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

Summary of Meeting¹ May 31 - June 1, 2023

The National Advisory Neurological Disorders and Stroke (NANDS) Council was convened for its 219th meeting on May 31 - June 1, 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: May 31, 2023: 12:32 p.m. to 4:42 p.m. for the review and discussion of

program development, needs, and policy; and

Closed: May 31, 2023: 4:50 p.m. to 6 p.m. and June 1, 2023: 9:33 a.m. to 10:56 a.m. for

the consideration of individual grant applications.

Council members present:	Ad Hoc Council Members:
Dr. Allan Basbaum	Mr. Hank Greely
Dr. Amy Brin	Dr. Yishi Jin
Dr. Robert Brown Jr.	Dr. Jane Larkindale
Dr. Claudia Lucchinetti	Dr. Jin-Moo Lee
Dr. Kenneth Maynard	Dr. Hank Paulson
Dr. John Maunsell	
Dr. Louise McCullough	Ex officio members present:
Dr. Gina Poe	Dr. David Brody
Dr. Ekemini Riley	Dr. Christopher Bever, Jr.
Dr. Timothy Ryan	
Dr. Sameer Sheth	
Dr. N. Edwin Trevathan	
Ms. Christin Veasley	

Council Roster (Attachment 1)

The meeting was held at Rockledge II 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.

Members of the public present for portions of the open meeting included:

Dr. Maynard Friesz, Cure SMA

Dr. Ron Bartek, FARA

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 219th meeting of the National Advisory Neurological Disorders and Stroke Council.

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

- A. Approval of Council Minutes—Dr. Finkelstein requested, and the Council voted approval of the February 1-2, 2023, Council meeting minutes.
- B. The following future Council meeting dates were confirmed:

Wednesday and Thursday, September 6-7, 2023

Wednesday and Thursday, February 14-15, 2024

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 – Each Council round, a subset of Council members approves applications in advance of the meeting with scores within the payline. 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 shortly after Council.

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

III. Report of the Director, NINDS - Dr. Walter Koroshetz, Director, NINDS

NIH and NINDS Leadership Changes — Dr. Koroshetz began by announcing that President Biden intends to nominate National Cancer Institute (NCI) Director Dr. Monica Bertagnolli for NIH Director, which is a Senate-confirmed position.

Budget — The President's NINDS base budget for Fiscal Year (FY) 2024 is lower (\$2.163 billion) than the FY 2023 appropriations (\$2.168 billion). Considering the FY 2024 President's budget and Congressional discussions, it is possible that the NINDS FY 2024 budget will remain flat or experience a significant cut.

The White House and Congressional leaders have reached an agreement around the debt ceiling, which suspends the nation's borrowing limit until January 2025 and holds the non-defense discretionary spending flat in FY 2024 with a potential 1 percent increase in FY 2025. This budget outlook points to multiple challenges ahead and will affect NINDS's activities. NINDS is developing funding strategies and considering policy changes to best advance the mission of NINDS.

NINDS 2021–2026 Strategic Plan — The NINDS strategic plan for 2021–2026 includes several cross-cutting themes that are relevant to neuroscience research, training and diversity, communications, workforce culture, and stewardship of taxpayer money. Core cross-cutting strategies focus on rigor and transparency, investigator-initiated research, diversity and inclusion, team science, data sharing and data science, neuroethics, patient engagement, technology access, models for neuroscience research, collaboration and partnership, and optimizing the NINDS intramural research program.

75th **Anniversary of NINDS in 2025** — For its 75th anniversary, NINDS would like to celebrate progress toward unraveling the mysteries of the brain and nervous system and charting the future of neuroscience.

Advanced Research Projects Agency for Health (ARPA-H) — <u>ARPA-H</u> has released a broad call for proposals that investigate unconventional approaches and challenge accepted assumptions to enable leaps forward in science, technology, systems, and related capabilities. Dr. Koroshetz encouraged NINDS stakeholders to submit neuroscience proposals.

NIH Researching COVID-19 to Enhance Recovery (RECOVER) Initiative — NINDS and the National Heart, Lung, and Blood Institute are working closely on the RECOVER Initiative, which strives to improve understanding of and ability to predict, treat, and prevent post-acute sequelae of SARS-CoV-2 (PASC), including Long COVID-19. RECOVER aims to understand the clinical spectrum/biology underlying recovery over time; define risk factors, incidence/prevalence, and distinct PASC-sub-phenotypes; study pathogenesis over time and possible relation to other organ dysfunction/disorders; and identify interventions to treat and prevent PASC.

Within 16 months, RECOVER has enrolled over 20,000 new/diverse patients, started analyzing data from 49,000 adults and 12,000 children in community-based cohorts, analyzed over 60 million adults and pediatric electronic health records, submitted first interim results from the adult cohort study, launched over 40 studies to identify the pathobiology of COVID-19's long-term effects and therapeutic targets, and begun development of 5 adaptive master protocols for clinical trials. To date, RECOVER findings have been described in 15 published reports, 10 reports in preprint, and more than 50 reports in preparation.

RECOVER will increasingly yield insights into Long COVID-19 and test a range of potential treatments through FY 2024. Dr. Koroshetz highlighted that understanding the long-term effects of COVID-19 will require additional work and he encouraged investigators to submit grant proposals.

New Common Fund Projects — Dr. Koroshetz described several new trans-NIH initiatives including the <u>Bespoke Gene Therapy Consortium</u>, and the <u>Undiagnosed Diseases Network (UDN) Phase 3</u>, <u>Somatic Mosaicism across Human Tissues</u>, and <u>Somatic Cell Genome Editing Phase 2</u> programs. Initially, these programs will target rare genetic diseases. UDN has moved its leadership to NINDS and has published multiple requests for applications (RFAs).

