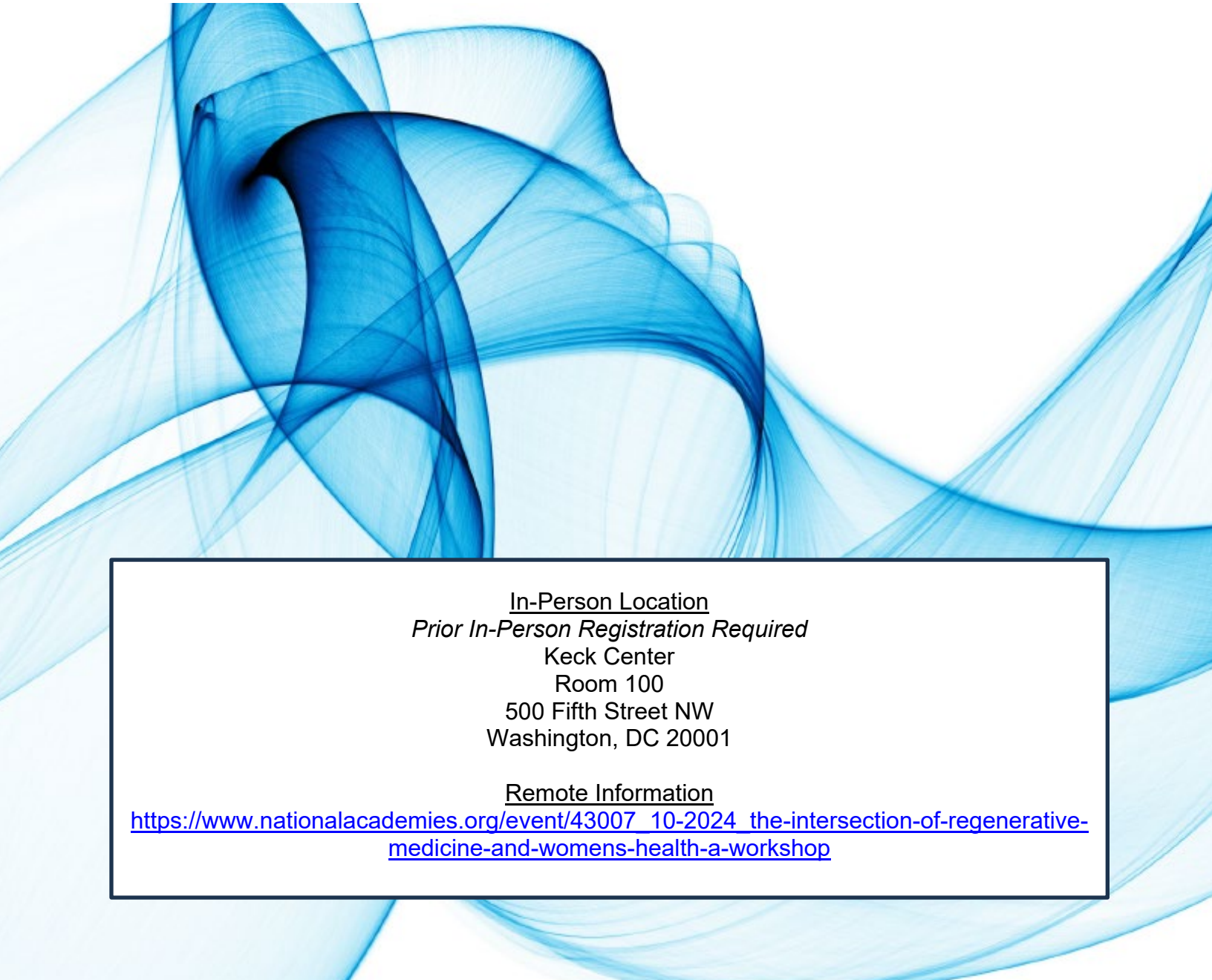
NATIONAL ACADEMIES Sciences Engineering Medicine

Board on Health Sciences Policy

The Intersection of Regenerative Medicine and Women's Health: A Workshop

October 1, 2024



In-Person Location
Prior In-Person Registration Required
Keck Center
Room 100
500 Fifth Street NW
Washington, DC 20001

Remote Information
https://www.nationalacademies.org/event/43007_10-2024_the-intersection-of-regenerative-medicine-and-womens-health-a-workshop

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Forum on Regenerative Medicine
Forum on Temporomandibular Disorders

October 1, 2024

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AGENDA

The Intersection of Regenerative Medicine and Women's Health: A Workshop

Tuesday, October 1, 2024

Statement of Task

A planning committee of the National Academies of Sciences, Engineering, and Medicine will organize and conduct a public workshop to examine opportunities in regenerative medicine to address current gaps in basic science, translational research, and related therapies that, if not considered, may result in health care disparities for women. The overarching goal of this workshop is to explore strategies to better understand underlying biology that would enable development of regenerative medicine therapies for women. The public workshop may include invited presentations and discussions to:

- Consider the gaps within regenerative medicine basic and translational research (including the development of cell and animal models) related to conditions that are female-specific and/or are more common or differently impact women.
- Explore emerging regenerative medicine therapies and technologies (and gaps in these areas) for conditions that are female-specific and/or are more common or differently impact women.
- Understand the representation of women within the regenerative medicine workforce, efforts to expand representation, and how research and clinical care may be impacted.
- Examine obstacles that may restrict access to regenerative medicine therapies, opportunities to expand access to care, and efforts to improve health literacy and communication.

The planning committee will organize the workshop, develop the agenda, select and invite speakers and discussants, and moderate or identify moderators for the discussions. A proceedings-in brief of the presentations and discussions at the workshop

SESSION I: Opening Remarks and Keynote

8:30 – 8:35 AM ET

Welcoming Remarks

Katherine Tsokas, *Forum Co-Chair*
Vice President
Regulatory, Quality, Risk Management and Drug Safety
Johnson & Johnson Innovative Medicine

Krishnendu Roy, *Forum Co-Chair*
Bruce and Bridgitt Evans Dean of Engineering and University Distinguished Professor
Vanderbilt University

8:35 – 8:40 AM

Introduction and Charge to the Workshop Speakers and Participants

Kimberlee Potter, *Workshop Planning Committee Co-Chair*
Scientific Program Officer
Department of Veterans Affairs

8:40 – 9:00 AM

Keynote

Vivian Ota Wang, *Workshop Planning Committee Co-Chair*

Deputy Director
NIH Office of Research on Women's Health

9:00 – 9:10 AM **Reactants**

Linda Goler Blount
President and CEO
Black Women's Health Imperative

Teonna Woolford
Co-Founder and CEO
Sickle Cell Reproductive Health Education Directive

9:10 – 9:45 AM **Panel Discussion**

Moderator: Elizabeth Garner, KNI Health Consultants, American Medical Women's Association

SESSION II: The Impact of Sex and Hormones on Regenerative Medicine

Moderator: Kathleen Zackowski, National Multiple Sclerosis Society

Session Objectives:

- Examine the impact of sex and hormones on innate regeneration and as a biological variable in the efficacy of regenerative therapies.
- Discuss how the inclusion/exclusion of sex as a biological variable and women in clinical trials has resulted in gaps within basic and translational research and impacted the translation of regenerative therapies.

9:45 – 10:00 AM

Monica Laronda
Assistant Professor
Stanley Manne Children's Research Institute
Ann & Robert H. Lurie Children's Hospital of Chicago
Department of Pediatrics
Department of Obstetrics and Gynecology
Feinberg School of Medicine
Northwestern University

10:00 – 10:15 AM

Riley Bove
Associate Professor, Neurology
University of California, San Francisco

10:15 – 10:30 AM

Kimberly J. Templeton
Professor
Orthopedic Surgery and Sports Medicine
University of Kansas Medical Center

10:30 – 10:55 AM **Panel Discussion**

10:55 – 11:00 AM **Reflections on the Discussion**

Kathleen Zackowski, National Multiple Sclerosis Society

11:00 – 11:15 AM **Break**

SESSION III: Cellular Approaches to Address Women's Health

Moderator: Juan Gnecco, Tufts University

Session Objectives:

- Consider recent advances in understanding the innate regenerative capacity of female-specific cells and tissues, examining how these advances inform the development of therapies aimed at treating conditions that are female-specific and/or are more common in or differently impact women.
- Explore different cellular approaches aimed at addressing the current gaps in regenerative medicine basic and translational research and treating such conditions.

11:15 – 11:30 AM ET **Caroline Gargett**
Research Group Head
Endometrial Stem Cell Biology
Hudson Institute of Medical Research

11:30 – 11:45 AM **Ji-Yong Julie Kim**
Susy Y. Hung Professor
Professor of Obstetrics & Gynecology in the Division of Reproductive Science in Medicine
Co-Director, Center of Reproductive Science
Northwestern University

11:45 – 12:00 PM **Melissa Kaufman**
Professor, Department of Urology
Patricia and Rodes Hart Professor of Urologic Surgery
Chief Division of Reconstructive Urology and Pelvic Health
Vanderbilt University Medical Center

12:00 – 12:15 PM **Doris A. Taylor**
Chief Executive Officer
Organamet Bio Inc.

12:15 – 12:30 PM **Samik Basu**
Chief Scientific Officer
Cabaletta Bio

12:30 – 12:55 PM **Panel Discussion**

12:55 – 1:00 PM **Reflections on the Discussion**
Juan Gnecco, Tufts University

1:00 – 2:00 PM **Break for Lunch**

SESSION IV: Non-Cellular Innovations in Women's Health

Moderator: Margot Damaser, The Cleveland Clinic

Session Objectives:

- Discuss non-cellular innovations used to advance regenerative basic and translational research and improve the diagnosis of conditions that are female-specific and/or are more common in or differently impact women.
- Explore emerging non-cellular regenerative therapies, such as biomaterial-based and gene therapies, developed to treat these conditions.

