethics issues arising from research and uses of new technologies. Mr. Werner is the co-founder and Executive Director of the Alliance for Regenerative Medicine, a Washington, DC-based organization comprised of almost 250 life sciences companies, academic institutions, clinical centers, patient advocacy groups and investors whose mission is to advocate for federal funding, regulatory and reimbursement policies that will advance regenerative medicine research and product development. Mr. Werner is a partner in the Washington, DC office of Holland & Knight, LLP.

Brad Wise, Ph.D. (*for Candace Kerr*)
Dr. Wise is Chief of the Neurobiology of Aging Branch in the Division of Neuroscience. He joined NIA in 1996 as the program director for the Fundamental Neuroscience Section, developing and administering research programs in neurodegeneration, neuroplasticity, neural stem cells, glia, and basic science (e.g. bioenergetics, oxidative stress, protein homeostasis, genetics) of brain aging. His branch also supports research on integrative neurobiology, sleep disorders and biological rhythms, receptors, the

cerebrovasculature, and systemic metabolism. Dr. Wise received his B.A. in Chemistry from Duke University in 1975 and his Ph.D. in Pharmacology from Emory University School of Medicine in 1981. His postdoctoral training was at the National Institute of Mental Health intramural research program, first as a PRAT fellow and then staff fellow. Dr. Wise was a laboratory chief in the Fidia-Georgetown Institute for the Neurosciences (1985-1994) and a faculty member in the Department of Pharmacology at Georgetown University Medical Center (1985-1996), where he conducted research on the cellular and molecular mechanisms regulating nerve growth factor expression. At the NIA, Dr. Wise continues to manage and develop the research areas mentioned above, serves on several NIA and NIH committees, and has received several NIA/NIH awards.

Celia M. Witten, M.D., Ph.D.
Celia M. Witten, Ph.D., M. D. is the Deputy Director of the Center for Biologics Evaluation and Research at the Food and Drug Administration (FDA/CBER). Between 2005 and 2016 she served as the Director of the Office of Cellular, Tissue and Gene Therapy at the FDA/CBER. Between 1996 and 2005 she served as Director of the Division of General, Restorative, and Neurological Devices in the Office of Device Evaluation in the Center for Devices and Radiological Health (CDRH). Previous to FDA, she worked for over 10 years as a practicing physician at the National Rehabilitation Hospital (NRH) in Washington, D.C. Her educational background includes a B.A. earned at Princeton University (Magna Cum Laude), a Ph.D. from Stanford University, and an M.D. from the University of Miami School of Medicine. In addition to her academic achievements she is Board Certified in Physical Medicine and Rehabilitation.

Claudia Zylberberg, Ph.D.
Dr. Zylberberg is the Founder and CEO of Akron Biotech. She has more than 25 years' experience in the biomedical research and biotechnology industries, and first-hand knowledge of what it takes to bring products through R&D, and on to approval and commercialization. She is highly knowledgeable about current FDA regulations, qualification of raw materials, process design and validation, and bioassay development. Dr. Zylberberg is proud to act as advisor and consultant to organizations worldwide regarding the regulatory roadmap and commercialization of cell therapies and stem cell banking. In addition, she brings her expertise in recombinant proteins, media development, combinational (devices), and platform technologies to Akron. She is the inventor of numerous patented proprietary technologies, and has an extensive peer-reviewed publication record. Dr. Zylberberg is affiliated with the International Society for Cell Therapy (ISCT) and holds many nonexecutive positions: Board Member and Scientific Advisor, Alliance for Regenerative Medicine (ARM); Board Member, BioFlorida; Board Member, Banner Center of Life Sciences, Palm Beach State College; and Chair of Industry Advisory Board, West Palm Beach, Florida.

WORKSHOP INFORMATION

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Board on Health Sciences Policy
Forum on Regenerative Medicine

Understanding the Role of the Immune System in Improving Tissue Regeneration: A Workshop

Planning Committee Co-Chairs

Nadya Lumelsky, Ph.D.
Chief, Integrative Biology and Infectious Diseases Branch
Director, Tissue Engineering and Regenerative Medicine Program
National Institute of Dental and Craniofacial Research (NIDCR)
National Institutes of Health

Kimberlee Potter, Ph.D.
Scientific Program Manager, Biomedical Laboratory R&D
Office of Research & Development
Department of Veterans Affairs

Planning Committee Members

Steven Becker, Ph.D.
Program Director, Division of Cancer Biology
National Cancer Institute (NCI)
National Institutes of Health (NIH)

Jennifer Elisseeff, Ph.D.
Jules Stein Professor, Biomedical Engineering
Morton Goldberg Professor, Ophthalmology
Professor, Materials Science & Engineering, Chemical and Biomolecular Engineering
Director, Translational Tissue Engineering Center
Johns Hopkins University

Sadik Kassim, Ph.D.
Chief Technology Officer
Vor Biopharma

Candace Kerr, M.S., Ph.D.
Program Officer, Division of Aging Biology
National Institute on Aging (NIA)
National Institutes of Health (NIH)

Cato Laurencin, M.D., Ph.D.
Albert and Wilda Van Dusen Distinguished Professor, Orthopaedic Surgery
Professor, Chemical Engineering, Biomedical Engineering, Materials Science and Engineering

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Director, Raymond and Beverly Sackler Center for Biomedical, Biological, Physical and Engineering Sciences
Chief Executive Officer, Connecticut Convergence Institute for Translation in Regenerative Engineering
University of Connecticut

Richard McFarland, Ph.D., M.D.
Chief Regulatory Officer
Advanced Regenerative Manufacturing Institute

Rachel Salzman, D.V.M.
Chair, Government Relations Committee
American Society of Gene and Cell Therapy

Sohel Talib, Ph.D.
Senior Science Officer and Director of Therapeutics
California Institute for Regenerative Medicine

Daniel Weiss, M.D., Ph.D.
Chief Scientific Officer
International Society for Cell & Gene Therapy
Professor, Medicine – Pulmonary Disease and Critical Care
University of Vermont

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Board on Health Sciences Policy
Forum on Regenerative Medicine

Understanding the Role of the Immune System in Improving Tissue Regeneration: A Workshop

November 2-3, 2021

Planning Committee Biographies

Nadya Lumelsky (co-chair), Ph.D., is a Chief of Integrative Biology and Infectious Diseases Branch and a Director of Tissue Engineering and Regenerative Medicine Program at the National Institute of Dental and Craniofacial Research (NIDCR) at the National Institutes of Health (NIH). Prior to joining NIDCR in 2006, she was an investigator at the intramural NIH Program at the National Institute of Neurological Disorders and Stroke and a Section Chief at the National Institute of Diabetes & Digestive & and Kidney Diseases. Earlier in her career, Dr. Lumelsky conducted research at the University of Wisconsin/Madison and Yale University. She has a wide-ranging expertise in stem cell and developmental biology, cell biology, and bioengineering, and has been a leading and senior author on publications in Science, Nature, Diabetes, Stem Cells, Molecular and Cellular Biology, Tissue Engineering and other high impact Journals.