Accelerating Access to Critical Therapies (ACT) for Amyotrophic Lateral Sclerosis (ALS)—ACT for ALS provisions that are directly relevant to NIH include funding for research involving expanded access to therapies for individuals not otherwise eligible for clinical trials. In addition, the new Critical Path for Rare Neurodegenerative Diseases (CP-RND) Program is a public-private partnership (PPP) that will bring together multiple experts in rare neurodegenerative diseases, including ALS, as well as private entities, patient communities, and advocacy organizations to accelerate and advance understanding of disease pathology, treatment options, diagnostics, and drug development. The Accelerating Medicines Partnership® ALS (AMP® ALS), an important new expansion of this PPP, will engage NIH, the Food and Drug Administration (FDA), and other organizations in harmonization and connection of clinical data; establish a large-scale repository for ALS; create a repository of research tools, protocols, and resources; and integrate clinical data with biologic measures to identify biomarkers.

National Academies of Sciences, Engineering, and Medicine (NASEM) Reports — NASEM has published its Nonhuman Primate Models in Biomedical Research: State of the Science and Future Needs consensus study report calling for a national plan to address nonhuman primate (NHP) availability and infrastructure. NHP models are essential to the study and understanding of the human brain. Challenges in the use of these models include problems with availability and rising maintenance costs, facility maintenance, and a shortage of trained scientific and animal husbandry staff.

NASEM also published Advancing Anti-Racism, Diversity, Equity, and Inclusion in STEM Organizations: A Consensus Study recommending development and implementation of an inclusive, multi-faceted plan to support people from disadvantaged groups at all levels of science, technology, engineering, mathematics, and medicine organizations; funding grants to understand and translate policies, programs, and practices of minority-serving institutions to other universities; and collection of data on gatekeeper decisions, development of systems for more inclusive decision-making processes and shared authority over resource allocation, and inclusion of antiracism, diversity, equity, and inclusion responsibilities in job descriptions for leadership roles.

Advisory Committee to the NIH Director (ACD) Postdoc Working Group Update — The ACD Working Group on Re-envisioning NIH-Supported Postdoctoral Training was assembled to evaluate evidence of postdoc shortage, assess contributing factors, review and compare approaches, consider ways to support quality of life and improve retention, and engage key parties. The ACD will release an interim report in June 2023. Cross-cutting themes and suggestions from community participants obtained from ACD Listening Sessions include the need for increased financial support (e.g., higher salaries, benefits, childcare support), more support for nonacademic research transitions, equitable treatment by employing institutions, increased

accountability and oversight of institutions and mentors, infrastructure changes in postdoc training, increased research funding opportunities, financial and administrative support to navigate immigration- and visa-related issues, and creation of permanent nonfaculty positions to retain international talent.

NIH Policies for National Research Service Award (NRSA) Stipends, Compensation and Other Income notice of special interest (NOSI; NOT-OD-23-111) addresses postdocs' concerns about federal funding. NIH provides stipends to NRSA trainees to help defray living expenses during training, not as a condition of employment, and does not intend to discourage recipient institutions from hiring NRSA trainees and fellows as employees or providing them with benefits.

Review of NRSA Fellowship Application — A Center for Scientific Review Advisory Council working group was charged with evaluating the application review process and providing recommendations to make the process more fair, effective, and efficient. In their <u>final report</u>, the working group suggested that NIH is excluding highly promising scientists because the process favors elite institutions and well-known sponsors, and emphasizes traditional markers of early academic success. The working group has released a request for information (RFI) on recommendations for improving NRSA fellowship review (<u>NOT-OD-23-110</u>) to obtain additional community input.

NINDS Interdisciplinary Team Science — The NINDS Interdisciplinary Team Science Grant (RM1 Clinical Trial Optional) funding opportunity (RFA-NS-22-036) is designed to support an integrated team effort from 3 to 6 PD/PIs with distinct scientific viewpoints or expertise necessary to solve an important problem in science in 5 years. Plans for Enhancing Diverse Perspectives are required in the proposed research.

Rigor and Transparency — Dr. Koroshetz stated that NINDS is encouraging the use of rigor-related icons (e.g., indicating blinding, randomization, excluded outliers) in slides and posters to convey complex information efficiently, thus enhancing transparency and facilitating interpretation of data.

NINDS Mission Statement — The ACD working group on Diversity Subgroup on Individuals with Disabilities asked NIH to remove language about "reducing disability" from the NIH mission statement in support of disability inclusion. This phrase could be viewed as perpetuating ableist beliefs that disabled people are flawed and need to be "fixed."

The current NINDS mission statement is: The mission of NINDS is to seek fundamental knowledge about the brain and nervous system and to use that knowledge to reduce the burden of neurological disease for all people. Dr. Koroshetz pointed out that the word *burden* could be misinterpreted; he proposed the updated mission statement: The mission of NINDS is to seek fundamental knowledge about the nervous system and its disorders to improve the neurological health of all people.

Open Positions at NINDS — NINDS recently launched a <u>search for a deputy director</u>. The position involves managing daily operations of the Institute in support of the NINDS strategic vision and

mission. Responsibilities include building teams that launch programs in response to identified neuroscience gaps or congressional priorities; working collaboratively across NIH, throughout the federal government, and with science organizations and patient groups; and serving as ambassador and spokesperson for the Institute. The deadline for applications is July 24, 2023.

The search for Director of the Research Training and Career Development (RTCD) Office, NINDS Division of Intramural Research, is in its final stages. The RTCD is committed to enriching the training and mentoring experiences of all intramural scientists while promoting diversity in the neuroscience workforce.

<u>NINDS</u> is seeking potential candidates to fill various positions including program director, program manager, staff clinician, and director in several areas of interest.

Upcoming NIH Meetings — The <u>9th Annual BRAIN® Initiative meeting</u> will be held June 12–13 in Bethesda, MD, with a virtual option. The <u>Understanding and Restoring Whole Joint Health in Pain Management: An NIH HEAL Initiative Workshop</u> is scheduled for July 25–26 (virtual); registration is required.

