

Forum on Neuroscience and Nervous System Disorders

# Examining Glucagon-Like Peptide-1 Receptor (GLP-1R) Agonists for Central Nervous System Disorders: A Workshop

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September 10, 2024 | 9:00–4:30pm ET | Hybrid

ATTENDEE PACKET



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# Examining Glucagon-Like Peptide-1 Receptor (GLP-1R) Agonists for Central Nervous System Disorders

A Workshop

Tuesday, September 10, 2024: 9:00 am – 4:30 pm ET

## Objectives

- Review the current state of knowledge regarding the mechanisms of action of GLP-1R agonists and their therapeutic applications across different disease areas, with a focus on central nervous disorders.
- Discuss available scientific evidence on the clinical efficacy of GLP-1R agonists, among other considerations, for treating various central nervous system disorders, specifically, eating disorders, neurodegenerative diseases, alcohol and substance use disorders.
- Examine clinical trial and regulatory considerations surrounding the application of GLP-1R agonists as therapeutic treatments for central nervous system disorders.
- Highlight current research gaps (e.g., GLP-1R agonists for pain management) and consider opportunities to move the field forward.

## TUESDAY, SEPTEMBER 10<sup>TH</sup>, 2024

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### 9:00am      **Introductory Remarks**

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

**Deanna Barch**, University of Washington in St. Louis, *Forum on Neuroscience and Nervous System Disorders Co-chair*

### 9:05am      **Workshop Overview**

**Matthew Hayes**, University of Pennsylvania, *Workshop Co-Chair*

**Brian Fiske**, The Michael J. Fox Foundation for Parkinson's Research, *Workshop Co-Chair*

### 9:10am      **Keynote Presentation: History of GLP-1Rs and Current Therapeutic Applications**

**Daniel Drucker**, University of Toronto (*Zoom*)

### 9:25am      **Overview of GLP-1 circuitry in the Central Nervous System**

**Linda Rinaman**, Florida State University

**Anna Secher**, Novo Nordisk (*Zoom*)

**9:45am**      **Moderated Panel & Audience Q&A**

**10:05am**      **Session 1: Clinical Efficacy & Mechanisms of Action of GLP-1R Agonists in Central Nervous Systems**

*Objective:*

- Review the current state of knowledge regarding the mechanisms of action of GLP-1R agonists and their therapeutic applications across different disease areas.
- Discuss available scientific evidence on the clinical efficacy of GLP-1R agonists, among other considerations, for treating various central nervous system disorders, including eating disorders, neurodegenerative diseases, and alcohol and substance use disorders.
- Consider the unique challenges (e.g., stigma, health disparities, clinical trial design, biomarker development) for each disease area.

**10:05am**      **Session 1a: Ingestive Behavior Disorders**

**10:05am**      **Session Overview**

**Kimberlei Richardson**, Howard University

**10:10am**      **A Lived Experience Utilizing GLP-1R Agonists**

**Patricia Nece**, Obesity Action Coalition

**10:20am**      **Speaker Presentations**

**Jon Davis**, Novo Nordisk

**Elizabeth Mietlicki-Baase**, University of Buffalo

**Susan McElroy**, University of Cincinnati (Zoom)

**10:45am**      **Moderated Panel and Audience Q&A**

**11:10am**      **BREAK**

**11:25am      Session 1b: Substance Use Disorder & Alcohol Use Disorder**

**11:25am      Session Overview**

**Lorenzo Leggio**, National Institute on Drug Abuse & National Institute on Alcohol Abuse and Alcoholism

**11:30am      Speaker Presentations**

**Elisabet Jerlhag Holm**, University of Gothenburg (*Zoom*)

**Heath Schmidt**, University of Pennsylvania

**Mehdi Farokhnia**, National Institute on Drug Abuse & National Institute on Alcohol Abuse and Alcoholism

**Rong Xu**, Case Western Reserve

**Patricia (“Sue”) Grigson**, Penn State University

**12:10pm      Moderated Panel and Audience Q&A**

**12:35pm      LUNCH BREAK**

**1:15pm      Session 1c: Neurodegenerative Disorders and Other Emerging Areas**

**1:15pm      Session Overview**

**Edwin (“Ted”) George**, Food and Drug Administration

**1:20pm      Speaker Presentations**

**Nigel Greig**, National Institute on Aging

**Dilan Athauda**, University College London & The Francis Crick Institute

**Christian Hölscher**, Kariya Pharmaceuticals

**Alexandra Sinclair**, University of Birmingham

**1:50pm      Biomarker Development for Clinical Evidence & Regulatory Approval**

**Laura Jawidzik**, Food and Drug Administration

**2:00pm      Moderated Panel and Audience Q&A**

**2:25pm**      **BREAK**

**2:40pm**      **Session 2: Real-World Evidence, Accessibility, and Health Equity**

*Objectives:*

- Consider the role of real-world evidence (RWE) for the repurposing of GLP-1R agonist in CNS disorders.
- Evaluate the impact of widespread usage of GLP-1R agonists on patient and public accessibility and the supply chain.
- Consider future challenges and opportunities to improve health equity for the use of GLP-1R in different therapeutic areas.

**2:40pm**      **Session Overview**

**Serena Jingchuan Guo**, University of Florida

**2:45pm**      **A Lived Experience Perspective on Accessibility and Equity**

**Karen Glanz**, University of Pennsylvania

**2:50pm**      **Speaker Remarks**

**Jiang Bian**, University of Florida

**Robert Kosko**, Food and Drug Administration (*Zoom*)

**Fatima Cody Stanford**, Massachusetts General Hospital & Harvard Medical School

**3:10pm**      **Moderated Panel and Audience Q&A**

**3:50pm**      **Session 3: Synthesis & Opportunities to Move Forward**

*Objectives:*

- Examine the core themes that have been highlighted during the workshop.
- Highlight current research gaps and consider opportunities to move the field forward.

**3:50pm**      **Session Overview**

**Matthew Hayes**, University of Pennsylvania, *Workshop Co-Chair*

**Brian Fiske**, The Michael J. Fox Foundation for Parkinson's Research, *Workshop Co-Chair*

**3:55pm Themes & Future Opportunities Discussion**

**Matthew Coghlan**, Eli Lilly and Company

**Karen Glanz**, University of Pennsylvania

**Serena Jingchuan Guo**, University of Florida

**Iván Montoya**, National Institute on Drug Abuse

**Patricia Nece**, Obesity Action Coalition

**4:25pm Concluding Remarks**

**Matthew Hayes**, University of Pennsylvania, *Workshop Co-Chair*

**Brian Fiske**, The Michael J. Fox Foundation for Parkinson's Research, *Workshop Co-Chair*

**4:30pm Adjourn**

This event was planned by the following experts: Matthew Hayes, University of Pennsylvania; Brian Fiske, The Michael J. Fox Foundation for Parkinson's Research; Lawrence Charnas, Pfizer; Matthew Coghlan, Eli Lilly and Company; Eva L. Feldman, University of Michigan; Edwin (Ted) George, Food and Drug Administration; Serena Jingchuan Guo, University of Florida; Elisabet Jerlhag Holm, University of Gothenburg; Lorenzo Leggio, National Institute on Drug Abuse & National Institute on Alcohol Abuse and Alcoholism; Iván Montoya, National Institute on Drug Abuse; Kimberlei Richardson, Howard University; Linda Rinaman, Florida State University.