2:00 – 2:15 PM

Erika Moore
Assistant Professor
Fishell Department of Bioengineering
University of Maryland

2:15 – 2:30 PM

Manu O. Platt
Director
Center for Biomedical Engineering Technology Acceleration (BETA)
Senior Investigator
Head
Mechanics and Tissue Remodeling In Computational & Experimental Systems (MATRICES)
NIH Distinguished Scholar
Associate Director for Scientific DEIA
NIH National Institute of Biomedical Imaging and Bioengineering

2:30 – 2:45 PM

Brendan Harley
Robert W. Schaefer Professor
Chemical and Biomolecular Engineering
University of Illinois Urbana-Champaign

2:45 – 3:00 PM

Alejandro J. Almarza
Professor
Department of Oral and Craniofacial Sciences
University of Pittsburgh

3:00 – 3:15 PM

Karen Christman
Associate Dean for Faculty Affairs and Welfare
Pierre Galletti Endowed Chair for Bioengineering Innovation
Professor of Bioengineering
Jacobs School of Engineering
University of California San Diego

3:15 – 3:40 PM **Panel Discussion**

3:40 – 3:45 PM **Reflections on the Discussion**
Margot Damaser, The Cleveland Clinic

3:45 – 4:00 PM **Break**

SESSION V: Final Reflections and Future Opportunities

Session Objectives:

- Discuss opportunities in the regenerative medicine field to further address health care disparities for women.
- Consider how the representation of women within the regenerative medicine workforce impacts research and clinical care and explore efforts to expand representation.
- Examine obstacles that may restrict access to regenerative medicine therapies, opportunities to expand access to care, and efforts to improve health literacy and communication.

4:00 – 4:45 PM **Panel Discussion**

Moderators: Eric Sid, NIH National Center for Advancing Translational Sciences, Katherine Tsokas, Johnson & Johnson Innovative Medicine

Linda Goler Blount
President and CEO
Black Women's Health Imperative

Erika Moore
Assistant Professor
Fishell Department of Bioengineering
University of Maryland

Akua Roach
Health Science Program Manager
Congressionally Directed Medical Research Programs

Doris A. Taylor
Chief Executive Officer
Organamet Bio Inc.

Kimberly J. Templeton
Professor
Orthopedic Surgery and Sports Medicine
University of Kansas Medical Center

4:45 – 5:00 PM **Closing Remarks**

Kimberlee Potter, *Workshop Planning Committee Co-Chair*
Vivian Ota Wang, *Workshop Planning Committee Co-Chair*

5:00 PM **Adjourn**

FORUM INFORMATION

NATIONAL ACADEMIES Sciences Engineering Medicine

Board on Health Sciences Policy

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 interested parties; 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.

NATIONAL ACADEMIES *Sciences Engineering Medicine*

Board on Health Sciences Policy

Forum on Regenerative Medicine

Membership

Co-Chairs: Krishnendu Roy, PhD, Vanderbilt University
Katherine Tsokas, JD, Johnson & Johnson Innovative Medicine

Robert Carter, MD, National Institute of Arthritis and Musculoskeletal and Skin Diseases

Tammy Collins, PhD, Burroughs Wellcome Fund

Larry Goldstein, PhD, Sanford Consortium for Regenerative Medicine; UCSD School of Medicine

Albert Hwa, PhD, National Institute of Diabetes and Digestive and Kidney Diseases

Cato T. Laurencin, MD, PhD, The Connecticut Convergence Institute for Translation in Regenerative Engineering; The University of Connecticut

Michael May, PhD, Centre for Commercialization of Regenerative Medicine

Richard McFarland, PhD, MD, Advanced Regenerative Manufacturing Institute

Jack Mosher, PhD, International Society for Stem Cell Research

Lisa A. Neuhold, PhD, National Eye Institute

Amy Patterson, MD, National Heart, Lung, and Blood Institute

Duanqing Pei, PhD, Chinese Academy of Sciences

Thomas Petersen, MD, PhD, United Therapeutics

Anne Plant, PhD, National Institute of Standards and Technology

Kimberlee Potter, PhD, Department of Veterans Affairs

David Rampulla, PhD, National Institute of Biomedical Imaging and Bioengineering

Derek Robertson, JD, MBA, CHC, Maryland Sickle Cell Disease Association

Derrick Rossi, PhD, New York Stem Cell Foundation

Krishanu Saha, PhD, University of Wisconsin-Madison

Rachel Salzman, DVM, American Society of Gene & Cell Therapy

Eric Sid, MD, National Center for Advancing Translational Sciences

Jay Siegel, MD, retired, Johnson & Johnson

Sohel Talib, PhD, California Institute for Regenerative Medicine

Fei Wang, PhD, National Institute of Aging

Daniel Weiss, MD, PhD, International Society for Cellular Therapy

Michael Werner, JD, Alliance for Regenerative Medicine

Celia M. Witten, PhD, MD, Food and Drug Administration

Kathleen Zackowski, PhD, National Multiple Sclerosis Society

Claudia Zylberberg, PhD, formerly, Akron Biotech LLC

Project Staff

Sarah Beachy, PhD, PMP, *Forum Director*
Michelle Drewry, PhD, *Associate Program Officer*
Kathryn Asalone, PhD, *Associate Program Officer*
Ashley Pitt, *Senior Program Assistant*
Samantha Schumm, PhD, *Program Officer*
Email: regenmed@nas.edu

NATIONAL ACADEMIES Sciences Engineering Medicine

FORUM ON REGENERATIVE MEDICINE

Our **purpose** is to spark exchange and inspire action among diverse interested parties to advance regenerative medicine for the benefit of all.

Our actions are guided by the following principles:

Innovation	Intention	Collaboration	Integrity

We effect change using these strategies:

- Foster a diverse and inclusive future generation of thinkers and doers in the field
- Proactively discern critical scientific, medical, and social issues and provide fit-for-purpose venues for reflection and response
- Engage and collaborate with those whose work aligns with ours
- Translate and disseminate what we learn to catalyze action in the field

The priorities of our work:

Diversity, Equity & Inclusion	Workforce Development	Manufacturing & Supply Chain	Emerging Issues
Advance the Forum's commitment to diversity, equity, and inclusion	Examine incentives and disincentives for expanding the regenerative medicine workforce	Explore obstacles to the delivery of regenerative medicine to patients	Highlight emerging scientific, policy-related, or other issues in the field

We **commit** to upholding the Diversity and Inclusion Statement of the National Academies of Sciences, Engineering, and Medicine. Furthermore, we commit to developing a Diversity, Equity & Inclusion Statement that is more specific to our Forum's work.

The National Academies of Sciences, Engineering, and Medicine value diversity in our members, volunteers, and staff and strive for a culture of inclusion in our workplace and activities. Convening a diverse community to exchange ideas and perspectives enhances the quality of our work and increases our relevance as advisers to the nation about the most complex issues facing the nation and the world.

Temporomandibular disorders (TMDs) are significant and complex health problems that affect people of all ages. It is estimated that almost 5 percent of U.S. adults had pain in the region of the TMJ that could be related to TMDs. As a set of diverse and multifactorial conditions, TMDs have a range of causes and often co-occur with a number of overlapping medical conditions—including headaches, fibromyalgia, back pain, and irritable bowel syndrome. While research in the last decade has revealed significant findings related to TMDs, many questions and challenges remain, including the need for more accurate diagnoses of TMDs and bridging the medical-dental practitioner divide to help improve and expand quality care for individuals with a TMD.

The National Academies' report *Temporomandibular Disorders: Priorities for Research and Care*, released in March 2020, provides an overview of the current state of knowledge on TMDs and offers recommendations for building collaborative and multidisciplinary research, improving access to high quality TMD care, enhancing health professional education about TMDs, raising public awareness, and reducing stigma associated with TMDs.

Moving Forward with a Forum

As a next step, the National Academies launched a new Forum in December 2023 on TMD research and care that will bring together interested parties from public and private sectors to work together in addressing issues of shared interest and concern. The Forum will provide an ongoing mechanism and a neutral setting in which to collaborate and engage in discussions that will facilitate cross-sector action and foster long-term multidisciplinary relationships – all focused on improving research and care for people with TMDs. The Forum activities will clarify and expand areas of agreement and explore new approaches to issues that have been gridlocked. Through a combination of Forum member meetings and public workshops, the Forum will focus on the etiology of TMDs, the acceleration of effective care and treatment of patients, and the enhancement of interprofessional collaborative action and education.

The TMD Forum will focus efforts on:

- Spurring greater understanding of the complex etiology of TMDs and their related conditions.
- Expanding multidisciplinary research efforts into the causes and potential treatments for TMDs.
- Bridging the medical-dental practice divide.
- Inspiring action to improve access to appropriate, high quality TMD care.
- Exploring issues related to insurance coverage and costs of TMD care.
- Considering approaches for increasing awareness and confronting misinformation and stigma among patients, professionals, and the public.
- Addressing TMD from a bioethical perspective.

How Forums Operate and What They Do

National Academies' forums convene leaders in government, industry, academia, patient advocacy, foundations, and other interested parties to discuss complex issues of mutual interest in a neutral setting. Members meet 2 – 3 times per year to share ideas and information, refine Forum priorities, conduct public workshops, and commission papers and other products – all focused on informing the Forum members themselves, other stakeholders, and the public about emerging issues that deserve attention and resolution.

