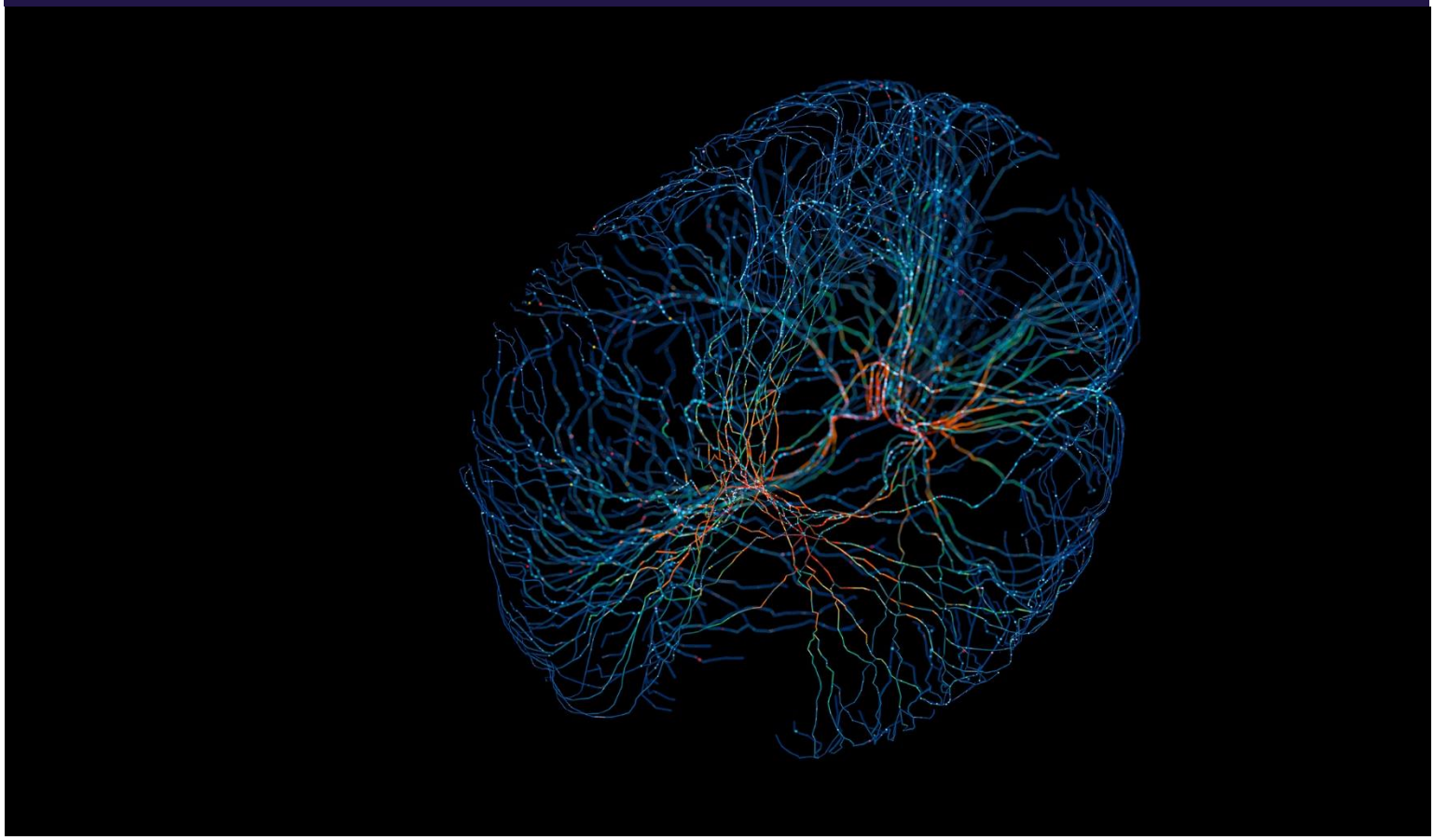
NATIONAL ACADEMIES Sciences Engineering Medicine

Forum on Neuroscience and Nervous System Disorders

Exploring the Adoption of Implantable Brain Stimulation into Standard of Care for Central Nervous System Disorders: A Workshop

October 31, 2023 | 9:00–4:30pm ET | Hybrid

ATTENDEE PACKET



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Agenda

Keck Center (Room 100) | 500 Fifth Street, NW, Washington, DC 20001

TUESDAY, OCTOBER 31, 2023

Objectives

- Review the current state of knowledge regarding the clinical utilization of implantable brain stimulation across various CNS disorders and consider the future potential to improve quality of life for patients.
- Explore barriers and potential solutions to adopting implantable brain stimulation into standard of care such as: safety and efficacy, scalability, and regulatory support.
- Discuss the ethical and equity implications associated with reimbursement practices, accessibility, and technological distribution.
- Examine opportunities to enhance health professional and patient education to ensure informed access to implantable brain stimulation.

9:00am **Welcome**

Frances Jensen, University of Pennsylvania; *Co-chair, Forum on Neuroscience and Nervous System Disorders*

John Krystal, Yale University; *Co-chair, Forum on Neuroscience and Nervous System Disorders*

Session I: Crossing the Chasm – Lessons Learn Across Technology

Objectives:

- Review the current state of knowledge regarding the clinical utilization of implantable brain stimulation across various CNS disorders and consider the future potential to improve quality of life for patients.
- Discuss the lessons learned from other technologies that have or have not “crossed the chasm” to become adopted into clinical care.
- Consider how these lessons learned might be applied to implantable brain stimulation.

9:05am **Workshop Overview**

Tim Denison, University of Oxford; *Workshop Co-Chair*

Helen Mayberg, Icahn School of Medicine at Mount Sinai; *Workshop Co-Chair*

Objectives:

- Share the scope of the workshop and what will not be covered.
- Introduce technology adoption theory as the theme for this workshop.
- Highlight that scalability, technology, co-morbidities considerations, and opportunities to overcome these barriers will be implicit throughout the workshop.

9:15am **Setting the Stage: Where Do We Want To Be?**

Brian Litt, University of Pennsylvania

Objectives:

- What does it mean to be a part of the standard of care?
- Provide a brief history about cardiac pacemakers and defibrillators.
- What would be required for implantable brain stimulation to be adopted into the standard of care?

9:20am **Lessons Learned Across Therapeutic Areas**

Objectives:

- Provide an overview of the therapy and the patient need that was being addressed.
- Share insights into why the therapy has been or not been adopted into clinical care.
- What are some of the lessons learned that should be considered for any new implantable brain stimulation therapy?