*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.*

# 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](http://www.nas.edu/NeuroForum).

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## MEMBERS

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

**Deanna Barch, PhD, co-chair**  
Washington University in St. Louis

**Shelli Avenevoli, PhD**  
National Institute of Mental Health

**Rita Balice-Gordon, PhD**  
Muna Therapeutics

**Bruce Bebo, PhD**  
National Multiple Sclerosis Society

**Diane Bovenkamp, PhD**  
BrightFocus Foundation

**Katja Brose, PhD**  
Chan Zuckerberg Initiative

**Teresa Buracchio, MD**  
Food and Drug Administration

**Sarah Caddick, PhD**  
Gatsby Charitable Foundation

**Rosa Canet-Avilés, PhD**  
California Institute for Regenerative Medicine (CIRM)

**Maria Carrillo, PhD**  
Alzheimer's Association

**Michael Chiang, MD**  
National Eye Institute

**Beverly Davidson, PhD**  
Children's Hospital of Philadelphia

**M. Denise Dearing, Ph.D**  
National Science Foundation

**Nita Farahany, JD, PhD**  
Duke University

**Eva L. Feldman, MD, PhD**  
University of Michigan

**Brian Fiske, PhD**  
The Michael J. Fox Foundation for Parkinson's Research

**Danielle Graham, PhD**  
American College of Neuropsychopharmacology

**Morten Grunnet, PhD**  
Lundbeck

**Magali Haas, MD, PhD, MSE**  
Cohen Veterans Bioscience

**Richard Hodes, MD**  
National Institute on Aging

**Stuart W. Hoffman, PhD**  
Department of Veterans Affairs

**Yasmin Hurd, PhD**  
Icahn School of Medicine at Mount Sinai

**Steven E. Hyman, MD**  
Broad Institute of MIT and Harvard

**Michael Irizarry, MD**  
Eisai

**George Koob, PhD**  
National Institute on Alcohol Abuse and Alcoholism

**Walter Koroshetz, MD**  
National Institute of Neurological Disorders and Stroke

**John Krystal, MD,**  
Yale University

**Robert C. Malenka, MD, PhD**  
Stanford University

**Husseini Manji, MD, FRCP**  
Oxford University; Duke University; UK Government Mental Health Mission



## Forum on Neuroscience and Nervous System Disorders

### **Hugh Marston, PhD**

Boehringer Ingelheim

### **Bill Martin, PhD**

Janssen Research & Development

### **Caroline Montojo, PhD**

Dana Foundation

### **John J. Ngai, PhD**

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

### **Gentry Patrick, PhD**

University of California San Diego

### **Steve Marc Paul, MD**

Karuna Therapeutics (formerly)

### **Kathryn Richmond, MBA, PhD**

Allen Institute

### **M. Elizabeth Ross, MD, PhD, FANA**

American Neurological Association

### **Marsie Ross, PharmD**

Harmony Biosciences

### **Katie Sale, BA**

American Brain Coalition

### **Raymond Sanchez, MD**

Cerevel Therapeutics

### **Terrence Sejnowski, PhD**

Salk Institute for Biological Studies

### **Joan Sereno, PhD**

National Science Foundation

### **Sarah Shnider, PhD, MSc**

One Mind

### **David Shurtleff, PhD**

National Center for Complementary and Integrative Health

### **John Spiro, PhD**

Simons Foundation

### **Alessio Travaglia, PhD**

Foundation for the National Institutes of Health

### **Nora D. Volkow, MD**

National Institute on Drug Abuse

### **Doug Williamson, MBChB, MRCPsych**

Acadia Pharmaceuticals, Inc (formerly)

### **Richard Woychik, PhD**

National Institute of Environmental Health Sciences

### **Stevin Zorn, PhD**

MindImmune Therapeutics

## Forum Staff

### **Sheena Posey Norris, MS, PMP**

Director, Forum on Neuroscience and Nervous System Disorders

### **Eva Childers, PhD**

Associate Program Officer

### **Kimberly Ogun, BS**

Senior Program Assistant

### **Clare Stroud, PhD**

Senior Board Director, Board on Health Sciences Policy

## Upcoming Events

[Examining Glucagon-Like Peptide-1 \(GLP-1R\) Agonists for Central Nervous System Disorders \(September 10, 2024\)](#)

[Approaches to Address Unmet Research Needs in Traumatic Brain Injury Among Older Adults \(October 21, 2024\)](#) *A collaboration with the Forum on Traumatic Brain Injury*

[Applying Neurobiological Insights on Stress to Foster Resilience Across the Lifespan \(March 24-25, 2025\)](#)

## Recent Events

[Exploring the Bidirectional Relationship between Artificial Intelligence and Neuroscience \(2024\)](#)

[Mitigating Health Disparities in Brain Disorders Starting with Basic Science: A Workshop \(2023\)](#)

[Exploring the Adoption of Implantable Brain Stimulation into Standard of Care for Central Nervous System Disorders: A Workshop \(2023\)](#)

[Addressing Health Disparities in Central Nervous System Disorders: A Virtual Workshop Series \(2023\)](#)

**[Toward a Common Research Agenda in Infection-Associated Chronic Illnesses: A Workshop to Examine Common, Overlapping Clinical and Biological Factors \(2023\)](#)** *A collaboration with the Forum on Microbial Threats*

**[Multimodal Biomarkers for Central Nervous System Disorders: Development, Integration, and Clinical Utility: A Workshop \(2023\)](#)**

**[Exploring Sleep Disturbance in Central Nervous System Disorders \(2022\)](#)**

**[Exploring Psychedelics and Entactogens as Treatments for Psychiatric Disorders: A Workshop \(2022\)](#)**

The National Academies of Sciences, Engineering, and Medicine are private, nonprofit institutions that provide independent, objective analysis and advice to the nation and conduct other activities to solve complex problems and inform public policy decisions related to science, technology, and medicine. The National Academies operate under an 1863 congressional charter to the National Academy of Sciences, signed by President Lincoln. For additional information on the Forum on Neuroscience and Nervous System Disorders, visit [www.nas.edu/NeuroForum](http://www.nas.edu/NeuroForum) or contact Sheena Posey Norris ([sposey@nas.edu](mailto:sposey@nas.edu), 202-334-2429).