Contacts: Clare Stroud, PhD, Senior Director, Board on Health Sciences Policy (CStroud@nas.edu); Sharyl Nass, PhD, Senior Director, Board on Health Care Services (SNass@nas.edu); Andrew Pope, PhD, Advisor (APope@nas.edu); Rebecca English, MPH, Senior Program Officer (REnglish@nas.edu)

NATIONAL ACADEMIES Sciences Engineering Medicine

Board on Health Sciences Policy
Board on Health Care Services

Forum on Temporomandibular Disorders

Membership

Enriqueta Bond, Ph.D., (Co-chair)
President Emerita
Burroughs Wellcome Fund

Alejandro Almarza, Ph.D.
Professor, Department of Oral and Craniofacial Sciences
University of Pittsburgh

Kyriacos Athanasiou, Ph.D., Ph.M.
Professor, Biomedical Engineering
University of California – Irvine

Briana Burris, D.D.S.
Attending Surgeon, Division of Oral and Maxillofacial Surgery & Professor
Massachusetts General Hospital
Harvard School of Dental Medicine

Robert Carter, M.D.
Deputy Director
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Natalia Chalmers, D.D.S., Ph.D.
Chief Dental Officer
Centers for Medicare and Medicaid Services

Christian Stohler, D.M.D., (Co-chair)
Professor and Dean
Columbia University College of Dental Medicine

Allen Cowley, Jr., Ph.D.
Professor of Physiology
Medical College of Wisconsin

Vincent DiFabio, D.D.S.
American Society of Temporomandibular Joint Surgeons
Oral Surgeon & Associate Professor of Oral and Maxillofacial Surgery
University of Maryland Hospital – Baltimore

Rena D'Souza, D.D.S., Ph.D.
Director
National Institute on Dental and Craniofacial Research

Justin Durham, Ph.D.
Head, School of Dental Sciences
Newcastle University

Henri Ford, M.D.
Dean & Chief Academic Officer
University of Miami Miller School of Medicine

Leslie Halpern, M.D., D.D.S., Ph.D.
American Medical Women's Association
Professor/ Section Chief/ Program director residency, Oral and Maxillofacial Surgery
New York Medical College & HHC: Metropolitan Hospital

Karen Kelly-Blake, Ph.D.
Associate Director of Academic Programming
Associate Professor, Center for Bioethics and Social Justice
Michigan State University

Danica Marinac-Dabic, M.D., Ph.D.
Associate Director, Office of Clinical Evidence and Analysis
U.S. Food and Drug Administration

Ann McCulloch, M.B.A.
Chief Executive Officer
Orofacial Therapeutics Inc.

Robert Mier, D.D.S.
American Academy of Orofacial Pain
Adjunct Professor
Tufts University School of Dentistry

Joel Napeñas, D.D.S.
The American Academy of Oral Medicine
Clinical Associate Professor
Wake Forest School of Medicine

Janey Prodoehl, Ph.D.
Academy of Orthopaedic Physical Therapy
Professor, Physical Therapy Program and College of Dental Medicine – Illinois
Midwestern University

Mary Lou Sabino, D.D.S.
Veterans Administration
Head of Department
William S. Middleton VA Hospital and Clinics

Christin Veasley
Co-founder & Director
Chronic Pain Research Alliance

Grace Wittenberg
Medical Student
Medical College of Wisconsin – Central Wisconsin

WORKSHOP INFORMATION

NATIONAL ACADEMIES Sciences Engineering Medicine

Board on Health Sciences Policy

Forum on Regenerative Medicine
Forum on Temporomandibular Disorders

The Intersection of Regenerative Medicine and Women's Health: A Workshop

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Planning Committee Member Roster

Co-Chairs

Kimberlee Potter, Ph.D.
Scientific Program Officer
Department of Veterans Affairs

Vivian Ota Wang, Ph.D.
Deputy Director
NIH Office of Research on Women's Health

Members

Alejandro Almarza, Ph.D.
Professor
Department of Oral and Craniofacial Sciences
University of Pittsburgh

Cristina H. Amon, Sc.D.
Professor
Mechanical Engineering
University of Toronto

Tammy Collins, Ph.D.
Program Officer
Burroughs Wellcome Fund

Margot Damaser, Ph.D.
Full Staff
Department of Biomedical Engineering
Lerner Research Institute
The Cleveland Clinic

Elizabeth Garner, M.D., MPH
President, KNI Health Consultants
Immediate Past President American Medical Women's Association (AMWA)

Juan Gnecco, Ph.D.
Assistant Professor
Biomedical Engineering
Tufts University

Eric Sid, M.D., MHA
Program Director
National Center for Advancing Translational Sciences
Division of Rare Diseases Research Innovation
National Institutes of Health

Katherine Tsokas, J.D.
Vice President
Regulatory, Quality, Risk Management and Drug Safety
Johnson & Johnson Innovative Medicine

Kathleen Zackowski, Ph.D.
Associate Vice President
National Multiple Sclerosis Society

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Planning Committee Member Biographies

Kimberlee Potter, Ph.D., is the Scientific Portfolio Manager of Surgery, Trauma, and Restorative Medicine in the Office of Research and Development at the Department of Veterans Affairs. She oversees research on musculoskeletal disorders, frailty, geroscience, and surgery. She is the co-founder of the VA's Biofabrication Community of Science and serves on the VA's Women's Health IPT. Her other roles include VA representative on the National Academies of Sciences, Engineering, and Medicine (NASEM) Forum for Regenerative Medicine, the External Advisory Board for Armed Forces Institute of Regenerative Medicine, and the Programmatic Committee for the Congressionally Directed Medical Research Program for Reconstructive Transplantation Research Program. Before joining VA, Dr. Potter worked at the Armed Forces Institute of Pathology (AFIP) 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 the human cases of blast-induced traumatic brain injury and the application of medical imaging in virtual autopsies. She received her B.Sc. degree in Engineering Chemistry from Queen's University in Canada and her Ph.D. from Cambridge University in England. She completed her post-doctoral training at the University of California at Santa Barbara in the Department of Chemical & Nuclear Engineering, after which she served as a visiting scientist at the National Institute on Aging and the National Institute on Child Health and Human Diseases.

Vivian Ota Wang, Ph.D., as a psychologist, geneticist, and genetic counselor, has domestic and global experiences in research, education, policy, and ethics that span biomedical, psychological, genomic, nanoscale, and data sciences. She applies her expertise in racial identity, community engagement, and ethics to scientific leadership and oversight of women's health research as the NIH's Office of Research on Women's Health's Deputy Director. Previously, she was the inaugural Policy, Ethics, and COVID Lead at the Office of Data Science Strategy where she established the NIH Rapid Acceleration of Diagnostics (RADx) Data Repository, one of the largest NIH COVID-19 databases, that accelerated COVD-19 testing innovation and testing in underserved populations. She also envisioned and spearheaded the RADx Tribal Data Repository, the first NIH sovereignty-based research data repository. Her other public service includes the inaugural NCI-NIH Office of Data Sharing Deputy Director, NHGRI-NIH Data Access and Sharing and ELSI Research Program Directors, and Senior Advisor to NIH's Office of Behavioral and Social Sciences Research Director and Executive Office of the President (Bush/Obama administrations) where she developed public engagement & ELSI guidance for nanoscience/nanotechnology. Prior to public service, she was a genetic counselor at the University of Colorado, and then held tenure-track faculty positions at Rutgers, Arizona State, and Vanderbilt universities where her research focused on racial identity and multicultural competencies related to research ethics, program development/evaluation, and community engagement. Her clinical expertise is in congenital & acquired disabilities, traumatic brain injury, and bereavement. Her accomplishments are recognized by university, professional, and government awards. She earned a BA-Biology (Colorado College), MS-Genetic Counseling (University of Colorado) and MPhil/PhD-Counseling Psychology (Columbia University). She is an American Medical Association Fellow (American College of Medical Genetics), and a

diplomate of the American Psychological Association, American Board of Medical Genetics, and American Board of Genetic Counseling, and is a licensed psychologist.

Alejandro Almarza, Ph.D., is a professor in Oral and Craniofacial Sciences in the School of Dental Medicine with a secondary appointment in the Department of Bioengineering and the University of Pittsburgh McGowan Institute of Regenerative Medicine. His research interests are temporomandibular joint cartilage and bone regeneration and biomechanics; identifying appropriate polymeric scaffolds for tissue engineering approaches for tri-layer interface tissues; arthritis from altered loading; 3D innervation patterns imaged with light sheet microscopy, and CRISPR epigenome modulation for pain and joint damage.

Cristina H. Amon, Sc.D., is a University Professor, Alumni Distinguished Professor and Dean Emerita at the University of Toronto's Faculty of Applied Science and Engineering. Under her leadership, Canada's #1 ranked engineering school has become a global hub for inter-disciplinary research and education known for its strategic Faculty-wide initiatives, cross-Faculty centres and institutes, and innovative undergraduate and graduate programming.

Prior to joining U of T in 2006, she was the Raymond J. Lane Distinguished Professor and Director of the Institute for Complex Engineered at Carnegie Mellon University. She has pioneered the field of Computational Fluid Dynamics and the development of multidisciplinary multi-scale hierarchical modelling, concurrent design and optimization methodologies for thermo-fluid transport phenomena, with applications to thermal management of electronics and electric vehicles, renewable energy and biomedical devices.

Professor Amon was appointed to the Order of Canada and inducted into the Canadian Academy of Engineering, Hispanic Engineer Hall of Fame, Royal Society of Canada, Spanish Royal Academy and US National Academy of Engineering. She is a fellow of all major professional societies in her field and has contributed over 400 refereed articles to the education and research literature.

Among her many accolades, she received the ASEE Westinghouse Medal, ASEE Ralph Coats Roe Award, ASME Heat Transfer Memorial Award, ASME InterPACK Achievement Award, EIC Sir John Kennedy Medal, and CSME Robert W. Angus Medal. She was recognized as one of Canada's Most Influential Women in 2012, received the Engineers Canada Award for the Support of Women, was named one of the YWCA's Women of Distinction, and received the highest honor for Engineers in Canada (2020 Engineers Canada Gold Medal) and Ontario (2015 PEO Gold Medal) for outstanding engineering public service, technical excellence and professional leadership.