Kimberlee Potter (co-chair), Ph.D., is the Portfolio Manager of Surgery, Trauma, and Restorative Medicine in the Office of Research and Development at the Department of Veterans Affairs where she serves as the VA representative on the National Academies of Sciences, Engineering, and Medicine (NASEM) Forum for Regenerative Medicine, the Armed Forces Institute of Regenerative Medicine IIPT, and the Congressionally Directed Medical Research Program for the Reconstructive Transplantation Research Program. She is also a member of the Veterans Health Administration NASEM Strategic Workgroup. Prior to joining VA, Dr. Potter worked at Armed Forces Institute of Pathology as the Technical Director of the Magnetic Resonance Microscopy Facility where she applied non-invasive imaging techniques to the study of forensic, pathologic, and engineered tissues. She worked with the Office of the Armed Forces Medical Examiners on blast-induced traumatic brain injury and the application of medical imaging for virtual autopsies. Prior to joining AFIP, she was a visiting scientist at National Institutes of Health at the National Institute on Aging and then at the National Institute on Child Health and Human Development. She received her post-doctoral training at the University of California at Santa Barbara in the Department of Chemical & Nuclear Engineering. Dr. Potter received her B.S. degree in Engineering Chemistry from Queen's University (Canada) and her Ph.D. from Cambridge University (England).

Steven Becker, Ph.D., currently leads the NEI Office of Regenerative Medicine as its Associate Director. The office coordinates the regenerative medicine programs at NEI which include the Audacious Goals Initiative (AGI) for Regenerative Medicine, the 3-D Retina Organoid Challenge (3D ROC), and the AMD Integrative Biology Initiative. Dr. Becker represents the NEI

on a number of committees including the NIH Regenerative Medicine Innovation Project (RMIP), the National Academies of Sciences, Engineering, and Medicine Forum on Regenerative Medicine, and the BRAIN Initiative's Dissemination Team.

Jennifer Elisseeff, Ph.D., received a bachelors degree in Chemistry from Carnegie Mellon University and a PhD in Medical Engineering from the Harvard-MIT Division of Health Sciences and Technology. After doctoral studies, Dr. Elisseeff was a Fellow at the National Institute of General Medical Sciences Pharmacology Research Associate Program where she worked in the National Institute of Dental and Craniofacial Research. In 2001, Dr. Elisseeff became an assistant professor in the Department of Biomedical Engineering at Johns Hopkins University. In 2004, Elisseeff cofounded Cartilix, Inc., a startup that translated adhesive and biomaterial technologies for treating orthopedic disease, acquired by Biomet Inc in 2009. In 2009, she also founded Aegeria Soft Tissue and Tissue Repair, new startups focused on soft tissue regeneration and wound healing. Dr. Elisseeff is a Morton Goldberg Professor of Ophthalmology and directs the recently established Translational Tissue Engineering Center at Johns Hopkins in collaboration with Biomedical Engineering. She serves on the Scientific Advisory Boards of Bausch and Lomb, Kythera Biopharmaceutical, and Cellular Bioengineering Inc. Dr. Elisseeff has received awards including the Carnegie Mellon Young Alumni Award, Arthritis Investigator Award from the Arthritis Foundation, Yasuda Award from the Society of Physical Regulation in Medicine and Biology, and was named by Technology Review magazine as a top innovator under 35 in 2002 and top 10 technologies to change the future. In 2008, Dr. Elisseeff was elected a fellow in the American Institute for Medical and Biological Engineering and a Young Global Leader in the World Economic Forum. She has published over 120 articles, book chapters and patent applications and given over 130 national and international invited lectures.

Sadik Kassim, Ph.D., has a wealth of experience that he brings to his role as Chief Technology Officer at Vor. He is a cell and gene therapy bioprocessing and translational research expert. Prior to joining Vor, Dr. Kassim served as Executive Director at Kite Pharma where he led the development of manufacturing processes for autologous CAR-T and TCR-based cell therapies. He and his team at Kite led the BLA and MAA filing efforts for Kite's X-19 product, which is a CD19 CAR-T therapy for Mantle Cell Lymphoma. Before Kite, Dr. Kassim served as Chief Scientific Officer at Mustang Bio, where he was the first employee and oversaw the foundational build-out of the company's preclinical and manufacturing activities. Earlier in his career, Dr. Kassim was Head of Early Analytical Development for Novartis' Cell and Gene Therapies Unit, where he and his team contributed to the BLA and MAA filings for Kymriah. Prior to Novartis, Dr. Kassim was a research biologist at the National Cancer Institute, where he worked with Dr. Steven Rosenberg and was involved in early research and CMC projects that led to the development of several first-in-human TCR and CAR-T products, including the CD19 CAR-T therapy that would be developed into Yescarta. Dr. Kassim earned his BS in cell and molecular biology from Tulane University and received his PhD in microbiology and immunology from Louisiana State University. After receiving his PhD, he was a research fellow in the lab of Dr. James Wilson at the University of Pennsylvania's Gene Therapy Program, where he led the

initial discovery and preclinical studies for an AAV8 based gene therapy for familial hypercholesterolemia, a program that is now in the clinic.

Candace Kerr, Ph.D., is the program officer for the Stem Cell Program in the Aging Physiology Branch of the Division of Aging Biology at the National Institute on Aging. NIA's Stem Cell Program has supported major findings on the genetics regulating stem cell lifespan and genomic stability, the relationships between stem cell survival and aged health, and the discovery of molecules that facilitate stem cell depletion and cellular senescence. Before joining the NIA in 2017, Dr. Kerr was on the faculty of the University of Maryland School of Medicine researching human adult and cancer stem cells, and earlier on the faculty at Johns Hopkins University School of Medicine where her laboratory studied human pluripotent stem cells and the translation of these cells to treat reproductive and neurological conditions. Dr. Kerr received her M.S. in molecular genetics at the University of Maine and her Ph.D. in quantitative genetics and biochemistry from Pennsylvania State University. As a postdoctoral fellow at Johns Hopkins University School of Public Health, she also studied the glycobiological interactions in receptor binding and endocrine functions in mice fertility and reproduction. Dr. Kerr is the author of 35 peer-reviewed research papers and 14 review articles, textbook chapters, and commentaries. She has also shared her expertise as editor for several journals related to the stem cell biology field.