IV. Discussion of Director's Report

Council members and presenters commented on the proposed changes to the NINDS mission statement. It was concluded that the funding of clinical trials by NINDS is implied by the statement that NINDS seeks to improve neurological health. One Council member asked about including language about preventing the economic burden of health disparities. Dr. Koroshetz replied that incorporating that language would be challenging and that the government considers the burden of all neurodegenerative diseases to society to include the economic burden.

Council members and presenters discussed future budget cuts and future graduate student stipend increases. Determining areas that will undergo budget cuts will be challenging. Dr. Koroshetz confirmed that postdoctoral salaries will increase, but the challenge is to determine how that increase will be funded. Council members suggested an NIH policy change that would allow use of other federal funds to supplement postdoctoral trainees' salaries in order to retain them. A discussion on budget cuts was recommended for the next Council meeting agenda.

V. BRAIN® Initiative Update and Council Discussion

Dr. John Ngai, Director, BRAIN Initiative

Dr. Ngai presented an update on BRAIN Initiative activities. The BRAIN Initiative budget, which includes base and 21st Century Cures Act funds, has grown since 2014, reaching \$680 million in FY 2023. To date, BRAIN has supported 1,200 PIs across 234 institutions and funded almost 1,000 awards. The multidisciplinary nature of the BRAIN Initiative is evident in the over 6,000 impactful publications in a wide range of journals authored by funded investigators.

Notable upcoming events include the <u>NIH BRAIN Neuroethics Working Group Workshop on the Ethics of Sharing Individual Level Human Brain Data Collected in Biomedical Research</u>, an <u>informational webinar on the Targeted Genome Editor Delivery Challenge</u>, and the <u>9th Annual BRAIN Initiative meeting</u>.

Dr. Ngai highlighted underrepresentation of women and minority groups in FY 2022 BRAIN demographics, a challenge that is being addressed through multiple efforts including the novel <u>Plan for Enhancing Diverse Perspectives</u> (PEDP). Early data indicate that RFA requiring a PEDP are showing increased diversity in their teams.

<u>BRAIN 2.0 transformative projects</u> are interlocking efforts aimed at changing neuroscience research. Projects include the BRAIN Initiative Cell Atlas Network (BICAN), the BRAIN Initiative Connectivity Across Scales Network (BRAIN CONNECTS), and the Armamentarium for Precision Brain Cell Access.

The Brain Behavior Quantification and Synchronization (BBQS) Program aims to support the development and validation of next-generation tools, methods, and analytic approaches to precisely quantify complex behaviors and combine them with simultaneous recordings of brain activity (RFA-MH-23-335, RFA-DA-23-030, and RFA-MH-23-130).

New BRAIN <u>funding</u> and <u>training</u> opportunities include notices of funding opportunities (NOFOs; <u>RFA-MH-22-245</u>, <u>RFA-MH-23-130</u>, and <u>RFA-DC-24-001</u>), a recent BRAIN reissue (<u>RFA-MH-23-290</u>), two partnerships (<u>PAR-23-122</u> and <u>PAR-23-137</u>), general training opportunities (RFA-MH-23-110 and NOT-OD-21-134), and diversity-focused funding announcements (<u>RFA-NS-21-012</u>, <u>RFA-MH-23-330/331</u>, and <u>NOT-NS-22-012</u>).

Recent BRAIN-supported research advances include a <u>3D electron microscopy-based reconstruction of the larval fruit fly brain</u>, the <u>Seattle Alzheimer's Disease Brain Cell Atlas</u>, the <u>first-in-human prediction of chronic pain state using intracranial neural biomarkers</u>, and a <u>study of epidural stimulation of the cervical spinal cord for post-stroke upper-limb paresis</u> that results in functional recovery of limb coordination including the ability to self-feed.

Discussion

A Council member asked whether the BRAIN® Plan for Enhancing Diverse Perspectives (PEDP) will improve diversity pipelines and strengthen the ability to do scientific research. Dr. Ngai expressed the hope that these efforts accomplish both and added that BRAIN® is interested in building capacity and rewarding PIs who are committed to mentoring.

A Council member commented on the administrative burden of grant applications and suggested that BRAIN® provide examples of model PEDPs in grant applications. Dr. Ngai agreed and shared that BRAIN® is helping applicants be competitive.

One Council member asked what portion of the epidural stimulation study was funded by BRAIN® and how the initiative decides to fund costly complex trials versus basic studies. The BRAIN® Initiative is mindful of not allocating too many resources into a single area and funds valuable, first-in-human (not larger) trials, clinically-oriented trials that record neural activity to inform deep brain stimulation for several different conditions. Conducting these studies in humans on a broader scale will require complementary efforts from other organizations.

VI. Blueprint MedTech Summary

Dr. Nick Langhals, Program Director, Blueprint Medtech

Dr. Langhals described the mission, structure, governance, and oversight of the <u>Blueprint MedTech Program</u>. Launched in 2022 with funding from 12 NIH institutes, the program catalyzes translation of new technologies from early-stage development to first-in-human clinical studies. Two U54 incubator hubs, a Center for Innovative NeuroTech Advancement, and multiple NIH R&D contracts support individual seedling, development, and translator (cooperative agreements) projects. Additional resources such as consulting, contract resources, and clinical study support are provided to investigators.

The Blueprint MedTech Incubator includes the seedling and development projects solicited by the hubs to scale toward human devices. The evaluation process of seedlings and development proposals includes triage, viability, and deep-dive evaluations. To date, interest in this program has been overwhelming; 450 pre-proposals have been received across three rounds. Initially, seven pilot seedling program technologies were funded for a broad range of disorders, including psychiatric disorders, neuromuscular injury, and myasthenia gravis. A second round of seedlings and development projects has been recommended for funding.

