DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH
NATIONAL ADVISORY NEUROLOGICAL DISORDERS AND STROKE COUNCIL

Summary of Meeting[1]
February 1-2, 2023

The National Advisory Neurological Disorders and Stroke (NANDS) Council was convened for its 218th meeting on February 1-2, 2023 via Zoom remote meeting. Dr. Walter Koroshetz, Director of the National Institute of Neurological Disorders and Stroke (NINDS), served as Chairperson.

In accordance with Public Law 92-463, the meeting was:

Open: February 1,2023: 1:02 p.m. to 6:03 p.m. for the review and discussion of program development, needs, and policy; and
Closed: February 2, 2023: 1:01 p.m. to 3:53 p.m. for the consideration of individual grant applications.

Council members present:
Dr. Allan Basbaum (Thursday only)
Dr. Amy Brin
Dr. Robert Brown Jr. (Wednesday only)
Dr. Claudia Lucchinetti (Thursday only)
Dr. Kenneth Maynard
Dr. John Maunsell
Dr. Louise McCullough
Dr. Gina Poe
Dr. Ekemini Riley
Dr. Timothy Ryan
Dr. Sameer Sheth
Dr. N Edwin Trevathan
Ms. Christin Veasley

Subject Matter Expert Attendees:
Mr. Hank Greely
Dr. Yishi Jin
Dr. Jane Larkingdale
Dr. Jin-Moo Lee
Dr. Hank Paulson

Ex officio members present:
Dr. David Brody
Dr. Christopher Bever, Jr.

Council Roster (Attachment 1)

[1]For the record, it is noted that members absent themselves from the meeting when the Council is discussing applications (a) from their respective institutions or (b) in which a real or apparent conflict of interest might occur.

The entire meeting was held virtually over Zoom and all observers including members of the public attended virtually.

Some members of the public present for portions of the open meeting included:

Dr. Rita Sattler, Professor of Translational Neuroscience, Barrow Neurological Institute, Dignity Health St. Joseph's Hospital and Medical Center
Dr. Layne Oliff, NEALS Research Ambassador, The International Alliance of ALS/MND Associations
Ms. Ellyn Phillips, Caregiver, Board Chair Emeritus ALS Association Greater Philadelphia Chapter
Mr. Dan Doctoroff, Former Chairman and CEO, Sidewalk Labs, Founder and Board of Directors, Target ALS
Dr. Jacqueline Corrigan-Curay, Principal Deputy Center Director, Center for Drug Evaluation and Research, FDA

Federal attendees are listed at the end of these minutes.

I. Call to Order and Opening Remarks
Dr. Koroshetz welcomed Council members, visitors, and staff to the 218th meeting of the National Advisory Neurological Disorders and Stroke Council.

II. Report of the Director, Division of Extramural Activities, NINDS
Dr. Robert Finkelstein

Approval of Council Minutes—Dr. Finkelstein requested, and the Council voted approval of the September 7-8, 2022, Council meeting minutes.

The following future Council meeting dates were confirmed:

Wed & Thurs, May 31, 2023-June 1, 2023
Wed & Thurs, September 6-7, 2023
Wed & Thurs, February 14-15, 2024
Wed & Thurs, May 15-16, 2024
Wed & Thurs, September 4-5, 2024

Expedited Review Process – Each Council round, a subset of Council members approves applications with scores within the payline in advance of the meeting. This expedited review process focuses on applications for which there are no unresolved issues. Dr. Finkelstein thanked Council members Ken Maynard and John Maunsell for handling this responsibility for this meeting and the fiscal year. For the current Council round, 142 applications were eligible to be expedited. A portion of these awards already have been issued, and the others will be issued after Council.

Extramural Announcements
All extramural introductions were posted to the NINDS Electronic Council Book (ECB).

Approval of Operating Procedures

Dr. Robert Finkelstein, Associate Director, Division of Extramural Activities; Executive Secretary, NANDS Council

Dr. Finkelstein presented a proposal for a minor modification to the Council Operating Procedure. This modification would change the Council delegated authorities to allow the granting of proposed co-funds of $100,000 or less without explicit Council approval.

Council voted to approve the Council Operating Procedure

III. Report of the Director, NINDS

Dr. Walter Koroshetz, Director, NINDS

NIH and NINDS Leadership Changes—Dr. Koroshetz began by acknowledging Dr. Ralph Sacco's passing. Dr. Sacco was a former Council member and an outstanding NINDS grantee who worked on health disparities. He was the first neurologist to serve as American Heart Association President and also served as President of the American Academy of Neurology.

Dr. Nina F. Schor has been appointed as the new NIH Acting Deputy Director for Intramural Research (DDIR). Dr. Renee Wegrzyn has been named Director for the Advanced Research Projects Agency for Health. Dr. Joni L. Rutter has been named Director of the National Center for Advancing Translational Sciences.

In December, Dr. Anthony S. Fauci stepped down from his positions as Director of the National Institute of Allergy and Infectious Diseases (NIAID), Chief of the NIAID Laboratory of Immunoregulation, and Chief Medical Advisor to President Biden. Dr. Hugh Auchincloss, who served as Deputy Director of NIAID for many years, has been named Acting Director of NIAID. Dr. Roger Glass has stepped down as Director of the Fogarty International Center, and Dr. Peter Kilmarx has been named Acting Director. Dr. Jim Anderson has stepped down from his position as Director of the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) within the Office of the NIH Director; Dr. Robert W. Eisinger has been appointed Acting Director of DPCPSI.

Budget—The Fiscal Year (FY) 2023 budget has been signed by President Biden and includes a 4 percent increase to the NINDS base and a 7.8 percent increase to the total NINDS appropriation. The Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN®) budget increased overall by 11 percent, mainly due to the budget increase of the Cures Act and despite a decrease in the BRAIN® base budget. Helping to End Addiction Long Term® (HEAL®) appropriations increased by 3.7 percent and, for the first time, $75 million of the Alzheimer's initiative budget was appropriated directly to NINDS. An additional $2 million in dedicated funds for the Undiagnosed Disease Network were added to the NINDS appropriation.

The John Edward Porter Neuroscience Research Center Flood Disaster and Recovery Update—On December 24–25, the Porter Neuroscience Research Center, which houses 85 laboratories encompassing more than 800 scientists from multiple neuroscience Institutes and Centers, experienced two catastrophic floods. Affected laboratories are not yet open; 18 are NINDS laboratories. Remediation work is ongoing.

Amyotrophic Lateral Sclerosis (ALS) Appropriations Update—President Biden signed the Accelerating Access to Critical Therapies (ACT for ALS) Act, which provides $75 million for

research under the Expanded Access (EA) program and other activities. The top priority is Expanded Access research, including the funding of grants for research in persons treated with Small Business Innovation Research (SBIR) investigational interventions currently in Phase 3 trials under EA designation from the U.S. Food and Drug Administration (FDA). The funding opportunity announcement ([FOA] RFA-NS-23-012) was released on January 1, and two technical webinars ((NOT-NS-23-060) are scheduled for February 15 and 22, 2023. In FY 2022, NINDS spent $18 million on EA grants. Given the longer lead time and outreach from NINDS and the ALS community, a more robust response is expected in FY2023.