Cato T. Laurencin, M.D., Ph.D., is the University Professor and Albert and Wilda Van Dusen Distinguished Endowed Professor of Orthopaedic Surgery at the University of Connecticut. He is Professor of Chemical Engineering, Professor of Materials Science and Engineering and Professor of Biomedical Engineering at the school. He serves as the Chief Executive Officer of The Connecticut Convergence Institute for Translation in Regenerative Engineering and the Director of the Raymond and Beverly Sackler Center for Biomedical, Biological, Physical and Engineering Sciences at UConn. Dr. Laurencin earned a B.S.E. in Chemical Engineering from Princeton University, and his M.D., Magna Cum Laude, from the Harvard Medical School, and received the Robinson Award for Surgery. He earned his Ph.D. in Biochemical Engineering/Biotechnology from the Massachusetts Institute of Technology where he was named a Hugh Hampton Young Fellow. A practicing sports medicine and shoulder surgeon, Dr. Laurencin has been named to America's Top Doctors for over fifteen years. He is a Fellow of the American Academy of Orthopaedic Surgeons, a Fellow of the American Orthopaedic Association, a Fellow of the American College of Surgeons and a member of the American Surgical Association. He received the Nicolas Andry Award, the highest honor of the Association of Bone and Joint Surgeons. Dr. Laurencin served as Dean of the Medical School and Vice President for Health Affairs at the University of Connecticut.

Richard McFarland, Ph.D., M.D., joined ARMI as its Chief Regulatory Officer on May 1, 2017. Dr. McFarland comes to ARMI from the Food and Drug Administration's Center for Biologics Evaluation and Research (FDA/CBER) where his career spanning 16 years involved review over an extensive range of products and policy development in numerous areas both inside FDA, across the federal government, and internationally. He spent more than a decade as Associate Director of Policy for FDA/CBER's Office of Tissues and Advanced Therapies and its predecessor office, the Office of Cellular, Tissue and Gene Therapies. In this position, he was

heavily involved in policy development for tissue engineering, regenerative medicine, and alternatives to animal use in regulatory decision making. In addition to development of risk-based regulatory oversight paradigms within FDA, his interests included broader efforts to create an interlocking network of interagency efforts to foster growth of basic and translational science to support maturation of the overlapping fields of tissue engineering and regenerative medicine from primarily discovery science toward a stage of commercial development. His position at ARMI will allow him to apply the knowledge and experiences gained over the last decade and half in the field to ARMI's efforts to establish an industrial common, in the form of a Manufacturing Innovation Institute within the Manufacturing USA network, with the aims to coalesce the field and provide a route for nascent product concepts to reach the marketplace. Bringing these products to the market will benefit critical U.S. public health needs and will provide the economic drivers needed to create new highly-skilled jobs. Dr. McFarland received his B.S., Ph.D., and M.D. from the University of North Carolina at Chapel Hill, and completed his anatomic/clinical pathology residency and immunopathology fellowship training at UT Southwestern in Dallas. Immediately prior to joining the FDA, he was on the faculty of the Pathology Department of the University of Texas Southwestern in Dallas. In addition to FDA policy documents he has co-authored over 25 articles in peer-reviewed articles journals including Nature, the Proceedings of the National Academy of Science (PNAS), and Blood.

Rachel Salzman, D.V.M., serves as Chief Scientific Officer of The Stop ALD Foundation (SALD), and has held this position since 2001. SALD is a non-profit Medical Research Organization dedicated to employing entrepreneurial approaches and innovative methodology towards effective therapies, cures, and prevention of x-linked adrenoleukodystrophy (ALD), an often fatal neurodegenerative disease. The biomedical interests of the Foundation include gene therapy, hematopoietic stem cells and other adult stem cells, genomics, and small molecules. In this context SALD made critical contributions to the groundbreaking ex vivo lenti trial conducted in pediatric patients in France, which is now a pivotal clinical study sponsored by a publicly owned US-based biotech. Rachel also consults for large pharma and biotech in the field of drug development, including preclinical and clinical analysis in a variety of therapeutic areas including oncology, metabolic disease, CNS disorders, and orphan indications. As an active member of The American Society of Gene and Cell Therapy (ASGCT) Dr. Salzman is an elected member of the Board of Directors and also serves as ASGCT's Chairperson of the Government Relations Committee. Prior to these roles, Rachel worked in private veterinary practice in both large and small animal medicine. She has a D.V.M. from Oklahoma State University and a B.S. from Rutgers University.

Sohel Talib, Ph.D., is Senior Science offer and Director, Therapeutics at California Institute for Regenerative Medicine (CIRM). He is responsible for developing and implementing CIRM's scientific programs and managing portfolio of clinical stage grants utilizing hematopoietic stem cell gene therapy approaches for the treatment of Hemoglobinopathies, Primary Immune Deficiency diseases (PID), HIV AIDS and Cancer. His scientific background is in the Stem Cell and Gene Therapy and has spent 20 years in the biotech industry. Before joining CIRM he was the Director of Product Development at Geron Corporation, Menlo Park, California. At Geron

Corporation, Sohel directed immune-oncology program on the development of an autologous dendritic cell vaccine for cancer (Geron VAC-1). Prior to Geron Corporation, Sohel Talib, served as the Director of Immunology at Cerus Corporation, a biotech company developing novel allogeneic stem cell therapy for the hematological malignancies. He was a cofounder of Applied Immune Sciences (AIS), which was acquired by Rhone Poulenc Rorer (RPR, currently Sanofi). AT RPR Gen Cell, he directed the development and execution of adoptive immunotherapy programs. Dr. Talib received his post-doctoral training at Stanford University, University of California, Berkeley and Roche Institute of Molecular Biology, Nutley. He obtained his Ph.D. in Biochemistry from Aligarh University, India and International DANIDA fellowship from Danish Institute of Protein Chemistry, Copenhagen.