Overview of Approved Neuromodulation Therapies

Vivek Pinto, Food and Drug Administration

Cochlear Implants and retinal implants

Carla Mann Woods, Adventus Ventures

Responsive neurostimulation for Epilepsy

Mindy Ganguly, University of Pennsylvania

Deep Brain Stimulation for Obsessive Compulsive Disorder (OCD)

Benjamin Greenberg, Brown University

9:45am **Moderated Discussion**

***Panel Moderator*:** Brian Litt, University of Pennsylvania

Session II: Benefits and Challenges Experienced By Individuals with Lived Experience

Objectives:

- Explore what patients need from implantable brain stimulation to define it as a successful treatment.
- Discuss how adoption of this technology can impact patients and their quality of life.
- Consider what challenges and barriers prevent patients from selecting this treatment or causes patients to perceive the treatment as a failure.

10:00am **Session Overview**

Laura Lubbers, CURE Epilepsy

10:05am **Speaker Remarks**

- Steve Austin, CURE Epilepsy
- Jim McNasby, The Michael J. Fox Foundation for Parkinson's Disease
- Jon Nelson, Jon Nelson Advisors, LLC
- Claudia Garrido-Revilla, The Michael J. Fox Foundation for Parkinson's Disease

10:25am **Moderated Discussion**

***Panel Moderator*:** Laura Lubbers, CURE Epilepsy

10:55am **BREAK**

Session III: Practical Barriers I – Patient Selection and Engagement

Objectives:

- Review the challenges associated with patient selection and engagement; and managing expectations of patients and their families.
- Consider the ethics of ensuring equitable access to all patients and demographics.
- Explore the potential opportunities or collaborations that are needed to develop informed patient selection practices and equitable access to the technology.
- Review the concerns of patients regarding the possible complications and side effects of implantable brain stimulation and potential educational campaigns to increase patient awareness of and comfort with the technology.

11:05am **Session Overview**

Sarah Perides, Evelina London's Children Hospital

11:10am **Moderated Panel & Audience Q&A**

***Panel Moderator*:** Sarah Perides, Evelina London's Children Hospital

- Joseph Candelario-McKeown, National Hospital for Neurology and Neurosurgery
- Rachel Davis, University of Colorado, Anschutz School of Medicine
- Nita Farahany, Duke University (*Zoom*)
- Doris Wang, University of California, San Francisco (*Zoom*)
- Alik Widge, University of Minnesota

12:10pm **LUNCH**

Session IV: Practical Barriers II – Health Physician Education & Adoption

Objectives:

- Discuss the current barriers to increase training and engagement among health professionals on implantable brain stimulation; and barriers of current practices.
- Explore what relationships might need to be developed across different specialties and clinical practices to facilitate referrals and continuance of care.

12:55pm **Session Overview**

David McMullen, Food and Drug Administration

1:00pm **Moderated Panel & Audience Q&A**

***Panel Moderator*:** David McMullen, Food and Drug Administration

- Lauren Hammer, University of California San Francisco (*Zoom*)
- Joan Miravite, Icahn School of Medicine at Mount Sinai
- Martha Morrell, NeuroPace, Inc
- Michael Okun, University of Florida
- Yagna Pathak, Abbott

2:00pm **BREAK**

Session V: Practical Barriers III – Reimbursement & Other Economic Considerations

Objectives:

- Consider the current economic barriers and technological limitations that prevent implantable brain stimulation from becoming scalable.
- Discuss what ongoing or future approaches need to be taken to improve the benefit-cost ratio and allow brain stimulation to be scalable for wider application in CNS disorders.
- Review the current status of reimbursement for implantable brain stimulation and discuss opportunities to increase reimbursement.

2:10pm **Session Overview**

Yagna Pathak, Abbott

2:15pm **Moderated Panel & Audience Q&A**

***Panel Moderator*:** Yagna Pathak, Abbott

- Julie Brown, Spark Biomedical (*Zoom*)
- Kevin Mahoney, University of Pennsylvania Health System
- Susan Miller, Centers for Medicare & Medicaid Services (*Zoom*)
- Peter Silburn, Queensland Brain Institute (*Zoom*)

3:15pm **BREAK**

Session VI: Synthesis of Workshop Themes

Objectives:

- Review the core themes and takeaways shared across the previous sessions
- Based on previous discussions, explore creative approaches or collaborations needed to move the field forwards towards the end goal of adoption of implantable brain stimulation into the standard of care.
- Discuss the implications of comorbidities and opportunities to develop technologies and treatments to holistically treat patients.

3:25pm **Session Overview**

Tim Denison, University of Oxford; *Workshop Co-Chair*

Helen Mayberg, Icahn School of Medicine at Mount Sinai; *Workshop Co-Chair*

3:30pm **Moderated Panel & Audience Q&A**

***Panel Moderator*:** Tim Denison, University of Oxford & Helen Mayberg, Icahn School of Medicine at Mount Sinai

- Brandy Ellis, Neuromodulation Patient Advocate
- Lauren Hammer, University of California San Francisco (Zoom)
- Doug Kelly, Food and Drug Administration
- Sarah Hollingsworth Lisanby, National Institute of Mental Health
- Kevin Mahoney, University of Pennsylvania Health System
- Chris Pulliam, Case Western University

4:25pm **Synthesis and Concluding Remarks**

Tim Denison, University of Oxford; *Workshop Co-Chair*

Helen Mayberg, Icahn School of Medicine at Mount Sinai; *Workshop Co-Chair*

This event was planned by the following experts: Tim Denison, University of Oxford; Helen Mayberg, Icahn School of Medicine at Mount Sinai; Nita Farahany, Duke University; Sarah Lisanby, National Institute of Mental Health; Brian Litt, University of Pennsylvania; Laura Lubbers, CURE Epilepsy; David McMullen, Food and Drug Administration; Jim McNasby, The Michael J. Fox Foundation for Parkinson's Research; Martha Morrell, NeuroPace, Inc; Yagna Pathak, Abbott; Sarah Perides, Evelina London Children's Hospital; Rita Valentino, National Institute on Drug Abuse; Alik Widge, University of Minnesota.

Note: The planning committee's role is limited to organizing the event. A proceedings based on the event will be prepared by an independent rapporteur.

Article I. Forum on Neuroscience and Nervous System Disorders

The Forum on Neuroscience and Nervous System Disorders was established in 2006 to provide a venue for building partnerships, addressing challenges, and highlighting emerging issues related to brain disorders, which are common, major causes of premature mortality, and, in aggregate, the largest cause of disability worldwide. The Forum's meetings bring together leaders from government, industry, academia, disease advocacy organizations, philanthropic foundations, and other interested parties to examine significant—and sometimes contentious—issues concerning scientific opportunities, priority setting, and policies related to research on neuroscience and brain disorders; the development, regulation, and use of interventions for the nervous system; and related ethical, legal, and social implications.