The Blueprint MedTech Translator includes later stage projects (<u>PAR-21-315</u> and <u>PAR-21-282</u>) that focus on regulatory approvals and first-in-human clinical studies to de-risk technologies. The first Translator project was awarded to Prapela for development of a cost-effective stochastic vibrotactile device to improve the clinical course of premature infants with apnea.

Discussion

Dr. Langhals clarified that all evaluation stages involve consultants with medical device experience. Incubator hubs have personnel with medical device experience and leverage the expertise of consultants.

A Council member asked what could make this initiative even more effective. Dr. Langhals responded that it is too early to know this. Blueprint MedTech personnel go through a process of continuous improvement, considering the review cycles, and understanding resource needs and the burden of the evaluations. Increased funds could support bringing in more experts and mentors.

Dr. Langhals described strategies for handling the placebo effect that are discussed in various meetings and conferences; for example, considering the patient to be their own control may mitigate the placebo effect or prevent a washout. In diagnostics, the approach is to compare with available devices, although the devices being developed through the program may be too novel to enable a comparison. The program works closely with the FDA's Center for Devices and Radiological Health to determine guidelines for approval.

Dr. Langhals and Council members commented on the justification for conducting this work through the BluePrint MedTech Program, which is an NIH-wide effort, rather than within NINDS. This initiative provides the needed expertise and venture capital investment strategy as well as offloading of staffing needs of the evaluation process. This initiative also implements the hub

model, which focuses on soliciting and reviewing projects that are headed toward commercialization and considers aspects that may be deemed unnecessary in a research grant.

VII. NIH Health Equities Strategic Plan Update

Dr. Richard Benson, Director, Division of Clinical Research, Office of Global Health and Health Disparities (OGHHD), NINDS

Although the NINDS mission is to reduce the burden of neurological diseases for all, there are disparities and inequities in neurological disorders and care borne by underserved groups of society. Deliberate and targeted approaches are needed to address these inequities.

<u>Healthy People 2030</u> defines health equity as the attainment of the highest level of health for all people. Achieving health equity requires valuing everyone equally and societal efforts to address avoidable inequalities, historical and contemporary injustices, and elimination of health disparities. A one-size-fits-all strategy does not work.

In 2020, Dr. Koroshetz commissioned the NANDS Council Health Equity Working Group (HEWG) to develop a comprehensive strategic plan to guide research investments toward advancing health equity in neurological disorders over the next 5–10 years. HEWG activities include an RFI to obtain stakeholder input, a portfolio analysis, and the <u>HEADWAY Workshop</u>. The output of this effort includes 10 manuscripts that have been submitted to the *Journal of Neurology* with an anticipated publication date of August 2023. HEWG recommendations and manuscripts cover a broad range of topics including community engagement, training and education, and health equity research and were described during the February 2022 NANDS Council meeting.

Currently, NINDS is focused on strategic implementation of these recommendations and the strategic plan.

VIII. Community-Engaged Health Equity Research in Neuroscience Initiative (HERN)

Dr. Cheryse Sankar, Program Director, OGHHD, NINDS

Dr. Sankar provided an overview of initiatives proposed in response to the NANDS Council HEWG recommendations including <u>HERN</u>, which aims to understand specific drivers of health disparities and barriers to neurological health equity, prevent and decrease neurological morbidity and mortality, and develop sustainable interventions to reduce disparities in neurological health among disadvantaged groups.

The overarching goals of HERN will be accomplished through early community engagement, health equity research, and multidisciplinary research teams, with training and capacity building as an overarching theme. Key recommendations are outlined below.

 Community engagement. The recommendation includes involvement in reviewers' evaluations and identifying and implementing effective strategies to address community distrust. Thus, HERN will aim to increase community-driven or -led research that broadly

- implements community engagement principles to involve people with lived experience, patients, and caregivers throughout the research process.
- Health equity research. The recommendation encourages research to identify/validate
 approaches to eliminate disparities affected by social determinants of health (SDOH),
 structural racism, and provider bias; increase minority participation in clinical trials;
 address specific SDOH-related questions across the lifespan; and develop
 multidisciplinary targeted interventions. HERN will conduct culturally responsive,
 inclusive health equity research to understand the role of SDOH in neurological health
 disparities through appropriate assessment screenings and measurements.
- Promotion of health equity research for underrepresented minorities (URM) and non-URM investigators. The recommendation includes training URM and non-URM junior investigators developing academic careers in health equity research. HERN will build multidisciplinary research teams with research expertise in health equity, neurological disorders, and community-engaged research; diverse education and training in cultural competency, sensitivity, and humility, as well as community-based participatory research; and diverse perspectives across career stages and representative of populations that experience health disparities, URMs, and non-URMs.

Concept for Council Clearance: Community-Engaged HERN

Dr. Sankar presented the community-engaged HERN initiative concept for Council clearance. Proposed funding mechanisms include 5–7 R34 awards (NOT-NS-23-071), 5–7 awards R01 (NOT-NS-23-070), and up to 5 administrative supplements. HERN R34 and R01 awards would be funded in parallel. To ensure that community engagement, recruitment/retention, and workforce diversity are centered on populations that experience health disparities, a Community Engagement and Research Inclusion plan, a Recruitment and Retention Plan, and a PEDP will be required. This initiative will ensure the reporting and reviewing of health disparities prevention, community engagement strategies, and support of URM and non-URM researchers' career development.

Discussion

Council members commented on recent bills banning diversity, equity, and inclusion (DEI) offices, programs, and training that may limit training and responses to initiatives and the need to ensure that investigators are not affected. This difficult challenge is being discussed at NINDS. Council members suggested using language in funding opportunity announcements (FOAs) to ensure there is no conflict with these laws and focusing on health disparity research. Dr. Koroshetz noted that the aim of these initiatives is to improve health, which is an unopposable goal.