A second priority is the expansion of public-private partnerships (PPP) for rare neurodegenerative diseases between NIH and FDA. In FY 2022, funds were transferred to FDA for PPP run by the Critical Path Institute (C-Path) and for a natural history study in ALS. NINDS will prepare for the potential to expand the PPP with FDA and C-Path in FY 2023. A third priority is funding meritorious ALS research.

NIH funding for ALS research has nearly tripled in the last decade. NINDS manages a large proportion of ALS funding, as well as the majority of the funds for frontotemporal dementia.

ALS Strategic Planning—An NINDS Council working group drafted an ALS Strategic Plan and will present recommendations for review during this Council meeting.

National Academy of Sciences (NAS) Study on Research, Care, and Services for ALS—The NIH commissioned NAS to conduct a study to identify key actions for the public, private, and nonprofit sectors to undertake to make ALS a livable disease within a decade and build on the research priorities in the NIH ALS Strategic Plan.

Roy Blunt Center for Alzheimer's Disease Related Dementias (ADRD) Research—The Roy Blunt Center for ADRD Research recently opened at NIH and is a state-of-the art building designed to support close collaboration across the NIH Intramural Program among a variety of scientific disciplines to drive cutting-edge research.

Proposed Changes to Research Project Grant Review—NIH is focused on facilitating identification of the strongest, potentially highest-impact research by reducing bias in the research project grant (RPG) review process. The goals are to refocus peer review on assessing scientific/technical merit of grant applications by focusing on the big questions and reducing the burden of administrative items as well as requiring evaluation of the investigator and the environment in the context of the proposed research. The proposed framework for RPG review includes reducing the five scored review criteria to three factors: importance of the research, feasibility and rigor, and expertise and resources. Every application will continue to receive an overall impact score (1–9) based on factors 1–3 and additional review criteria (e.g., human subjects). A Request for Information ([RFI] NOT-OD-23-034) on the proposed simplified review framework for NIH RPG applications has been released; comments will be accepted through March 10, 2023.

NIH Data Management and Sharing Policy: Implementation—The new NIH Data Management and Sharing Policy is in effect and mandates that applications received after January 25, 2023, include a plan for sharing published and nonpublished scientific data. NIH and NINDS have developed resources to help researchers prepare their applications and encourage thoughtful, effective planning. NINDS welcomes feedback. The community is encouraged to consider how to best make the posted data useful.

White House Policy on Public Access to Federally Funded Research—The new guidance from the White House Office of Science and Technology Policy (OSTP) on public access to federally funded research indicates that agencies must make results of taxpayer-supported research immediately available without embargo to the American public at no cost. All agencies will implement updated policies, including ending the optional 12-month embargo, no later than December 31, 2025. A draft plan and opportunity for further comment on how NIH will respond to the OSTP memorandum will be available soon.

Advisory Committee to the Director Working Group on Diversity, Subgroup on Individuals with Disabilities—Findings from the Advisory Committee to the Director (ACD) Working Group on Diversity, Subgroup on Individuals with Disabilities report include the following: (1) people with disabilities (PWD) are the single largest and fastest growing minority population in the United States; (2) PWD represent about 9 percent of the scientific workforce; and (3) data indicate that disability representation in the scientific workforce decreases throughout the career path. Suggestions for ACD consideration include updating the NIH mission statement; developing an NIH-wide effort to identify and address any structural ableism that may exist and promote disability inclusion; expanding efforts to include disability communities and the perspectives of PWD; conducting research on health and healthcare disparities and equity; ensuring that disability inclusion/anti-ableism are core components of all NIH Diversity, Equity, Inclusion, and Accessibility efforts; and maintaining accountability for disability inclusion efforts.

In addition, NINDS CARES Community Conversations are held to educate, bring awareness, and open conversation with the NINDS community about racial and ethnic groups; lesbian, gay, bisexual, and transgender (LGBTQ+) and all gender identities; and people/persons with disabilities. A CARES Community Conversation on disabilities was held on October 14, 2022, with 88 percent of NINDS staff attending. Suggestions for improvement offered during this NINDS Community Conversation are being considered.

New Advisory Committee to the Director Working Groups—

1) Due to the decline in the number of postdoctoral trainees, the NIH Director has charged a new ACD working group on re-envisioning NIH-supported postdoctoral training to evaluate evidence on the perceived shortage in PhDs seeking U.S. postdoctoral training, assess and consider factors influencing the scope and persistence of the issue, review and compare other approaches to postdoctoral training, consider ways to support postdoctoral quality of life and work-life balance, and engage key internal stakeholders. Initial data show multiple forces driving the decline in postdoctoral training. Over the last 6 years, the number of F32 applications at NINDS has declined while K99 application numbers have increased. Early Stage Investigator (ESI) applicants and awardees are increasing across NIH and NINDS; NINDS funded 7 percent of NIH ESIs in 2022.

2) A new ACD working group is focused on catalyzing the development and use of novel, non-animal-based approaches to advance biomedical research. This group will identify alternative methods being developed in biomedical research and assess their strengths and weaknesses. Final recommendations are expected in December 2023.

Open Positions at NINDS. NINDS is seeking bright, creative, and visionary scientists, engineers, and physicians to fill a number of roles, including program director, project manager, health program specialist, and health science policy analyst in various areas of interest.

NINDS-Supported Scientific Advances. Numerous NINDS-supported scientific advances from 2022 are described in the NINDS Director's message "Optimism and progress: Reflecting on 2022."

IV. Discussion of Director's Report

Concern was expressed about NINDS personnel being overtaxed due to increased NINDS funding without an equivalent addition of personnel. Dr. Koroshetz shared that NINDS staff remain responsive but agreed that stress levels of personnel are sometimes high. A hybrid work model is being implemented to increase efficiency and counteract high costs of living in the metropolitan area. The biggest current challenge is recruitment, not retention. Suggestions included forming an internal committee to study the health, wellness, and turnover of current staff to ensure that hiring is conducted effectively and informed by exit interviews. Dr. Koroshetz welcomed help from Council members in identifying people to contribute at NINDS.

A Council member applauded NIH on the effort to avoid bias in the grant review process. This approach will enhance NIH's emphasis on diversity, equity, and inclusion. It was noted that diversity of thought leads to increased innovation and productivity.

Council members commented on declining postdoctoral numbers. The increased number of ESIs suggests that NIH is recruiting those who desire academic jobs and that academic positions are being filled. Many talented people are leaving for various reasons, including women who leave due to the lack of accommodation for having children. An examination of the culture of academic research is necessary to determine how to improve that culture and attract and retain women.

Council members asked whether the decrease in the BRAIN® base budget reflects balancing of the budget. Dr. Koroshetz responded that recent changes in Congress likely will not benefit NIH; thus, NINDS is preparing for a flat budget for FY 2024.