## Sponsoring Members of the Forum on Neuroscience and Nervous System Disorders

### ACADEMIA

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The George & Anne Ryan Institute for Neuroscience at the University of Rhode Island

### GOVERNMENT

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California Institute for Regenerative Medicine  
Department of Veterans Affairs  
Food and Drug Administration  
National Center for Complementary and Integrative Health  
National Eye Institute  
National Institute of Environmental Health Sciences  
National Institute of Mental Health

National Institute of Neurological Disorders and Stroke  
National Institute on Aging  
National Institute on Alcohol Abuse and Alcoholism  
National Institute on Drug Abuse  
National Institutes of Health BRAIN Initiative  
National Science Foundation

### INDUSTRY

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Acadia Pharmaceuticals  
Boehringer Ingelheim  
Cerevel Therapeutics  
Eisai

Harmony Biosciences  
Janssen Research & Development, LLC  
Lundbeck Research USA, Inc

### NONPROFIT ORGANIZATIONS

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Alzheimer's Association  
American Brain Coalition  
BrightFocus® Foundation  
Cohen Veterans Bioscience  
Dana Foundation

Foundation for the National Institutes of Health  
Michael J. Fox Foundation for Parkinson's Research  
National Multiple Sclerosis Society  
One Mind  
Paul G. Allen Frontiers Group  
Simons Foundation Autism Research Initiative

### PRIVATE FOUNDATION

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Gatsby Charitable Foundation

### PROFESSIONAL SOCIETY

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American College of Neuropsychopharmacology  
American Neurological Association

## Biosketches of Speakers

### Dilan Athauda, MBBS, MRCP,

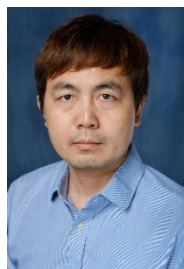


Dilan Athauda, MBBS, MRCP, is a consultant neurologist and neuroscientist, based at Guys' & St Thomas' Hospital, and the Department of Clinical and Movement Neurosciences at the Institute of Neurology, University College London. His main interest is in Parkinson's disease with an emphasis on how metabolism impacts neurodegeneration. Dr. Athauda is a co-investigator on the Exenatide-PD3 and Exenatide-MSA clinical trials and a visiting scientist in the Gandhi Lab, where he is exploring mechanisms underlying the effects of glucagon-like peptide-1 (GLP-1) agonists in human induced pluripotent stem cell models of Parkinson's disease, and the use of extracellular vesicles to monitor and track disease.

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### Jiang Bian, Ph.D.



Jiang Bian, Ph.D., is a Professor and Division Chief of Biomedical Informatics in the College of Medicine at the University of Florida (UF). He serves as Chief Data Scientist and Chief Research Information Officer for UF Health, as well as Director of the Biomedical Informatics Program for the UF Clinical and Translational Science Institute (CTSI). Additionally, he is the Chief Data Scientist for both the UF Health Cancer Center and the OneFlorida+ Clinical Research Consortium. Dr. Bian's multidisciplinary expertise spans AI/machine learning, natural language processing, data integration, semantic web and ontology, network science, and software engineering. His work centers on a unifying theme: data science involving heterogeneous data, information, and knowledge resources. His research can be categorized into two main areas: (1) data-driven medicine—applying informatics techniques, including machine learning, to solve big data challenges in medicine; and (2) developing novel informatics methods, tools, and systems to support clinical and research activities, such as generating real-world evidence, data integration, cohort discovery, and clinical trial design. He has a strong track record of building clinical data infrastructure and leveraging real-world data to address critical biomedical problems, including neurodegenerative diseases like Alzheimer's.

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### Daniel Drucker, M.D., FRCPC



Daniel Drucker, M.D., FRCPC, is an endocrinologist and Professor of Medicine in the Division of Endocrinology at University of Toronto. He holds the Banting and Best Diabetes Centre-Novo Nordisk Chair in Incretin Biology. His laboratory is based in the Lunenfeld Tanenbaum Research Institute at Mount Sinai Hospital in Toronto and studies the molecular biology and physiology of the glucagon-like peptides. His discoveries have enabled the development of several new GLP-1-based therapies for the treatment of diabetes and obesity and GLP-2 analogues for intestinal failure. Drucker has received numerous international awards for his translational science and

has been elected to the Order of Canada, the Canadian Medical Hall of Fame, Fellowship in the Royal Society (London), and the National Academy of Sciences and National Academy of Medicine (USA).

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**Mehdi Farokhnia, M.D., M.P.H.**



Mehdi Farokhnia, M.D., M.P.H., is a physician-scientist at the National Institutes of Health (NIH) Intramural Research Program and adjunct faculty at Johns Hopkins Bloomberg School of Public Health. His research focuses on understanding the neurobiology of addictive behaviors and identifying novel therapeutic targets for alcohol and other substance use disorders, with a particular focus on neuroendocrine pathways. Dr. Farokhnia has published several papers on the role of GLP-1 in addiction and is currently leading a clinical trial with semaglutide in individuals with alcohol use disorder. He uses a combination of behavioral, pharmacological, genetic, and neuroimaging methods and is interested in investigating innovative human laboratory approaches, as well as large-scale epidemiological methods, to facilitate the crosstalk between preclinical, clinical, and population-based addiction research. He is also interested in using big data to characterize biobehavioral substrates of health disparity (e.g., gender/sex and racial/ethnic differences) in risk/resilience to addiction and other mental health conditions.

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**Karen Glanz Ph.D., M.P.H.**



Karen Glanz, Ph.D., MPH, is the George A. Weiss University Professor, and Professor in the Perelman School of Medicine and the School of Nursing, at the University of Pennsylvania (UPenn). She is Program Co-Leader for the Cancer Control Program at the Abramson Cancer Center at UPenn. Her research in community and healthcare settings focuses on obesity, nutrition, physical activity, skin cancer prevention; and the built environment; reducing health disparities; and dissemination and implementation science. Her research and publications about understanding, measuring and improving healthy food environments, beginning in the 1980's, has been widely recognized and replicated. She has published over 550 articles and chapters and is lead Editor on six editions of the widely used text, *Health Behavior: Theory, Research and Practice* (Jossey-Bass: 1990 to 2024). She was named by Clarivate (formerly ISI) as a Highly Cited Researcher (among the top 1% most cited in her subject field) since 2016; and was named among The World's Most Influential Scientific Minds in 2015. Dr. Glanz has been an elected member of the National Academy of Medicine (NAM) of the National Academy of Sciences, Engineering and Medicine since 2013.

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## Nigel Greig, Ph.D.