The number of existing grants that are potentially eligible for the proposed HERN administrative supplements is being investigated. Only human studies would be eligible. These administrative supplements are geared toward NINDS grants that address significant gaps in community engagement within the scope of neurological disorders. The HERN initiative is ready to move forward quickly upon approval by the Council.

At this stage, the HERN initiative is not proposing to support clinical trials; rather, it is focusing on determining barriers and engaging communities to achieve successful recruitment of specific

populations. Discussions about ensuring that recruitment goals are achieved are being held within the OGHHD Division of Clinical Research.

A motion to approve the HERN concept (i.e., R34, R01, and supplemental administrative funding mechanisms) was made, seconded, and approved.

IX. Diversity, Equity, Inclusion, and Accessibility (DEIA) Updates Across NIH

Dr. Michelle Jones-London, Chief, NINDS Office of Programs to Enhance Neuroscience Workforce Diversity (OPEN-WD); Dr. Michael Lauer, Director, NIH Office of Extramural Research; Dr. Marie A. Bernard, Chief Officer for Scientific Workforce Diversity (COSWD), NIH

NINDS Extramural Training and Career Development Programs — Dr. Jones-London briefly described NINDS programs designed to create recruitment strategies and retention opportunities and increase workforce diversity and span from high school students to new faculty.

Recruitment strategies include the <u>Enhancing Neuroscience Diversity through Undergraduate</u> <u>Research Education Experiences (ENDURE)</u> initiative that prepares undergraduates from diverse groups to enter and complete neuroscience Ph.D. programs (NOFO reissue <u>NOT-NS-23-048</u>). To date, 65 percent of ENDURE trainees have entered Ph.D. and M.D./Ph.D. programs.

The NIH <u>Blueprint and BRAIN Diversity Specialized Predoctoral and Postdoctoral Advancement in Neuroscience (D-SPAN) Award</u> (F99/K00) aims to retain diverse faculty in academia (<u>RFA-NS-21-012</u>), enhance self-efficacy by providing a clear pathway to postdoctoral training, and empower trainees to develop independent research plans within a strong, mentored environment.

,. NINDS and several other Institutes created <u>Research Opportunities for New and "At-Risk" Investigators to Promote Workforce Diversity (R01 Clinical Trial Optional)</u> (<u>PAR-22-181</u>) to encourage a pool of PIs with more diverse perspectives in their science to contribute to NIH research areas via R01 applications.

Analyses of Demographic-Specific Funding Rates for Type 1 Research Project Grant (RPG) and R01 Equivalent Applications — Dr. Lauer presented funding rate and applicant race/ethnicity data for Type 1 RPG and R01 (R01e) equivalent applications. Although NIH is currently funding more PIs than in previous years, the numbers of RPG awards and unique PIs for FY 1998–2020— a period that encompasses NIH doubling, budgetary stagnation, and budget increases—reveal that competition has increased greatly and overall NIH purchasing power has remained unchanged. The RPG funding rate data for FY 1998–2022 reveal a 10 percent increase since 2013, indicating the current hypercompetitive funding environment.

Dr. Lauer presented the number of Type 1 RPG applicants for FY 2010–2022 stratified by race/ethnicity (Asian, Black, Hispanic, unknown, White), highlighting that the number of Black and Hispanic applicants has remained low throughout this period. Although the numbers of Black and Hispanic applicants have increased, they are significantly lower compared with the numbers of White and Asian applicants. Type 1 R01e funding rates for all populations have increased through FY 2010–2022; however, funding rates for White applicants are higher than for all other populations. The funding rates for Black applicants and applicants with unknown ethnicity are

lower than funding rates of White, Hispanic, and Asian populations; the difference in funding rates for the Black population has recently narrowed. This pattern is observed in Type 1 RPG funding rates.

Dr. Lauer described characteristics (e.g., sex, degree, application behavior) of FY 2022 Type 1 RPG applicants from the different population groups. A higher percentage of Black applicants submitted human study applications and were early-stage investigators compared with White applicants.

Strong positive predictors for Type 1 RPG funding include being female or an early-stage investigator, having prior awards, submitting applications in FY 2022, and belonging to higher education institutions or independent academic hospitals. Negative predictors include Asian race/ethnicity, submitting R21s or R03s, and animal research applications.

Discussion

Presenters and Council members discussed the reasons for the low number of applicants from some racial groups. Dr. Lauer noted that this has been a long-standing issue and highlighted that the number of applicants parallels the low proportion of faculty from specific racial groups. Dr. Bernard commented that scientists from underrepresented groups encounter barriers at every step of their journey.

Dr. Lauer commented that similar analyses were done for R01 applicants, who constitute 75 percent of RPG applicants, revealing similar results to the data presented today.

Update on NIH DEIA Strategic Plans and the NIH-Wide UNITE External Workforce Initiatives Dr. Bernard presented an overview of the DEIA Strategic plan, activities of the COSWD Office, and NIH UNITE initiative efforts.

The FY 2023–2027 NIH-Wide Strategic Plan for Diversity, Equity, Inclusion, and Accessibility describes activities to embrace, integrate, and strengthen DEIA across all NIH activities to achieve the agency's mission. The vision is for NIH to be a people-centered organization, representative of the Nation's diversity, where all people feel a sense of belonging as they advance the NIH mission. This plan will be accomplished by growing and sustaining DEIA through structural and cultural change; implementing organizational practices to center and prioritize DEIA in the workforce; and advancing DEIA through research. Dr. Bernard highlighted efforts within this plan including the Native American Research Centers for Health Program, the Community Engagement Alliance Against COVID-19 Disparities, DEIA Performance Standards, and a review of NIH Director's Awards.

The <u>FY 2022–2026 COSWD Strategic Plan</u> envisions enabling NIH and NIH-funded institutions to benefit from the nation's full range of talent and foster creativity and innovation in science. The COSWD's mission is to be the NIH thought leader in the science of scientific workforce diversity, using evidence-based approaches to catalyze cultures of inclusive excellence. COSWD will build, disseminate, and act on the evidence by advancing integrated, institution-wide systems through efforts such as the <u>21st Century Scholars Program</u> and the <u>Scientific Workforce Diversity seminar series</u>.