Daniel Weiss, M.D., Ph.D., is Professor of Medicine at the University of Vermont. He received his PhD in Pharmacology in 1987 from the City University of New York and MD from the Mt. Sinai School of Medicine in 1988. Following internship and residency in internal medicine at the University of Michigan and subsequent fellowship training in pulmonary and critical care medicine at the University of Washington, Dr. Weiss was recruited to the University of Vermont in 2001. Dr. Weiss has a longstanding interest in lung repair and regeneration after injury, notably gene and cell therapy approaches for lung diseases. In particular this has included developing novel techniques with which to investigate and enhance lung gene and cell therapies. Recent published work in cell therapy approaches for lung diseases has included several benchmark publications that have included the first ever trial of cell therapy for emphysema and that have helped define whether exogenous cells can engraft in the lung. As such, Dr. Weiss is a translational scientist whose work spans from benchtop to clinical trials. Dr. Weiss has also instituted a biennial meeting held at the University of Vermont, Stem Cells and Cell Therapies in Lung Biology and Diseases, that is widely viewed by the NIH, FDA, and non-profit Respiratory Disease Foundations as the major meeting in the field. Dr. Weiss' overall goal is to provide a firm scientific basis for clinical application of cell therapies in lung diseases. He has been funded by the NIH, DOD, non-profit Respiratory Disease Foundations, and by industry sources since 1995 and has over 100 current publications. Current work in the laboratory is focused in three major areas: 1) Bioengineering approaches for development of functional lung tissue ex vivo; 2) Immunomodulation of lung inflammation by mesenchymal stromal cells (MSCs); 3) Development of cell therapy-based approaches for lung disease. Dr. Weiss has been involved with the ISCT for the past 10 years and currently serves as Chief Scientific Officer. A central goal of Dr. Weiss' activities with the ISCT is to promote education and actions against stem cell medical tourism.

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Board on Health Sciences Policy
Forum on Regenerative Medicine

Understanding the Role of the Immune System in Improving Tissue Regeneration: A Workshop

November 2-3, 2021

Speaker Biographies

Helen M. Blau, Ph.D., is the Donald E. and Delia B. Baxter Foundation professor and Director of the Baxter Laboratory for Stem Cell Biology at Stanford University. Blau's research area is regenerative medicine with a focus on stem cells. She is world-renowned for her work on nuclear reprogramming and demonstration of the plasticity of cell fate using cell fusion. Blau led the field with novel approaches to treating muscle damaged due to disease, injury, or aging. She pioneered the design of biomaterials to mimic the in vivo microenvironment and direct stem cell fate. Her laboratory discovered that transient exposure to Prostaglandin E2 rejuvenates muscle stem cell function long-term, enhancing muscle repair. She identified a novel hallmark of aging, the prostaglandin degrading enzyme, 15-PGDH, and showed that its inhibition augments aged muscle mass and strength. Blau served as President of the American Society for Developmental Biology, President of the International Society for Differentiation, and member of the Harvard University Board of Overseers. She is an elected member of the American Institute for Medical and Biological Engineering, the American Academy of Arts and Sciences, the American Association for the Advancement of Science, the National Academy of Medicine, and National Academy of Sciences.

Edward Botchwey, Ph.D., is Associate Professor in the Wallace H. Coulter Department of Biomedical Engineering at the Georgia Institute of Technology and Emory University. His research focuses on the delivery of naturally occurring small molecules and synthetic derivatives for applications in tissue engineering and regenerative medicine. He is particularly interested in how transient control of immune response using bioactive lipids can be exploited to control trafficking of stem cells, enhance tissue vascularization, and resolve inflammation. Dr. Botchwey received both M.E. and Ph.D. degrees in Materials Science Engineering and Bioengineering from the University of Pennsylvania in 1998 and 2002 respectively. He was recruited to the faculty at Georgia Tech in 2012. Dr. Botchwey is a former Ph.D. fellow of the National GEM Consortium, a former postdoctoral fellow of the UNCF-Merk Science Initiative, and a recipient of the Presidential Early Career Awards for Scientists and Engineers from the National Institutes of Health. Dr. Botchwey also serves on the Board of Directors of the Biomedical Engineering Society (BMES) and serves as the secretary to the Biomedical Engineering Decade committee.

Danielle Brooks, Ph.D., is a pharmacology/toxicology reviewer in the Office of Tissues and Advanced Therapies. She received her Ph.D. in Biomedical Sciences with a concentration in Cancer and Developmental Biology at The University of Tennessee Health Science Center in Memphis, TN. Following her graduate training, Dr. Brooks completed her post-doctoral training in the Women's Malignancies Branch of the National Cancer Institute. In 2017, she joined the

NCI-FDA Interagency Oncology Task Force Fellowship program as a product quality research/review fellow in the Cellular and Tissues Therapies Branch of OTAT. At the completion of her fellowship, Dr. Brooks joined PTB where she now focuses on the review of preclinical toxicology and pharmacology data to support the safety of cell and gene therapies, tissue-engineered products, devices and combination products.

Jennifer H. Elisseeff, Ph.D., is the Morton F. Goldberg Endowed Professor of ophthalmology and a professor orthopaedic surgery at the Johns Hopkins School of Medicine. She is the Jules Stein Professor of ophthalmology and also holds appointments in the Johns Hopkins Department of Chemical and Biological Engineering and Department of Materials Science and Engineering. Dr. Elisseeff is the Director of the Translational Tissue Engineering Center where she and her team of scientists are engaged in engineering technologies to repair lost tissues and are using biomaterials to develop a synthetic cornea. Dr. Elisseeff received a Ph.D. in Medical Engineering from the Harvard-MIT Division of Health Sciences and Technology. After doctoral studies, Dr. Elisseeff was a Fellow at the National Institute of General Medical Sciences Pharmacology Research Associate Program where she worked in the National Institute of Dental and Craniofacial Research. She joined the Johns Hopkins faculty in 2001. In 2004, Elisseeff cofounded Cartilix, Inc., a startup that translated adhesive and biomaterial technologies for treating orthopedic disease, acquired by Biomet Inc. in 2009. In 2009, she also founded Aegeria Soft Tissue and Tissue Repair, startups focused on soft tissue regeneration and wound healing. She serves on the Scientific Advisory Boards of Bausch and Lomb, Kythera Biopharmaceutical, and Cellular Bioengineering Inc.

Dr. Elisseeff has received awards including the Carnegie Mellon Young Alumni Award, Arthritis Investigator Award from the Arthritis Foundation, Yasuda Award from the Society of Physical Regulation in Medicine and Biology. She was recognized by *Technology Review* magazine as a top innovator under 35 in 2002 and included with the top 10 technologies to change the future. In 2008, Dr. Elisseeff was elected a fellow in the American Institute for Medical and Biological Engineering and a Young Global Leader in the World Economic Forum. In 2018, Dr. Elisseeff was elected to both the National Academy of Medicine and the National Academy of Engineering. She was the 2019 recipient of the NIH Director's Pioneer Award.

Sherilyn George-Clinton is a Leader and collaborator with the Multiple Sclerosis: You Are Not Alone (M.S. Y.A.N.A) organization and a science writer for The NeuroLeadership. The NeuroLeadership is a global research organization that partners with organizations to develop their leaders and transform their cultures. Ms. George-Clinton helps create content to reach customers and prospects with the practical application of their research in performance, culture & leadership, and diversity, equity & inclusion. As a freelance writer, Ms. George-Clinton communicates with or about patients using diverse means, working to convey technical information with non-technical people without talking down to them and foster engagement through storytelling. Ms. George-Clinton received her B.A. in English from Denison University.