Dr. Koroshetz clarified that the $75 million of the Alzheimer's initiative budget that was appropriated directly to NINDS is part of the 10 percent in NIA funding that is administered by NINDS.

Members commented on proposed changes to the RPG review process, which may not be sufficient to eliminate bias. Implementation of a truly blind review—removing all references to the institution and past work—was suggested; however, this approach has disadvantages (e.g., challenge to determining investigators' productivity). The American Heart Association is using a pilot review with a blinded letter of intent. The Center for Scientific Review recently experimented with a blind review in which the investigator was factored in after the review process.

A Council member asked about data sharing resources and how valuable older data are being preserved and shared. An initiative to save those data was suggested. Older data would be stored, and a link to those data would be included in publications. Sharing of old data is challenging; these data must be shared in a thoughtful manner so they are accessible and interpretable. Institutions (e.g., the University of Michigan) could help investigators place data in an academic and inexpensive environment. Because of the cost and maintenance involved in data sharing, it was recommended that NINDS and NIH make a commitment to this effort.

V. HEAL Initiative Update and Council Discussion

Dr. Michael Oshinsky, Program Director, Division of Neuroscience
Dr. Linda Porter, Program Director, Office of Pain Policy

Dr. Oshinsky presented an update on the HEAL® preclinical and translational programs that are focused on understanding the biological underpinnings of chronic pain and accelerating the discovery and preclinical development of nonaddictive pain treatments.

HEAL® programs for enhancing pain management are categorized into discovery, preclinical development, clinical trials, and implementation and dissemination. Pain target discovery and validation programs include the Discovery and Validation of Novel Targets for Safe and Effective Treatment of Pain program (RFA-NS-22-034, RFA-TR-22-011). The program aims to promote basic science discovery and validation of targets for the treatment of pain that can be used to develop treatments.. The Program to Reveal and Evaluate Cells-to-gene Information that Specify Intricacies, Origins, and the Nature of Human Pain (PRECISION Human Pain) Network has two objectives: 1) building comprehensive datasets of molecular signatures, cell types, and cellular function phenotypes that underlie human pain transmission and processing by using primary human tissues and cells and 2) coordinating, curating, and integrating the comprehensive datasets; enhancing data interoperability and harmonization; and creating digital resources for data integration, visualization, and dissemination. FY 2023 initiatives aimed at facilitating discovery at this early stage are Development and Validation of Animal Models and Outcome Measures for Pain (RFA-NS-22-070 ,NOT-NS-22-095) and Integrated Basic and Clinical Team-based Research in Pain (RFA-NS-22-069).

HEAL® early translational stage programs support early therapeutics development to advance a hit or lead toward meeting entry criteria for the Pain Therapeutics Development Program (PTDP) and include a 2-year R61 planning grant and the 5-year multicomponent U19 Team Research for Initial Translational Efforts In Non-addictive Analgesic Therapeutics Development . Pain Therapeutics Development Program (PTDP) is a multiphase virtual pharma model featuring grants and contracts that leverages pharma experience to help applicants form partnerships, complete Phase I trials, and prepare for Phase II trials. Multiple NIH Institutes, including NINDS participate in PTDP with projects representing a wide range of pain conditions and stages.

HEAL® SBIR and Small Business Technology Transfer (STTR) programs have funded 46 companies for 49 projects spanning the pain interests of nine NIH Institutes. To date, $38 million has been allocated to SBIR/STTR pain management awards. SBIR-funded businesses that are achieving transition of products to the clinic include Afasci, South Rampart Pharma, and Micro-Leads. SBIR funds also have facilitated commercialization of Hesperos for specialized chip technology. An event supporting commercialization of products include the HEAL® Pain Partnering Meeting scheduled for October 2023 and funding through the HEAL® Embedded Entrepreneur Program (PAR-23-069). The Preclinical Screening Platform for Pain (PSPP) profiling program focuses on accelerating discovery and preclinical development of nonopioid, nonaddictive treatments for acute and chronic pain conditions. Translating Discoveries into Effective Devices to Treat Pain supports development and clinical translation of safe, effective, nonaddictive devices for pain through the HEAL® Development of Devices for Pain and Opioid

Use Disorder ([OUD] FRA-EB-22-002) program. HEAL® Notice of Special Interest (NOSI) to Blueprint Medtech (NOT-NS-23-002, PAR-21-315, PAR-21-282), and HEAL® Interdisciplinary Team Science to Uncover the Mechanisms of Pain Relief by Medical Devices initiatives (RFA-NS-23-003) are several other programs that NINDS participates in to support this mission.

Dr. Oshinsky highlighted the HEAL® device portfolio, which contains 6 development projects, 8 clinical translation projects, 6 Early Feasibility Study clinical trials, 5 FDA Investigational Device Exemptions, 2 ongoing mechanistic trials, plus 3 awards to small business and 14 awards to academia. All HEAL® preclinical pain FOAs are open to both academia and industry. Nearly 100 percent of discovery-phase initiatives are pursued by academic institutions while industry pursues therapeutic development initiatives.

The Research Supplements to Promote Diversity program (NOT-NS-20-107 and PA-21-071) is recruiting diverse individuals into HEAL® projects and supporting individuals from the high school level through the early investigator stage. Since 2019, this initiative has supported 30 diverse scientists. To support a cohort of new and well-trained, independent investigators from diverse backgrounds, NINDS released K99/R00 advanced postdoctoral-to-independent career transition awards in pain and substance use disorder which include: RFA-NS-22-022, RFA-NS-22-023) and diversity RFA-NS-22-024, RFA-NS-22-025 programs.

Dr. Porter acknowledged the passing of Dr. Rob Dubner, a pioneer of pain research who spent the majority of his career at NIH. His valuable contributions generated part of the basis for the HEAL® portfolio.

An overview of data on the nationwide pain public health crisis was provided by Dr. Porter. In total, 50 million adults live with severe or high-impact chronic pain; more women than men have chronic pain and high-impact chronic pain; more rural than urban dwellers suffer chronic pain and high-impact chronic pain, and pain prevalence increases with age. The risk of high-impact chronic pain is associated with a wide range of health conditions.

Dr. Porter provided updates on HEAL® clinical research initiatives, including the Biomarker Program, Back Pain Research Consortium, Biomarkers for Evaluating Spine Treatments trial, Early Phase Pain Investigation Clinical Network, Comparative Effectiveness Research Network for Acute and Chronic Pain Management, PRagmatic and Implementation Studies for the Management of Pain, Integrative Management of Chronic Pain and OUD for Whole Recovery, and the Health Disparities in Pain and Co-occurring Health Conditions projects.

HEAL® also has cross-cutting efforts in community engagement, clinical pain research workforce enhancement, diversity, data harmonization, and secondary data analysis. Workforce enhancement awards include supplements to support early career trainees and protect mentors' time and two linked awards: National K12 Clinical Pain Career Development Program with Coordinating Center and R24 Coordinating Center for National Pain Scientists: Network and Gathering. The HEAL® Community Partner Committee, which will help identify, refine, and prioritize engagement activities linked to HEAL® science, includes patients, advocates, community advisors, and family members.