Nigel Greig, Ph.D., leads a multi-disciplinary research group (the Drug Design & Development Section within the Intramural Research Program of the National Institute on Aging [NIA], NIH) and cross-collaborates extensively with academic and pharma-related groups across the world. He focuses to design, synthesize, and develop novel agents against pivotal targets in aging prevalent diseases, with a CNS emphasis. Novel compounds are synthesized as pharmacologic probes to target biological mechanisms and, for those that appear involved in disease progression, early integration of 'drug-like' features provides experimental drugs that are evaluated in cellular and animal disease models and then translated, in line with regulatory requirements, into human clinical trials to test new hypotheses. Likewise, approved and well-tolerated drugs that target mechanisms of potential relevance across diseases are repurposed to new disorders that lack effective therapeutics. This strategy allows Dr. Greig and colleagues to validate/invalidate disease targets, and, as key elements of clinical drug development, to patent and out-license new drug candidates to support their clinical development to public use. These patents belong to NIH and, hence, the U.S. Government and U.S. nation.

As examples of ongoing work, Nigel's research resulted in the development Phenserine and Posiphen (Buntanetap) and GLP-1 receptor agonists (Exenatide, PT320) as new treatments for neurodegenerative disorders that are now in multiple clinical trials (including Parkinson's and Alzheimer's disease (PD, AD). Preclinically, the Greig NIA/NIH laboratory with collaborators developed the first amyloid precursor protein/amyloid- $\beta$  lowering agents to enter human trials, selective acetyl- and butyryl-cholinesterase inhibitors (Bisnorcymserine) that, likewise, have entered clinical trials, p53 inactivating agents and novel thalidomide analogs lacking classical cereblon binding. To undertake this work, an experienced multidisciplinary collaborative team covers preclinical medicinal chemistry and cellular/in vivo pharmacology to successfully test focused scientific hypotheses, and integrates this with neurological clinical trial design, biomarker evaluation (focused on plasma exosomes deriving from brain), clinical pharmacology and FDA regulatory requirements – to move new drug classes as well as repurposed drugs from conception into clinical trials. This team includes Dr. Greig, his research section, NIA and NIH colleagues, and a focused group of collaborative basic and clinical scientists from academia and pharma/biotech from across the globe.

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## Patricia ("Sue") Grigson, Ph.D., M.S.



Patricia "Sue" Grigson, Ph.D., M.S., earned her Bachelors of Science from Elizabethtown College in Psychology, her Master of Science and her Ph.D. from Rutgers University in Biopsychology in the study of reward with Dr. Charles Flaherty, and then completed her postdoctoral training at the Penn State College of Medicine in the study of taste and motivated behavior with Dr. Ralph Norgren. Thereafter, she accepted a tenure-track faculty position at the Penn State College of Medicine, where she is now a tenured professor and Chair of the Department of Neural and Behavioral Sciences and Interim Chair of Pharmacology. Over this time, Dr. Grigson and her students have studied the comparison of natural rewards with addictive substances, individual vulnerabilities to addiction, factors that reduce or accentuate the development of addiction and, along with her colleagues, novel interventions for the treatment of the disease in rats and humans. Dr. Grigson has received 30 years of

nearly continuous funding from the National Institutes of Health and via CURE funding from the Pennsylvania Department of Health. She is the recipient of a MERIT Award and currently is MPI of a UG3/UH3 award from the HEALing Initiative to test the safety and efficacy of glucagon-like peptide-1 (GLP-1) receptor agonists for the treatment of opioid use disorder in animal models and in humans. Among other awards, Dr. Grigson was the recipient of the College of Medicine's Annual Hinkle Society Junior Investigator Award in 2000, and in 2004 she received the Alan N. Epstein Research Award from the Society for the Study of Ingestive Behavior. Dr. Grigson co-founded the Penn State Hershey Commission for Women and she co-founded and is the Director of the Penn State Addiction Center for Translation.

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### Christian Hölscher, Ph.D.



Christian Hölscher, Ph.D., is a Professor of Neuroscience at the Henan Academy of Innovations in Medical Science. He is the CSO of the Biotech company Kariya, which aims to develop novel treatments for Alzheimer's disease and Parkinson's disease. He did his first degree in Physiology at the University of Tübingen in Germany and continued his career in England, working at several universities such as Oxford University and the Open University. His research is focused on the development of novel drug treatments for Alzheimer's and Parkinson's disease. He investigates the interaction between diabetes and neurodegeneration, which led him to discover the neuroprotective properties of incretin hormone analogues which are currently on the market to treat type 2 diabetes.

His research techniques include transgenic animal models of Alzheimer's and Parkinson's disease to profile new drug candidates in preclinical studies. Liraglutide, one of the drugs profiled by him is now in clinical trials in patients with Alzheimer's disease and a second trial in Parkinson's patients are currently ongoing. Two other clinical trials testing lixisenatide and semaglutide in patients with Parkinson's disease are in preparation. He developed novel dual GLP-1/GIP receptor agonists that can cross the blood-brain barrier and show improved neuroprotective effects in animal models of Alzheimer's or Parkinson's disease. Clinical trials testing these novel drug candidates are in planning.

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### Laura Jawidzik, M.D., FAAN



Laura Jawidzik, M.D., FAAN, is the deputy director of the Division of Neurology 1 (DN1) at the Food and Drug Administration (FDA). Dr. Jawidzik is a board-certified neurologist who joined the FDA in 2015 in the Division of Neurology 2 (DN2) initially as a clinical reviewer on the migraine/traumatic brain injury/stroke/hearing products team. Starting in 2020, she moved from DN2 to DN1 and has served as team leader of the neuromuscular team until becoming the deputy director of the division. Dr. Jawidzik earned her undergraduate degree in molecular biology from Princeton University, and her M.D. from the Georgetown University School of Medicine. Dr. Jawidzik completed her internship, neurology residency training, and clinical neurophysiology fellowship at Rush University Medical Center in Chicago. She is board certified in neurology, epilepsy, and clinical neurophysiology. Prior to joining



FDA, Dr. Jawidzik was in academic practice at Rush where she primarily saw general neurology patients and patients with neuromuscular disorders.

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**CDR Robert Kosko, Pharm.D., M.P.H.**



CDR Robert Kosko, a commissioned officer in the United States Public Health Service, currently serves as a Senior Program Management Officer for the Drug Shortage Staff within the U.S. Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER). As a drug supply subject matter expert, he provides guidance related to actual or potential drug shortages to senior representatives from CDER, the FDA, other Federal Agencies, and regulated industry. He has been a member of the Drug Shortage Staff since 2012 and serves as the FDA's international drug shortage lead. He holds a Doctor of Pharmacy degree, a Master of Public Health degree, and is certified in regulatory affairs and public health

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**Susan McElroy, M.D.**



Susan McElroy, M.D., is internationally known for her research in bipolar disorder, eating disorders, obesity, impulse control disorders and pharmacology. She is the author of over 500 scientific papers in leading medical journals and was the 8th most cited scientist in the world published in the fields of psychiatry and psychology since 1996. She has also authored over 130 reviews and chapters in major psychiatric textbooks. Dr. McElroy is the editor of 4 scientific books and serves on the editorial board of the Journal of Clinical Psychiatry.

