Department Of Health and Human Services Public Health Service National Institutes of Health National Advisory Neurological Disorders and Stroke Council

Summary of Meeting¹ February 14-15, 2024

The National Advisory Neurological Disorders and Stroke (NANDS) Council was convened for its 222nd meeting on February 14-15, 2024, in person and via Zoom. 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 14, 2024: 1:00 p.m. to 5:09 p.m. for the review and discussion of program development, needs, and policy; and

Closed: February 15, 2024: 1:00 p.m. to 2:15 p.m. for the consideration of individual grant applications.

Council members present:	Ad Hoc Council Members:
Dr. Amy Brin	Daniel Doctoroff
Dr. Robert Brown Jr.	Dr. Florian Eichler
Dr. Yishi Jin	Dr. Robert Gereau
Dr. Jane Larkindale	Dr. Frances Jensen
Dr. Jin-Moo Lee	Dr. Amy McGuire
Dr. John Maunsell	Kate Nicholson
Dr. Louise McCullough	Ms. Christin Veasley
Dr. Hank Paulson	
Dr. Gina Poe	Ex officio members present:
Dr. Ekemini Riley	Dr. David Brody
Dr. Timothy Ryan	Dr. Christopher Bever, Jr.
Dr. Sameer Sheth	

Council Roster (Attachment 1) NINDS employees in attendance (Attachment 2)

The meeting was held at the Neuroscience Center and virtually via Zoom.

¹For 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.

I. Call to Order and Opening Remarks

Dr. Koroshetz welcomed Council members, visitors, and staff to the 222nd meeting of the National Advisory Neurological Disorders and Stroke (NANDS) Council and introduced six new Ad-Hoc Council members.

II. Report of the Interim Director, Division of Extramural Activities, NINDS

Dr. David Owens, Acting Director, Division of Extramural Activities, NINDS

- A. Approval of Council Minutes Dr. Owens requested, and the Council voted to approve the August 24, 2023, and September 6-7, 2023 Council meeting minutes.
- B. The following future Council meeting dates were confirmed:

Wednesday and Thursday, May 15-16, 2024 Wednesday and Thursday, September 4-5, 2024 Wednesday and Thursday, February 12-13, 2025 Wednesday and Thursday, May 14-15, 2025 Wednesday and Thursday, September 3-4, 2025

C. Other Items

Expedited Review Process — In advance of each Council meeting, a subset of Council members are asked to approve a certain number of grant applications. This expedited review process focuses on applications with scores within the payline for which there are no unresolved issues. During this Council round, there were 118 applications that were eligible to be expedited. Dr. Owens thanked Council members Tim Ryan, Amy Brin, and Louise McCullough for their review of these applications

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

Council Operating Procedures – Council Operating Procedures were posted to the NINDS ECB. There was one modification, which was to place R13 conference grants under NINDS delegated authority up to \$50,000 direct costs per year. The Council voted to approve this modified Council Operating Procedure.

I. Report of the Director, NINDS

Dr. Walter Koroshetz, Director, NINDS

NIH and NINDS Leadership Changes – Dr. Koroshetz announced that Dr. Monica Bertagnolli was <u>confirmed</u> as the 17th NIH Director in November 2023. Two of Dr. Bertagnolli's guiding principles as NIH Director were the inclusion of research participants from all areas of the country and new tools, such as artificial intelligence (AI) and machine learning, to analyze large datasets. In addition, Dr. Tara Schwetz was named Director of NIH's Division of Program Coordination, Planning, and Strategic Initiatives; Dr. Kimryn Rathmell was named Director of the National Cancer Institute (NCI); and Dr. Sean Mooney was named Director of NIH's Center for Information Technology (CIT).

At NINDS, Dr. Dave Owens was appointed as Acting Director and Dr. Anna Taylor as Acting Deputy Director of the Division of Extramural Activities. Dr. Koroshetz announced that NIH was seeking a

Director for the Clinical Translational Intramural Program of the <u>Center for Alzheimer's and Related</u> <u>Dementias (CARD)</u>.

NINDS Budget — Dr. Koroshetz reviewed the fiscal year (FY) 2024 appropriations for NIH and NINDS, which were operating under a <u>continuing resolution</u> that was set to expire on March 8, 2024. The Senate Mark is proposing increases to HEAL, AD/ADRD and Undiagnosed Disease Network (UDN) appropriations as well continued funding of \$75M for <u>Accelerating Access to</u> <u>Critical Therapies for ALS Act</u>.

There was a possibility that the NINDS budget would drop by 1%, approximately \$21 million, if Congress does not pass a budget by May 1, 2024. Concurrent with these budget changes is a steady increase in the requested budget for applications, due to increasing costs for conducting research. The increase in total requested costs from applications to NINDS in 2024 is 13%.

Dr. Koroshetz reviewed options for managing potential budget cuts and noted the importance of messaging the value of NIH research to Congress.