Dr. Porter shared an overview of HEAL® clinical pain management research data and outlined the range of interventions used in HEAL® clinical pain management studies of back pain, one of the most prevalent pain conditions. Many other pain conditions (e.g., trauma pain, cancer pain, myofascial pain) are being considered for biomarker development or clinical trials.

Interventions being tested in clinical pain management research include behavioral health, exercise/physical therapy, and pharmacological interventions. Research settings (e.g., outpatient clinic, academic medical center, hospital) for these studies are representative of locations that provide care.

Discussion

A Council member asked about ongoing development of nonaddictive pharmacologic interventions that are as effective as opioids. Dr. Oshinsky reported that 56 non-opioid targets have been identified through the HEAL® program; μ opioid receptor agonists are excluded from HEAL® programs. Targets that are most likely to reach the market are those from SBIR device projects. Targets from other HEAL® initiatives are in clinical testing.

The funding announcement for development and validation of non-rodent mammalian models of pain (RFA-NS-22-070) delineates the criteria for suitable non-rodent models. Applications must include the feasibility of implementing the model in a preclinical setting.

VI. Amyotrophic Lateral Sclerosis (ALS) Strategic Planning

Dr. Amelie Gubitz, Program Director, Division of Neuroscience
Dr. Rita Sattler, Professor of Translational Neuroscience, Barrow Neurological Institute, Dignity Health St. Joseph's Hospital and Medical Center
Dr. Robert Brown, Director, Program in Neurological Therapeutics, UMass Chan Medical School
Dr. Layne Oliff, NEALS Research Ambassador, The International Alliance of ALS/MND Associations
Ms. Ellyn Phillips, Caregiver, Board Chair Emeritus ALS Association Greater Philadelphia Chapter
Mr. Dan Doctoroff, Former Chairman and CEO, Sidewalk Labs, Founder and Board of Directors, Target ALS
Dr. Jacqueline Corrigan-Curay, Principal Deputy Center Director, Center for Drug Evaluation and Research, FDA
Dr. Walter Koroshetz, Director, National Institute of Neurological Disorders and Stroke

Dr. Amelie Gubitz, Program Director, Division of Neuroscience

Discussants: Dr. Rita Sattler, Barrow Neurological Institute, Dignity Health St. Joseph's Hospital and Medical Center; Dr. Robert H. Brown, UMass Chan Medical School; Dr. Layne Oliff, Person Living with ALS, NEALS Research Ambassador/The International Alliance of ALS/MND Associations; Ms. Ellyn Phillips, Caregiver, Board Chair Emeritus, ALS Association Greater Philadelphia Chapter; and Mr. Dan Doctoroff, Person Living with ALS, former Chairman and CEO, Sidewalk Labs, Founder and Board of Directors member, Target ALS

Dr. Gubitz presented an overview of the strategic priorities for ALS research developed by the NIH ALS Strategic Planning effort. This effort aimed to identify the highest priorities for research that will lead to the discovery of effective interventions for the diagnosis, treatment, management, prevention, and cure of ALS. The strategic planning process included an initial RFI, generation of draft priorities, a public workshop, and revision of the draft priorities. If approved by the NINDS Council, NIH and other stakeholders will begin implementation of these priorities. The ALS Strategic Planning effort involved individuals affected by ALS, staff from

NINDS, other NIH ICs, the FDA, the Centers for Disease Control and Prevention, and the Department of Defense ALS Research Program.

Five Strategic Planning Working Groups focused on specific priorities:

1) The Accelerating Research on the Biology Behind ALS Working Group focused on identifying the cause of sporadic ALS, understanding disease heterogeneity, and employing novel technologies.
2) The From Research to Therapy Working Group focused on establishing ALS Centers of Excellence, enhancing infrastructure for biosample repositories, and enabling trials and fostering industry/academic collaborations.
3) The Optimizing Clinical Research Working Group prioritized defining ALS natural history, developing treatments across the disease spectrum, and defining early manifestations of ALS.
4) The Quality of Life for Persons Living with ALS Working Group focused on improving and optimizing symptom management, optimizing function, and identifying resources for ALS care.
5) The Opportunities for Collaborations and Partnerships Working Group prioritized establishing multimodal platforms for data sharing, developing a repository of research tools and protocols, and establishing a framework for collaboration between industry and academia.

Dr. Gubitz highlighted themes from public comment that informed prioritization of activities, including the urgency of determining presymptomatic disease biology and improving biomarker development, the need for inclusion of individuals at risk for ALS in clinical trial design, and ensuring that Centers of Excellence and this effort integrate diverse populations. Members of the public expressed concern about the ALS clock, implementation of the strategic plan (short- and long-term activities), and monitoring progress on set priorities.

ALS Strategic Planning Steering Committee members Ms. Phillips and Dr. Oliff presented impressions of the ALS Strategic Plan effort from the perspective of people with ALS (pALS) and caregivers for people with ALS (cALS). Dr. Oliff is a pALS who was originally diagnosed with primary lateral sclerosis in 2017. Ms. Phillips is a cALS and past NANDS Council member. She highlighted the importance of including experts with ALS experience in this process; every Working Group included a pALS, cALS, or gene carrier. These experts were involved in all stages of development of the Strategic Plan and provided valuable input and guidance. Dr. Oliff highlighted that all pALS/cALS/gene carriers were well received by NIH/NINDS, the Steering Committee, and Working Group members.

The proposed role for ALS experience experts upon the approval of the Strategic Plan is to (1) disseminate and promote the Strategic Plan for ALS community, (2) be members of an implementation Working Group to ensure the Strategic Plan priorities are achieved, and (3) monitor challenges and opportunities within the Strategic Plan. Dr. Oliff thanked NIH/NINDS for raising awareness of the role of pALS/cALS/gene carriers and ALS. Listening to the input of ALS experience experts has made this Strategic Plan more valuable to the ALS community.

Dr. Doctoroff is a pALS and the creator of TargetALS, which aims to accelerate research into clinical trials using various initiatives and the powerful combination of industry and academia. TargetALS funds multidisciplinary consortia of researchers that often are led by industry investigators and include a suite of core scientific research resources and engage industry in all activities. TargetALS has funded 53 consortia, 60 percent of which have resulted in the establishment of continuing drug discovery programs in biotech/pharma companies and six clinical trials. Currently, TargetALS engages 123 different biotech and pharma companies.

Dr. Doctoroff attributed progress in ALS research to increased funding from NIH/NINDS and philanthropy, and remarkable collaboration. The Strategic Planning process reflects this collaboration, and the resulting Strategic Plan outlines the path and accelerates the search for ALS treatments. Operationalization of this plan will be facilitated by funding provided by the ACT for ALS. NIH and NINDS are acting with a sense of urgency befitting the nature of this disease.

A motion to vote to accept the report was made, seconded, and carried.