As Chief Research Officer she currently oversees multiple ongoing studies in mood, anxiety, eating and impulse control disorders, genetics and psychopharmacology. She has received funding for her research from National Institute of Mental Health, Agency for Healthcare quality, the Stanley Foundation, and industry.

Dr. McElroy has been the recipient of numerous awards and honors including being recognized among the Best Mental Health Experts by Good Housekeeping Magazine; Best Doctors in America, a directory of the top one percent of physicians in the United States as rated by their peers; Top Doctors in Cincinnati by Cincinnati Magazine; Best Doctors in Dayton by the Dayton Business Courier; and, as one of America's Top Psychiatrists, by the Consumer Research Council. Additionally, she was a recipient of the Phillip L. Isenberg Teaching Award for dedication and excellence in the education of residents, McLean Hospital and Harvard Medical School; the Golden Apple Award for excellence in teaching of residents, University of Cincinnati College of Medicine; and a co-recipient of the Gerald L. Klerman Young Investigator Award of the National Depressive and Manic Depressive Association.

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### Elizabeth Mietlicki-Baase, Ph.D.



Elizabeth Mietlicki-Baase, Ph.D. is an Associate Professor in the Department of Exercise and Nutrition Sciences at the University at Buffalo. She earned her PhD in Behavioral Neuroscience at the University at Buffalo, followed by postdoctoral training in the Department of Psychiatry at the University of Pennsylvania. Dr. Mietlicki-Baase's research focuses on the neural controls of energy balance and motivated behavior. She is particularly interested in understanding how feeding-relevant hormones act in the reward systems of the brain to control food intake, body weight, and motivation for palatable foods.

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### Patricia Nece, J.D.



Patricia Nece, J.D., is an avid advocate for sound obesity treatments and the eradication of weight-based bias, stigma, and discrimination. She encourages change by sharing her own experiences of living with obesity. Her advocacy work has included testifying before the U.S. Food & Drug Administration; participating in numerous Congressional briefings; and providing a lived-experience perspective to legislators, healthcare professionals, researchers, employers, entertainers, journalists, and more. Patty is the Immediate Past Chair of the Obesity Action Coalition, an 85,000-member nonprofit organization dedicated to giving a voice to individuals affected by obesity. She currently chairs OAC's Weight Bias Committee. She is also a member of the National Academies of Sciences, Engineering, and Medicine's Roundtable on Obesity Solutions, the World Obesity Federation's Policy and Prevention Committee, and the International Obesity Collaboration. She was awarded OAC's Barbara Thompson Award for advocacy in 2015 and The Obesity Society's Presidential Medal in 2022 for her contributions to the field. Patty retired from the U.S. Department of Labor's Office of the Solicitor in 2022 after 37 years of service as an appellate litigator and regulatory/legislative counsel.

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### Heath D. Schmidt, Ph.D.



Heath D. Schmidt, Ph.D., earned his Ph.D. in Pharmacology and Biomedical Neurosciences from Boston University. Subsequently, he completed a post-doctoral fellowship at Yale University before joining the University of Pennsylvania as a faculty member. Dr. Schmidt's research program uses a multi-disciplinary approach to understand the neurobiological mechanisms underlying motivated behaviors. Specifically, his team investigates how chronic exposure to drugs of abuse (cocaine, nicotine, and opioids) changes the brain to produce addiction-like behaviors in rodents. The ultimate goal of these studies is to advance our understanding of the neurobiology of substance use disorders (SUDs) and identify molecular substrates that could serve as druggable targets for novel approaches to treating SUDs. Dr. Schmidt's preclinical studies have been translated into three clinical trials to date. Dr. Schmidt also directs and teaches a foundational course in advanced pharmacology in the School of Nursing. In addition, Dr. Schmidt provides a number of annual lectures to graduate students and residents in the Perelman School of Medicine.

### Anna Secher, Ph.D.



Anna Secher, Ph.D., is a Scientific Director within Obesity & MASH at Novo Nordisk. She graduated as a M.Sc. in 2003 and has a PhD in Neuroscience from the University of Copenhagen, Denmark. With over 15 years of experience at Novo Nordisk, Anna has worked as a scientific coordinator and project manager. She currently manages several international research collaborations and early drug discovery programs, as well as coordinates early and late development programs at Novo Nordisk. Anna's area of expertise is the brain control of metabolism and metabolic-related disorders, with a focus on supporting the development of new treatment therapies and understanding the mechanism of action of drugs for obesity, diabetes, and cognitive impairment.

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### Alexandra Sinclair, MBChB, MRCP, Ph.D.



Alexandra Sinclair, MBChB, MRCP, Ph.D., is a Professor of Neurology at the University of Birmingham and leads the Translational Brain Science Research Group. She focuses her research on headache, pain, Idiopathic Intracranial Hypertension (IIH) and traumatic brain injury. Her research portfolio encompasses in vitro and in vitro studies coupled with a clinical trials program and biomarker evaluation. Professor Sinclair's work encompasses identification of disease pathways, discovering novel compounds and subsequently evaluating these compounds in clinical studies to assess their utility in treating patients. The research is closely linked with the headache service at University Hospital NHS Foundation Trust, UK where she works as a consultant neurologist. Professor Sinclair has been personally awarded over £22M in peer reviewed grants from organizations such as the Medical Research Council, the National Institute for Health & Care Research, Dept. of Defense USA, the Ministry of Defence UK and the UK Space Agency.

She has published widely in high impact peer review journals. Her google scholar profile demonstrates an H-index of 52 with over 9267 citations of her work.

Professor Sinclair has driven her preclinical and translational findings into pharmaceutical development. By securing intellectual property (patents, orphan drug designation (ODD) granted by the FDA and European Medicines Agency and key proof of concept data) she was able to raise significant funding (\$38M) to create a University of Birmingham spin-out company. The company was launched on the Australian Stock market in July 2019. In her role as Chief Scientific Officer, she co-developed a comprehensive business strategy and led the drug repurposing and reformulation and then animal bridging studies and pharmacokinetic assessments in human volunteers. She has been involved with the strategic engagement with regulatory authorities (EMA and FDA) and investigational new drug applications (IND). She has designed both Phase 2 and 3 clinical trials run and has overseen analysis of data and Clinical Study Reports. She has overseen the filing to competent authorities for ethical approval in numerous geographies (US, Australia, New Zealand, Israel, Germany, France, UK). She actively involved in training and developing the next generation of clinical scientist.

Professor Sinclair has three children and enjoys road cycling and hiking.