Special Council Review Policy — The current threshold for NINDS grantees to undergo Special Council Review was \$2 million in NIH-funded total costs, including costs included in the pending grant application. By May 2024, NINDS will reduce this threshold to \$1.5 million total costs, excluding the pending grant application. NINDS will publish a notice to inform the community of this proposed change which will go into effect starting with May 2024 Council.

Helping to End Addiction Long-term (HEAL) INITIATIVE * 2.0 — NINDS and the National Institute on Drug Abuse (NIDA) co-lead the <u>HEAL Initiative</u> in collaboration with a committee of 14 NIH Institutes and Centers (IC) Directors (the HEAL Pain IC Directors' Committee), which was looking to engage NANDS Committee members to provide input on the strategic plan to guide research priorities. In addition to Council input, a Request for Information would be released to solicit input from the community.

Brain Research Through Advancing Innovative Neurotechnologies (BRAIN®) Initiative — The <u>BRAIN® Initiative</u> has supported several studies that have revolutionized the ability to understand the neural circuits that underlie complex behaviors in disease and led to important advances in diagnostics and therapies. Over the past several years, the BRAIN® Initiative has been funded through a combination of base funding and funds from the 21st Century Cures Act. In FY 2023, base funding for the BRAIN® Initiative was substantially reduced. Since the Cures Act funds decrease in 2024 and will end in FY 2026, there is a critical need to increase the base funding for the BRAIN® Initiative to continue its important scientific advances. There have been significant scientific advances from BRAIN® with publications in Nature and Science. A study funded by the BRAIN® Initiative demonstrated spinal cord stimulation is an emerging therapy for <u>paralysis after stroke and spinal cord injury.</u>

Working Groups — In December 2023, the <u>NIH Advisory Council to the Director (ACD) Working</u> <u>Group on Re-envisioning NIH-Supported Postdoctoral Training</u> released its <u>report of</u> <u>recommendations</u>, which called for increased pay and benefits, increased grant support, facilitated transition into next career stages, training and professional development, and a safe and diverse research environment. The <u>ACD Working Group on Catalyzing the Development and Use of Novel</u> <u>Alternative Methods (NAMs) to Advance Biomedical Research</u> also released a <u>report of</u> recommendations in December 2023. One such effort in NAMs was the NIH Common Fund's <u>Complement Animal Research In Experimentation (Complement-ARIE) Program</u>, which focused on new biomedical research models to accelerate the understanding of human health and disease. The <u>Fundamental Neuroscience Working Group (FNWG) of Council</u> released their <u>final report of</u> <u>recommendations</u> in September 2023. The next steps for the FNWG were to prioritize and operationalize these recommendations. The <u>NANDS Council Working Group for myalgic</u> <u>encephalomyelitis/chronic fatigue syndrome (ME/CFS)</u> was developing a Research Roadmap and sought <u>public input</u> on research priorities.

NINDS Turns 75 in 2025 — Dr. Koroshetz announced that NINDS will celebrate its 75th anniversary in 2025 and asked Council members to provide input on how to celebrate past accomplishments and forge future priorities for neuroscience.

Upcoming Meetings — Dr. Koroshetz reviewed upcoming events, including <u>the Team Science to</u> <u>Advance Neural Exposome Research</u> workshop on February 29, 2024; the <u>Advancing Health Equity</u> <u>in Pain Management</u> videocast on March 13, 2024; and the <u>American Academy of Neurology Pre-</u> <u>Conference: Understanding and Advancing Neuropalliative Care and Aging Research</u> on April 12. 2024.

Science Highlights — Dr. Koroshetz provided highlights of NINDS-funded research, including an <u>supplemental issue</u> in *Neurology* focused on health equity, a <u>study in *Lancet Neurology*</u> on a genetic training program in Africa to identify linkages to Parkinson's disease, a <u>study in *Nature Medicine*</u> on a spinal cord stimulator, a <u>study in *Nature Neuroscience*</u> on intracranial recordings in chronic pain states, a <u>study in *Neurology, Neuroimmunology, & Neuroinflammation* on spinal fluid abnormalities in long COVID, a <u>study in *Lancet Neurology*</u> on chimeric antigen receptor (CAR) T cells in myasthenia gravis, and a <u>study in *Nature Immunology*</u> on the role of microglia in repairing damaged brain vasculature. Dr. Koroshetz also reviewed three studies on TDP-43 in <u>Science</u> <u>Translational Medicine, Science</u>, and <u>Molecular Neurodegeneration</u>.</u>

II. Discussion of Director's Report

Several Council members expressed concern about potential budget cuts and mitigation strategies such as administrative cuts. Council members suggested that lowering the NIH budget threshold for pre-submission approval of large budget grant applications could help investigators adjust their scope of work and scientific aims. Dr. Koroshetz emphasized an ongoing commitment to early-stage investigators as an investment in the future and the importance of not exerting budget caps in a way that would curtail important, but more expensive, research.