Cristina Amon is the founding chair of the Global Engineering Deans Council and has served on numerous editorial and technical conference roles, advisory and review boards in North America and abroad. She received her Mechanical Engineering degree from Simon Bolivar University in Venezuela, and her M.S. and Sc.D. from the Massachusetts Institute of Technology.

Tammy Collins, Ph.D., is a program officer with the Burroughs Wellcome Fund where she leads the Fund's efforts in interdisciplinary science, including the Career Awards at the Scientific Interface, and regulatory science. She spent the past decade with the National Institute of Environmental Health Sciences (NIEHS) as director of the NIEHS Office of Fellows' Career Development. Her work included a focus on increasing mentorship at NIEHS and publishing results of NIEHS postdoctoral career outcomes. Dr. Collins received her B.S. in Chemistry from Appalachian State University, where she became Appalachian's first Goldwater Scholar and her Ph.D. in Biochemistry from Duke University. After a brief postdoc at Duke University, she joined NIEHS as a postdoc in 2009 where she developed her passion for working in the scientific career development field.

Margot Damaser, Ph.D., earned her Ph.D. in Bioengineering from the University of California Berkeley & San Francisco joint program in Bioengineering. She then completed 2 postdoctoral fellowships at the University of Lund in Sweden and at the University of Pennsylvania in Philadelphia, PA USA. For over 25 years, she has led a laboratory conducting research on the causes of and treatments for female pelvic floor disorders, including stress urinary incontinence, pelvic organ prolapse, and fecal incontinence. Dr. Damaser and her team have developed and used animal models to test novel regenerative therapeutics for female pelvic floor disorders. She uses the animal models to investigate the effects of comorbidities such as diabetes, obesity, age, and other pelvic floor disorders, on urinary incontinence and the response to regenerative therapies. In collaboration with a team of engineers and physicians, Dr. Damaser has also developed several novel wireless catheter-free devices for improved diagnosis and treatment of incontinence. She has also She holds 6 issued US Patents and has 3 pending US Patent applications. Dr. Damaser has over 200 peer-reviewed publications and has had continuous research funding from VA and NIH for over 20 years in addition to collaborative research grants from private foundations and several companies. She is widely regarded as an international expert on urodynamics, models for studying female pelvic floor disorders, and new technologies in female urology and pelvic floor disorders. Dr. Damaser has won multiple awards for innovative science, her scientific writing, and her outstanding mentoring. In 2004, Dr. Damaser received the Presidential Early Career Award for Scientists and Engineers, awarded to her for outstanding research on the human urinary bladder using mathematical modeling along with physiological and neurological studies. In 2014 she was elected by her colleagues to the American Institute for Medical and Biological Engineering (AIMBE) College of Fellows, representing the top 2% of medical and biological engineers. More recently, in 2022, Dr. Damaser was awarded the prestigious Society of Women in Urology (SWIU) – Society of Basic Science Research (SBUR) Award for Excellence in Urologic Research. Dr. Damaser was recently inducted as a Senior Member of the National Academy of Inventors in Washington DC.

Elizabeth (Beth) Garner, M.D., M.P.H., is a seasoned strategic- and business-minded pharmaceutical executive and corporate board member with a career-long focus on addressing unmet medical needs that affect women's health and quality of life. Born and raised in Nigeria, she brings a global view to her work in both the corporate and non-profit worlds. Most recently, Dr. Garner was Chief Scientific Officer of Ferring Pharmaceuticals US, a mid-size global

company focused on reproductive and maternal health, microbiome and gastrointestinal therapeutics, and uro-oncology. From 2019-2022, she was Chief Medical Officer (CMO) of ObsEva, a company focused on addressing unmet needs in women's health. Prior to that, she was CMO of Agile Therapeutics, where she led the company's clinical development, regulatory, and medical affairs strategies, including designing and leading the Phase 3 SECURE trial which led to FDA approval of the Twirla contraceptive patch. Dr. Garner has also held leadership roles at Myriad Genetics, Abbott Laboratories, and at Merck Research Labs where she was a key contributor on the Gardasil and Gardasil9 vaccines.

Dr. Garner is an experienced corporate board member and is currently on the Boards of Directors of Kezar Life Sciences (KZR), which develops novel therapies for autoimmune diseases and cancer, Sermonix Pharmaceuticals, a company focused on targeted breast cancer therapies, and is Chair of the Board of NUA Surgical, a start-up company dedicated to creating innovative surgical solutions in obstetrics and gynecology. She is also the Immediate Past President of the American Medical Women's Association (AMWA), a professional organization whose mission is to advance women physicians, advocate for equity, and ensure excellence in healthcare.

Beth received joint M.D. and M.P.H. degrees from Harvard Medical and Public Health Schools, trained in obstetrics and gynecology at Brigham and Women's (BWH)/Massachusetts General Hospitals, and completed a fellowship in gynecologic oncology at BWH/Dana Farber Cancer Institute. Prior to transitioning into industry in 2007, she was Assistant Professor at Harvard Medical School, where she focused on academic clinical practice in gynecologic oncology, basic science ovarian cancer research, and teaching and mentorship of medical students, residents, and fellowship trainees.

Elizabeth has extensive experience as a media spokesperson and is a frequent panelist and speaker on a range of topics including innovation and investment in women's health, women's leadership, diversity, equity, and inclusion (DEI), and diversity in clinical trials. She is an author on close to 40 peer-reviewed scientific papers and published her first essay in (https://hms.harvard.edu/magazine/womens-health/cri-de-coeur). Garner is a 2019 and 2023 awardee of the PharmaVoice 100 Most Inspiring Individuals in the life sciences industry and was the 2022 recipient of the Woman in Science Award from the American Medical Women's Association.

Juan Gnecco, Ph.D., is an Assistant Professor in the Department of Biomedical Engineering at Tufts University and associate Principal Investigator at the Mother Infant Research Institute (MIRI) at Tufts Medical Center. His work lies at the interface of tissue engineering and reproductive biology to understand the immune-endocrine mechanisms driving uterine physiology and disease pathogenesis. Dr. Gnecco obtained his B.S. in Biotechnology from Rutgers University, and a Ph.D. in Cellular and Molecular Pathology from Vanderbilt University Medical Center (VUMC) where he developed the first organ-on-chip (OoC) model of the perivascular endometrium to study the effects exerted by environmental toxicants on the female reproductive tract. Dr. Gnecco conducted his post-doctoral training at Massachusetts Institute of

Technology (MIT) in the Department of Biological Engineering where he led efforts to transform the human clinical relevance of 3-dimensional (3D) reproductive tract models by defining the interplay between biophysical and cellular cues using organoid technologies and high-content 3D imaging approaches. He has been awarded three rounds of funding from Gates Foundation (2018-present) for his work building phenotypic 3D models of the endometrial microenvironment. He is the project lead in the World Endometriosis Research Foundation (WERF) Experimental Organoid Model Unification initiative, was selected as a Rising Star in Engineering and Health by Columbia University, and serves on the editorial board for Frontiers in Reproductive Health. He is committed to advance women's health through inclusive educational engineering strategies.

Eric Sid, M.D., M.H.A., joined the National Center for Advancing Translational Science (NCATS) in the Division of Rare Diseases Research Innovation in 2017, for which he is currently a Program Director and manages a public health information center focuses on patients affected by rare diseases, coordinates other programs that enable patient organizations to actively engage in the research process by providing educational and training support, and as a scientist on projects targeted at improving diagnostics across genetic and rare diseases. Dr. Sid represents NCATS on the National Institutes of Health's (NIH) UNITE initiative, which was established to identify and address structural racism within the NIH-supported and greater scientific community, as well as the Trans-NIH Diversity, Equity, Inclusion, Accessibility Strategic Plan Working Group. Sid is the current chair for NCATS' Inclusion, Diversity, Equity in Action (IDEA) Council. Dr. Sid received his M.D. and M.H.A. (Masters in Healthcare Administration) from the University of Washington. He completed a Presidential Management Fellowship (PMF), which is the Federal Government's flagship leadership development program, for which he was stationed at the NIH and with the Department of Veterans Affairs (VA). Eric's interests are in advancing the use of information science in accelerating the dissemination of research for public health uses, the engagement and partnership of patient organizations in research, and fostering greater diversity, equity, inclusivity, and accessibility across the biomedical research enterprise for the benefit of patients and their communities.

Katherine Tsokas, J.D., has over 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.

Katherine is the Vice President Regulatory, Quality, Risk Management and Drug Safety for Johnson & Johnson Innovative Medicine (J&J IM) Canada. As part of the J&J IM Canada Leadership Team, she is responsible for the Regulatory strategy, including leadership oversight for Drug Safety, Risk Management and Commercial Quality. In this role she works closely with the J&J IM Global and North American organizations and assures J&J IM as a key partner with Health Canada and external trade associations. She holds a position on the Innovation Medicines Canada (IMC) Regulatory Operations Team.

Previously, Katherine was the Regulatory Head of Regenerative Medicine & Advanced Therapy (RMAT). In this role, she ensured global regulatory policy strategies contributed to and supported development plans for RMAT products across several therapeutic areas and facilitated J&J enterprise wide efforts to enhance awareness and connectivity for the development of processes that enable assessing, partnering, and developing safe and effective advanced therapies globally. She also headed the Global Regulatory Affairs (GRA) Data Science team focused on the use of Data Science in regulatory decision making and represented GRA on cross-functional Leadership teams.

Katherine continues to hold external RMAT leadership roles as Co-chair of the National Academy Science Engineering Medicine Regenerative Medicine Forum, and Advanced Therapy Industry Liaison of the Asia Pacific Economic Cooperation Regulatory Harmonization Steering Committee. Additionally, Katherine is an adjunct professor at Syracuse University College of Engineering and Computer Science teaching Introduction to Global Regulatory Affairs. She 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.