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**Fatima Cody Stanford, M.D., M.P.H., M.P.A., M.B.A.**



Fatima Cody Stanford, M.D., M.P.H., M.P.A., M.B.A., is an Associate Professor of Medicine and Pediatrics who practices and teaches at Massachusetts General Hospital (MGH)/ Harvard Medical School (HMS) as one of the first fellowship-trained obesity medicine physicians worldwide. She is among the most highly cited obesity medicine physician-scientists, with over 200 peer-reviewed publications. Dr. Stanford received her BS and MPH from Emory University as an MLK Scholar, her MD from the Medical College of Georgia School of Medicine as a Stoney Scholar, her MPA from the Harvard Kennedy School of Government as a Zuckerman Fellow in the Harvard Center for Public Leadership and her executive MBA as a merit-based scholarship recipient from the Quantic School of Business and Technology. She completed her Obesity Medicine & Nutrition Fellowship at MGH/HMS after completing her internal medicine and pediatrics residency at the University of South Carolina. She has served as a health communications fellow at the Centers for Disease Control and Prevention and as a behavioral sciences intern at the American Cancer Society. Upon completing her MPH, she received the Gold Congressional Award, the highest honor Congress bestows upon America's youth.

Dr. Stanford has completed a medicine and media internship at the Discovery Channel. An American Medical Association (AMA) Foundation Leadership Award recipient in 2005 and an AMA Paul Ambrose Award for national leadership among resident physicians in 2009, she was selected for the AMA Inspirational Physician Award in 2015. The American College of Physicians (ACP) selected her as the 2013 Joseph E. Johnson Leadership Award recipient, and the Massachusetts ACP selected her for the Young Leadership Award in 2015. She is the 2017 recipient of the HMS Amos Diversity Award and the Massachusetts Medical Society (MMS) Award for Women's Health. In 2019, she was selected as the Suffolk District Community Clinician of the Year for the Reducing Health Disparities Award for MMS. She was chosen for The Obesity Society Clinician of the Year in 2020. In 2021, she was awarded the MMS Grant Rodkey Award for her dedication to medical students and the AMA Dr. Edmond and Rima Cabbabe Dedication to the Profession Award, which recognizes a physician who demonstrates active and productive improvement to the profession of medicine through community service, advocacy, leadership, teaching, or philanthropy. She is the 2021 Recipient of the Emory Rollins School of Public Health Distinguished Alumni Award. In 2022, the National Academy of Medicine selected her as a Scholar in Diagnostic Excellence. She was named to the 2025 Dietary Guidelines Advisory Committee by the US Department of Health and Human Services (HHS) and Agriculture (USDA). The National Medical Association selected her for the Meritorious Award, which recognizes a physician with national and international achievement and prominence for exceptional work in medical service, medical research, and academic medicine.

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## Rong Xu, Ph.D.



Rong Xu, PhD, is a Professor of Biomedical Informatics and founding Director of the Center for Artificial Intelligence in Drug Discovery at Case Western Reserve University. Dr. Xu earned her BS in Biology from Peking University, M.S in Biology from Case Western Reserve University, M.S in Computer Science, and Ph.D. in Biomedical Informatics both from Stanford University. Dr. Xu's research falls into two broad categories: theoretical computer algorithm development and translational biomedical research. Her research interests in computer science focus on artificial intelligence, natural language processing, machine learning, data mining, statistical learning, systems biology, and other advanced computational techniques that can create, integrate, and analyze large amounts of heterogeneous and complex biological and health data. Her research interests in biomedical sciences include drug discovery, disease gene discovery, precision medicine, and health outcomes research. Dr. Xu is an elected Fellow of American College of Medical Informatics and has received The NIH Director's New Innovator Award, the Landon-AACR (American Association for Cancer Research) Innovator Award for Cancer Prevention Research, and the American Medical Informatics Association New Investigator award. Dr Xu has published over 150 peer-reviewed research articles in high impact journals including Nature Medicine, JAMA, and Annals of Internal Medicine. Her research on the COVID-19 pandemic has been included in the CDC guidelines. Dr Xu's recent research on semaglutide (Ozempic and Wegovy) has contributed to drug label changes by the European Medicine Agency and the US FDA. Dr. Xu's research works have been featured in thousands of national and international news, including Science, Nature, NIH, New Yorker Times, Washington Post, Wall Street Journal, Bloomberg, CNN, ABC, NBC, and National Geographic.

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## Biosketches of Planning Committee Members

### **Matthew Hayes, Ph.D.**

Planning Committee Co-Chair



Matthew R. Hayes, Ph.D. is the Albert J. Stunkard Professor in Psychiatry, Vice Chair of Basic and Translational Neuroscience and Director of the Molecular and Neural Basis of Psychiatric Disease Section in the Department of Psychiatry at the Perelman School of Medicine at the University of Pennsylvania. As an educator, Dr. Hayes holds a secondary appointment in the School of Nursing where he teaches core courses for the Nutrition Major at Penn. Dr. Hayes earned his Ph.D. in Nutritional Sciences from The Pennsylvania State University and conducted his postdoctoral fellowship in psychology and neuroscience at The University of Pennsylvania under the mentorship of Dr. Harvey Grill. Dr. Hayes is considered a leading expert on the neuroendocrine systems that regulate energy balance. In particular, the Hayes laboratory focusses their research efforts extensively on understanding the neural, behavioral, cellular, molecular, and physiological mechanisms by which hormones, such as GLP-1, amylin, GIP, PYY, and leptin regulate food intake and body weight through action in the caudal brainstem and mesolimbic reward system. These basic science research efforts are conducted with the intention that they will translate into improved pharmacological / behavioral treatments for obesity, diabetes, and co-morbid diseases. Dr. Hayes has been PI / MPI on multiple NIDDK R01 awards, as well as Investigator Initiated Sponsored Proposals from pharmaceutical partners. These and other awards have supported his research into neuroendocrine controls of energy balance and obesity, with a track record of ~140 publications in this area. He has and continues to provide service as program chair and as an executive board member and scientific advisor for multiple international scientific societies, industry partners, and non-profit organizations dedicated towards neuroscience, nutrition, diabetes and obesity research / clinical care.

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### **Brian Fiske, Ph.D.**

Planning Committee Co-Chair



Brian Fiske, Ph.D., is Co-Chief Scientific Officer for The Michael J. Fox Foundation for Parkinson's Research (MJFF), shaping and stewarding the Foundation's strategic research agenda for enabling development of improved therapies for people with Parkinson's disease. In his role, Brian supports MJFF programs that seek to translate Parkinson's biology understanding into potentially promising therapeutic approaches and accelerate testing of those approaches through critical preclinical and early clinical testing. Brian received his PhD in neuroscience from the University of Virginia and completed postdoctoral research at Columbia University before joining MJFF in 2004. He has represented MJFF at many National Academies workshops and Forum activities.