A Council member asked about the implementation of the recommendation to increase postdoctoral benefits and salaries within an environment of decreasing budgets. Dr. Koroshetz said that most NIH-funded postdoctoral investigators were funded through grants and not fellowship grants. The aim of the recommendation was to raise postdoctoral benefits and salaries to the same level as fellowship grants.

A Council member raised a question about how NINDS was responding to the numerous recent reports of plagiarism and AI methods to detect plagiarism. Dr. Koroshetz answered that NIH took two approaches—a confidential system to investigate and act on such allegations and an

educational initiative to promote scientific rigor. The Council member suggested that a proactive approach may be best because the recent allegations were related to prominent investigators.

III. New Directions in Musculoskeletal Pain Research

Dr. Helene M. Langevin, Director, National Center for Complementary and Integrative Health

Dr. Langevin talked about two overarching gaps in pain research: 1) connecting the nervous system with musculoskeletal tissue and 2) understanding and preventing endogenous pain from acute to chronic musculoskeletal pain transition. Traditionally, pain research had been focused on the neuro-psycho-social environment of pain—how the nervous system mediates the development of chronic pain and the emotional mechanisms associated with suffering. Many measures of the neuro-psycho-social environment of pain included patient-reported outcomes such as mood effects, sleep, and cognitive function; neuroimaging to quantify sensory experiences; and systemic factors such as blood markers.

A more holistic approach to understanding pain would also involve musculoskeletal tissues. For instance, the orthopedic approach to a patient with knee pain would focus on the articulating bone or cartilage. However, the knee pain might also be affected by the peripheral tissues, such as the joint capsules, ligaments, tendons, muscles, fascia, and connective tissue. Within these tissues were nociceptors (a type of sensory neuron) that communicate the sensation of pain. Some tissues, such as adipose tissue, can contribute to an inflammatory response. Tissues also had important mechanical and structural relationships to each other. When tissues lacked mobility, whether from inflammation or adhesion, it could affect how the nociceptors respond within those tissues.

Dr. Langevin talked about the need to prevent and resolve endogenous pain. There was a sensitive period between illness and return to health (i.e., convalescence), during which some recovered fully, and others experienced a post-acute syndrome of continued symptoms. There was very little research on the peripheral tissues that contribute to pain resolution or continuation. Movement, mechanical stimulation, stress management, and sleep may be very important factors during the recovery period that can preserve long-term joint health.

The HEAL Initiative had been an important program for understanding how tissues impact pain. For example, the <u>Restoring Joint Health and Function to Reduce Pain (RE-JOIN) program</u> within the HEAL Initiative focused on sensory innervation within joint tissues. The <u>Back Pain Consortium</u> (<u>BACPAC</u>) was another HEAL Initiative program that focused on the development of models to integrate different factors, including tissues, involved in back pain. In July 2023, the HEAL Initiative hosted the <u>Understanding and Restoring Whole Joint Health in Pain Management workshop</u>. Dr. Langevin expressed appreciation for the HEAL Initiative in working toward a better understanding of how peripheral tissues impact pain and pain resolution.

Discussion

A Council member asked whether there were efforts to research the role of genetics and central nervous system (CNS) dysfunction to better understand who can prevent chronic pain from developing and who cannot. Dr. Langevin said that one of the unanswered research questions was

if some people had a genetic predisposition to developing chronic pain regardless of therapeutic approaches or time in convalescence. Genetics could not only impact pain pathways, but also musculoskeletal tissues. For example, a person with a hypermobility spectrum disorder, such as Ehlers-Danlos syndrome, would be predisposed to joint instability and injury.

A Council member asked about the future of wearable technology to measure mobility, shear stress, and inflammation. Dr. Langevin answered that the future of wearables for measuring myofascial pain was near, and that there was a need for identifying the right measures to support the development of wearable technologies. Another Council member suggested that measuring as much as possible would help the field understand the many factors involved in recovery. Dr. Langevin agreed and emphasized that helping people understand how their bodies were reacting during good versus bad days would help their recovery.

A Council member asked how musculoskeletal manipulations helped in pain resolution. Dr. Langevin clarified that not all mechanical forces acted in the same way. There could be a difference between how inflammatory versus anti-inflammatory cytokines responded to large or small mechanical forces. For example, a recent study found that a very small mechanical force resulted in reduced inflammation and faster muscle recovery. The study also showed that dextran cleared from tissue faster in response to the mechanical force, which could be an important mechanism for moderating the effects of injury.