George Hajishengallis, D.D.S., Ph.D., earned a D.D.S. from the University of Athens (1989) and a Ph.D. in Microbiology/Immunology from the University of Alabama at Birmingham

(1994). He is currently the Thomas W. Evans Centennial Professor at the University of Pennsylvania, School of Dental Medicine, Department of Basic and Translational Sciences. His field of interest lies at the host-microbe interface where his work has illuminated novel mechanisms of microbial dysbiosis and inflammation as well as inflammation resolution and tissue regeneration. A current focus of his laboratory involves the immunometabolic regulation of trained myelopoiesis and its effects on health and disease. He combines basic and translational research leading to innovative approaches to clinical problems, such as exemplified by periodontitis, where his preclinical work has recently led to a phase 2a clinical trial in patients with periodontal inflammation (successfully treated with a complement C3 inhibitor; AMY-101). He published over 210 papers (with over 24,000 citations), including in Cell, Nature Immunology, Science Translational Medicine, J. Clin. Invest., Cell Host Microbe, PNAS, N. Engl. J. Med., and Nature Reviews Immunology. He received the IADR Distinguished Scientist Award in Oral Biology in 2012 and the NIH/NIDCR MERIT Award in 2016. He was named Highly Cited Researcher (Clarivate/Web-of-Science) in 2018 and 2020.

Robert Jenq, M.D., is Deputy Department Chair and Associate Professor in the Department of Genomic Medicine and an Associate Professor in the Department of Stem Cell Transplantation at the University of Texas MD Anderson Cancer Center. His career aim is to develop and evaluate strategies that improve outcomes after hematopoietic stem cell transplantation (HSCT), in particular by augmenting graft-versus-tumor (GVT) to reduce the rates of malignant relapse and alleviating graft-versus-host disease (GVHD). To this goal, he has studied therapies that modulate alloreactive T cells in GVT and GVHD, using mouse models of HSCT. To develop strategies of augmenting anti-tumor immunity following HSCT, he has focused in particular on T cell repertoire enhancement strategies. Simultaneously, he has begun to study the T cell repertoire in the setting of GVHD. Finally, he has also examined how aspects of mucosal immunology can impact intestinal GVHD, including the microbial flora and dietary factors.

James L. Kirkland, M.D., Ph.D., is Director of the Robert and Arlene Kogod Center on Aging at Mayo Clinic and Noaber Foundation Professor of Aging Research. Dr. Kirkland's research is on the contribution of fundamental aging processes, particularly cellular senescence, to age-related and chronic diseases and development of agents and strategies for targeting fundamental aging mechanisms to treat age- and chronic disease-related conditions. Additional research areas include molecular and physiological mechanisms of age-related adipose tissue and metabolic dysfunction, frailty, and loss of resilience to infections and acute diseases in old age. Dr. Kirkland's laboratory published the first article about agents that selectively eliminate senescent cells - senolytic drugs. Dr. Kirkland demonstrated that senolytic agents enhance healthspan and delay, prevent, or alleviate multiple age-related disorders and diseases in mouse models. He published the first clinical trials of senolytic drugs. He is preparing or conducting clinical studies of senolytics, including for COVID-19, frailty in elderly women, Alzheimer's disease, diabetes/obesity, osteoporosis, childhood cancer survivors, restoring function of organs from old donors to enable transplantation, idiopathic pulmonary fibrosis, pre-eclampsia, and others. He has more than 225 publications and holds over 50 patents. Dr. Kirkland is Principal Investigator of the Translational Geroscience Network (R33 AG061456), which brings together 8 academic institutions to translate healthspan interventions, including senolytics and other drugs that target

fundamental aging processes, from bench to bedside. He is a scientific advisory board member for several companies and academic organizations. He is President of the American Federation for Aging Research, a past member of the National Advisory Council on Aging of the National Institutes of Health, past chair of the Biological Sciences Section of the Gerontological Society of America, and past member of the Clinical Trials Advisory Panel of the National Institute on Aging. He is a board-certified specialist in internal medicine, geriatrics, and endocrinology and metabolism. Dr. Kirkland is the 2020 recipient of the Irving S. Wright Award of Distinction from the American Federation for Aging Research.

Katarina Le Blanc, M.D., Ph.D., is Professor of Clinical Stem Cell Research at Karolinska Institutet. Dr. Le Blanc received her M.D. from the Karolinska Institutet in 1993, and her Ph.D. in 1999, also from the Karolinska Institutet. In 2002 she became a certified specialist in hematology. She has mentored many trainees, PhD students and post docs over the years. Dr. Le Blanc has published well over 100 peer-reviewed publications and review articles, been cited more than 12.000 times, and given some 140 presentations at various national and international meetings over the last 10 years. Dr. Le Blanc's main research interest is mesenchymal stem cells, haematopoietic stem cell transplantation and immunology. Dr. Le Blanc is a member of several international and national committees including notably the Nobel Assembly at Karolinska Institutet and The Royal Swedish Academy of Science. She is also the member of several advisory boards and has been responsible for the organization of several national and international scientific meetings, and also served on many program committees. She is the recipient of several awards including the Knut & Alice Wallenberg Foundation award for young female researchers, Swedish Medical Society award for young scientists, and the Tobias Foundation Prize for the excellent studies of the immunological properties of mesenchymal stem cells and their use in mesenchymal stem cell therapy awarded by the Royal Swedish Academy of Science.

Ruslan M. Medzhitov, Ph.D., is the Sterling Professor of Immunobiology at Yale University School of Medicine. He is interested in understanding biological processes and phenomena from first principles. Currently, Medzhitov and his team have several areas of focus: evolutionary medicine; biology of inflammation and its relation to physiology and homeostasis; mechanisms and functions of allergy; tissue biology; non-canonical functions of the immune system; and the logic of gene expression programs.

Erika Moore, Ph.D., is the Rhines Rising Star Assistant Professor in the Department of Materials Science and Engineering at the University of Florida. She earned her Ph.D. in Biomedical Engineering from Duke University in 2018 and her bachelor's degree in Biomedical Engineering from the Johns Hopkins University in 2013. Under the guidance of Dr. Jennifer L. West, Moore's doctoral thesis focused on the use of macrophages, innate immune cells, to support vascularized engineered tissue. She was awarded the Outstanding Doctoral Dissertation Award from Duke University for this work. Dr. Moore was the Provost's Post-Doctoral Fellow and a visiting professor at the Johns Hopkins University in the Department of Biomedical Engineering until June 2020. Ongoing research efforts of the Moore Lab seek to understand how immune cells can be leveraged to enhance tissue regeneration, develop materials capable of

directing immune cells towards desired clinical outcomes, and create *in vitro* tissue models to profile immune cell-blood vessel interactions in clinically relevant disease settings. Her lab is especially interested in applications for the autoimmune disorder lupus, which disproportionately affects Black women. Recently acknowledged as Forbes 30 Under 30 in the Healthcare category, Dr. Moore is a former Trustee on the Duke Board of Trustees. She has been awarded the KL2 NIH Training grant through the UF Clinical and Translational Science Institute, a Space Research Initiative grant, the NSF Graduate Research Fellowship and the Ford Foundation Fellowship.