NIH UNITE is a people-focused and data-drive initiative centered around health disparities/minority health research, the internal NIH workforce, and the external biomedical and behavioral research workforce. To advance health disparities/minority health research, the Common Fund Community Partnerships to Advance Science for Society Program will develop community-led, health equity structural interventions through health equity research hubs (OTA-22-007, RFA-23-012, and RFA-RM-23-001). The Power of an Inclusive Workforce Recognition Project was launched to illustrate the diversity of the NIH workforce. The Distinguished Scholars Program (DSP) aims to build a self-reinforcing community of investigators devoted to diversity and inclusion and has led to an increase in the percentage of URM and female Intramural Research Program tenure-track investigators. The Faculty Institutional Recruitment for Sustainable Transformation initiative aims to establish at least 15 cohorts involving several institutions across the nation that will support about 150 early-career scientists with an interest in DEIA through tenure and becoming R01 investigators at NIH. NIH supports a safe and respectful workplace at institutions that receive NIH funding and provides information and resources in this domain.

Recently enhanced and released DEIA-focused Notice of Funding Opportunity (NOFOs) are the Science Education Partnership Awards, the Research With Activities Related to Diversity initiative (<u>PAR-23-122</u>), the Instrumentation Grant Program for Resource-Limited Institutions (<u>PAR-23-138</u>), and Strengthening Research Opportunities for NIH Grants: Structured Institutional Needs Assessments and Action Plan Development for Resource Limited Institutions (<u>PAR-23-144</u>).

The National Institute of General Medical Sciences Council has approved the Institutional Assessment and DEI Action Plan Development Grants and the Research Capacity Building Program to Enhance Workforce Diversity initiative. The National Institute on Minority Health and Health Disparities Council approved the Institutional Research Capacity Building Needs Assessment and Action Plan Development Grant.

COSWD is holding the <u>NIH Institutional Excellence in DEIA Prize Competition</u> to recognize and award up to 10 academic institutions that have identified gaps in DEIA and designed, implemented, and evaluated interventions to address them toward improving DEIA within the institution.

Discussion

Council members and presenters commented on the success of the DSP, which may be due to the recruitment of a small number of investigators and opportunities for peer-to-peer support, peer and formal mentors, meetings with leading scientists, and funding.

Analyses of funding rates in institutions with relatively large numbers of investigators reveal institutional heterogeneity. Diverse investigators in institutions with more diverse populations and higher funding success rates have higher success.

Dr. Bernard noted that workforce diversity will be successfully achieved when the likelihood of being successful and obtaining NIH funding cannot be predicted by race/ethnicity and NIH

hierarchy is not based upon race/ethnicity, gender, sexual orientation, or disability. Many at NIH are leaning into this work, and she forecasts that momentum in this effort will be maintained.

Council members commented on the importance of robust dissemination tactics for DEIA success and commended NIH for gathering data and its willingness to change internal behaviors and practices.

Dr. Koroshetz commented on the low number of NINDS applicants and encouraged consideration of the type of research that is important to investigators from underrepresented communities. There is an inherent barrier within the NIH structure: topic areas that are of greater interest to African American scientists (i.e., studies involving human subjects) are areas of special interest for Institutes and Centers with lower funding success rates.

NIH cannot interpret state or local laws banning DEI but encourages institutions to work with their general legal counsels to determine how specific laws intersect with funding announcements. An in-depth analysis is needed to determine their impact.

X. Additional Initiatives for Concept Clearance

- 1. Reissue Undiagnosed Diseases Network (UDN) Clinical Site U01 Lead: Argenia Doss
- 2. Reissue Research on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) (R01 Clinical Trials Allowed) *Lead: Vicky Whittemore*
- 3. Reissue Research on Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) (R21 Clinical Trials Allowed) *Lead: Vicky Whittemore*
- 4. Reissue Clinical Trial Methods in Neurological Disorders Course Lead: Sophie Cho
- 5. Reissue NIH Blueprint and BRAIN Initiative D-SPAN Award (F99/K00) Lead: Lauren Ulrich
- 6. Reissue Wellstone Centers Lead: Glen Nuckolls
- 7. Reissue NINDS Research Education Program for Residents and Fellows in Neurological Disorders and Stroke (PAR) and Administrative Supplement for the NINDS Research Education Program for Residents and Fellows in Neurology, Neurosurgery, Neuropathology, Neuroradiology, and Emergency Medicine (NOSI) Lead: Steve Korn
- 8. Reissue NINDS Institutional Research Training Program (T32 Clinical Trial Not Allowed)

 Lead: Steve Korn
- 9. Reissue NIH Blueprint Neurotherapeutics Network (BPN) NOFO's (PAR-20-111/PAR-20-122) Lead: Charles Cywin
- 10. Reissue RFA-NS-21-010 (HEAL Initiative: Non-Addictive Analgesic Therapeutics Development [Small Molecules and Biologics] to Treat Pain (UG3/UH3 Clinical Trial Optional) Lead: Mary Ann Pelleymounter
- 11. Reissue NINDS Exploratory Clinical Trials for Small Business (R41/R42 Clinical Trial Required) Lead: Emily Caporello
- 12. Reissue NINDS Exploratory Clinical Trials for Small Business (R43/R44 Clinical Trial Required) Lead: Emily Caporello
- 13. Analysis of Data in the COVID-19 Neuro Databank-Biobank (R03 Clinical Trial Not Allowed)

 Lead: Barbara Karp

- 14. Contributions to Cognitive Impairment and Dementia (VCID) Center Without Walls (CWOW) for Understanding and Leveraging Small Vessel Cerebrovascular Disease Mechanisms in Alzheimer's Disease-Related Dementia (ADRD) Lead: Rod Corriveau
- 15. Validating Digital Health Technologies for Monitoring Biomarkers in ADRD Clinical Trials Lead: Carol Taylor-Burds
- 16. Role of Environmental Stress in the Health Inequities of ADRD *Lead: Richard Benson* Council voted to approve proposed concepts 2–17.