Forum members meet several times a year to exchange information, ideas, and differing perspectives. The Forum also sponsors workshops (symposia), workshop proceedings, and commissioned papers as additional mechanisms for informing its membership, other stakeholders, and the public about emerging issues and matters deserving scrutiny. Additional information is available at www.nas.edu/NeuroForum.

(i) MEMBERS

Frances Jensen, MD, *co-chair*
University of Pennsylvania

John Krystal, MD, *co-chair*
Yale University

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Muna Therapeutics

Deanna Barch, PhD
Washington University in St. Louis

Diane Bovenkamp, PhD
BrightFocus Foundation

Katja Brose, PhD
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Oxford University; Duke University; UK Government Mental Health Mission

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Bill Martin, PhD
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National Institute of Health's Brain Research through Advancing Innovative Neurotechnologies (BRAIN®) Initiative

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Simons Foundation

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Foundation for the National Institutes of Health

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Doug Williamson, MBChB, MRCPsych
Acadia Pharmaceuticals, Inc

Richard Woychik, PhD
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Kimberly Ogun, BS
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Senior Board Director, Board on Health Sciences Policy

Article II. Biosketches of Speakers

Steve Austin

Steve Austin has practiced corporate communications for almost 25 years, managing strategic communications, and crisis / reputation management in the financial services industry.

He is also a Board member for CURE Epilepsy and has been a supporter for many years, with a passion to help others with this condition, which he was diagnosed with at the age of 12.

Julie Brown Alder, MBA

Julie Alder Brown, MBA, a dedicated Health Economics and Market Access professional, embarked on her healthcare journey as a pharmaceutical representative, gaining valuable insights into the industry's intricacies. With a background in sales and marketing strategy, Julie honed her market access expertise while working with a diverse range of medical device companies, from startups to industry giants, at a Chicago boutique market access consulting firm.

During her tenure at Abbott Neuromodulation, Julie specialized in advancing deep brain stimulation and chronic pain stimulation implantable technologies. Her role not only involved the development of innovative medical devices but also ensuring their seamless integration into the healthcare ecosystem. Currently employed at Spark Biomedical, Julie is responsible for obtaining reimbursement for a revolutionary wearable neurostimulation technology designed to aid individuals undergoing opioid withdrawal treatment. Her passion for patient-centric solutions drives her to navigate complex reimbursement landscapes, ensuring innovative healthcare technologies reach those in need.

Julie's approach to healthcare economics is characterized by a commitment to patient well-being and a determination to drive positive change. Through strategic collaboration and innovative insights, she continues to make a significant impact in the lives of patients, shaping the future of healthcare accessibility and affordability.

Joseph Candelario-McKeown, MS

Joseph Candelario-McKeown, MS**,** is an Advanced Nurse Practitioner – Nurse Specialist is Deep Brain Stimulation for 16 years at National Hospital for Neurology and Neurosurgery. His academic achievement includes BSc in Nursing from Central Luzon Doctors' Hospital – School of Nursing in Philippines and recently completed MSc in Advanced Nurse Practice with distinction at City University London. Joseph has a special interest in exploring patient expectations in DBS treatment. He is an advocate for the developing the role and profile of nurse specialist in DBS through continuous education, networking and innovation. He is also currently the chair of the Deep Brain Stimulation Nurse Association (DBSNA) in UK. He published the Standards of Practice and Competency Framework for DBS Nurse Specialist in 2020

which is ratified by Royal College of Nursing (RCN). He has collaborated to a number of published scientific papers. Also, he has peer reviewed scientific papers for publication.

Rachel A. Davis, MD

Rachel A. Davis, MD, is associate professor of psychiatry and neurosurgery at the University of Colorado Anschutz School of Medicine, where she serves as Vice Chair for Clinical Affairs and Strategy in the Department of Psychiatry. Dr. Davis specializes in treating severe and refractory psychiatric illness as Director of Interventional Psychiatry and co-director of the OCD Surgical program. She is medical director of the CU Anschutz OCD Program and Chief of Service for the University of Colorado Medicine outpatient psychiatry practices.

Dr. Davis is PI on an NIH BRAIN initiative studying the ethics of deep brain stimulation in schizophrenia, and she is the Director of Behavioral Health for The Hummingbird Initiative, a partnership between CU Anschutz and the Colorado Behavioral Health Administration which aims to increase diversity in the behavioral health workforce by providing programming and professional opportunities to students at rural, suburban, and urban high schools.

Brandy D. Ellis

Brandy D. Ellis is a passionate lived-experience advocate for neuromodulation and mental health. Her remarkable journey as a patient-participant in implanted neural device clinical trials has garnered international attention, with her story and insights featured in radio interviews with the BBC, podcasts, articles, and presentations at prestigious institutions. In 2011, Brandy bravely enrolled in a subcallosal cingulate Deep Brain Stimulation (DBS) study for treatment-resistant depression with Abbott Neuromodulation (formerly St. Jude), marking the beginning of her transformative journey towards remission from treatment-resistant depression.

Brandy thrives on engaging in deep and meaningful conversations about her personal experience with DBS and the profound impact it has had on her life. Through these discussions, she serves as a beacon of support for all individuals navigating the complex terrain of neuromodulation and mental health. Her advocacy work reflects her genuine desire to make a positive difference in the lives of others, serving as an inspiration to all who encounter her journey.

Mindy Ganguly, MD

Mindy Ganguly, MD, earned her medical degree from Case Western Reserve University School of Medicine. She then completed her neurology and epilepsy training at the Hospital of the University of Pennsylvania, including a clinical trials fellowship through the Institute for Translational Medicine and Therapeutics.

Board certified in neurology and epilepsy, Dr. Ganguly specializes in the treatment of epilepsy and the interpretation of EEGs. She has a special interest in emerging devices to help with the diagnosis and treatment of epilepsy, and has given regional and national talks on this topic. Dr. Ganguly is a collaborating clinician for the Center for Neuro-Engineering and Therapeutics, an affiliated scientist for the Penn Brainstim Center, and also adjudicates clinical trials as a member of the Penn Institutional Review board. Dr. Ganguly also attends on both the inpatient EEG and Epilepsy Monitoring Unit (EMU) services. In additional to her work in clinical trials and the EMU, Dr. Ganguly enjoys resident and fellow education.