Kathleen Zackowski, Ph.D., is the Associate Vice President for Research at the National MS Society. She manages the Society's research portfolio focused on clinical and rehabilitation care, the development of the Society's Wellness Initiative, as well as the Society's Community Review of MS Research committee. In addition, Dr. Zackowski serves on the scientific leadership team of the International Progressive MS Alliance. Dr. Zackowski received her Ph.D. from Washington University in St. Louis in movement science and completed a post-doctoral fellowship in neuroscience and neurology at the Johns Hopkins School of Medicine. Following her post-doctoral fellowship, she joined the faculty in the Departments of Physical Medicine & Rehabilitation and Neurology at Johns Hopkins School of Medicine and the Kennedy Krieger Institute where she ran her laboratory for 15 years, investigating the mechanisms that underlie sensorimotor impairments and disability resulting from damage to the central nervous system. She remains on faculty as Adjunct Associate Professor in the Departments of Physical Medicine & Rehabilitation and Neurology at Johns Hopkins School of Medicine and the Kennedy Krieger Institute. Dr. Zackowski is also an Occupational Therapist with 25 years of clinical experience in adult rehabilitation, having an MS practice for over 15 years in treating individuals with multiple sclerosis at the Johns Hopkins MS Center.

NATIONAL ACADEMIES Sciences Engineering Medicine

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Forum on Regenerative Medicine
Forum on Temporomandibular Disorders

The Intersection of Regenerative Medicine and Women's Health: A Workshop

October 1, 2024

Speaker Biographies

Alejandro J. Almarza, Ph.D., is a professor in Oral and Craniofacial Sciences in the School of Dental Medicine with a secondary appointment in the Department of Bioengineering and the University of Pittsburgh McGowan Institute of Regenerative Medicine. His research interests are temporomandibular joint cartilage and bone regeneration and biomechanics; identifying appropriate polymeric scaffolds for tissue engineering approaches for tri-layer interface tissues; arthritis from altered loading; 3D innervation patterns imaged with light sheet microscopy, and CRISPR epigenome modulation for pain and joint damage.

Samik Basu, M.D., joined Cabaletta in December 2019 and was most recently Vice President of Preclinical Research and Translational Medicine before assuming his new role as Chief Scientific Officer. Prior to joining Cabaletta, Dr. Basu was Head of Translational Sciences (Medicine) at Adaptimmune Therapeutics, Plc, where he led research efforts focused on understanding the mechanisms of resistance and response to TCR based adoptive immunotherapies to inform next generation approaches and clinical strategies. Before that, Dr. Basu co-led preclinical development efforts for Keytruda (pembrolizumab) at Merck Research Laboratories. He is a physician-scientist with over 15 years of industry and academic experience in adoptive immunotherapy, translational research, autoimmunity, and tumor immunology with prior roles at the National Institutes of Health, Albert Einstein College of Medicine, and the University of Pennsylvania. Dr. Basu received his M.D. from Temple University and completed residency training in Clinical Pathology.

Linda Goler Blount, M.P.H., is an epidemiologist and President of the Black Women's Health Imperative, the first national non-profit organization focused on Black women's health and wellness. Ms. Blount has overseen more than $30 million invested in research to prevent chronic disease and HIV, ensure reproductive justice and healthy maternal outcomes, and advocate for health-promoting policies. Ms. Blount is also the Executive Chair of the Rare Disease Diversity Coalition, a $20M collaborative of over 80 organizations formed to ensure patients of color, low-income, and rural patients are centered in research, advocacy, and policy.

Her career includes leadership tenures at the CDC, the Coca-Cola Company, and the American Cancer Society. She also has extensive international health expertise and has served as a consultant to government ministries in Germany, South Africa, Zimbabwe, Malawi, Jamaica, and Trinidad and Tobago, where she lived for four years. A Michigan native, Linda holds a Master of Public Health degree in Epidemiology from the University of Michigan and a Bachelor of Science in Computer Engineering/Operations Research from Eastern Michigan University.

Riley Bove, M.D., received her AB from Harvard College and her M.D. and M.Sc. degrees from Harvard Medical School. She completed her Neurology training at Mass General Brigham Hospitals and her clinical research fellowship in Neuroimmunology at the Partners Multiple Sclerosis Center. She joined the UCSF faculty in 2015, where her Lab promotes person-centered research particularly in the arenas of sex and gender informed Neurology, and digital health. She is Founding Director of the Sex and Gender Enriched (SAGE) Neurology Program at UCSF, Co-PI of the BRIDGE precision medicine platform, and Director of Digital Innovation for the Neuroimmunology Division. She has received research support from the NIH, National Multiple Sclerosis Society, Department of Defense, NSF, as well as industry partners and private foundations. Clinically, she guides patients during pregnancy planning, menopause management, and other life events.

Karen Christman, Ph.D., is a Professor in the Shu Chien-Gene Lay Department of Bioengineering, the Associate Dean for Faculty Affairs and Welfare, and holds the Pierre Galletti Endowed Chair for Bioengineering Innovation in the Jacobs School of Engineering at UC San Diego. She received her B.S. in Biomedical Engineering from Northwestern University in 2000 and her Ph.D. from the University of California San Francisco and Berkeley Joint Bioengineering Graduate Group in 2003, where she examined in situ approaches to myocardial tissue engineering. She was also a NIH postdoctoral fellow at the University of California, Los Angeles in the fields of polymer chemistry and nanotechnology. Dr. Christman joined the Department of Bioengineering in 2007 and is Co-Director of the Sanford Advanced Therapy Center at the UC San Diego. Her lab, which is housed in the Sanford Consortium for Regenerative Medicine, focuses on developing novel biomaterials for tissue engineering and regenerative medicine applications, and has a strong translational focus with the main goal of developing minimally invasive therapies for cardiovascular disease and women's health. Dr. Christman is a fellow of the American Heart Association, the American Institute for Medical and Biological Engineering, the Biomedical Engineering Society, and the Tissue Engineering and Regenerative Medicine International Society, and has received several awards including the NIH Director's New Innovator and Transformative Research Awards, the Wallace H. Coulter Foundation Early Career Translational Research Award, the Tissue Engineering and Regenerative Medicine International Society's Young Investigator and Senior Scientist Awards, the Society for Biomaterials Clemson Award for Applied Research, and the AIMBE Professional Impact Award for Diversity, Equity, and Inclusion. Dr. Christman is also a Senior Member of the National Academy of Inventors and a co-founder of Ventrix, Inc. and Karios Technologies, Inc.

Caroline Gargett, Ph.D., is an NHMRC Leadership Fellow at Hudson Institute of Medical Research where she leads the Women's Health Theme and heads the Endometrial Stem Cell Biology Laboratory. She is also an Adjunct Professor and Executive member of the Department of Obstetrics and Gynaecology, Monash University. She discovered and characterised endometrial stem/progenitor cells in human, mouse and sheep, investigating their role in endometriosis aetiology and pioneering the development of bioengineering approaches for treating and preventing pelvic organ prolapse. International recognition of her research includes the US$1M Magee Prize (co-recipient) to identify human Vaginal Stem Cells (2021), Society for Reproductive Investigation President's Achievement Award (2013) and Endometriosis Foundation of America Honoree (2011). Directorships include the National Stem Cell Foundation of Australia and Stem Cells Limited. She is a Scientific Advisory Board member of the Endometriosis Foundation of America, Fondation Pour la Recherche sur Endometriose and Julia Argyrou Endometriosis Centre Epworth.

Brendan Harley, Ph.D., is the Robert W. Schaefer Professor in the Dept. of Chemical and Biomolecular Engineering at the University of Illinois at Urbana-Champaign. He received a B.S. in Engineering Sciences from Harvard University (2000), a Sc.D. in Mechanical Engineering from MIT (2006), and performed postdoctoral studies at the Joint Program for Transfusion Medicine at Children's Hospital Boston (2006-2008). His research group develops biomaterial platforms to dynamically regulate cell behavior for applications in musculoskeletal regeneration, hematopoietic stem cell biomanufacturing, as well as to investigate endometrial pathologies and invasive brain cancer. He has received funding from the NSF, NIH, American Cancer Society, the U.S. Army, and the AO Foundation. Prof. Harley co-founded a regenerative medicine company, Orthomimetics Ltd., to commercialize a biomaterial for osteochondral regeneration. Dr. Harley has received a number of awards and honors including an NSF CAREER award (2013), the Young Investigator Award (2014) and the Clemson Award for Basic Research (2021) from the Society for Biomaterials, as well as university research, teaching, and promotion awards (U. Illinois). He is an elected Fellow of the American Association for the Advancement of Science (2014), the American Institute for Medical and Biological Engineering (2018), and the Biomedical Engineering Society (2021).

Melissa Kaufman, M.D., Ph.D., is Professor of Urology and Chief of the Division of Reconstructive Urology and Pelvic Health at Vanderbilt Medical Center. She received her B.A. from Washington University – St. Louis and Ph.D. in Microbial Genetics at University of Tennessee. Following postdoctoral research at Stanford and completion of medical school in her home state of Arkansas, Dr. Kaufman commenced her Urology residency at Vanderbilt in 2002. She completed fellowship training in both Male Reconstruction and Female Pelvic Medicine and Reconstructive Surgery in 2009 at Vanderbilt. Her practice focuses on female and male voiding dysfunction and incontinence, cancer survivorship, pelvic organ prolapse, neurourology, transitional care for congenital urologic conditions, urologic prosthetics, as well as reconstructive surgery for urethral stricture, fistula and trauma. She is additionally a past-president of the Society of Women in Urology.