Update from the FDA—ACT for ALS Activities

Dr. Jacqueline Corrigan-Curay, Principal Deputy Director, Center for Drug Evaluation and Research, FDA

Dr. Corrigan-Curay provided an overview of the ACT for ALS; the FDA Rare Neurodegenerative Disease Grant Program; the FDA Action Plan for Rare Neurodegenerative Diseases, including ALS; and the Critical Path Neurodegenerative Disease Public-Private Partnership.

The ACT for ALS (Public Law 117-79) establishes Grants for Research on Therapies for ALS, the Department of Health and Human Services (HHS) Public-Private Partnership for Rare Neurodegenerative Diseases, and the Rare Neurodegenerative Disease Program. It mandates an FDA action plan (ALS and Other Rare Neurodegenerative Disease Action Plan) and submission of a Government Accountability Office report and includes authorization of appropriations. The Rare Neurodegenerative Disease Grant Program awards grants and contracts to cover costs to prevent, diagnose, mitigate, treat, or cure ALS and other rare neurodegenerative diseases. A docket was opened for funding concepts for FY 2023 grants and an RFI was published to conduct a landscape analysis for clinical outcome assessments in FY 2023. FY 2023 FDA funding plans include natural history and biomarker studies for rare neurodegenerative diseases, a landscape analysis of efficacy assessments for communication BCIs, continued support of the Myotonic Dystrophy-Type 1 Natural History Study and additional support for Dr. David Walk's ALS Natural History Study.

The FDA Action Plan for Rare Neurodegenerative Diseases, including ALS is a 5-year action plan to advance innovation that promotes and accelerates medical product development for the treatment of rare neurodegenerative diseases. The plan describes activities to address the unmet medical needs of individuals with rare neurodegenerative diseases, an ALS science strategy to address substantiative issues in drug development, and a multipronged approach to implement the Action Plan.

The ALS Action Plan focuses on improving characterization of disease pathogenesis and natural history, facilitating access to investigational new drugs, and enhancing clinical trial infrastructure and agility. The FDA has supported ALS drug development through the 2019 Guidance for Industry: Amyotrophic Lateral Sclerosis: Developing Drugs for Treatment, a workshop series for the exploration of science for ALS, the Draft Guidance for Industry: Human Gene Therapy for Neurodegenerative Diseases, and collaboration with stakeholders.

Dr. Corrigan-Curay outlined the near-, medium-, and long-term goals of the ALS Action Plan. Future priorities of the FDA Center for Devices are to develop BCIs to enable communication and *in vitro* diagnostics. FDA also is prioritizing digital health technologies to transform the study of medical products for patients with ALS (e.g., capturing real-world data and patient-generated health data). The FDA Task Force for Rare Neurodegenerative Diseases was formed

to coordinate input for the PPP and other activities related to implementation of ACT for ALS and ensure cohesion in FDA's approach.

The Center for Drug Evaluation and Research's Accelerating Rare Disease Cures (ARC) Program drives scientific and regulatory innovation and engagement to accelerate the availability of treatments for patients with rare diseases.

In September 2022, FDA and NIH launched a new PPP for Rare Neurodegenerative Diseases: Critical Path for Rare Neurodegenerative Diseases (CP-RND). C-Path is the convener of CP-RND. In addition to prepping a data strategy for ALS, C-Path is developing an ALS stakeholder map, an ALS industry landscape, and an ALS modeling inventory.

The ACT for ALS lays out a multifaceted approach to advancing drug development for ALS and other rare neurological diseases. FDA is engaging on multiple fronts and looks forward to working with NIH to advance new therapies that will address significant unmet medical needs.

NINDS ALS Strategic Plan

Dr. Walter Koroshetz, Director, NINDS

Dr. Koroshetz expressed enthusiasm about working with FDA and pointed to the complementarity of NIH and FDA efforts. He provided examples of NINDS work towards ALS Strategic Plan priorities such as BCI devices and optimization of ALS clinical research alongside FDA.

NIH proposes expansion of the PPP for ALS research by developing a portal for harmonized ALS data from NIH-, FDA-, and nonprofit-funded research and industry, and analytic platforms stored on a fit-for-purpose data repository on Foundation for the NIH and C-Path portals. This initiative would join FDA and NIH efforts to accelerate development of effective treatments for ALS. Dr. Koroshetz indicated that NINDS will provide regular implementation updates.

Discussion

One Council member commented that the network of Centers of Excellence offers an opportunity to collect biomarker data and implement clinical trials; thus, most sites need a clinical trials core. A question was raised about how Centers of Excellence would be organized to conduct the most important activities. Dr. Brown clarified that not every Center of Excellence should conduct all activities, but there should be a mandate for the clinical assessment of a diverse population according to standardized approaches to allow clinical comparison across sites.

Receptor-mediated shuttle technology for delivering biological macromolecules across the blood-brain barrier is a key technology with great potential to advance ALS treatments. This technology has been implemented in Alzheimer's disease, brain cancers, and lysosomal storage disease and should be leveraged for ALS.

One Council member attributed the uniqueness and likely success of the ALS Strategic Plan to ALS patients who are thoughtful and high-powered individuals driving the strategic intent around ALS. This high level of patient engagement will attract pharmaceutical companies' engagement. Dr. Oliff noted that many pharma and biotech companies do not agree with involvement of patient advocacy groups; however, as this engagement has grown, companies have begun to see its value. ALS experience experts strive to engage pharma/biotech

companies and ensure that advocacy groups are involved. He commended NIH and NINDS for engaging this community and setting a precedent for companies to integrate ALS experience experts from the beginning of product development.

Council members commented that the ALS Strategic Planning approach is inspiring for ALS and other diseases.

VII. Initiatives for Concept Clearance

Five Concepts were presented for discussion

Concept 1: NINDS Sustainable Transformation of Institutional Research Rigor (STIRR)
Devon Crawford, Division of Extramural Activities, Office of Research Quality, NINDS
Shai Silberberg, Division of Extramural Activities, Office of Research Quality, NINDS

The proposed concept would support the establishment of programs to enhance rigor and transparency practices within academic and research institutions to promote a culture of high-quality neuroscience research. Both focused (e.g., recognition and awards to promote awareness and incentivize best practices) and broad programs (development of standard operating procedures (SOPs) and incorporation of new infrastructures) are included. The goal is for entities within institutions to support researchers to better value rigor and transparency and change how research is assessed and rewarded. By receiving this support, scientists may feel empowered to improve their research practices and transform local institutional culture.

Discussion

This is an ambitious program aimed at addressing an important and difficult issue.

Rigor and reproducibility and data sharing overlap; aligning these efforts would allow for data and analyses to be checked for rigor and for more effective use of data. Data sharing is within the scope of the STIRR program; data sharing and open science are part of the transparency arm.

Council members commented on the proposed concept and efforts to change the culture around rigor and transparency.

- One approach for NINDS and NIH to begin changing the culture around rigor is for study sections to consider rigor of applicants' publications. NIH Center for Scientific Review (CSR) criteria indicate that reviewers are not required to consider documents not provided with the grant application; however, efforts to modify CSR's SOPs have resulted in study sections taking rigor into account more than in the past.
- The extent of rigor consideration by NIH may change applicants' behavior and should be more widely publicized. Dr. Crawford commented that investigator rigor is considered after the scientific merit review; thus, this can be done programmatically.
- The most expeditious approach to changing the culture regarding rigor and reproducibility of science is to enact changes in NIH policy.