The open portion of the meeting was adjourned at 4:42 p.m. on Wednesday, May 31, 2023.

XI. Review of Conflict of Interest, Confidentiality, and Council Procedures

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 $(5 \text{ U.S.C.} \S \S 1001-1014)$.

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 389 research career development and institutional training grant applications with primary assignment to NINDS, and 233 of them (60 percent) were scored in the amount of \$30.7 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 \$8.9 million (88 grants).

Research Project and Center Awards – The Council reviewed a total of 1,485 research project and center applications with primary assignment to NINDS, and 860 of them (58 percent) were scored/percentiled in the amount of \$368.4 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 \$96.7 million (274 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 three Javits nominations at this meeting: Dalton Dietrich, Ph.D., Cecilia Moens, Ph.D., Gary Yellen, Ph.D.

Small Business Innovation Research and Small Business Technology Transfer Award Programs

– The Council reviewed a total of 156 Small Business Innovation Research (SBIR) and Small Technology Transfer Award (STTR) grant applications with primary assignment to NINDS, and 92 of them (59 percent) were scored in the amount of \$44.7 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 \$3.5 million (6 grants).

XII. Adjournment

The meeting was adjourned at 10:56 a.m. on Thursday, June 1, 2023.

NINDS employees present for portions of the meeting included:

Open Session:

DeAnna Adkins
Ram Arudchandran
Eric Atkinson
Taryn Aubrecht

Naomi Booker
Francesca Bosetti
Chris Boshoff
Giulia Bova

Hibah Awwad Edith Brignoni Perez
Debra Babcock Steve Britt
Julia Bachman Jeremy Brown
Farah Bader Emily Caporello
Kelly Baker Stacey Chambers

Linda Bambrick Chi Chang

Elena Barnaeva Thomas Cheever
Jennifer Barnes Daofen Chen
Ron Bartek Andrew Chen
Sai Basireddy Bo-Shiun Chen

Andrea Beckel-Mitchener Sophie Cho Jonathan Bennettq Severn Churn Karrah Benson Molly Cluster

William Benzing Christopher Conrad Clayton Bingham Rebekah Corlew Melissa Bojos Devon Crawford Carolyn Bondar Charles Cywin

William Daley Eric Hudak
Sara Dauber Xan Humphries
Karen David Grace Hwang
Michele Dean Smriti Iyengar
Alexander Denker Lyn Jakeman
Vedangi Desai Li Jla

Neel Dhruv Lataisia Jones Dana DiScenza Kevin Jones

Sara Dodson Michelle Jones-London

Anthony Domenichiello Barbara Karp Adele Doperalski Cory Kelly **Argenia Doss** Olivia Kent Kristin Dupre Noam Keren Jaclyn Durkin Brenda Kibler Anahid Ebrahimi Jenny Kim Judy Fabrikant Laura Kimberly Christina Fang Yasmin Kloth Carlos Faraco Jim Koenig Robin Felder Carol Kong Jessica Forbes Stephen Korn Kranthi Kotha Megan Frankowski Natalie Frazin Svetlana Kotliarova Maynard Friesz Sahana Kukke

Patrick Frost Bellgowan
Lina Garcia
Pascal Laeng
Shannon Garnett
Christine Lam
Hermon Gebrehiwet
Annette Gilchrist
Crystal Lantz

Marie Gill Timothy LaVaute
Ashley Givens Crystal Lee

Jordan Gladman Miriam Leenders
Jim Gnadt Janelle Letzen
Maureen Gormley Catherine Levy
Elizabeth Ha Nina Lichtenberg
Joseph Hall Erica Littlejohn

Joseph Hall Erica Littlejohn
Maureen Hambrecht Cara Long
Kristi Hardy Rosa Lopez
Brian Haugen Quynh Ly
Janet He Tim Lyden
Lanier Heyburn Ernie Lyons

David Higgins

Rebecca Hommer

Mir Ahamed Hossain

Mariah Hoye

Laura Mamounas

Gary Marlowe

Heidi Matos Galicia

Amber McCartney

Nina Hsu Amber McCartne
Linda McGavern

Barbara McMakin Pantea Moghimi DP Mohapatra Sandra Molina Joseph Monaco

Joseph Monaco Jill Morris Cristina Nigro Glen Nuckolls John Ogawa

Joan Ohayon Ana Olariu Jiaqi OReilly

Leslie Osborne Michael Oshinsky Kathy Partlow Tatiana Pasternak Michele Pearson

Mary Pelleymounter Marlene Peters Leah Pogorzala Linda Porter Pragya Prakash Rebecca Price

Shanta Rajaram Nagarajan Rangarajan

Sridhar Ravva Alva Recinos

Michele Pucak

CJ Puttaswamy

Shamsi Raeissi

K. Paul Rezaizadeh Ryan Richardson Bob Riddle

Sarah Robinson Schwartz

Xing Rong Becky Roof Cheryse Sankar Lumy Sawaki-Adams

Joel Saydoff
Iqbal Sayeed
Alisa Schaefer
Elyse Schauwecker
Gretchen Scott
Nilkantha Sen

Kelly Sheppard

Beth-Anne Sieber Shai Silberberg Adissa Silue Mary Sofranko Shardell Spriggs Rukma Sripathi Mark Stevens Natalia Strunnikova