Julie Kim, Ph.D., is the Susy Y. Hung Professor of Obstetrics and Gynecology in the Division of Reproductive Science in Medicine at Northwestern University. She is the Co-Director for the Center of Reproductive Science at Northwestern. Dr. Kim received a B.Sc. in Microbiology from the University of Toronto in Toronto, Ontario, Canada and a Ph.D. at Laval University in Quebec City, Canada. She completed post-doctoral training at the University of Illinois at Chicago and established an independent research laboratory at Northwestern University. Her laboratory is interested in understanding the pleiotropic actions of sex hormones and their intersection with risk factors that promote development and growth of uterine diseases including Endometrial Cancer, Uterine Fibroids and Endometriosis. The lab develops appropriate in vitro and in vivo models that best represent the physiology of reproductive tissues, including 3D organ cultures on microfluidic platforms, patient derived xenografted tumors, and iPSCs for disease modeling. The ultimate goal is to provide potential new drug targets as well as better drug screening approaches for these uterine diseases.

Monica M. Laronda, Ph.D., is the Director of Research for the Fertility & Hormone Preservation & Restoration Program at the Ann & Robert H. Lurie Children's Hospital of Chicago. She is the Gesualdo Family Research Scholar at the Stanley Manne Children's Research Institute and Assistant Professor in the Department of Pediatrics and Department of Obstetrics and Gynecology at Northwestern University. She has been awarded several National Institutes of Health grants to study foundational biology and to engineer regenerative techniques for both ovaries and testes.

Erika Moore, Ph.D., is an Assistant Professor within the Fischell Department of Bioengineering at the University of Maryland, College Park. Her academic journey began with a Bachelor's degree in Biomedical Engineering from Johns Hopkins University in 2013, followed by a Ph.D. in Biomedical Engineering from Duke University in 2018. As the Principal Investigator of the Moore lab, Dr. Moore is dedicated to engineering biomaterial models that harness the regenerative potential of macrophage immune cells in tissue repair and regeneration. Her research focuses on health inequities, spanning age-associated macrophage dysfunction, macrophage-endothelial inflammation mediation in lupus, and macrophage integrin ligand interactions within the extracellular matrix, and the role of macrophages in propagating uterine fibroids. Beyond her scientific endeavors, Dr. Moore is a fervent advocate for professional development and financial literacy, especially for underrepresented minorities in STEM. She co-founded #BlackInBME, a support group for black trainees and faculty in biomedical engineering. Dr. Moore also established Moore Wealth Inc., a non-profit organization aimed at empowering students with financial literacy skills. Recognized as a 2020 Forbes 30 Under 30 awardee in Healthcare and a 2024 TED Fellow, Dr. Moore's contributions have also been acknowledged through prestigious grants and awards, including the N.I.H. R35 Maximizing Investigators Research Award, Lupus Research Alliance Career Development Award, BMES Rita Schaffer Award, 3M Non-Tenured Faculty Award, and NSF CAREER Award.

Manu O. Platt, Ph.D., is a senior investigator, Section on Mechanics and Tissue Remodeling Integrating Computational & Experimental Systems (MATRICES) in NIBIB's intramural research program. His lab studies the transition of tissue from healthy to a diseased state and the underlying mechanisms driving disease progression. He is also the director of the NIH-wide Center for Biomedical Engineering Technology Acceleration (BETA Center), housed within the National Institute of Biomedical Imaging and Bioengineering (NIBIB) Intramural Research Program. The BETA Center serves as a model to bring a focused engineering approach for NIH researchers across disciplines to accelerate the development, validation and dissemination of cutting-edge technologies. As the BETA Center director, Platt will work to expand opportunities for biomedical engineering training and professional growth, including supporting individuals from diverse backgrounds. In addition, Dr. Platt is NIBIB associate director for Scientific Diversity, Equity and Inclusion.

Formerly, Dr. Platt was professor and Associate Chair of Graduate Studies in the Walter H. Coulter Department of Biomedical Engineering at the Georgia Institute of Technology and Emory University. He also was Georgia Research Alliance Distinguished Cancer Scientist and Deputy Director, Interdisciplinary Bioengineering Graduate Program at Georgia Tech Walter H. Coulter Distinguished Faculty Fellow.

As a scientific investigator for cutting-edge biomedical research projects, Platt has received numerous grants and research support from NIH, the National Science Foundation, the International AIDS Society and the Georgia Cancer Coalition, among other public and private research institutions. He has served on numerous review committees at NIH, is a member the Biomedical Engineering Society board of directors and is a former member of the NIBIB National Advisory Council for Biomedical Imaging and Bioengineering.

Dr. Platt earned a bachelor's degree in biology from Morehouse College in Atlanta and a Ph.D. in biomedical engineering at the Georgia Institute of Technology and Emory University in Atlanta. He was a postdoctoral fellow in biological engineering at the Massachusetts Institute of Technology, Cambridge.

A nationally-recognized leader in expanding diversity and inclusion in science, technology, engineering, and mathematics, Platt is the recipient of numerous awards and honors, including the NIH Director New Innovator award, an American Association for the Advancement of Science Mentor award, and the Biomedical Engineering Society Diversity Award. He co-founded Project ENGAGES: Engaging New Generations at Georgia Tech through Engineering and Science, which provides paid research lab experience for Atlanta area African American high school students, and directed the Georgia Tech Enhancing Science, Technology, Engineering, and Math Educational Diversity grant program, an NIH training program to increase and support diversity at the undergraduate level. Platt is a fellow of the Biomedical Engineering Society and the American Institute for Medical and Biological Engineering.

Akua Roach, Ph.D., is the Health Science Program Manager for the Peer Reviewed Orthopaedic Research Program, Arthritis Research Program, and the Orthotics and Prosthetics Outcomes Research Program, Congressionally Directed Medical Research Programs (CDMRP), U.S. Army Medical Research and Development Command. Dr. Roach received her Master's degree and Ph.D. in Molecular and Cellular Pharmacology from Stony Brook University. She earned her Bachelor of Science degree in Biochemistry and Molecular Biology from the University of Maryland, Baltimore County. As Program Manager, Dr. Roach is responsible for administering the program life cycle to include annual review of the program vision and mission, development and release of research funding opportunities, overseeing the two-tier review of research proposals, and overall program management and evaluation. Prior to joining CDMRP in 2014, Dr. Roach was the Regulatory Affairs Program Manager for Human Subjects Protection as a contractor to the National Institute of Allergy and Infectious Disease (NIAID) where she was responsible for the leadership, planning, and review of hundreds of regulatory documents in support of numerous Investigational New Drug applications supported by the NIAID.

Doris A. Taylor, Ph.D., is a dynamic innovator, scientist, entrepreneur, and a global thought leader in regenerative medicine and biomanufacturing holding over 20 patents in the field. She is passionate about creating cures for heart disease, which kills more people worldwide than any other disease and has an estimated economic impact of 219 billion dollars annually. In 2021she founded a new biotech company, Organamet Bio Inc. whose mission is to cure heart disease and reduce healthcare costs. Her goal is to bioengineer personalized replacement hearts on demand. She is equally committed to making those therapies available fairly, equitably, and as soon as they are shown to be safe and effective.

Taylor is credited with the first functional scientific repair of injured heart with stem cells in 1998. Her group further transformed the field of organ transplantation science in 2008 by developing a unique cell removal (decellularization) method that makes un-transplantable organs into usable scaffold frameworks for building new organs with stem cells. This was so revolutionary it was recognized as one of the "Top 10 Research Advances" by the American Heart Association and Taylor was nominated as one of "100 most influential people in the world" by Time magazine. Next, she turned to disease prevention and has begun to develop "cellular signatures" of heart disease and aging that appear to differ by sex, race and ethnicity. Taylor co-chaired a 2014 NIH working group on Sex Bias in Cardiovascular Research and was an invited participant at a 2015 National Policy and Science Summit on Women's Cardiovascular Health.

Dr. Taylor frequently appears as an expert on regenerative medicine, stem cells, women's health, cardiac repair and organ transplantation in the public media. Her work has been recognized and featured by 60 Minutes, CNN, The New York Times, The Wall Street Journal, Forbes, National Geographic, BBC Horizon, BBC News Health, ABC, NBC and CBS News, Associated Press, Good Morning America, NOVA Science Now, PBS NOVA Transplanting Hope, Discovery Channel's Through the Worm Hole with Morgan Freeman, Science Channel's Stem Cell Universe with Stephen Hawking, NPR's On Being with Krista Tippet, Sanjay Gupta's Champions for Change and most other worldwide media outlets.

Taylor has sat on numerous think tanks and international scientific committees including for the NIH, the FDA, the American Association of Blood Banks, and the Alliance for Regenerative Medicine. She was a recent member of the White House panel on Biomanufacturing and sat for almost 2 decades on the international jury for the Institut de France LeFoulon-Delalande Foundation Grand Prix, which is awarded annually to individuals making worldwide contributions to cardiovascular medicine.

Dr. Taylor earned a B.S. from Mississippi University for Women (MUW) and a Ph.D. from UT Southwestern Medical Center. She is appointed as a Fellow of the American Heart Association, American College of Cardiology, and European Society for Cardiology. She was awarded an honorary Doctor of Science degree by MUW and the national Distinguished Alumnus Award by the American Association of State Colleges and Universities. More recently she was elected as a Senior member of the National Academy of Inventors and as a fellow to the American Institute for Medical and Biological Engineering.

Her motto is, "Build the Future Today – and Do It with Heart."