Garry Nolan, Ph.D., is the Rachford and Carlota A. Harris Professor in the Department of Pathology at Stanford University School of Medicine. He trained with Leonard Herzenberg (for his Ph.D.) and Nobelist Dr. David Baltimore (for postdoctoral work for the first cloning/characterization of NF-κB p65/ RelA and the development of rapid retroviral production systems). He has published over 300 research articles and is the holder of 40 US patents, and has been honored as one of the top 25 inventors at Stanford University. Dr. Nolan is a member of the Parker Institute for Cancer Immunotherapy at Stanford. His areas of research include hematopoiesis, cancer and leukemia, autoimmunity and inflammation, and computational approaches for network and systems immunology. Dr. Nolan's recent efforts are focused on a single cell analysis advance using a mass spectrometry-flow cytometry hybrid device (CyTOF) and nanoscale imaging with the "Multiparameter Ion Beam Imager" (MIBI). Further developments in imaging are enabled by CODEX—a system that inexpensively converts fluorescence scopes into high dimensional imaging platforms. Dr. Nolan is the first recipient of the Teal Innovator Award (2012) from the Department of Defense, the first recipient of an FDA BAAA for “Bio-agent protection” from the FDA for a “Cross-Species Immune System Reference”, and received the award for “Outstanding Research Achievement in 2011” from the Nature Publishing Group for his development of CyTOF applications in the immune system. Dr. Nolan is an outspoken proponent of translating public investment in basic research to serve the public welfare. He has founded or co-founded several companies (Rigel Inc., Nodality Inc., BINA, Apprise, Ionpath, Akoya. He also serves on the Boards of Directors of several companies and consults for other biotechnology companies.

Michel Sadelain, M.D., Ph.D., is founding Director of the Center for Cell Engineering and head of the Gene Transfer and Gene Expression Laboratory at Memorial Sloan Kettering Cancer Center, where he holds the Stephen and Barbara Friedman Chair. He is also a member of the departments of medicine and pediatrics at Memorial Hospital and the molecular pharmacology and chemistry program of the Sloan Kettering Institute. Dr. Sadelain's research focuses on human cell engineering and cell therapy to treat cancer and hereditary blood disorders. He and his laboratory have made major contributions to the field of chimeric antigen receptors (CARs). His group was the first to report the design of “second-generation” CARs in 2002. In addition, the Sadelain Laboratory developed artificial antigen presenting cells, auto- and trans-costimulatory engineering strategies, combinatorial antigen approaches, and inhibitory CARs; his group was first to publish dramatic molecular remissions in patients with chemorefractory acute lymphoblastic leukemia following treatment with CD19-targeted T cells.

Dr. Sadelain received his M.D. from the University of Paris, France, in 1984 and his Ph.D. from the University of Alberta, Canada, in 1989. After completing a clinical residency at the Centre Hospitalier Universitaire Saint-Antoine in Paris, Dr. Sadelain carried out a postdoctoral fellowship with Richard Mulligan, Ph.D., at the Whitehead Institute for Biomedical Research, Massachusetts Institute of Technology, before joining Memorial Sloan Kettering in 1994 as an assistant member. Dr. Sadelain is a member of the American Society of Cell and Gene Therapy, where he served on the board of directors from 2004 to 2007, and is an elected member of the American Society for Clinical Investigation. He has authored more than 150 scientific papers and book chapters. Dr. Sadelain holds 13 patents in immunotherapy and received the 2012 William B. Coley Award for Distinguished Research in Tumor Immunology.

Kaitlyn Sadtler, Ph.D., is Earl Stadtman Tenure-Track Investigator and Chief of the Section for Immunoengineering at the National Institute of Biomedical Imaging and Bioengineering (NIBIB) of the National Institutes of Health. Her research focuses on how the tissue microenvironment changes a host response to regenerative scaffolds used in tissue engineering and how to manipulate that environment to promote tissue growth and regeneration. Dr. Sadtler has also lent her lab's expertise to the fight against COVID-19, launching the NIH Serologic Survey to determine the number of undiagnosed infections of SARS-CoV-2 in the United States via remote blood sampling and antibody testing. Prior to beginning her lab at NIBIB, Sadtler completed a postdoctoral fellowship at the Massachusetts Institute of Technology in the Department of Chemical Engineering. There, she was awarded a Ruth L. Kirschstein Postdoctoral Fellowship for her work on immunology and tissue engineering. Dr. Sadtler was listed on BioSpace's 10 Life Science Innovators Under 40 To Watch and StemCell Tech's Six Immunologists and Science Communicators to Follow. She was recognized as a 2018 TED Fellow and delivered a TED talk that has been viewed >2.4 million times and was listed as one of the top-viewed talks of 2018. Dr. Sadtler was selected for the 2019 Forbes 30 Under 30 List in Science and as a 2020 TEDMED Research Scholar. Dr. Sadtler received her Ph.D. from the Johns Hopkins University School of Medicine where her thesis research was published in *Science* magazine, *Nature Methods*, and others.

Sonja Schrepfer, M.D., Ph.D., is Professor at the University of California San Francisco (UCSF), Gladstone-UCSF Institute of Genomic Immunology, and a Scientific Founder and SVP (Head of the Hypoimmune Platform) of Sana Biotechnology, Inc. Dr. Schrepfer is the founder and director of the Transplant and Stem Cell Immunobiology (TSI) Lab. Work by Dr. Sonja Schrepfer is at the forefront of stem immunobiology and paves the way for treatment of a wide range of diseases – from supporting functional recovery of failing myocardium to the derivation of other cell types to treat diabetes, blindness, cancer, lung, neurodegenerative, and related diseases. Her work demonstrates that protecting transplanted cells from immune rejection is the key to unlocking the potential of regenerative medicine. Before pursuing a career as a research scientist, Dr. Schrepfer was trained in cardiac surgery and heart/lung transplantation and was a resident in the Cardiothoracic Surgery Departments in Munich and Hamburg, Germany. She received her Ph.D. in transplant immunology from the University of Hamburg. Dr. Schrepfer's findings have been published in leading journals such as *Nature* and *Science* and she has received numerous awards, such as the prestigious DFG-Heisenberg

professorship (2009), the Innovation Award from Academia (Germany, 2014), the science award from the German Academy of Sciences (Leopoldina, 2015), and the Galenus-von-Pergamon Medal in Basic Medical Sciences (2019).