Benjamin Greenberg, MD, PhD

Benjamin Greenberg, MD, PhD, after graduating Amherst College, Dr. Greenberg earned a PhD in Neurosciences from UCSD, an MD in the PhD to MD Program at the University of Miami, trained in neurology at Columbia, and completed psychiatry residency at Johns Hopkins. He became Chief of the Adult Obsessive-Compulsive Disorder (OCD) Unit at NIMH, where he studied the genetics of OCD and related conditions, and initiated TMS (transcranial magnetic stimulation) studies in OCD; he has continued to work developing noninvasive (TMS, focused ultrasound) and invasive (deep brain stimulation and ablative procedures) brain circuit-based therapies for conditions including OCD, PTSD, and MDD. He is currently Professor of Psychiatry, Alpert Medical School, Brown University, directs the COBRE Center for Neuromodulation at Butler Hospital, & co-Directs the Center for Neurorestoration and Neurotechnology at the Providence VA.

Lauren Hammer, MD, PhD

Benjamin Greenberg, MD, PhD, after graduating Amherst College, Dr. Greenberg earned a PhD in Neurosciences from UCSD, an MD in the PhD to MD Program at the University of Miami, trained in neurology at Columbia, and completed psychiatry residency at Johns Hopkins. He became Chief of the Adult Obsessive-Compulsive Disorder (OCD) Unit at NIMH, where he studied the genetics of OCD and related conditions, and initiated TMS (transcranial magnetic stimulation) studies in OCD; he has continued to work developing noninvasive (TMS, focused ultrasound) and invasive (deep brain stimulation and ablative procedures) brain circuit-based therapies for conditions including OCD, PTSD, and MDD. He is currently Professor of Psychiatry, Alpert Medical School, Brown University, directs the COBRE Center for Neuromodulation at Butler Hospital, & co-Directs the Center for Neurorestoration and

Neurotechnology at the Providence VA.

Doug Kelly, MD

Doug Kelly, MD, became Deputy Director and Chief Scientist at the FDA's device, diagnostics, and digital health branch in 2020 after a 30-year seed and early-stage life sciences venture capital career starting, financing, growing and exiting companies spanning biotech, medical devices, robotics, laboratory tools, healthcare IT, ADME/Tox simulation and clinical trial software. At CDRH, Doug is the interface between the FDA and patient and physician groups, payors, industry, academia, innovators, investors, and other agencies and governments. His focus is on creating a more vibrant and sustainable MedTech ecosystem, to bring new innovations to patients faster to relieve suffering, especially in unserved and underserved populations. Doug received his BA in Biochemistry and Cell Biology with honors from University of California, San Diego, his MD from the Albert Einstein College of Medicine, and his MBA at the Stanford University Graduate School of Business. In addition to lecturing at the GSB and Stanford Medical School, he conceived of and taught the class "Financing the

Start-up", for over a decade the Stanford's Department of Continuing Education biggest and most popular class.

Kevin Mahoney, DBA, MBA

Kevin Mahoney, DBA, MBA**,** is chief executive officer of the University of Pennsylvania Health System, a pillar of the Penn Medicine enterprise. He leads health system operations, spanning six hospitals, 11 multispecialty centers and hundreds of outpatient facilities in Pennsylvania, Delaware and New Jersey. Penn Medicine consists of the University of Pennsylvania Health System and the Perelman School of Medicine. Together, they form one of the world’s leading—and America’s oldest—academic medical centers dedicated to the related missions of medical education, biomedical research, and excellence in patient care.

Mahoney joined Penn Medicine in 1996, holding leadership posts for nearly three decades. Before his appointment as CEO in July 2019, he served as executive vice president and chief administrative officer of the University of Pennsylvania Health System and as executive vice dean of the Perelman School of Medicine. Across Penn Medicine, Mahoney has led transformational initiatives focused on improving patient experience and care efficiency in treatment settings. Most recently, he oversaw the creation of the Pavilion, a 1.5-million-square-foot, future-forward hospital. He also directed a yearslong project to unite the health system’s hospitals, clinics and home care programs under one shared electronic health records platform.

An advocate for access and equity, Mahoney launched a partnership with the Wharton School of the University of Pennsylvania to provide investment funds to early-stage businesses focused on strengthening the social determinants of health in underserved populations. Beyond medicine, Mahoney has been a driving force to integrate Penn

Medicine discoveries into the landscape of “Cellicon Valley,” an emerging gene and cell therapy innovation cluster in Philadelphia. Mahoney has contributed to The New England Journal of Medicine, the Journal of the American Medical Association and The Philadelphia Inquirer, offering perspectives on health equity, access to quality care, social justice and more. In 2022, he was named one of the “100 Most Influential People in Health Care” by Modern Healthcare.

A graduate of Millersville State College in Millersville, Pennsylvania, Mahoney earned a bachelor’s degree in economics. He also holds an MBA and a doctorate from the Fox School of Business at Temple University in Philadelphia.

Susan Miller, MD

Susan Miller, MD**,** is a board-certified physiatrist who practiced for over 20 years before joining the Centers for Medicare & Medicaid Services’ Coverage and Analysis Group.

Joan Miravite, DNP, MSN, BSN, RN, FNP-BC, FAAN, FAANP

Joan Miravite, DNP, MSN, BSN, RN, FNP-BC, FAAN, FAANP, is a practicing Nurse Practitioner with over 22 years of clinical experience working in Neurology. Joan holds Bachelor of Science degrees in both Biology and Nursing. She received her Bachelor and Master of Science in Nursing from Columbia University. She completed her Doctorate in Nursing Practice at NYU. She was appointed Assistant Professor of Neurology for the Icahn School of Medicine at Mount Sinai and is now the Director of Interdisciplinary Clinical Care for Movement Disorders at Mount Sinai. As the Chair for the American Academy of Neurology Consortium of Neurology Advanced Practice Providers (APPs), she represents over 1,900 clinicians across the country. She collaborates on multiple advisory boards and partners with APPs nationally on mentorship, recruitment, and networking. She has extensive experience in the evaluation and programming of Deep Brain Stimulation (DBS) for Parkinson's disease (PD), Essential Tremor, and Dystonia. She has been the Clinical Coordinator of the Parkinson's Foundation Center of Excellence at Mount Sinai Beth Israel since 2009. Joan is an invited member of multiple Parkinson's Foundation Advisory Committees. Additionally, Dr. Miravite is core faculty for the Parkinson's Foundation Team Training Program, with a focus on interdisciplinary clinical care for patients with PD. She has lectured at local, regional and national conferences, participates in clinical research and has published multiple articles in peer reviewed journals.