Kimberly J. Templeton, M.D., is Professor and Department Vice-chair in the Department of Orthopaedic Surgery and Associate Dean for Continuing Medical Education at the University of Kansas Medical Center in Kansas City. She is past-president of the American Medical Women's Association and has worked with the Association's Sex and Gender Health Collaborative since its inception. Dr. Templeton is past vice-chair of the AMA Women Physician Section, past chair of the AMA Orthopaedic Section, and a member of the AMA Foundation LGBTQ+ Fellowship Commission. Dr. Templeton is a prior member of the NBME and is a member of the ACGME Orthopaedic Residency Review Committee and a member of the NIH Advisory Committee on Research on Women's Health. She received the inaugural Women Leaders in Medicine Award from the American Medical Student Association in 2008; the Marjorie J. Siddridge leadership award for women in medicine in 2012 and the Excellence in Mentoring Residents Award in 2018, both from the University of Kansas; the Washington University Distinguished Alum Award in 2019; the Elizabeth Blackwell Award for outstanding contributions to the cause of women in the field of medicine in 2013, the Bertha Van Hoosen Award in 2019 for exceptional leadership and service to women physicians and students, and the INSPIRE Award in 2022, all from the American Medical Women's Association; the Edith J. Levit Distinguished Service Award from the National Board of Medical Examiners in 2021; the Dr. Edmond and Rima Cabbabe Dedication to the Profession Award from the AMA Foundation in 2022; and the Bernadine Healy Award for Visionary Leadership in Women's Health in 2022. Dr. Templeton was named to the University of Kansas Women's Hall of Fame and an honorary alumnus of the University of Kansas, both in 2014. Dr. Templeton's areas of focus in research include issues faced by women physicians and the impacts of sex and gender on health. Her work addressing the issues of women physicians extends from medical students to those nearing the end of practice. Dr. Templeton was the lead author on the National Academy of Medicine paper on burnout among women physicians that was published in 2019 and the senior author of a paper published in 2020 that was the first to address issues faced by senior women physicians.

Vivian Ota Wang, Ph.D., as a psychologist, geneticist, and genetic counselor, has domestic and global experiences in research, education, policy, and ethics that span biomedical, psychological, genomic, nanoscale, and data sciences. She applies her expertise in racial identity, community engagement, and ethics to scientific leadership and oversight of women's health research as the NIH's Office of Research on Women's Health's Deputy Director. Previously, she was the inaugural Policy, Ethics, and COVID Lead at the Office of Data Science Strategy where she established the NIH Rapid Acceleration of Diagnostics (RADx) Data Repository, one of the largest NIH COVID-19 databases, that accelerated COVD-19 testing innovation and testing in underserved populations. She also envisioned and spearheaded the RADx Tribal Data Repository, the first NIH sovereignty-based research data repository. Her other public service includes the inaugural NCI-NIH Office of Data Sharing Deputy Director, NHGRI-NIH Data Access and Sharing and ELSI Research Program Directors, and Senior Advisor to NIH's Office of Behavioral and Social Sciences Research Director and Executive Office of the President (Bush/Obama administrations) where she developed public engagement & ELSI guidance for nanoscience/nanotechnology. Prior to public service, she was a genetic counselor at the University of Colorado, and then held tenure-track faculty positions at Rutgers, Arizona State, and Vanderbilt universities where her research focused on racial identity and multicultural competencies related to research ethics, program development/evaluation, and community engagement. Her clinical expertise is in congenital & acquired disabilities, traumatic brain injury, and bereavement. Her accomplishments are recognized by university, professional, and government awards. She earned a BA-Biology (Colorado College), MS-Genetic Counseling (University of Colorado) and MPhil/PhD-Counseling Psychology (Columbia University). She is an American Medical Association Fellow (American College of Medical Genetics), and a diplomate of the American Psychological Association, American Board of Medical Genetics, and American Board of Genetic Counseling, and is a licensed psychologist.

Teonna Woolford was born and raised in Baltimore Maryland. She has always been talkative, friendly, and full of life. She has Sickle Cell Anemia SS and has faced numerous health complications as a result. A true fighter at heart, she has recovered from numerous complications including bilateral hip replacements, a failed bone marrow transplant, many pain crises, and several other complications. She has a zeal for effecting change throughout the Sickle Cell community and understands the realities of those impacted by the disease. While sickle cell has been a huge part of Teonna's life, she does her best not to let sickle cell define who she is. Teonna has been blessed to sit at some incredible tables and contributed to publications and working committees with the American Society of Hematology and NHLBI. She is also the founder and CEO of a new nonprofit organization, The Sickle Cell Reproductive Health Education Directive.

The Intersection of Regenerative Medicine and Women's Health: A Workshop

October 1, 2024

LOCATION
The Keck Center, Room 100
500 5th St. NW
Washington, DC 20001

CONTEXT & KEY QUESTIONS

The Forum on Regenerative Medicine on Regenerative Medicine and the Forum on Temporomandibular Disorders are co-hosting this workshop to examine opportunities in regenerative medicine to address current gaps in basic science, translational research, and related therapies that, if not considered, may result in health care disparities for women. The workshop will explore strategies to better understand underlying biology that would enable development of regenerative medicine therapies for women. Thank you for joining us for this workshop!

Session I: Opening Remarks and Keynote

Questions for Speakers

1. What are the largest research and clinical gaps preventing the advancement of regenerative medicine therapies for the health of women? What are the growing areas in research within this space?
2. What are some of the lessons learned in developing and enabling access to treatments for women that we can adopt for regenerative medicine to reduce disparities in women's health?
3. How should developers of regenerative medicine products think about sex and gender during recruitment for clinical trials?
4. What are some strategies to ensure the inclusion of women in the regenerative medicine workforce?
5. How do can the regenerative medicine field build trustworthiness in and best communicate with a variety of communities about the potential benefits of advanced regenerative medicine products, especially when considering life-changing therapies?

Session II: The Impact of Sex and Hormones on Regenerative Medicine

Questions for Speakers

1. Has the appropriate amount of attention been given to research on the role of sex and hormones in biological systems? Why or why not? What could be done to address this?

2. What are the strengths and limitations of animal models related to the impact of sex and hormones on disease in human biological systems?
3. How could sex and hormones impact the efficacy of regenerative therapies?
4. How has the inclusion/exclusion of sex as a biological variable and women in clinical trials impacted research and the translation of regenerative therapies, and what potential is there for future impact?

Session III: Cellular Approaches to Address Women's Health

Questions for Speakers

1. What are some of the specific challenges to investigating cellular approaches for women's health?
2. How can regenerative medicine be used to address limitations in animal models? How do we increase the translational (pre-clinical) potential of regenerative therapies considering that the immune and endocrine systems of the human female reproductive tract is different in human biological systems than the animal model systems used to develop these therapies?
3. What challenges need to be addressed to better understand endocrine-tissue interactions? What strategies can be taken to increase the understanding of endocrine-tissue interactions beyond the female reproductive tract?
4. What are the potential benefits of targeting the immune system to better restore the regenerative properties of tissues and treat women's health-related disorders
5. What are the hurdles to translation of regenerative therapies into the clinic and how can we overcome them?
6. How do you think about precision-based approaches compared to a one-size-fits-all approach to modeling and treating disorders that impact women?
7. What are some strategies you would recommend for encouraging collaborations and making connections within this space?

Session IV: Non-Cellular Innovations in Women's Health

Questions for Speakers

1. What are the specific challenges to investigating non-cellular approaches for women's health?
2. What are the advantages and disadvantages of non-cellular therapies compared to cellular therapies for women's health?
3. How can regenerative medicine be used to address limitations in animal models? How do we increase the translational (pre-clinical) potential of regenerative therapies considering that the immune and endocrine systems of the human female reproductive tract is different in human biological systems than the animal model systems used to develop these therapies?
4. What challenges need to be addressed to better understand endocrine-tissue interactions? What strategies can be taken to increase the understanding of endocrine-tissue interactions beyond the female reproductive tract?
5. What are the potential benefits of targeting the immune system to better restore the regenerative properties of tissues and treat disorders that affect women?
6. What are the hurdles to translation of regenerative therapies into the clinic and how can we overcome them?

7. How do you think about precision-based approaches compared to a one-size-fits-all approach to modeling and treating disorders that impact women?
8. What are some strategies for encouraging collaborations and making connections within this space?
9. Are there opportunities for secondary data analyses to increase the power and rigor of the science in situations where there may not be large numbers of participants or patients?

Session V: Final Reflections and Future Opportunities

Questions for Speakers

1. What immediate actions can attendees take at their institutions to increase representation of women in the regenerative medicine workforce?
2. How can educational strategies in regenerative medicine help address the gaps in women's health?
3. What immediate steps can be taken to increase access to regenerative medicine therapies? What strategies can be identified to increase the accessibility to and scalability of regenerative medicines in women's health considering the potential of precision medicine and global impact?
4. What advancements would it take to propel this space of regenerative medicine and women's health forward that could make a significant impact on health and treatment?
5. Given the convening power of the Forums at the National Academies, what do you think we could explore next and why?

NATIONAL ACADEMIES Sciences Engineering Medicine

PREVENTING DISCRIMINATION, HARASSMENT, AND BULLYING:
POLICY FOR PARTICIPANTS IN NASEM ACTIVITIES

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- Reporting the incident to an employee involved in the activity in which the member or volunteer is participating, who will then file a complaint with the Office of Human Resources.