- It would be beneficial for the rigor and reliability of studies to be more visible in publications.
- Some journals are addressing the reproducibility issue by requiring a transparency, rigor, and reproducibility statement.
- One challenge for reviewers and applicants is the unclear criteria on rigor. A key focus in the grant application review process is supporting data, which facilitate evaluation of the rigor of the applicant's work. NIH provides guidance on rigor and is developing additional educational resources for scientists.
- There are unknown variables that may cause unreproducible results; thus, NIH is emphasizing transparency as well as rigor to motivate scientists to clearly report methods used. Some journals also require extensive description of methods.
- Although costly, reproducibility is necessary for the transition to clinical trial.
- The proposed STIRR initiative likely will be very impactful and should enact strong measures.
- This effort is important because the wrong elements currently are being incentivized, which is costing research productivity.

Council voted to approve the proposed concept.

Concept 2: Reissue ME/CFS Collaborative Research Centers (CRCs) (U54)
Vicky Whittemore, Division of Neuroscience, Channels, Synapses and Circuits Cluster, NINDS
The proposed concept would support a network of Centers that will work collaboratively to define the cause(s) of and discover improved treatments for MS/CFS. Each Center would advance synergistic, interdisciplinary programs while serving as local resources and national leaders in MS/CFS research.

Concept 3: Understanding Neurological Effects of COVID-19 and Post-Acute Sequelae of SARS-CoV-2 Infection (R01)
Lumy Sawaki-Adams, Division of Clinical Research, NINDS

Concept 4: Understanding Neurological Effects of COVID-19 and Post-Acute Sequelae of SARS-CoV-2 Infection (R21)
Lumy Sawaki-Adams, Division of Clinical Research, NINDS
The proposed concepts #3 and #4 would solicit applications addressing the mechanisms, biomarkers, and pathophysiology of neurological manifestations of COVID-19 and post-acute sequelae of SARS-CoV-2 infection (PASC). Applications elucidating scientifically compelling pathways to identify targets that prevent or treat PASC-related neurological complications are of particular interest for this FOA (interventional trials testing safety and efficacy are out of scope for these RFAs). There are two receipt dates and a Special Emphasis Panel will be requested to bring appropriate expertise to the review.

*Editor's note, the concepts were released March 29, 2023

RFA-NS-23-021 Understanding Neurological Effects of COVID-19 and Post-Acute Sequelae of SARS-CoV-2 Infection (R01)

RFA-NS-23-022 Understanding Neurological Effects of COVID-19 and Post-Acute Sequelae of SARS-CoV-2 Infection (R21)

Concept 5: Emergency Medicine (K12)
Stephen, Korn, Division of Extramural Activities, Office of Training & Workforce Development, NINDS

The proposed concept would support development of an emergency medicine clinician workforce posed to launch funded research programs. This national institutional program (K12) would be modeled after the successful Neurosurgeon Research Career Development and the Child Neurologist Career Development Programs. This program would be supported by NINDS, the National Institute on Drug Abuse (NIDA), NIA, and, potentially, the National Institute on Child Health and Human Development (NICHD). NINDS would support three new scholars per year. Expertise on clinical trials and statistics and ethics would be required. Success would be measured by the percentage of EMRCDP-NS scholars and applicants receiving major funding as well as growth in the number of funded emergency medicine clinicians beyond EMRCDP-NS participants.

Discussion

One Council member noted that though research is costly, it raises the rankings of clinical departments and makes them seem more attractive. A cultural shift is needed to motivate emergency department (ED) chairs to allow clinicians to conduct research. Dr. Korn agreed and added that the goal is for the community to embrace the need for research in their specialty.

Another Council member noted that EDs may be perceived as a conduit to medical research and an entry point to research projects in different areas, including neurology. Deans' endorsement of chairs' support of research would be helpful. Council members expressed enthusiasm for the proposed EMRCDP-NS program, which is needed and welcome across the country. K12 programs are very effective and introduce young clinicians to NIH processes.

The prestige that research brings to academic medicine attracts clinicians, and these clinicians bring the revenue that supports research. Blue Ridge Institute for Medical Research rankings are an important aspect of performance of clinical departments.

Council also voted to approve all of the above concepts (2–4).

The Council also voted to approve the Initiatives for Concept Clearance from the Miscellaneous Section

Additional Concepts

5. Reissue: NINDS Exploratory Grant Program in Parkinson's Disease Research (P20; Clinical Trial Optional) *Lead: Beth-Anne Sieber*

6. Reissue: Morris K. Udall Centers of Excellence for Parkinson's Disease Research (P50; Clinical Trial Optional) *Lead: Beth-Anne Sieber*
7. Reissue: Blueprint ENDURE R25 *Lead: Michelle Jones-London*
8. Reissue: Institutional Translational Research Training Program (T32) *Lead: Stephen Korn*
9. Reissue: NINDS Postdoctoral Mentored Career Development Award (K01) *Lead: Stephen Korn*
10. Reissue: PAR-20-253: NIH Countermeasures Against Chemical Threats (CounterACT): Translational Exploratory/Development Research Projects (R21 Clinical Trial Not Allowed) *Lead: Shardell Spriggs*
11. Reissue: Amyotrophic Lateral Sclerosis (ALS) Intermediate Patient Population Expanded Access (U01 Clinical Trial Required) *Lead: Amelie Gubitz*
12. Recompeting of Existing NIH Blueprint Neurotherapeutics Network (BPN) Contracts *Lead: Charles Cywin*
13. BRAIN® Initiative: Exploratory Research Opportunities Using Invasive Neural Recording and Stimulating Technologies in the Human Brain (R61 Basic Experimental Studies with Humans Required) *Lead: Jim Gnadt*
14. Exposome Factors That Influence Pain Severity, Persistence and Resilience After Surgery (HEAL®) *Lead: Dave Jett*
15. Mechanistic Studies on the Effect of the Exposome on Acute and Chronic Pain (HEAL®) *Lead: Dave Jett*
16. Development and Validation of Remote or Patient Wearable Device Derived Objective Biosignatures or Functional Assessments to Monitor Pain for Use as Endpoints in Clinical Trials (HEAL®) *Lead: Ram Arudchandran*
17. HEAL® Initiative: Individual Differences in Human Pain Conditions and Comorbidities *Leads: Sarah Woller/D.P. Mohapatra*
18. The HEAL® Initiative Partnerships to Advance Interdisciplinary (PAIN) Training in Clinical Pain Research *Lead: Laura Wandner*
19. Reissue: Blood Brain Barrier Response to Antibodies Targeting Beta-Amyloid *Lead: Roderick Corriveau*
20. Development & Characterization of Experimental Models of Post-TBI ADRD *Lead: Hibah Awwad*
21. Neuropathological Interactions Between COVID-19 and ADRD *Leads: Linda McGavern/Becky Roof*
22. Reissue: Early-Stage Therapy Development for ADRD *Lead: Becky Roof*
23. Reissue: Genome Editing for ADRD *Leads: Timothy LaVaute/Chris Boshoff*

24. Investigating Distinct and Overlapping Mechanisms in TDP-43 Proteinopathies, Including in LATE, FTD, and other ADRDs *Lead: Linda McGavern*
25. Mechanistic Investigations into ADRD Multiple Etiology Dementias *Lead: Linda McGavern*
26. Multi-Target Validation for ADRD *Lead: Becky Roof*
27. Neuropathological Interactions Between COVID-19 and ADRD *Lead: Will Daley*
28. Reissue: PET Ligand Development for the ADRDs *Lead: Deb Babcock*

The council voted to approve proposed concepts 5–28.