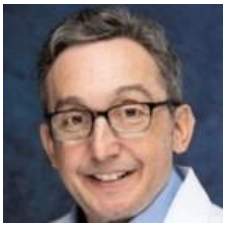
As a planning committee member and nurse activity director of the Education Series for Community Providers through the Parkinson's Foundation, with support from CVS Health Foundation, Joan advocates for the healthcare equity for patients with PD. Joan has received multiple awards for excellence in advance practice nursing and patient advocacy. She is a Fellow of the American Academy of Nursing and Fellow of the American Association of Nurse Practitioners.

Jon Nelson

Jon Nelson has battled treatment resistant major depressive disorder for a decade and is a survivor of mental illness. He was given his life back on August 23, 2022, after participating in a major depressive disorder clinical trial for deep brain stimulation from Mt Sinai Hospital in NYC.

He is a 47-year-old father of 3 beautifully unique children with an amazingly supportive and caring wife. He has dedicated his life to destroying the stigma of mental illness while also advocating for those suffering.

Michael S. Okun, MD



Michael S. Okun, MD, is an American neurologist, neuroscientist, and author. He is the co-founder and director of the Norman Fixel Institute for Neurological Diseases at the University of Florida (2019-current) and served as the chair of the Department of Neurology at the University of Florida (2015-2023) and the Medical Director/Advisor for the Parkinson's Foundation (2006- current). Okun opened his laboratory (2002) and the goals of his research included uncovering the underpinnings of human tic in Tourette syndrome, exploring non-motor basal ganglia circuitry and innovating neuromodulation and circuit-based treatments for human disease. Okun has advocated and implemented a neuroethics- based approach to utilizing the operating room and the outpatient clinic setting for research to better understand these neurological conditions. The Okun laboratory originally focused on the paroxysmal nature of human tic, which made it an ideal model to explore the physiological underpinnings of the movement disorder. His work has been important in understanding the biological changes underpinning the neural network changes which underpin the symptomatic benefits of deep brain stimulation and it has been important in shifting the field toward circuit-based treatments rather than disease based treatments.

Vivek Pinto, PhD, MBA, MS

Vivek Pinto, PhD, MBA, MS, is currently serving as the Director for the Division of Neuromodulation and Physical Medicine Devices in the Office of Neurological and Physical Medicine Devices at the FDA. Dr. Pinto has been with the agency for the past 11 years reviewing premarket and postmarket submissions for medical devices. He has experience making regulatory decisions on array of device types including deep brain stimulation, brain computer interface devices, vagal nerve stimulator, digital therapeutics, assistive devices, and non-invasive rehabilitation devices, among others. Prior to joining the agency, Dr. Pinto received his BS degree in Mechanical Engineering from the University of Pittsburgh along with product design and manufacturing experience at Mine Safety Appliances. In addition, Dr. Pinto received his MS and PhD degrees from New York University in Ergonomics and Biomechanics while conducting clinical trials research for the NYU Hospital for Joint Diseases. He's

currently enrolled in an Executive MBA program at New York University.

Christopher Pulliam, PhD, MS

Christopher Pulliam, PhD, MS, is an Assistant Professor of Biomedical Engineering at Case Western Reserve University, specializing in novel treatments and assessments for neurological ad neuromuscular disorders. Prior to his academic appointment, he held various roles in the medical device industry in both small (Great Lakes NeuroTechnologies) and multinational Medtronic Neuromodulation) companies. His work in the medical device sector has earned him nearly 30 U.S. patents, contributing to the development of Class II and III medical devices. A passionate advocate for diversity and inclusion, Dr. Pulliam also serves on the board of RePlay for Kids, a nonprofit dedicated to repairing and adapting toys and assistive devices for children with disabilities in Northeast Ohio. He was born and raised in Baton Rouge, LA, and holds BS, MS, and Ph.D. degrees in Biomedical Engineering, all from Case Western Reserve University.

Claudia Garrido-Revilla

Claudia Garrido-Revilla is a 58 year old Parkinson's disease patient, diagnosed at the age of 45. As a busy full time mom to two young boys and wife to her husband, Carlos, her diagnosis of an incurable and progressive neurological disease was devastating, to say the least. Her doctor warned that the standard medication to treat Parkinson's would become less and less effective with disease progression, never mentioning the possibility of participation in research or even DBS. The negative prognosis provided by this initial physician prompted her to do her own research and found The Michael J. Fox Foundation for Parkinson's Research. Finding the right physician and participating in every opportunity created by the MJFF to further research and to help improve the quality of life of patients and caregivers has been part of her life since diagnosis. Mrs. Revilla currently serves as a Member of the Patient Council of the MJFF. She is a strong advocate for patient educattion, participation in research and clinical trials and of social involvement within her community as a volunteer in various organizations. She and her husband Carlos recently moved to Spring, TX to enjoy retirement and warmer weather.

Peter Silburn, AM, PhD, MBBS, FRACP, BSc

Peter Silburn, AM, PhD, MBBS, FRACP, BSc, is internationally renowned as a clinical researcher in the field of Neurology and advanced treatments such as Deep Brain Stimulation. He was appointed Foundation Chair in Clinical Neurosciences at the University of Queensland in 2007 and played an instrumental role in establishing the University of Queensland's Asia Pacific Centre for Neuromodulation where he is Clinical and Education Director and member of the Board of Directors. He was awarded for his contributions to Neurology and Neuroscience with and Order of

Australia (AM) by the Australian Government.

Professor Silburn is Australian, Oxford trained and returned to Australia at the end of 1996. Since then, he has published over 200 internationally peer reviewed papers in the field of neurodegeneration, particularly in the areas of Parkinson's disease, molecular neuroscience, and deep brain stimulation. He has contributed to the establishment of Neuromodulation Centres throughout Australia and the Asia Pacific region and a foundation member of the Deep Brain Stimulation User Group of Asia Pacific.

Doris Wu Wang, MD, PhD

Doris Du Wang, MD, PhD, is a neurosurgeon-scientist and an Associate Professor in the Department of Neurological Surgery at UCSF who specializes in deep brain stimulation surgery for patients with movement disorders. Dr. Wang completed her undergraduate studies in biology at Yale University and her MD/PhD degrees at UCSF. Dr. Wang then completed her neurosurgery residency and fellowship training in Stereotactic and Functional Neurosurgery at UCSF.

The overall goal of Dr. Wang's research is to understand the neural mechanisms that underlie human motor control, study the pathophysiology when these circuits are disrupted in movement disorders, and restore these diseased circuits to their normal states using neuromodulation. Her group uses a variety of novel intraoperative and chronic recording techniques to address core questions in the neurophysiology human motor control.