IV. HEAL Pain Preclinical and Translational Research

Dr. Michael Oshinsky, Director, NINDS Office of Preclinical Pain Research

Dr. Oshinsky provided an update on preclinical and translational pain research within the HEAL Initiative. The aim of HEAL's pain research was to develop novel, effective, and non-addictive pain treatments. A recent study found that there was a significant difference between the success of pain treatments that had high abuse potential (nearly 30% success) compared to those with low abuse potential (less than 5% success). There was therefore a need to facilitate and de-risk the development of novel pain treatments with low abuse potential to accelerate pre-clinical trials and entry into commercialization. More than 50 targets were in the validation stage, most of which underwent thorough abuse liability testing to eliminate those with high abuse potential.

Dr. Oshinsky reviewed some key highlights of the program. The <u>Program to Reveal and Evaluate</u> <u>Cells-to-gene Information that Specify Intricacies, Origins, and the Nature of Human Pain</u> (PRECISION) Pain Network aimed to generate datasets of cell types, their molecular signatures, and their functional phenotypes. These data were housed in data coordination centers using the <u>SPARC</u> <u>portal</u> as a sharing platform to help drug development researchers ensure that their targets existed in human tissues and cells. The Restoring Joint Health and Function to Reduce Pain (<u>RE-JOIN</u>) Consortium was an example of a program that shared data on human tissues involved in pain.

The <u>HEAL Pain Therapeutics Development Program (PTDP)</u> is a flagship program that supported both early translation and lead selection efforts to develop biologic and small molecule therapeutics. The PTDP has a diverse range of innovative targets and 17 therapeutic modalities, two of which were poised for Investigational New Drug (IND) submission in February 2024—

intrathecal delivery of nociceptin-1 agonist for chronic, severe back pain and MNK-1 inhibitors for neuropathic pain. The <u>Preclinical Screening Platform for Pain (PSPP)</u> program is evaluating 31 assets and had a public-facing website that housed data for the methods and controls used in validation studies so that other researchers could use the same techniques. Dr. Oshinsky reviewed a new R15 concept to support underrepresented pain researchers and trainees to build collaborative teams focused on translational research projects. He also reviewed a reissue R61/R33 program to enable the development of analgesics.

Discussion

A Council member asked for specific examples of targets that had worked well in animal models but not in human tissue. Dr. Oshinsky answered that substance P antagonist was one example of a target that worked very well in animal models but reacted differently in humans. The primary goal of the PRECISION Pain Network was to identify these differences early to prevent such targets from going to clinical trial.

V. HEAL Pain Clinical Research

Dr. Linda Porter, Director, Office of Pain Policy and Planning

Dr. Porter provided a brief overview of population levels of pain in the U.S. Pain was the most common reason people sought medical help. 2020 <u>National Health Interview Survey (NHIS) data</u> indicated that approximately 50 million adults in the U.S. reported chronic pain over the last three months, more than half of whom were affected daily by severe pain. A recent <u>study</u> showed that once a person had pain, it tended to increases in intensity over time. Further, the new incidence of chronic and high impact chronic pain had increased significantly from 2019 to 2020. Chronic pain also disproportionately impacted rural populations, who also experienced more barriers to accessing pain care. Women were more likely than men to experience chronic pain conditions such as migraine, pelvic pain, temporomandibular disorder, trigeminal neuralgia, irritable bowel syndrome, and fibromyalgia.

The HEAL Initiative had a <u>robust portfolio</u> of chronic pain research at varying stages of the clinical trial process. For example, the Integrative Management of chronic Pain and OUD for Whole Recovery (IMPOWR) and the Multilevel Interventions to Reduce Harm and Improve Quality of Life for Patients on Long Term Opioid Therapy (MIRHIQL) <u>programs</u> aimed to identity best practices for delivering care to people who had or were at-risk of substance use disorder. There were also several studies centered on health equity in pain and comorbid conditions. The <u>Native Collective</u> <u>Research Effort to Enhance Wellness (N CREW)</u> Program was a new initiative that addressed the high rate of overdose deaths among Native Americans and supported research priorities identified by Tribes and Native American Serving Organizations.

HEAL also supported large comparative effectiveness studies across different pain conditions. Two early phase trials were near completion—the <u>Early Phase Pain Investigation Clinical Network (EPPIC-Net)</u> that was testing a novel target for knee osteoarthritis pain and the <u>Hemodialysis Opioid</u> <u>Prescription Effort (HOPE)</u> focused on self-management strategies for weaning off opioid use. There were also clinical trials exploring the identification of biomarkers through wearable devices, for specific conditions and clinical trials, and for latent and painful myofascial tissues. The HEAL

Initiative also supported workforce enhancement efforts such as the <u>K-12 National Clinic Pain</u> <u>Career Development Program</u>, the <u>Positively Uniting Researchers of Pain to Opine, Synthesize, &</u> <u>Engage (PURPOSE)</u> Network, <u>K99/R00 grants for Independent Basic Experimental Studies with</u> <u>Humans</u>, and <u>T90/R90 training grants</u> for postdoctoral pain researchers. Dr. Porter reviewed several reissued programs for 2025 and 2026, as well as new concepts such as the <u>NIH-DoD-VA</u> <u>Pain Management Collaboratory</u> and eight K23/K08 awards for career development in pain research.