Charles N. Serhan, Ph.D., D.Sc., is the Gelman Professor at Harvard Medical School and co-Director of Brigham Research Institute. His lab focuses on structural elucidation of molecules and pathways that activate resolution of inflammation. He is PI/PD of Program Project "Resolution Mechanisms in Acute Inflammation: Resolution Pharmacology" (P01-GM095467). Dr. Serhan has over 25 years of experience leading multidisciplinary research teams and led as Principle Investigator/Program Director Program (PI/PD) Project "Molecular Mechanisms in Leukocyte-Mediated Tissue Injury" (P01-DE13499) and was PI/PD for "Specialized Center for Oral Inflammation and Resolution" (P50-DE016191). Importantly, he is hands-on at the bench and has trained > 60 fellows and trainees that have successful careers in academic medicine and industry.

Megan Sykes, M.D., is the Michael J. Friedlander Professor of Medicine and Professor of Microbiology & Immunology and Surgical Sciences (in Surgery) at Columbia University. She is the founding Director of the Columbia Center for Translational Immunology (CCTI) at Columbia University, Director of Research for the Transplant Initiative at Columbia University Medical Center (CUMC) and Director of Bone Marrow Transplantation Research, Division of Hematology/Oncology at CUMC. Dr. Sykes completed her MD training at the University of Toronto in 1982, after which she completed a medical residency, then moved to the National Institutes of Health, Bethesda, MD in 1985 as a Fogarty Visiting Associate. She joined the Massachusetts General Hospital and Harvard Medical School as an Assistant Professor in 1990 and was tenured as a full Professor in 1999, then named to the Harold and Ellen Danser Chair in Surgery. She moved to Columbia University in 2010 to establish the CCTI, which now includes a thriving pre-clinical transplant program and a staff of 115 people, including 19 faculty members, 16 laboratory programs in transplantation, autoimmune disease, infection and cancer immunology and 6 core facilities.

Dr. Sykes introduced the idea that graft-versus-leukemia/lymphoma effects could be separated from graft-versus-host disease (GVHD) following hematopoietic cell transplantation (HCT) by allowing GVH-reactive T cells to expand while preventing migration to the epithelial GVHD target tissues. She showed that inflammation was a critical checkpoint for such migration, which was avoided when GVH-reactive T cells were administered after conditioning-induced inflammation had subsided in mixed chimeras. These studies led to clinical trials of nonmyeloablative haploidentical HCT that achieved mixed chimerism across HLA barriers without GVHD. These results paved the way for the first clinical trials of mixed chimerism that achieved renal allograft tolerance across HLA barriers. Dr. Sykes dissected the role of intrathymic and peripheral tolerance mechanisms and pioneered minimal conditioning approaches for using HCT to achieve allograft and xenograft tolerance. Her work demonstrated that (and identified mechanisms by which) mixed chimerism achieves natural antibody-producing B cell tolerance and NK cell tolerance in addition to T cell tolerance. She developed a method of tracking the alloreactive T cell repertoire in human transplant recipients and has used

it along with other techniques to understand T lymphocyte dynamics in the graft and the periphery of human transplant recipients. This work led to the discovery of hematopoietic progenitors in the human intestinal mucosa and demonstration of their turnover from a circulating pool in human intestinal allograft recipients. She has pioneered the development and use of humanized mouse models for the study of Type 1 diabetes and for xenograft tolerance induction. Her work on xenogeneic thymic transplantation for tolerance induction led, for the first time, to long-term kidney xenograft survival in non-human primates.

Dr. Sykes has published more than 473 papers and chapters describing her work. She has served on the Transplantation Society (TTS) Council and has been President of the International Xenotransplantation Association (IXA) and Vice President of TTS. She has received many honors and awards, including the Wyeth-Ayerst Young Investigator Award from the American Society of Transplant Physicians (1998), the AST Basic Science Established Investigator Award (2007), the TTS Roche Award for Outstanding Achievement in Transplantation Science (Basic) (2010), the TTS Award for Outstanding Achievement in Transplantation (Basic Science) (2014), and the 2018 Medawar Prize. She is a member of the Association of American Physicians, a Distinguished Fellow of the American Association of Immunologists, a Fellow of the American Association for the Advancement of Science, and an Honorary Member of IXA. She was inducted into the Institute of Medicine of the National Academies (now the National Academy of Medicine) in 2009. Dr. Sykes is President-Elect of the Federation of Clinical Immunology Societies (FOCIS).

Bob Valamehr, Ph.D., is Chief Research and Development Officer at Fate Therapeutics, overseeing the company's research and development activities. Previously, Dr. Valamehr has held the positions of Chief Development Officer and Vice President of Cancer Immunotherapy at Fate Therapeutics. Prior to that, he played key scientific roles at Amgen, the Center for Cell Control (an NIH Nanomedicine Development Center), and the Broad Stem Cell Research Center, developing novel methods to control pluripotency, to modulate stem cell fate including hematopoiesis, and to better understand cellular signaling pathways associated with cancer. He has co-authored numerous studies and patents related to stem cell biology, oncology, and materials science. Dr. Valamehr received his Ph.D. from the Department of Molecular and Medical Pharmacology at the University of California Los Angeles (UCLA), his M.B.A. from Pepperdine University, and his B.S. from the Department of Chemistry and Biochemistry at UCLA.

Thomas Wynn, Ph.D., is Vice President of Discovery in the Inflammation and Immunology Research Unit at Pfizer and Director of Pfizer's post-doctoral training program. He currently leads Pfizer's discovery efforts in the areas of immune tolerance, epithelial cell biology, immunometabolism, innate immunity, and fibrosis. Dr. Wynn is a recognized expert on immunology and fibrosis who spent 26 years at the National Institutes of Health, most recently as a Senior Investigator and Chief of the Immunopathogenesis Section of the Laboratory of Parasitic Disease, in the National Institute of Allergy and Infectious Diseases. He received his Ph.D. from the Department of Medical Microbiology and Immunology at the University of Wisconsin in Madison, Wisconsin and has published over 200 research papers, reviews, and

book chapters in many prestigious journals such as *Nature*, *Science*, and *Nature Immunology*. Dr. Wynn has been included on the Thomson Reuters list of Highly Cited Researchers due to his important contributions to understanding the role of cytokines and growth factors in the progression and resolution of chronic inflammation, tissue regeneration, and fibrosis.