Carla Mann Woods

Carla Mann Woods, a USC graduate in Business Administration and Entrepreneurship, has been developing and marketing medical devices for over twenty years. At Advanced Bionics Corporation, she was a key executive building the company up to and through its acquisition by Boston Scientific. She began her career at Pacesetter Systems where she planned new technology applications and product needs for pacemakers. During her tenure at Advanced Bionics/Boston Scientific, she led the business development, product development, industrial design, education, clinical research and marketing for the company and its products including the Precision Spinal Cord Stimulator, the BION® microstimulator, implantable infusion pumps, and the cochlear implant. For these products she holds over 60 U.S. patents. Carla was the recipient of the Boston Scientific Patent Milestone Award and the Advanced Bionics Business Leadership Award. She was a senior executive on the company's intellectual property review board and was the shareholder representative in the Boston Scientific acquisition of Advanced Bionics. In 2007, she became the Vice President of Program Development and Strategic Planning for the Alfred Mann Foundation for Biomedical Engineering. Carla is on the Board of the USC Viterbi School of Engineering and has served on the board of the Pacific Neuroscience Institute, AMI Institutes at USC and Purdue University, the Center for Global

Innovation at the USC Marshall School of Business, the National Pain Foundation and the Fulfilment Fund.

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Article III. Biosketches of Planning Committee Members

Tim Denison, MD, MS

Planning Committee Co-Chair

Tim Denison MD, MS, holds a joint appointment in Engineering Science and Clinical Neurosciences at Oxford, where he explores the fundamentals of physiologic closed-loop systems in collaboration with the MRC Brain Network Dynamics Unit. Tim also serves as an advisor to several governments and industry boards on the field of translational medical devices; in particular, helping define strategies for mapping scientific discovery to product development roadmaps within the regulatory and economic constraints of medical systems. He is currently the Chief Engineer at Amber Therapeutics which recently acquired Bioinduction Limited and its Picostim DyNeuMo neuromodulation therapy platform. Prior to Oxford, Tim was a Technical Fellow at Medtronic PLC and Vice President of Research & Core Technology for the Restorative Therapies Group, where he helped oversee the design of next generation neural interface and algorithm technologies for the treatment of chronic neurological disease. In 2015, he was elected to the College of Fellows for the American Institute of Medical and Biological Engineering (AIMBE). He has an MS and PhD from MIT in electrical engineering, and an AB in Physics and MBA from the University of Chicago.

Helen Mayberg, MD

Planning Committee Co-Chair

Helen Mayberg (Co-Chair), MD, a neurologist, is Professor of Neurology, Neurosurgery, Psychiatry and Neuroscience, and the Mount Sinai Professor in Neurotherapeutics at the Icahn School of Medicine where she serves as Founding Director of the Nash Family Center for Advanced Circuit Therapeutics. Recognized for her neuroimaging studies of brain circuits in depression and their translation to the development of deep brain stimulation as a novel therapeutic for treatment resistant patients, she now leads a patient-focused transdisciplinary research team with the shared mission to advance precision surgical treatments for complex neuropsychiatric disorders. Active studies focus on refinement of deep brain stimulation for treatment resistant depression utilizing a range of mechanism-of-action and predictive biomarker strategies including collaborations involving animal models. Complementary strategies using chronic intracranial monitoring, computer vision and machine learning approaches are being developed to detect more subtle changes in core depression-relevant behaviors relevant to further DBS optimization. She serves on the scientific advisory boards for Blackrock Neuro, Cogwear, and NextSense and as a consultant to Abbott Labs. Dr. Mayberg is a member of the U.S. National Academy of Sciences, the National Academy of Medicine, the National Academy of Inventors and the American Academy of Arts and Sciences and participates in a wide variety of advisory and scientific activities across multiple fields in neuroscience.

Nita Farahany, JD, PhD

Nita Farahany, JD, PhD, is a leading authority on law, ethics, and emerging technology, and serves as a distinguished professor of law and philosophy and founding director of Duke University's Science & Society initiative. Dr. Farahany also serves on the Blackrock Neurotech Ethics Advisory Board. In her book, The Battle for Your Brain, she champions cognitive liberty in the digital era. Her insights, shared from TED stages to global policy forums, guide responsible advancements in science and technology.

Sarah Hollingsworth “Holly” Lisanby, MD, DLFAPA

Sarah Hollingsworth "Holly" Lisanby, MD, DLFAPA, an internationally renowned innovator of neuromodulation technologies, is Director of the Division of Translational Research at the National Institute of Mental Health (NIMH), which funds research supporting the discovery of preventions, treatments, and cures for mental illness across the lifespan. She founded and directs the Noninvasive Neuromodulation Unit in the NIMH Intramural Research Program, a pioneering translational research program specializing in the use of brain stimulation tools to measure and modulate neuroplasticity to improve mental health. Currently, she is Professor Emeritus at Duke University Department of Psychiatry and Behavioral Sciences. Previously, she was the first woman to serve as Chair of the Duke University Department of Psychiatry. She founded and directed both the Duke University and the Columbia University Divisions of Brain Stimulation, where she built interdisciplinary research programs specializing in the convergence of Psychiatry, Neuroscience and Engineering. She co-led the NIH BRAIN Initiative Team focused on largescale neural recording and modulation devices. Dr. Lisanby's laboratory has been continuously federally funded for over 20 years. She has been principal investigator on a series of NIH and DARPA funded studies on the development of novel neuromodulation technologies, including studies on the rational design of magnetic and electrical seizure therapies. Her team pioneered magnetic seizure therapy (MST) as a novel depression treatment from the stages of animal testing, first-in-human, and now international trials. A prolific author with over 290 scientific publications, she has received national and international recognition, including the Distinguished Investigator Award from the National Alliance for Research on Schizophrenia and Depression (NARSAD), the Max Hamilton Memorial Prize of the Collegium Internationale Neuro-Psychopharmacologicum (CINP), the Gerald Klerman Award from the National Depression and Manic Depression Association (NDMDA), and the Eva King Killam Research Award from the American College of Neuropsychopharmacology (ACNP). Dr. Lisanby serves on the FDA Neurological Devices Advisory Panel and has held key leadership positions in professional organizations including serving as President of the International Society for ECT and Neurostimulation and Chair of the American Psychiatric Association Task Force to Revise the Practice on Electroconvulsive Therapy (ECT). A Board-Certified Psychiatrist and Distinguished Life Fellow of the American Psychiatric Association (DLFAPA), Dr. Lisanby received her dual BS in Mathematics and Psychology and her MD at Duke University as an Angier Biddle Duke Scholar.