Discussion

Council members commended the efforts to support early investigators and asked about the challenges in recruiting the next generation of pain researchers. Dr. Porter said that a survey of different professional organizations found that pain researchers felt they were not well supported. In addition, clinical pain researchers tended to be clinicians who found it challenging to find time to conduct research. Another challenge for researchers was finding a program that supported the multidisciplinary nature of pain research. The new T90/R90 program required that trainees receive training in both standard pain research, as well as important disciplines related to pain. Dr. Oshinsky added that there was a disconnect between the type of pain research being conducted and the type of research needed by industry. New funding announcements had encouraged people toward the type of target validation studies that were needed to move targets into the market.

Dr. Koroshetz noted that one of the challenges for neurologists was that reimbursement for pain treatment had mostly moved into procedural pain centers. A Council member agreed and asked whether there could be a program to link neurologists with peripheral pain researchers to bring the two fields together. Dr. Oshinsky reviewed different efforts within HEAL to bring together the research in neurological conditions, such as migraine or trigeminal neuralgia, and pain research. Dr. Porter added that the PURPOSE Network could be a good way to link the two disciplines. A Council member talked about efforts in the K-12 program to link researchers with clinical, community, and patient mentors who have enhanced pain research with lived experience perspectives.

VI. Initiatives for Concept Clearance

Dr. David Owens, Acting Director, Division of Extramural Activities, NINDS

Concept 1: Reissue—NINDS Program Project Grant (P01)

Lead: Dr. Alisa Schaefer, Program Director, Division of Extramural Activities

Dr. Owens said that this concept was ready to sunset because the number of applications and awards had declined significantly. He asked Council whether they would prefer the concept to not be reissued at all, or be re-issued for two, or five additional receipt dates.

Council members expressed a preference for two receipt dates. Dr. Owens emphasized NINDS would alert the community of the sunsetting.

Concept 2: New—Institutional Research Training Program for Neurological Health Disparities/ Health Equity (HD/HE) Research

Dr. Cheryse Sankar, Program Director, Office of Global Health & Health Disparities Dr. Tish Weigand, Program Director, Office of Training & Workforce Development

The purpose of this concept was to provide comprehensive training and development to early investigators in neurological health disparities in health research. The training would: 1) be anchored in research projects focused on disparities in neurological health; 2) provide additional training, strategies, and approaches for bi-directional communication and engagement with the community and people with lived experience; 3) provide education into the culture, race, discrimination, and root causes of health disparities; and 4) provide training in research methods critical for health disparities and health equity research.

Discussion

Council members expressed support for this concept. Some Council members suggested that there may be some communities that were primed for this type of research and others that needed more infrastructure. There was some concern about ensuring that the grant mechanism reached the right people needed to navigate health equity. Council members recommended reaching out to community organizations and community health workers to help bridge researchers to the community. Another suggestion was to promote partnerships with universities primed to conduct health disparities research.

Dr. Koroshetz pointed out that the grant mechanism was an important consideration. For instance, T32 grants did not allow non-citizens to apply. Dr. Weigand suggested that a number of mechanisms could be used to maximize and target the right groups.

Council voted to approve the proposed concept.

Concept 3: Alzheimer's Disease-Related Dementias (ADRD) Program

Dr. Roderick Corriveau, Program Lead, AD/ADRD Program

The ADRD Program was a large effort involving several reissued and new concepts. These concepts were aligned with recommendations and milestones that were made at the ADRD Summit in 2022 through robust discussion by Program Directors and input from the NIA and NINDS Directors.

Council voted to approve the proposed concepts.

Additional Concepts:

- 4. Reissue: Amyotrophic Lateral Sclerosis (ALS) Intermediate Patient Population Expanded Access (U01 Clinical Trial Required) *Lead: Lumy Sawaki-Adams*
- 5. Reissue: NINDS Faculty Development Award to Promote Diversity in Neuroscience Research (K01) *Lead: Lauren Ulrich*
- 6. Reissue: Materials to Enhance Training in Experimental Rigor (METER) (UE5 Clinical Trial Not Allowed) *Lead: Devon Crawford*
- 7. Reissue: Summer Research Education Experience Program (R25) *Lead: Marguerite Matthews*
- 8. Reissue: SuRE Program Lead: Lauren Ulrich
- 9. Reissue: Child Neurologist Career Development Program (CNCDP) [K12] Lead: K Rezaizadeh