VIII. Adjournment

The meeting was adjourned at 6:02 p.m. on Wednesday, February 1, 2023.

IX. Review of Conflict of Interest, Confidentiality, and Council Procedures; Council Consideration of Pending Applications

This portion of the meeting is being closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. §§ 1001-1014 and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

Conflict of Interest – Regulations concerning conflict of interest were reviewed. Council members were reminded that materials furnished for review purposes and discussion during the closed portions of the meeting are considered privileged information. All Council members present signed a statement certifying that they had not been involved in any conflict-of-interest situations during the review of grant applications.

Confidentiality – During the closed session, any information that is discussed and the outcome of any recommendation are considered privileged information. They may not be discussed outside of the closed session. If an applicant requests support for his or her application from a Council member, the Council member must respond that he/she is not permitted to discuss the application. Any inquiry should be referred to Dr. Robert Finkelstein, NINDS Advisory Council Executive Secretary, who then will refer the question to the appropriate staff member for response.

Research Training and Career Development Programs – The Council reviewed a total of 330 research career development and institutional training grant applications with primary assignment to NINDS, and 199 of them (60 percent) were scored in the amount of $35.1 million first-year direct costs. It is anticipated that, of the research career development and institutional training grant applications competing at this Council, NINDS will be able to pay first-year direct costs of approximately $8.7 million (92 grants).

Research Project and Center Awards – The Council reviewed a total of 1,491 research project and center applications with primary assignment to NINDS, and 870 of them (58 percent) were scored/percentiled in the amount of $375.4 million first-year direct costs. It is anticipated that,

of the research grants competing at this Council, NINDS will be able to pay first-year direct costs of approximately $73.4 million (240 grants).

Senator Jacob Javits Neuroscience Investigator Awards – The Senator Jacob Javits Neuroscience Investigator Awards are made to distinguished investigators who have a record of scientific excellence and productivity, who are actively pursuing an area of research of strategic importance, and who can be expected to continue to be highly productive for a seven-year period. Candidates are nominated and selected at each Council meeting. Council approved one Javits nomination at this meeting: John Byrne, Ph.D. (University of Texas Health Center Houston)

Small Business Innovation Research and Small Business Technology Transfer Award Programs – The Council reviewed a total of 167 Small Business Innovation Research (SBIR) and Small Technology Transfer Award (STTR) grant applications with primary assignment to NINDS, and 90 of them (54 percent) were scored in the amount of $46.4 million first-year direct costs. It is anticipated that, of the SBIR and STTR applications competing at this Council, NINDS will be able to pay first-year direct costs of approximately $3.4 million (5 grants).

X. Adjournment

The meeting was adjourned at 3:53 p.m. on Thursday, February 2, 2023

NINDS employees present for portions of the meeting included:

Open Session:

Sue Ano
Ram Arudchandran
Eric Atkinson
Taryn Aubrecht
Hibah Awwad
Debra Babcock
Julia Bachman
Farah Bader
Rebecca Baker
Linda Bambrick
Elena Barnaeva
Jennifer Barnes
Janna Belsen-Ehrlich
Janna Belser-Ehrlich
Jonathan Bennett
Ros Benson
Richard Benson
William Benzing
Victoria Bitzer-Wales
Melissa Bojos
Marci Bollt
Carolyn Bondar
Naomi Booker
Francesca Bosetti
Chris Boshoff
Edith Brignoni Perez
Steve Britt
Jeremy Brown
Erin Bryant
Ryan Calabrese
Roger Campbell
Emily Caporello
Maria Charlier
Denise Chatman
Thomas Cheever
Andrew Chen

Daofen Chen
Bo-Shiun Chen
Sophie Cho
Ben Churn
Christopher Conrad
Rebekah Corlew
Devon Crawford
Charles Cywin
William Daley
Sara Dauber
Dana Day
Alexander Denker
Vedangi Desai
Neel Dhruv
Alicia Diggs
Dana DiScenza
Sara Dodson
Anthony Domenichiello
Adele Doperalski
Denise Dorsey
Argenia Doss
Oksana Dukhanina
Kristin Dupre
Jaclyn Durkin
Ana Ebrahimi
Debbie Eng
Judy Fabrikant
Christina Fang
Carlos Faraco
Cassandra Fields
Robert Finkelstein
Claudia Figueroa-Romero
Nhi Floyd
Jessica Forbes
Jane Fountain
Captioner Fran
Megan Frankowski
Sonia GALES
Alissa Gallagher
Lina Garcia
Shannon Garnett
Hermon Gebrehiwet
Annette Gilchrist
Marie Gill
Jordan Gladman
Jim Gnadt
Maureen Gormley
Amelie Gubitz
Joseph Hall
Maureen Hambrecht
Kristina Hardy
Adam Hartman
Brandon Hartsell
Brian Haugen
Jane Hettinger
Lanier Heyburn
David Higgins
Rebecca Hommer
Mir Ahamed Hossain
Mariah Hoye
Nina Hsu
Eric Hudak
Xan Humphries
Sarah Hutchison
Smriti Iyengar
Scott Janis
Lyn Jakeman
David Jett
Lisa Joliet
Kevin Jones
Lataisia Jones
Michelle Jones-London
Barbara Karp
Cory Kelly
Brenda Kibler
Jenny Kim
Sandeep Kishore
Brian Klein
Yasmin Kloth
Jim Koenig
Stephen Korn
Walter Koroshetz
Svetlana Kotliarova
Jonathan Kreisler
Sahana Kukke
Pascal Laeng
Christine Lam
Nick Langhals
Nick Langhals
Crystal Lantz
Timothy LaVaute
Crystal Lee