Abhi Subedi Tao Sun

Maripierre Surpris

Christine Swanson-Fischer

Elizabeth Sypek Edmund Talley Laaurent Taupenot

Anna Taylor

Carol Taylor-Burds Michael Tennekoon Shruthi Thomas Christine Torborg

Jose Toro
Delany Torres
Natalie Trzcinski
Eric Tucker
William Tyler
George Umanah
Ursula Utz
Nasim Vahidi
Joanna Vivalda

Tam Vo Cheryl Wall Laura Wandner James Washington Anne-Sophie Wattiez

Tish Weigand
Rachel Weinberg
Elyse White
Matthew White
Vicky Whittemore
Shellie Wilburn
Michael Wolfson

Ling Wong Alynda Wood Guangying Wu Xiling Yin Ran Zhang Wei-Qiu Zhen

Closed Session:

DeAnna Adkins William Daley Stephen Akomah Sara Dauber Ram Arudchandran Karen David

Eric Atkinson Alexander Denker

Taryn Aubrecht

Hibah Awwad

Debra Babcock

Julia Bachman

Neel Dhruv

Pamela Dillard

Dana DiScenza

Sara Dodson

Farah Bader Anthony Domenichiello

Linda Bambrick Adele Doperalski Elena Barnaeva **Argenia Doss** Jennifer Barnes Jaclyn Durkin Janna Belser-Ehrlich Anahid Ebrahimi Richard Benson Judy Fabrikant Karrah Benson Christina Fang Carlos Faraco William Benzing Robin Felder Clayton Bingham

Carolyn Bondar Claudia Figueroa-Romero

Naomi Booker Jessica Forbes
Francesca Bosetti Megan Frankowski
Chris Boshoff Patrick Frost Bellgowan

Giulia Boya Lina Garcia

Edith Brignoni Perez Hermon Gebrehiwet Steve Britt Annette Gilchrist

David Brody Marie Gill

Erin Bryant Jordan Gladman
Roger Campbell Jim Gnadt
Emily Caporello Amelie Gubitz

Stacey Chambers Elizabeth Ha
Chi Chang Joseph Hall

Denise Chatman Maureen Hambrecht

Thomas Cheever Kristi Hardy
Daofen Chen Adam Hartman
Bo-Shiun Chen Brandon Hartsell
Andrew Chen Brian Haugen
Sophie Cho Janet He

Severn Churn

Molly Cluster

Christopher Conrad

Lanier Heyburn

Rebecca Hommer

Mir Ahamed Hossain

Rebekah Corlew Mariah Hoye Devon Crawford Nina Hsu Charles Cywin Eric Hudak Xan Humphries
Grace Hwang
Smriti Ivengar

Smriti Iyengar Scott Janis Li Jla

Darryl Johnson Kevin Jones Lataisia Jones

Michelle Jones-London

Barbara Karp Cory Kelly Olivia Kent Noam Keren Brenda Kibler Jenny Kim Laura Kimberly

Jim Koenig Carol Kong Stephen Korn Svetlana Kotliarova Sahana Kukke

Pascal Laeng Christine Lam Nick Langhals

Crystal Lantz Timothy LaVaute Crystal Lee

Miriam Leenders

Janelle Letzen

Catherine Levy Erica Littlejohn Cara Long

Rosa Lopez Ernie Lyons

Laura Mamounas Gary Marlowe Heidi Matos Galicia Amber McCartney Linda McGavern Barbara McMakin

Carolina Mendoza-Puccini

Mirela Milescu Daniel Miller Pantea Moghimi DP Mohapatra Joseph Monaco

Jill Morris Glen Nuckolls John Ogawa Joan Ohayon Ana Olariu

Oreisa Oneil Jiaqi OReilly Leslie Osborne Michael Oshinsky

David Owens
Tatiana Pasternak
Michele Pearson
Mary Pelleymounter
Marlene Peters
Leah Pogorzala

Leah Pogorzala Linda Porter Pragya Prakash Rebecca Price Michele Pucak CJ Puttaswamy Shamsi Raeissi Shanta Rajaram

Srikanth Ranganathan Nagarajan Rangarajan

Alva Recinos Robert Riddle

Sarah Robinson Schwartz

Sabrina Rodriguez

Xing Rong Rebecca Roof Cheryse Sankar Lumy Sawaki-Adams

Joel Saydoff
Iqbal Sayeed
Alisa Schaefer
Elyse Schauwecker
Gretchen Scott
Paul Scott
Nilkantha Sen
Kelly Sheppard

Frank Shewmaker Andrew Siddons Beth-Anne Sieber Shai Silberberg Adissa Silue Shardel Spriggs Natalia Strunnikova Abhi Subedi

Tao Sun Maripierre Surpris Christine Swanson-Fischer Elizabeth Sypek

Edmund Talley Anna Taylor

Carol Taylor-Burds
Michael Tennekoon
Shruthi Thomas
Christine Torborg
Delany Torres
Natalie Trzcinski
Eric Tucker

George Umanah

William Tyler

Nsini Umoh Ursula Utz Nasim Vahidi Joanna Vivalda

Tam Vo Cheryl Wall Laura Wandner James Washington Rachel Weinberg

Elyse White
Vicky Whittemore
Shellie Wilburn
Ling Wong
Alynda Wood
Guangying Wu

Xiling Yin Ariel Zane Ran Zhang

Other federal employees present for portions of the meeting included:

Wei-Qin Zhao, CSR

Roger Bannister, CSR

Kathy Partlow, CSR Laurent Taupenot, CSR

Anne-Sophie Wattiez, CSR

Aleksey Kazantsev, CSR

Suzan Nadi, CSR

Bernard Srambical-Wilfred, CSR

Stephanie Nagle-Emmens, CSR

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

Robert Finkelstein, Ph.D.

August 23, 2023

Executive Secretary

Robert Finkelstein

National Advisory Neurological Disorders and Stroke Council

Director, Division of Extramural Activities

National Institute of Neurological Disorders and Stroke

Walter J. Koros hetz mi)

Walter Koroshetz, M.D.

August 23, 2023

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.