- 10. Reissue: Joint NINDS/NIMH Exploratory Neuroscience Research Grant (R21 Clinical Trial Not allowed) *Lead: Alisa Schaefer*
- 11. Reissue: Single Source for completion of the Hyperbaric Oxygen Brain Injury Treatment (HOBIT) Trial (U01) *Lead: Gretchen Scott*
- 12. Reissue: Re-issuing of NINDS Ruth L. Kirschstein National Research Service Award (NRSA) for Training of Postdoctoral Fellows (F32) *Lead: Michael Tennekoon*
- 13. Reissue: The NINDS Human Cell and Data Repository (U24 Clinical Trial Not Allowed) Lead: Rebecca Price
- 14. Reissue: Blueprint Neurotherapeutics Network (BPN) Biologic-based Drug Discovery and Development for Disorders of the Nervous System NOFOs (PAR-21-163 PAR-21-233) *Lead: Kelly Sheppard*
- 15. Reissue: NINDS Renewal Awards of SBIR Phase II Grants (Phase IIB) for Clinical Trials and Clinical Research (R44 Clinical Trial Optional) *Lead: Emily Caporello*
- 16. Reissue: NINDS Renewal Awards of SBIR Phase II Grants (Phase IIB) for Pre-Clinical Research (R44 Clinical Trial Not Allowed) *Lead: Emily Caporello*
- 17. Reissue: Innovation Grants to Nurture Initial Translational Efforts (IGNITE) NOFOs (PAR-21-122, PAR-21-123, PAR-21-124) *Lead: Becky Roof*
- 18. Reissue: NINDS Program Project Grant (P01 Clinical Trial Optional) (PAR-21-181) Lead: Alisa Schaefer
- 19. New: Blueprint Neurotherapeutics Network (BPN) Biologic-based Drug Discovery and Development for Disorders of the Nervous System NOFOs (PAR-21-163 PAR-21-233) *Lead: Will Daley*
- 20. New: NINDS Exploratory Grant Program in Myalgic Encephalomyelitis/Chronic Fatigue Syndrome Research (P20- Clinical Trial Optional) *Lead: Vicky Whittemore*

The Council voted to approve proposed new and re-issue concepts.

VII. 75th Anniversary

Ms. Alissa Gallagher, Director, Office of Neuroscience Communication & Engagement

Ms. Gallagher presented a number of ideas to celebrate the 75th anniversary of NINDS and asked Council members to provide ideas and feedback. The purpose of the 75th anniversary celebration was to celebrate past accomplishments, share current research priorities, highlight advances, strengthen public trust, broaden networks, increase collaboration opportunities, and imagine the future of neuroscience. Some of the ideas that Ms. Gallagher's office was working on included developing a short commemorative video using footage from the Office of NIH History, a commemorative booklet, digital toolkits and multimedia outreach materials, banners on NIH campus, an NINDS Day, presentations on historic breakthroughs, symposiums, a road trip to highlight partnerships, and engagement with partners to begin the next NINDS strategic planning process. Ms. Gallagher invited Committee members to be involved in planning, join one of the planning subcommittees, and share any ideas in the general communications inbox.

Discussion

Council members suggested partnering with science museums across the U.S. to exhibit scientific advances, which would help support public outreach. They also suggested partnering with patient advocacy groups to help share lived experiences and patient perspectives. Council members suggested using both social media and interactive digital campaigns, as well as durable commemorations such as a print book with photographs.

VIII. State of Intramural Research Program

Dr. Jeffrey Diamond, Scientific Director, Intramural Research Program

Dr. Diamond provided a brief overview of new staff, newly tenured investigators, and retirees from the Intramural Research Program, as well as investigators who had received distinguished honors. He also reviewed a major effort by approximately 5,000 NIH fellows to unionize. On December 7, 2023, a majority of the voting NIH fellows elected to be represented by the International Union of United Automobile, Aerospace, and Agricultural Implement Workers of America (UAW). NIH will partner with UAW to negotiate a collective bargaining agreement.

Dr. Diamond reviewed five scientific highlights from the Intramural Research Program, including a <u>study</u> from Dr. Kenton Swartz's lab on biophysical mechanisms in ion channel inactivation, a <u>study</u> from Dr. Sonja Scholtz's lab on genetic variations involved in non-Alzheimer's dementias, a <u>study</u> from Dr. Dorian McGovern's lab on how monocytes program microglia to rebuild brain vasculature, a <u>study</u> from Ariel Levine's lab on the cellular diversity on the human spinal cord, and a <u>study</u> from Kareem Zaghioul's lab using EEG to locate seizure foci.

Discussion

A Council member asked whether CARD investigators worked under NIA or NINDS. Dr. Diamond answered that most of the funding for CARD came from NIA, but NINDS would be involved in the clinical aspects of the research.

IX. Adjournment

The open session of meeting was adjourned at 5:09 p.m. on Wednesday, February 14, 2024.

X. Review of Conflict of Interest, Confidentiality, and Council Consideration of Pending Applications

This portion of the meeting was closed to the public in accordance with the determination that it was concerned with matters exempt from mandatory disclosure under sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., and section 1009(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. §§ 1001-1014).