Brian Litt, MD

Brian Litt, MD, is the Perelman Professor of Neurology, Neurosurgery and Bioengineering at the University of Pennsylvania. Hedivides his time equally between the Schools of Medicine and Engineering, as the founding director of both Penn's Center for Neuroengineering and Therapeutics and a cross-campus medical technology initiative, Penn's Center for Health, Technology and Devices (Penn Health-Tech). He has served on the faculty at Johns Hopkins University, Emory University and the Georgia Institute of Technology, in addition to Penn.

Dr. Litt is a neurologist who treats patients with epilepsy. His research focuses on NeuroEngineering: materials, hardware, imaging, algorithms, data science, machine learning, and high-speed computing for neural interfaces and devices. His laboratory translates basic science into new diagnostic and therapeutic technologies, with a focus Epilepsy and other brain network disorders. Dr. Litt also works on international collaboration for data sharing and integration at scale, and training underrepresented groups in STEM and neuro-related fields. He specializes in translating health technologies to industry, and its interface with academia. Dr. Litt holds a substantial portfolio of patents, advises, contributes to and has co-founded a number of device companies including Neuropace, MC10, Blackfynn, Hyperfine, Butterfly Systems, and Jonathan Rothberg's 4Catalyzer companies. Dr. Litt has trained over 80 PhD students, Postdocs, and many more clinical trainees. He has won a number of awards for his research and mentoring, most recently an NIH Pioneer Award, and the NINDS Landis Award for mentoring.

Laura Lubbers, PhD, MS

Laura Lubbers, PhD, MS, brings more than 25 years of research experience to her position of Chief Scientific Officer at CURE Epilepsy, the largest non-governmental funder of epilepsy research. She is responsible for developing the organization's research strategy, and developing and overseeing all research programs which collectively seek to cure epilepsy, not just treat the symptoms. Dr. Lubbers also contributes to educational and federal advocacy activities to increase awareness of epilepsy and federal investment in epilepsy research. Prior to joining CURE Epilepsy, she spent 15 years in a large pharmaceutical company as a drug discovery scientist. Importantly, Dr. Lubbers' sister suffered from intractable epilepsy from an early age and her mother was diagnosed later in life. The impact of epilepsy on her family has fueled her passion to find better healthcare solutions for people with epilepsy. Dr. Lubbers holds a Bachelor of Science in Physiology, as well as a Master of Science and a PhD from the University of Illinois, Urbana.

David McMullen, MD

David McMullen, MD, is the Director of the Office of Neurological & Physical Medicine Devices (OHT5) within the FDA's Center for Devices and Radiological Health. OHT5 is responsible for the total product lifecycle review of neurosurgical, neurointerventional, neurodiagnostic, neuromodulation, and rehabilitation devices. Dr. McMullen was previously the Program Chief of the Neuromodulation and Neurostimulation Program at the National Institute of Mental Health (NIMH) and co-leader of the NIH BRAIN Initiative team focused on the development of non-invasive brain stimulation. Dr. McMullen is a neuroscientist and medical doctor whose program of research focuses on sensorimotor neuroscience and improving brain-computer interfaces (BCIs) by incorporating novel technology, such as augmented reality interfaces and intelligent robotics.

Jim McNasby, JD

Jim McNasby, JD, is the General Counsel of the Michael J Fox Foundation for Parkinson's Research (MJFF). Before joining MJFF, Jim served as Managing Director, Global Sales (2017-2020) and General Counsel (2007-2017), for Marsh LLC, the world's leading insurance broker and risk advisor. Prior to Marsh, Jim held various in-house legal positions at Kraft Foods (2004-2007) and Altria (1998-2004) in the US and abroad. He began private practice in New York at Davis Polk & Wardwell (1995-1998), after serving as a law clerk to the Chief Judge of the US District Court in Providence, RI. Jim attended the University of Virginia ('91) and Harvard Law School ('94). He is currently a Director of The Billy Rose Foundation. He formerly served as a director of United Biscuits Group Investments, PLC, in the UK (2004-2006). Jim was diagnosed with Parkinson's disease in 2000 and had deep brain surgery in 2019 and 2022.

Martha Morrell, MD, FAAN

Martha Morrell, MD, FAAN, is Chief Medical Officer of NeuroPace, Inc. and a Clinical Professor of Neurology at Stanford University. Previous positions include the Caitlin Tynan Doyle Professor of Clinical Neurology at Columbia University and Director of the Columbia Comprehensive Epilepsy Center at New York Presbyterian Hospital in New York City, and earlier, Director of the Stanford Comprehensive Epilepsy Center.

Dr. Morrell has been actively involved in helping to bring new therapies to patients. Her responsibilities at NeuroPace include all clinical and pre-clinical research for a novel responsive neurostimulator for the treatment of medically uncontrolled epilepsy. She has also been actively involved in investigational trials of new epilepsy therapies as an academic investigator. She is the principal investigator of an NIH funded UH3 grant to study responsive cortical and thalamic stimulation for treatment of Lennox-Gastaut Syndrome, a devastating epilepsy.

Yagna Pathak, PhD

Yagna Pathak, PhD, is currently focused on improving the application of neuromodulation therapies in a patient-centric manner as a Medical Science Manager at Abbott Neuromodulation. She leads the efforts on novel digital solutions for expanding the application of Neuromodulation therapies and has contributed to several high-impact products, including the award-winning Neurosphere™ Virtual Clinic, a unique telemedicine platform. She is passionate about innovating with a purpose and holds several patents in the neuromodulation space aimed at improving healthcare inclusivity.

Prior to joining Abbott Neuromodulation, Yagna received her bachelor's degree in biomedical engineering from Illinois Institute of Technology and her master's from Cornell University. To further pursue her research interests, she received her PhD in Biomedical Engineering under the guidance of Dr. Chris Butson (Marquette University) and completed a postdoctoral fellowship in Neurosurgery with Dr. Sameer Sheth (Columbia University), both focused on the application of neuromodulation therapies for neurological and psychiatric disorders.

Sarah Perides, MSc

Sarah Perides, MSc, is a Pediatric Advanced Nurse Practitioner working with the Complex Motor Disorder Service at the Evelina London Children's Hospital, one of the largest pediatric deep brain stimulation (DBS) centers internationally. She has over 13 years' experience working with deep brain stimulation and other motor disorder management and treatment strategies including intrathecal baclofen and polypharmacy. Within pediatric movement disorders her specialty is dystonia covering genetic, acquired, idiopathic and neurodegenerative etiologies, she has experience in DBS programming, troubleshooting, assessment, and selection of all subgroups. Her current interests include transitioning young people with movement disorders to adult services and the positive impact that deep brain stimulation can have on painful dystonia. She believes wholly in multi-disciplinary care and the importance of lifelong support.