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Board on Health Sciences Policy
Forum on Regenerative Medicine

Understanding the Role of the Immune System in Improving Tissue Regeneration: A Workshop

November 2-3, 2021
Virtual Workshop

TIMELINE:
November 2, 2021: 11:30 AM – 4:30 PM
November 3, 2021: 12:00 PM – 4:00 PM

Speaker Guidance Questions

KEYNOTE LECTURE

Speaker: Ruslan Medzhitov

1. What is currently known and unknown about the immunological factors that contribute to having a "good" or "bad" immune state? How can someone's immune status impact their response to and outcomes of a regenerative or cell-based therapy?
2. What are general approaches to allow non-invasive targeted manipulation of immune state?
3. How are researchers currently studying the immune system in the context of regenerative medicine? Where do you see the gaps in this research?
4. From your perspective, why have regenerative medicine products thus far not produced as many expected positive results in the clinic? What about the immune system do we not understand that would be helpful to know?

COMMENT FROM THE PATIENT PERSPECTIVE

Speaker: Sherilyn George-Clinton

Key Questions:

1. Why is it important to engage patients as partners in research studies? What can researchers learn from patients?
2. How can the patient be best prepared to receive a therapy?
3. From a patient perspective, what should the workshop participants and speakers keep in mind throughout the workshop?
4. Why are scientific advances important for patients? What questions should the scientific community ask as new scientific advances are made?

SESSION I. LESSONS LEARNED ON IMMUNE TOLERANCE AND GRAFT ACCEPTANCE

Speakers: Megan Sykes, Robert Jenq, Ruslan Medzhitov

1. What are the 2-3 most important lessons we have learned about tolerance induction from areas such as transplant immunology, oncology, and the study of autoimmune diseases that can impact regenerative medicine?
2. From your perspective, what are the open questions that remain about mechanisms of the human immune system and more specifically about tolerance induction that can impact cell-based therapies? Are there lessons learned from autologous transplantation? How could a better understanding of those areas lead to improved patient outcomes with regenerative medicines?

SESSION II. ENGINEERING OF ALLOGENEIC DONOR CELLS FOR ACCEPTANCE BY THE HOST'S IMMUNE SYSTEM

Speakers: Katarina Le Blanc, Sonja Schrepfer, Bob Valamehr

1. Please describe a few examples of ongoing research that is looking to engineer allogeneic donor cells for acceptance by the host's immune system. What are the potential advantages and disadvantages of these approaches? How far along is this area of research and what questions need to be answered to advance the field?
2. What is known about the immunomodulatory properties of fetal and adult mesenchymal stem cells (MSCs)? Do MSCs and their secretome interact with immune cells, and for what conditions are they being tested in patients? What barriers are there to using MSC immunomodulatory therapy successfully? What are the approaches to monitor MSCs action in vivo?

SESSION III. ENDOGENOUS REGENERATION AND THE ROLE OF THE LOCAL ENVIRONMENT IN REPAIR

Speakers: Helen Blau, Erika Moore, George Hajishengallis

1. What are the key immune system characteristics of "productive" or "effective" wound healing and tissue regeneration? What cell types play an important role? Which components of endogenous tissue microenvironment and stem cell niches interact with the immune system to support or interfere with tissue regeneration?
2. What happens to stem cells and other components of the immune system as human beings age? How do these changes affect endogenous repair, regeneration, and wound healing?
3. From your perspective, what are the open research questions with regard to the role of the local environment in wound healing and repair? If answered, how would that new knowledge move the field of regenerative medicine forward?

SESSION IV. MODULATING THE HOST IMMUNE SYSTEM TO CREATE A PRO-REGENERATION ENVIRONMENT

Speakers: Charles Serhan, Jennifer Elisseeff, James Kirkland

Key Questions:

1. What is known about the molecular events that take place in the local environment following an injury or with natural aging processes? What cell types are most important in the response to injury or aging?
2. What is the role of the innate and adaptive immune response in cell engraftment and endogenous tissue regeneration?
3. Can we tip the balance of wound healing response from fibrosis toward functional tissue regeneration?
4. Are certain individuals predisposed to having a pro-regenerative environment? Can genetic or molecular biomarkers be used to predict or measure the regenerative capacity of an individual?
5. What approaches, if any, are available or currently being tested to activate or amplify endogenous mechanisms of tissue repair? What are the open scientific questions with regard to these approaches?

SESSION V. DEVELOPING TOOLS AND PRECLINICAL MODELS FOR MONITORING AND OPTIMIZING THE HOST'S PRO-REGENERATIVE ENVIRONMENT

Speakers: Kaitlyn Sadtler, Garry Nolan, Michel Sadelain

Key Questions:

1. Please describe recent advances in monitoring and imaging the immune system to reveal its functional organization and principles of operation. What can be learned from these types of approaches? Do artificial intelligence and other new approaches have implications for clinical translation of regenerative medicines?
2. What are challenges with regard to preclinical models to study the immune system's involvement in outcomes to regenerative medicine? Where do you envision new opportunities in this area?
3. Please address application of natural and engineered biomaterials and other bioengineering strategies to augment immune responses that promote endogenous tissue regeneration.

SESSION VI. FINAL PANEL: WHAT ARE SOME POSSIBILITIES TO HARNESS THE IMMUNE SYSTEM TO IMPROVE OUTCOMES FOR PATIENTS?

Speakers: Edward Botchwey, Danielle Brooks, Jennifer Elisseeff, Sherilyn George-Clinton, Sonja Schrepfer, Thomas Wynn

Key Questions:

1. From a patient perspective, how can the immune system impact the therapeutic experience?
2. How can we use tools (e.g., profiling, informatics, imaging) to improve patient selection and patient outcomes? Given the uncertainty of tools, how do you translate into the clinic? How can you use tools to better predict graft failure?
3. What are the low-hanging fruits and/or the greatest areas of opportunity for harnessing the immune system to improve tissue regeneration?
4. Are there immune system components that should be modulated rather than enhanced?
5. What factors can influence variability between patients as well as variability in patient selection?
6. Where is the future of allogeneic donor cell engineering (e.g., off-the-shelf, commercialization)?
7. What areas may be in need of additional clinical trials? What can be learned from failed trials?
8. What non-clinical tools, humanized animal models, aesthetics, tissue chips, or other tools can help improve success?
9. What 1 or 2 obstacles that you have heard about during the workshop deserve more attention? Are there potential solutions that could start to address these road blocks?
10. What have you learned during that workshop that you will take back to your work/team to change the way that you work or think? What did we not cover during the workshop that needs attention? Are there other stakeholders that need to be part of the conversation?

BACKGROUND INFORMATION

Links to Additional Resources

Session I: Lessons Learned about Immune Tolerance and Graft Acceptance

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Session V: Developing Tools and Preclinical Models for Monitoring and Optimizing the Host's Pro-Regenerative Environment

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