Members absented themselves from the meeting during discussion of and voting on applications from their own institutions, or other applications in which there was a potential conflict of interest, real or apparent.

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 309 research career development and institutional training grant applications with primary assignment to NINDS, and 181 of them (58 percent) were scored in the amount of \$26.8 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 \$11 million (78 grants).

Research Project and Center Awards – The Council reviewed a total of 1,862 research project and center applications with primary assignment to NINDS, and 1043 of them (56 percent) were scored/percentiled in the amount of \$494.1 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 \$70.7 million (224 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 six Javits nominations at this meeting: Alice Chen-Plotkin, M.D. (University of Pennsylvania), Bingwei Lu, Ph.D. (Stanford University), Charles Heckman Ph.D. (Northwestern), Diane Merry Ph.D. (Thomas Jefferson University), Lewis Morgenstern M.D. (University of Michigan), and Lynda Lisabeth Ph.D. (University of Michigan).

Small Business Innovation Research and Small Business Technology Transfer Award Programs – The Council reviewed a total of 235 Small Business Innovation Research (SBIR) and Small Technology Transfer Award (STTR) grant applications with primary assignment to NINDS, and 134 of them (57 percent) were scored in the amount of \$70 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 \$10.4 million (15 grants).

XI. Adjournment

The meeting was adjourned at 2:30 p.m. on Wednesday, February 15, 2024.

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

David Owens, Ph.D. Acting Executive Secretary National Advisory Neurological Disorders and Stroke Council Acting Director, Division of Extramural Activities National Institute of Neurological Disorders and Stroke

Walter J. Kowshetz mi)

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.

National Advisory Neurological Disorders and Stroke (NANDS) Council February 14-15, 2024, Meeting

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Sameer A. Sheth, M.D., Ph.D. (2024) Associate Professor and Vice Chair of Clinical Research Department of Neurosurgery Baylor College of Medicine Houston, TX 77030

Terms end July 31 of the designated year.

Ex Officio Members

Xavier Becerra Secretary Department of Health and Human Services Washington, DC 20201

Monica M. Bertagnolli, M.D. Director National Institutes of Health Bethesda, Md 20892

Christopher T. Bever, Jr., M.D. Director, Biomedical and Laboratory Research Office of Research and Development Department of Veterans Affairs Washington, DC 20003

David L. Brody, M.D., Ph.D. Professor of Neurology Uniformed Services University of the Health Science Director, Center for Neuroscience and Regenerative Medicine Director, USU/NIH Traumatic Brain Injury Research Center Bethesda, MD 20892

Executive Secretary

David Owens, Ph.D. Acting Director, Division of Extramural Activities National Institute of Neurological Disorders and Stroke National Institutes of Health Bethesda, MD 20892

Subject Matter Experts

Daniel L. Doctoroff, J.D. Founder and Board Chair Target ALS New York, NY 10023

Florian S. Eichler, M.D. Associate Professor Department of Neurology Harvard Medical School Massachusetts General Hospital Boston, MA 02114

Robert W. Gereau, IV, Ph.D. Vice-Chair for Research Director, Washington University Pain Center Dr. Seymour and Rose T. Brown Professor of Anesthesiology and Department of Neuroscience Washington University School of Medicine St. Louis, MO 63110

Frances E. Jensen, M.D. Professor and Chair Department of Neurology Perelman School of Medicine University of Pennsylvania Pennsylvania, PA 19104

Amy L. McGuire, Ph.D., J.D. Leon Jaworski Professor Center for Medical Ethics and Health Policy Baylor College of Medicine Houston, TX 77030

Kate M. Nicholson, J.D. President and Founder The National Pain Advocacy Center Boulder, CO 80302

Christin L. Veasley Co-Founder and Director Chronic Pain Research Alliance North Kingstown, RI 02852

National Advisory Neurological Disorders and Stroke (NANDS) Council February 14-15, 2024, Meeting Attachment 2

NINDS employees present for portions of the meeting included:

Sid Abeywickrama Amy Adams Deanna Adkins Mariam Afzal Mir Ahamed Hossain Laureni Ajayi-Obe Ram Arudchandran Herson Astacio **Eric Atkinson** Taryn Aubrecht Hibah Awwad Debra Babcock Julia Bachman Linda Bambrick **Roger Bannister** Elena Barnaeva Jennifer Barnes Sai Basireddy Patrick Bellgowan Mary Bennett Kaitlyn Benson Karrah Benson William Benzing **Clayton Bingham** Victoria Bitzer-Wales Sunil Bogisam Melissa Bojos Naomi Booker Francesca Bosetti Chris Boshoff Giulia Bova Vicki Brings Steve Britt Jeremy Brown Erin Bryant **Ryan Calabrese Roger Campbell Emily Caporello** Scarlette Cella **Stacey Chambers** Chi Chang **Denise Chatman Thomas Cheever**