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### **Lawrence Charnas, M.D., Ph.D.**



Lawrence Charnas, M.D., Ph.D., has been Head of the Clinical Research Collaboration Center of Excellence at Pfizer since 2023. He previously held positions as Executive Director & Head, Rare Disease Neurology at Pfizer and Global Program Clinical Head at Novartis in Neuroscience. His expertise is in translational, early clinical trials developing evidence for proof of mechanism and clinical evidence for both novel new molecular entities of therapeutics as part of life cycle management. He is trained in Adult and Child Neurology and Medical Genetics to use his MD & PhD degrees.

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### **Matthew Coghlan, Ph.D.**



Matthew Coghlan, Ph.D., received his doctorate in Biochemistry from the University of Cambridge and was a Royal Society NATO Post-Doctoral Fellow at Harvard Medical School. Subsequently, Dr. Coghlan has gained 25 years of experience in Pharmaceutical R&D in Metabolic Disease across several global Pharma companies in Europe and the US. Since joining Eli Lilly and Company in 2018, Dr. Coghlan has provided strategic leadership of the Incretin Portfolio that includes peptide and small molecule programs from early Research through the end of Phase 2. Further, Dr. Coghlan has overseen an extensive program of pre-clinical research in support of the Lilly Incretin R&D Portfolio. This highly collaborative research continues to yield new insights into the mechanisms of action of tirzepatide, retatrutide and orforglipron.

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### **Jon Davis, Ph.D.**



Jon Davis, Ph.D., is currently a principal scientist at Novo Nordisk and previously held a faculty position at Washington State University. His primary research interests include detailing the gastrointestinal-central nervous system signalling mechanisms that control appetite. In this capacity, he currently oversees the appetite regulation biology group at Novo Nordisk. He is a member and fellow of the obesity society (TOS) as well as the society for study of ingestive behavior (SSIB). In 2014, he received the distinguished chairman's choice award from Biological Psychiatry. He received a B.A. in biology from Maryville College and a Ph.D. from the University of Cincinnati.

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### **Eva L. Feldman, M.D., Ph.D.**



Eva L. Feldman, M.D., Ph.D., received her M.D., Ph.D. from the University of Michigan, completed neurology training at Johns Hopkins University, and returned to the University of Michigan where she is now the James W. Albers Distinguished University Professor and Russell N. DeJong Professor of Neurology. Dr. Feldman is a renowned clinician scientist who has devoted her career towards understanding and treating neurological disorders. She is Director of the ALS Center of Excellence, the NeuroNetwork for Emerging Therapies and is annually listed in Best Doctors in America, a tribute to her active clinical practice. A Past President of the American Neurological Association, and member and current councilor of the National Academy

of Medicine, her research is internationally recognized, with >500 published articles and >55,000 citations and an H index of 122. The inaugural Director of the A. Alfred Taubman Medical Research Institute when Taubman gave \$100 million to support translational research, she has been continuously funded by NIH funded since 1989. Her team of 25 scientists conduct pioneering studies on the pathogenesis of dementia in metabolic diseases and the effect of the exposome on ALS, leveraging in vitro and in vivo models, clinical specimens, multiple omics-based approaches, and clinical trials. Her research identified dyslipidemia during diabetes as a key driver of nervous system damage, contributing to new patient care guidelines. With a strong track record of directly translating basic research into advances in clinical treatment for neurological disorders, she has mentored over 100 fellows and 10 graduate students, and currently oversees >10 federal grants.

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### Edwin (Ted) George, M.D., Ph.D.



Edwin (Ted) George, M.D., Ph.D., currently works for the FDA's Center for Drug Evaluation and Research as a Clinical Reviewer in the Office of New Drugs. He retired from the faculty of Wayne State University in 2022 where he was Director of the Wayne State University Movement Disorders Center and Associate Professor of Neurology. He is a member and previous chairman of the Board of Directors and the Professional Advisory Board of the Michigan Parkinson's Foundation. His research interests include Parkinson's disease and movement disorders, and he has been active in clinical trials for Parkinson's disease and dystonia, as well as laboratory research focused on neuronal reaction to injury and neural regeneration. He has lectured and written extensively on movement disorders and has served as a consultant to pharmaceutical firms. Dr. George is a Fellow of the American Academy of Neurology and a member of the International Parkinson and Movement Disorders Society, and Sigma Xi. He received a B.A. in Economics and a B.A. summa cum laude in Biophysics in 1980 from Amherst College in Massachusetts, a Ph.D. in Pharmacology in 1985 and an M.D. in 1987 from Case Western Reserve University in Cleveland, OH. He was a Grass Summer Fellow in Neurophysiology in 1986 at the Marine Biological Laboratory, Woods Hole, Massachusetts, and did a Neurology Residency and Peripheral Nerve Fellowship at The Johns Hopkins Hospital in Baltimore, Maryland. He is Board Certified in Neurology and has received the Added Qualification in Clinical Neurophysiology.

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### Serena Jingchuan Guo, M.D., Ph.D



Serena Jingchuan Guo, M.D., Ph.D., is an Assistant Professor in the Department of Pharmaceutical Outcomes and Policy at the University of Florida (UF) College of Pharmacy. She specializes in pharmacoepidemiology and pharmacoinformatics, with a focus on cardiometabolic diseases and neurodegenerative conditions, aiming to advance precision treatment and health equity. Utilizing extensive real-world data, such as electronic health records and insurance claims, alongside advanced analytics, including AI/machine learning and causal-principled modeling, her research assesses the comparative effectiveness and safety of treatments and interventions (e.g., repurposing GLP1 receptor agonists) and identifies heterogeneous treatment effects

(HTEs). Additionally, she develops personalized and intelligent social risk management tools for clinical integration. Dr. Guo has authored over 90 peer-reviewed manuscripts, with publications in top-tier journals like Diabetes Care, Lancet, and BMJ, and her work has been highlighted by major media outlets including the Washington Post, NPR, and CNN. Her research and collaborations are funded by the NIH, Veterans Affairs, CDC, FDA, and the PhRMA Foundation. She received the Assistant Professor Award of Excellence at UF and the JMCP Award for Excellence from the Academy of Managed Care Pharmacy. Dr. Guo earned her M.D. from Peking University in China and her Ph.D. in Epidemiology from the University of Pittsburgh.

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### Elisabet Jerlhag Holm, Ph.D.