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Updated December 2, 2021

BACKGROUND INFORMATION

Links to Additional Resources

Session I: Keynote

- NIH Considerations of Sex and Gender. https://orwh.od.nih.gov/sex-gender
- NIH Policy on Sex as a Biological Variable. https://orwh.od.nih.gov/sex-gender/orwh-mission-area-sex-gender-in-research/nih-policy-on-sex-as-biological-variable
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Session V: Final Reflections and Future Opportunities

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- Department of Defense Funding Announcement: https://www.defense.gov/News/Releases/Release/Article/3913913/dod-commits-500-million-for-womens-health-research-supports-better-care-for-all/#:~:text=the%20.gov%20website.-,DoD%20Commits%20%24500%20Million%20for%20Women's%20Health%20Research,Better%20Care%20for%20All%20Women&text=The%20Department%20of%20Defense%20(DoD,uniquely%2C%20disproportionately%2C%20or%20differently.
- ARPA-H Sprint for Women's Health: https://arpa-h.gov/engage-and-transition/sprint

ANNOUNCEMENTS

NATIONAL ACADEMIES Sciences Engineering Medicine

New Proceedings of a Workshop—in Brief

Women's Health Research at the National Institutes of Health

NATIONAL ACADEMIES Sciences Engineering Medicine

Proceedings of a Workshop—in Brief

Overview of Research Gaps for Selected Conditions in Women's Health Research at the National Institutes of Health

Proceedings of a Workshop—in Brief

The National Academies of Sciences, Engineering, and Medicine (the National Academies) convened an ad hoc committee with scientific, ethical, regulatory, and policy expertise to address the persistent gaps that remain in the knowledge of women's health research across the National Institutes of Health (NIH). It was tasked with analyzing the proportion of NIH funding that supports conditions that are female specific and/or more common in women or affect women differently and to determine the level of funding needed to address gaps in women's health research. The committee was also tasked with developing recommendations regarding the structure of the NIH and the systems and processes needed to ensure optimal women's health research. To inform its deliberation process, the Committee on Assessment of NIH Research on Women's Health held a second public workshop on March 7, 2024.[1] The discussions included the science of sex differences, research needs within reproductive and gynecologic health, and research efforts aimed at women's mental and behavioral health, women's cancers, and nonmalignant gynecologic conditions. Speakers shared suggestions for how to improve and advance women's health research at NIH (see Box 1).

[1] The first public workshop for this study was held on January 25, 2024. More information can be found here: https://www.nationalacademies.org/event/45691_01-2024_assessment-of-nih-research-on-womens-health-meeting-2-part-1 (accessed June 11, 2024).

The workshop represents only part of the committee's information gathering process; the topics covered are not meant to be comprehensive or cover all women's health issues, and the complex interactions among these conditions, across the life course. This Proceedings of a Workshop—in Brief summarizes the presentations and discussions and should not be seen as a consensus of the workshop participants, committee, or National Academies.

SCIENCE OF SEX DIFFERENCES

Margaret McCarthy, University of Maryland School of Medicine, studies sex differences in the brain. She noted boys are typically more likely to be born prematurely, suffer injuries at birth, and be diagnosed with neuropsychiatric or neurological disorders originating in development. Conversely, she continued, women are more likely to experience interpersonal sexual violence, suffer from affective disorders and chronic pain, and be diagnosed with autoimmune disorders. Overall, male-biased disorders are typically diagnosed in childhood and female-biased disorders in adulthood. This profound gender bias compels her research team to understand the origins of risk and resilience to brain disorders, said McCarthy. Brain sexual differentiation occurs during a sensitive period early in development. Her lab focuses on the sensitive period when this cella-

AUGUST 2024 | 1

A National Academies committee held a public hybrid workshop in March 2024 on the state of women's health research for select conditions and to hear perspectives from the public. Topics included the science of sex differences and research needs in women's cancers, reproductive and gynecologic health, and mental and behavioral health.

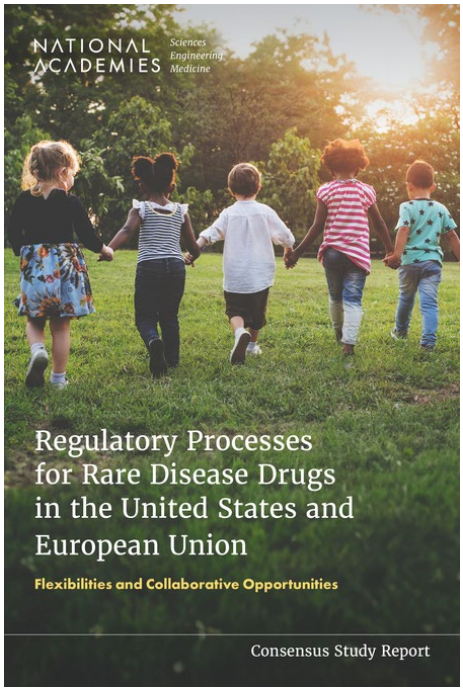
Link: https://doi.org/10.17226/27932

Released August 20, 2024

NATIONAL ACADEMIES Sciences Engineering Medicine

New Consensus Study

Regulatory Processes for Rare Disease Drugs in the United States and European Union



Rare diseases, such as sickle cell disease and thalassemia, affect up to 30 million people in the United States and at least 300 million across the globe. Congress called on the U.S. Food and Drug Administration (FDA) to sponsor a National Academies study on processes for evaluating the safety and efficacy of drugs for rare diseases or conditions in the United States and the European Union. The resulting report provides recommendations for enhancing and promoting rare disease drug development by improving engagement with people affected by a rare disease, advancing regulatory science, and fostering collaboration between FDA and the European Medicines Agency.

Link: https://doi.org/10.17226/27968

Released September 12, 2024

NATIONAL ACADEMIES Sciences Engineering Medicine

Upcoming Consensus Study Report Release (coming late October 2024)

The Use of Race & Ethnicity in Biomedical Research

An ad hoc committee of the National Academies of Sciences, Engineering, and Medicine will assess the current use of the social constructs of race and ethnicity in biomedical research and provide recommendations to guide the scientific community in the future use of race and ethnicity in biomedical research.

More specifically, the committee will:

- Document and evaluate how racialized group and ethnic categories are currently being used in biomedical research (e.g., as a descriptor, to stratify data, to apply race norming, to infer differences between groups due to environmental and social impacts), including describing consequences and contributions to health inequities in current clinical practices;
- Identify the circumstances in which it is appropriate to use the social constructs of race and ethnicity in biomedical research, for example in studying the health effects of racism, and the circumstances in which race and ethnicity should not be used to inform inferences;
- Review existing guidance for researchers on the use of race as a variable in biomedical research.

Based on its review of the literature and other expert input, the committee will develop a report with its findings, conclusions, and recommendations for entities such as researchers, funders, publishers, scientific and medical societies, health systems, and industry regarding:

- The use of race and ethnicity in biomedical research, including identifying current practices that should be continued, stopped, or modified.
- Policy changes to reform the use of race and ethnicity in biomedical research, with specific attention to the practice of race norming or race correction.
- Implementation strategies to help enhance the adoption of best practices across the biomedical research community.

The committee's work will focus on the use of racialized group and ethnic categories across the spectrum of biomedical research, including the development of clinical prediction models and other clinical decision tools. Related topics in the provision of clinical care, such as inequitable access to health care and racism in care delivery, are beyond the scope of this study.

NATIONAL ACADEMIES *Sciences Engineering Medicine*

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University of California, San Francisco

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Johns Hopkins Bloomberg School of Public Health

Shyam Visweswaran, M.D., Ph.D.
University of Pittsburgh

Genevieve L. Wojcik, Ph.D.
John Hopkins Bloomberg School of Public Health

Ruqaiijah Yearby, J.D., M.P.H
The Ohio State University

Funded by the Doris Duke Foundation and the Burroughs Welcome Fund

Link: https://www.nationalacademies.org/our-work/the-use-of-race-and-ethnicity-in-biomedical-research

NATIONAL ACADEMIES Sciences Engineering Medicine

Roundtable on Genomics and Precision Health

National Cancer Policy Forum

Upcoming Workshop

Examining Clinical Guidelines for the Adoption of Genomic Testing: A Workshop

October 29, 2024

Washington D.C.

Statement of Task:

A planning committee of the National Academies of Sciences, Engineering, and Medicine will organize and conduct a public workshop to examine how clinical practice guidelines can impact adoption of genomics into routine medical care. The workshop will examine how guidelines for genomic testing are developed by various organizations and implemented within clinical practice, with a focus on exploring inconsistencies across guidelines.

The workshop's presentations and discussions may focus on:

- Exploring the processes and methodologies used by different professional societies, organizations, and collaborations to gather evidence and develop clinical guidelines for appropriate genomic testing.
- Understanding how clinicians, payers, test developers, laboratory partners, and others decide which guideline(s) to follow and how they use these guidelines in practice.
- Examining elements that are consistent and those that differ across clinical guidelines for genomics and how these areas impact patients (e.g., access, coverage, and equity in care), clinicians, payers, test developers, laboratories, and others.
- Discussing opportunities for a possible path forward for more compatible clinical guidelines for genomics to improve patient care.

The planning committee will organize the workshop, develop the agenda, select and invite speakers and discussants, and moderate or identify moderators for the discussions. A proceedings-in brief of the presentations and discussions at the workshop will be prepared by a designated rapporteur in accordance with institutional guidelines.

NATIONAL ACADEMIES Sciences Engineering Medicine

Roundtable on Genomics and Precision Health

National Cancer Policy Forum

Planning Committee Members

Co-Chairs

Mylynda Massart
UPMC Primary Care Precision Medicine Center

Victoria Pratt
Representing Association for Molecular Pathology; Agena Biosciences

Members

Trish Brown
CVS Health

Pranil Chandra
PathGroup

W. Gregory Feero
Representing Journal of American Medical Association; Geisel School of Medicine; Maine Dartmouth Family Medicine Residency Program

Gabriel Lazarin
Myriad Genetics

Funda Meric-Bernstam
MD Anderson Cancer Center

Rebecca Morgan
Evidence Foundation; McMaster University; Case Western Reserve University

Wanda Nicholson
George Washington University Milken Institute School of Public Health

Mary Nix
Agency for Healthcare Research and Quality

Pim Suwannarat
Mid-Atlantic Permanente Medical Group

Link: https://www.nationalacademies.org/event/43378_10-2024_examining-clinical-guidelines-for-the-adoption-of-genomic-testing-a-workshop