Andrew Chen **Bo-Shiun Chen** Daofen Chen Sophie Cho Severn Churn Molly Cluster **Christopher Conrad Rebekah Corlew Rod Corriveau** Devon Crawford **Cheryl Cudzilo** Adi Cymerblit-Sabba **Charles** Cywin William Daley Sara Dauber Karen David Michele Dean Alexander Denker Vedangi Desai Neel Dhruv Jeff Diamond **Dustin Diep** Damon Disabato Dana Discenza Sara Dodson Adele Doperalski Argenia Doss **Kristin Dupre** Nancy Eaby Ana Ebrahimi Debbie Eng Yasmin Espinoza Judy Fabrikant Christina Fang Carlos Faraco Nicole Farhat **Robin Felder** Cassandra Fields Claudia Figueroa-Romero **Monica Flemming** Jessica Forbes Jane Fountain Megan Frankowski

Lauren Friedman Alissa Gallagher Lina Garcia Shannon Garnett Hermon Gebrehiwet Annette Gilchrist Marie Gill Jordan Gladman James Gnadt Tom Greenwell **Brooks Gross** Amelie Gubitz Luis Guerra Mohamed Hachicha Joseph Hall Maureen Hambrecht Kristi Hardy Adam Hartman **Brandon Hartsell** Ali Hassani **Brian Haugen** Janet He Lanier Heyburn **David Higgins Rebecca Hommer** Mariah Hove Nina Hsu Eric Hudak Xan Humphries Grace Hwang Lyn Jakeman Justin Jang Scott Janis David Jett Li Jia Kari Johnson **Kevin Jones** Lataisia Jones Michelle Jones-London Aleksey Kazantsev Cory Kelly **Elyse Kemmerer White** Brenda Kibler

Jenny Kim Laura Kimberly Brian Klein Jim Koenig Stephen Korn Svetlana Kotliarova Jonathan Kreisler Lauren Laboissonniere Joshua Lacy Pascal Laeng Christine Lam Nick Langhals Chelsea Lanson **Crystal Lantz Timothy Lavaute** Crystal Lee Miriam Leenders Janelle Letzen Nina Lichtenberg Cara Long Rosa Lopez Quynh Ly Timothy Lyden Smriti Lyengar Heidi Matos Galicia Marguerite Matthews Sade Matthews-Fitch Amber McCartney Linda McGavern Barbara McMakin Carolina Mendoza-Puccini Mirela Milescu **Daniel Miller Stephanie Mitchell** Dp Mohapatra Suzan Nadi Stephanie Nagle Emmens John Ngai **Cristina Nigro Glen Nuckolls** Michael Obodozie Joan Ohayon Ana Olariu Oreisa O'Neil Julia O'Reilly Leslie Osborne Michael Oshinsky **Hyejung Park**

Kathy Partlow Tatiana Pasternak K. Paul Rezaizadeh Michele Pearson Mary Pelleymounter Elio Peraza Marlene Peters-Lawrence Leah Pogorzala Linda Porter **Kevin Powell** Pragya Prakash **Rebecca Price** Michele Pucak CJ Puttaswamy Elizabeth Quartey Shamsi Raeissi Shanta Rajaram Srikanth Ranganathan Nagarajan Rangarajan Yogendra Raol Alva Recinos Katie Reichard Matthew Rice **Robert Riddle** Sarah Robinson Schwartz Rebecca Roof Marie Rowland Sara Sameni Joshua Sanchez **Cheryse Sankar** Shireen Sarraf Lumy Sawaki-Adams Joel Saydoff Igbal Sayeed Alisa Schaefer **Gretchen Scott** Paul Scott Nilkantha Sen Surojeet Sengupta Shalini Sharma **Kelly Sheppard** Frank Shewmaker Arvind Shukla Beth-Anne Sieber Shai Silberberg Maryann Sofranko Sudha Srinivasan **Rukmareddy Sripathi**

Mark Stevens Valerie Stoehr Natalia Strunnikova Abhi Subedi Luis Sullivan Tao Sun **Maripierre Surpris Christine Swanson-Fischer** Elizabeth Sypek Amir Tamiz James Taylor **Carol Taylor-Burds** Anna Tavlor Michael Tennekoon Shruthi Thomas **Christine Torborg** Jose Toro Natalie Trzcinski Amy Tsou Eric Tucker William Tyler Lauren Ullrich George Umanah Nsini Umoh Ursula Utz Nasim Vahidi Yee Vang **Claudio Villalobos Dintrans** Joanna Vivalda Kevin Vizcayno Laura Wandner Jackie Ward Anne-Sophie Wattiez **Tish Weigand Rachel Weinberg Elyse White** Matthew White Vicky Whittemore Shellie Wilburn Alexandra Winkler Sarah Woller Ling Wong Alynda Wood **Clinton Wright** Patrick Wright **Guangying Wu** Xiling Yin Arlene Zhen