Elisabet Jerlhag Holm, Ph.D., is currently a professor in pharmacology at the University of Gothenburg. Her work has substantially contributed to our understanding of the role of the gut-brain axis, specifically GLP-1, in reward-regulation and addiction. Professor Jerlhag was first to show that GLP-1 reduces alcohol intake and suppresses alcohol-related responses in rodents. Further, pioneering work by Prof. Jerlhag established that activation of GLP-1 receptors reduces artificial (amphetamine, cocaine, nicotine) and natural rewards (sex, foraging, aggression). As a result, she has identified novel targets for treatment of alcohol use disorder (AUD). Her work has been cited over 6,000 times, providing her an H-index of 40. In recognition of her outstanding quality of research, in 2017, Prof. Jerlhag was awarded the Swedish Fernström Award at Sahlgrenska Academy. Moreover, she has obtained additional awards including the ESBRA Nordmann award for being the most promising young European addiction researcher (2012) and the Transitional Researcher Award from the Swedish Medical Society (2014). Prof. Jerlhag got her Ph.D. in medicine in 2007 at the University of Gothenburg. She then combined a short postdoctoral visit at Gallo Institute at UCSF, USA, with research at the University of Gothenburg. Subsequently, she established her own research group at the Department of Pharmacology at the University of Gothenburg. She became an associate professor in 2011, and received a full professorship in 2020.

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### Lorenzo Leggio, M.D., Ph.D.



Lorenzo Leggio, M.D., Ph.D., is a physician-scientist, whose clinical work and clinical research have been primarily focused on the treatment of alcohol and substance use disorders and on the medical consequences of alcohol use disorder, especially alcohol-associated liver and cardiovascular diseases. Dr. Leggio, together with his team of trainees, staff, colleagues, and collaborators, have conducted research on medication development, on the role of the microbiome-gut-liver-brain axis, on the role of neuroendocrine pathways in addiction, via human laboratory studies and clinical trials as well as via translational and reverse translational experimental medicine approaches in animal models. Dr. Leggio received his M.D. and Ph.D. from the Catholic University of Rome and Agostino Gemelli Hospital, where he also completed residency and received Board Certification in Internal Medicine. He was a postdoctoral



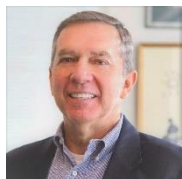
research associate in Psychiatry and Human Behavior at Brown University, Providence, RI, where he joined the core faculty of the Center for Alcohol and Addiction Studies as Assistant Professor in 2010. As PI at Brown University, he received extramural research funding from NIAAA and NIDA, as well as from several foundations. Dr. Leggio was recruited as a Tenure-Track Clinical Investigator (joint NIAAA/NIDA) at the NIH IRP, where he also serves as a NIH Senior Attending Medical Staff. In 2018, Dr. Leggio was awarded NIH tenure through the Central Tenure Committee and promoted to Senior Investigator (Clinical).

Dr. Leggio currently serves as the NIDA Clinical Director and Deputy Scientific Director. He was the founder in 2012 and current Chief of the Clinical Psychoneuroendocrinology and Neuropsychopharmacology Section, a joint NIDA and NIAAA laboratory. He was the founder in 2020 and current Chief of the NIDA IRP Translational Addiction Medicine Branch. Dr. Leggio was also the founder and serves as the Director of the NIDA IRP Translational Analytical Core. He further serves as Senior Medical Advisor to the NIAAA Director. He is also Adjunct Professor of Behavioral and Social Sciences at Brown University, Adjunct Professor of Addiction Medicine at Johns Hopkins University and Adjunct Professor of Neuroscience at Georgetown University. He previously served on other NIH IRP roles, including Associate Director for Clinical Research for the NIDA IRP Medication Development Program, NIDA Acting Clinical Director, Chair of the joint NIAAA/NIDA Scientific Review Committee, and Vice-Chair of the joint NIDA/NIAAA Addictions Institutional Review Board.

In 2022, Dr. Leggio was elected Fellow of the American College on Neuropsychopharmacology. Among other honors, Dr. Leggio received the 2008 Nordmann Award from the European Society for Biomedical Research on Alcoholism, a 2010 Young Investigator Award from the Brain and Behavior Research Foundation, the 2016 Early Career Investigator Award from the Research Society on Alcohol, the 2018 Eva King Killam Award from the American College on Neuropsychopharmacology, the 2020 Jacob P. Waletzky Award from the Society for Neuroscience, the 2023 Ward & Ryan Donovan Lectureship Award from the American College of Medical Toxicology, and the 2024 Max Glatt Memorial Lectureship Award from the U.K. Medical Council on Alcohol. Dr. Leggio was also presented as one of the twelve 2023 recipients of the 2023 Arthur S. Flemming Award (Social Science, Clinical Trials, and Translational Research category) for his groundbreaking research in addiction science.

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### Iván Montoya, M.D., M.P.H.



Iván Montoya, M.D., M.P.H., is the Director of the Division of Therapeutics and Medical Consequences at the National Institute on Drug Abuse. He has more than 25 years of research experience in the development of safe and effective treatments for Substance Use Disorders (SUD). He has been the recipient multiple times of the NIH Director's Award of Merit for his scientific contributions to improve the treatment of SUDs. He is a psychiatrist and epidemiologist from University of Antioquia and Johns Hopkins University, respectively.

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### Kimberlei Richardson, Ph.D.



Kimberlei Richardson, Ph.D., is an Associate Professor in the Department of Pharmacology at Howard University College of Medicine. Her laboratory utilizes neurochemical, pharmacological, and behavioral strategies to study the role of neuropeptide regulation on substance use disorders (i.e., drugs of abuse and food). Her work has contributed to the understanding of the role of the orexin system in drug reward. Specifically, the interaction between orexin projections and the ventral tegmental area during protracted abstinence from chronic morphine. More recently, her work has focused on the influence of neuropeptide regulation and gut microbiota on foraging and food choice. Dr. Richardson has received numerous honors including the Grass Foundation Fellowship, the American Psychological Association Neuroscience Fellowship, and been awarded grants from the National Science Foundation, National Institutes of Health, the National Science Foundation, and the Charles and Mary Latham Foundation. Dr. Richardson has been a member of several scientific societies and organizations including the Society for Neuroscience and the American Society for Pharmacology and Experimental Therapeutics. She earned her undergraduate (B.S., Chemistry) and doctoral degree (Ph.D., Pharmacology) from Howard University and conducted postdoctoral trainings at Johns Hopkins Hospital and the Medical University of South Carolina.

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### Linda Rinaman, Ph.D.



Linda Rinaman, Ph.D., is a Distinguished Research Professor in the Department of Psychology and the R. Bruce Masterton Professor of Neuroscience at Florida State University. She previously was Professor of Neuroscience and Assistant Dean of Graduate Studies at the University of Pittsburgh. Dr. Rinaman's research program has been continuously funded by the NIH for more than 25 years. Her laboratory uses rodent models to investigate the central neural controls of motivated behavior and stress responses, and how early life nutrition and other experiences shape the development and function of these neural systems. Dr. Rinaman earned her doctorate degree in Neuroscience at the University of Pennsylvania, followed by postdoctoral training in Developmental Neurobiology with Dr. Pat Levitt, and training in Neuroanatomy and Endocrinology with Dr. Joseph Verbalis and Dr. Gloria Hoffman.

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## **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 1.01 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 1.02 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*

## **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.<sup>[1]</sup> 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.

<sup>[1]</sup> 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.