Rita Valentino, PhD

Rita Valentino, PhD, is the Director of the Division of Neuroscience and Behavior at the National Institute on Drug Abuse. She received a B.S. in Pharmacy from the University of Rhode Island and a Ph.D. in Pharmacology from the University of Michigan. She went on to postdoctoral fellowships at the University of North Carolina and the Salk Institute. Dr. Valentino has held faculty positions in the Department of Pharmacology at George Washington University, the Department of Mental Health Sciences at Hahnemann University and Department of Anesthesiology at the University of Pennsylvania. She directed the Stress Neurobiology Division within the Department of Anesthesiology at The Children's Hospital of Philadelphia.

Dr. Valentino is particularly recognized for her research on the effects of stress on brain function and behavior and the impact of sex, age and coping style in stress vulnerability. Her laboratory was the first to demonstrate sex differences in receptor signaling and intracellular trafficking. Her laboratory's research demonstrating sex differences in signaling and trafficking of corticotropin-releasing factor receptors provided a molecular basis for increased sensitivity of females to stressors. She is a Fellow and Secretary-Elect of the American College of Neuropsychopharmacology, a Fellow of the American Society for Pharmacology and Experimental Therapeutics and a member of the Scientific Advisory Board of the Brain Behavior Foundation. She is also the Editor-in-Chief of Neurobiology of Stress.

Alik Widge, MD, PhD

Alik Widge, MD, PhD, is a brain stimulation psychiatrist and biomedical engineer. He is an Associate Professor of Psychiatry at the University of Minnesota, where he directs the Translational NeuroEngineering Lab. Dr. Widge completed his MD at the University of Pittsburgh, his PhD in Robotics at Carnegie Mellon University, psychiatry residency at the University of Washington, and fellowships at Massachusetts General Hospital and the Massachusetts Institute of Technology. His research focuses on brain stimulation for severe and treatment-resistant mental illness, with particular emphasis on deep brain stimulation and related implantable technologies. Dr. Widge's recent work has demonstrated new algorithms for closed-loop brain stimulation, stimulation methods for modifying connectivity in the distributed circuits of mental illness, and hardware solutions for embodying those insights. His laboratory studies both rodent models for prototyping these new technologies and human participants to identify biomarkers and targets for future intervention. Dr. Widge serves as a consultant to Abbott on clinical trial design.

Article IV. Preventing Discrimination, Harassment, and Bullying Expectations for Participants in NASEM Activities

The National Academies of Sciences, Engineering, and Medicine (NASEM) are committed to the principles of diversity, integrity, civility, and respect in all of our activities. We look to you to be a partner in this commitment by helping us to maintain a professional and cordial environment. All forms of discrimination, harassment, and bullying are prohibited in any NASEM activity. This commitment applies to all participants in all settings and locations in which NASEM work and activities are conducted, including committee meetings, workshops, conferences, and other work and social functions where employees, volunteers, sponsors, vendors, or guests are present.

Discrimination is prejudicial treatment of individuals or groups of people based on their race, ethnicity, color, national origin, sex, sexual orientation, gender identity, age, religion, disability, veteran status, or any other characteristic protected by applicable laws.

Sexual harassment is unwelcome sexual advances, requests for sexual favors, and other verbal or physical conduct of a sexual nature that creates an intimidating, hostile, or offensive environment.

Other types of harassment include any verbal or physical conduct directed at individuals or groups of people because of their race, ethnicity, color, national origin, sex, sexual orientation, gender identity, age, religion, disability, veteran status, or any other characteristic protected by applicable laws, that creates an intimidating, hostile, or offensive environment.

Bullying is unwelcome, aggressive behavior involving the use of influence, threat, intimidation, or coercion to dominate others in the professional environment.

Section 4.01 REPORTING AND RESOLUTION

Any violation of this policy should be reported. If you experience or witness discrimination, harassment, or bullying, you are encouraged to make your unease or disapproval known to the individual, if you are comfortable doing so. You are also urged to report any incident by:

- Filing a complaint with the Office of Human Resources at 202-334-3400, or
- 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.

Complaints should be filed as soon as possible after an incident. To ensure the prompt and thorough investigation of the complaint, the complainant should provide as much information as is possible, such as names, dates, locations, and steps taken. The Office of Human Resources will investigate the alleged violation in consultation with the Office of the General Counsel.

If an investigation results in a finding that an individual has committed a violation, NASEM will take the actions necessary to protect those involved in its activities from any future discrimination, harassment, or bullying, including in appropriate circumstances the removal of an individual from current NASEM activities and a ban on participation in future activities.

Section 4.02 CONFIDENTIALITY

Information contained in a complaint is kept confidential, and information is revealed only on a need-to-know basis. NASEM will not retaliate or tolerate retaliation against anyone who makes a good faith report of discrimination, harassment, or bullying.

Updated June 7, 2018

Article V. Diversity, Equity, and Inclusion Statement and Guiding Principles

We, the National Academies of Sciences, Engineering, and Medicine (the National Academies), value diversity among our staff, members, volunteers, partners, vendors, and audiences. We recognize that talent is broadly distributed in society and that many perspectives enhance the quality of our work and drive innovation and impact.

We pledge to cultivate a workplace culture and climate that promotes inclusion, belonging, accessibility, and anti-racism; upholds equity; and values the participation of all who are engaged in advancing our mission.[1] By embracing the values of diversity, equity, and inclusion in our programs, institutional policies and practices, and products, we will be able to better advise the nation on the most complex issues facing society and the world.

Guiding Principles:

The following diversity, equity, and inclusion principles guide our work at the National Academies:

1. Integrate diverse perspectives and experiences into our programs, institutional policies and practices, and products.
2. Foster a culture of inclusion where all staff, members, and volunteers have full access to participation and feel welcomed, respected, valued, and a sense of belonging.
3. Approach scientific endeavors with a consideration of diversity, equity, and inclusion frameworks.
4. Cultivate mutually beneficial diverse partnerships and collaborations with a variety of communities, including, but not limited to, marginalized and underrepresented communities.

Our institutional strategy for putting these values and principles into practice are outlined in the National Academies DEI Action Plan, a comprehensive five-year plan that charts a path toward achieving our diversity, equity, and inclusion goals. The DEI Action Plan is one of many ways that we commit to systems of accountability and transparency to uphold these principles and allow for continuous learning and improvement.

[1] The National Academies' mission is to provide independent, trustworthy advice and facilitate solutions to complex challenges by mobilizing expertise, practice, and knowledge in science, engineering, and medicine.