Miriam Leenders
Janelle Letzen
Catherine Levy
Erica Littlejohn
Cara Long
Rosa Lopez
Quynh Ly
Tim Lyden
Ernie Lyons
Laura Mamounas
Gary Marlowe
Heidi Matos Galicia
Marguerite Matthews
Amber McCartney
Linda McGavern
Barbara McMakin
Carolina Mendoza-Puccini
Mirela Milescu
Daniel Miller
DP Mohapatra
Sandra Molina
Karen Molina
Joseph Monaco
Marilyn Moore-Hoon
Jill Morris
Cristina Nigro
Glen Nuckolls
Glen Nuckolls
John Ogawa
Joan Ohayon
Ana Olariu
Lola Olufemi
Oreisa O'Neil
Jiaqi O'Reilly
Leslie Osborne
Michael Oshinsky
David Owens
Nia P
Lax Pandeyl
Tatiana Pasternak
Mary Pelleymounter
Marlene Peters-Lawrence
Leah Pogorzala
Linda Porter
Kevin Powell
Kevin Powell
Pragya Prakash
Michele Pucak
CJ Puttaswamy
Elizabeth Quartey
Carlo Quintanilla
Shamsi Raeissi
Shanta Rajaram
Nagarajan Rangarajan
Yogendra Raol
Alva Recinos
K. Paul Rezaizadeh
Ryan Richardson
Robert Riddle
Becky Roof
Fernanda Ruiz
Cheryse Sankar
Lumy Sawaki-Adams
Joel Saydoff
Iqbal Sayeed
Alisa Schaefer
Paul Scott
Nilkantha Sen
Shalini Sharma
Kelly Sheppard
Arvind Shukla
Andrew Siddons
Beth-Anne Sieber
Beth-Anne Sieber
Shai Silberberg
Shai Silberberg
Adissa Silue
Maryann Sofranko
Shardell Spriggs
Rukma Sripathi
Natalia Strunnikova
Abhi Subedi
Tao Sun
Maripierre Surpris
Christine Swanson-Fischer
Zachary Sweet
Elizabeth Sypek
Edmund Talley
Amir Tamiz
Anna Taylor
James Taylor
Carol Taylor-Burds

Michael Tennekoon
Shruthi Thomas
Christine Torborg
Laurie Torchinsky
Jose Toro
Delany Torres
Natalie Trzcinski
Eric Tucker
William Tyler
Lauren Ullrich
George Umanah
Nsini Umoh
Ursula Utz
Nasim Vahidi
Andrea Varea
Joanna Vivalda
Tam Vo
Laura Wandner
Tish Weigand
Rachel Weinberg
Samantha White
Matthew White
Vicky Whittemore
Shellie Wilburn
Sarah Woller
Ling Wong
Alynda Wood
Clinton Wright
Patrick Wright
Xiling Yin
Monique Young
Kathryn Zaletel
Ariel Zane
Arlene Zheng

Closed Session:

DeAnna Adkins
Ram Arudchandran
Taryn Aubrecht
Hibah Awwad
Debra Babcock
Julia Bachman
Linda Bambrick
Roger Bannister
Elena Barnaeva
Jennifer Barnes
Andrea Beckel-Mitchener
Janna Belser-Ehrlich
Karrah Benson
William Benzing
Victoria Bitzer-Wales
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Roger Campbell
Emily Caporello
Stacey Chambers
Chi Chang
Maria Charlier
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Sara Dodson

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Jaclyn Durkin
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Judy Fabrikant
Christina Fang
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Jane Fountain
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Alissa Gallagher
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Hermon Gebrehiwet
Annette Gilchrist
Marie Gill
Jordan Gladman
Jim Gnadt
Patrice Gray
Brooks Gross
Amelie Gubitz
Joseph Hall
Maureen Hambrecht
Adam Hartman
Brandon Hartsell
Brian Haugen
Janet He
Jane Hettinger
Lanier Heyburn
Rebecca Hommer
Mariah Hoye
Nina Hsu
Eric Hudak
Xan Humphries
Sarah Hutchison
Smriti Iyengar
Scott Janis
David Jett
Li Jia
Lataisia Jones
Kevin Jones
Michelle Jones-London
Barbara Karp
Brenda Kibler
Jenny Kim
Sandeep Kishore
Brian Klein
Jim Koenig
Alexei Kondratyev
Stephen Korn
Svetlana Kotliarova
Sahana Kukke
Pascal Laeng
Christine Lam
Nick Langhals
Crystal Lantz
Timothy LaVaute
Crystal Lee
Miriam Leenders
Janelle Letzen
Catherine Levy
Nina Lichtenberg
Erica Littlejohn
Cara Long
Rosa Lopez
Quynh Ly
Laura Mamounas
Gary Marlowe
Heidi Matos
Amber McCartney
Linda McGavern
Barbara McMakin
Carolina Mendoza-Puccini
Mirela Milescu
Daniel Miller
Joseph Monaco
Jill Morris
Cristina Nigro
Glen Nuckolls
John Ogawa
Joan Ohayon
Ana Olariu
Oreisa O'Neil
Jiaqi O'Reilly
Leslie Osborne
Michael Oshinsky
Kathy Partlow

Tatiana Pasternak
Michele Pearson
Mary Pelleymounter
Marlene Peters-Lawrence
Leah Pogorzala
Linda Porter
Pragya Prakash
Michele Pucak
Carlo Quintanilla
Shamsi Raeissi
Shanta Rajaram
Nagarajan Rangarajan
Yogendra Raol
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Elyse Schauwecker
Paul Scott
Nilkantha Sen
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Arvind Shukla
Beth-Anne Sieber
Shai Silberberg
Shai Silberberg
Adissa Silue
Shardell Spriggs
Natalia Strunnikova
Abhi Subedi
Luis Sullivan
Tao Sun
Maripierre Surpris
Christine Swanson-Fischer
Elizabeth Sypek
Edmund Talley
Laurent Taupenot
James Taylor
Carol Taylor-Burds
Michael Tennekoon
Shruthi Thomas
Christine Torborg
Delany Torres
Natalie Trzcinski
Eric Tucker
William Tyler
Lauren Ullrich
George Umanah
Nsini Umoh
Ursula Utz
Nasim Vahidi
Andrea Varea
Joanna Vivalda
Tam Vo
Laura Wandner
Anne-Sophie Wattiez
Tish Weigand
Rachel Weinberg
Samantha White
Vicky Whittemore
Shellie Wilburn
Sarah Woller
Ling Wong
Alynda Wood
Xiling Yin
Ariel Zane
Wei-Qin Zhao

Other federal employees present for portions of the meeting included:

Wei-Qin Zhao, CSR
Roger Bannister, CSR
Kathy Partlow, CSR
Laurent Taupenot, CSR
Alexei Kondratyev, CSR
Anne-Sophie Wattiez, CSR

Carole Jelsema, CSR
Aleksey Kazantsev, CSR
Suzan Nadi, CSR
Elyse Schauwecker, CSR
Bernard Srambical-Wilfred, CSR

We certify that, to the best of our knowledge, the foregoing minutes and attachments are accurate and complete.

4/10/2023
_____
Date

_____
Robert Finkelstein, Ph.D.
Executive Secretary
National Advisory Neurological Disorders and Stroke Council

Director, Division of Extramural Activities
National Institute of Neurological Disorders and Stroke

4/10/2023
_____
Date

_____
Walter Koroshetz, M.D.
Chairperson
National Advisory Neurological Disorders and Stroke Council

Director
National Institute of Neurological Disorders and Stroke

These minutes will be formally considered by the Council at its next meeting. Corrections or notations will be incorporated in the minutes of that meeting.