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

Summary of Meeting[1]
September 3-4, 2025

The National Advisory Neurological Disorders and Stroke (NANDS) Council was convened for its 228th meeting on September 3, 2025, via Microsoft Teams. 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: September 3, 2025: 10:00 a.m. to 3:00 p.m. for the review and discussion of program development, needs, and policy; and

Closed: September 3, 2025: 3:00 p.m. to 5:00 p.m. for the consideration of individual grant applications.

Councilmembers present:	Subject Matter Experts:
Dr. Amy Brin	Dr. Sepideh Amin-Hanjani
Dr. Robert Brown Jr.	Dr. Graeme Davis
Dr. Yishi Jin	Dr. Lynn DeBar
Dr. Jane Larkindale	Daniel Doctoroff
Dr. Jin-Moo Lee	Dr. Hector Gonzalez
Dr. John H.R. Maunsell	Dr. Frances Jensen
Dr. Louise McCullough	Dr. Amy McGuire
Dr. Hank Paulson	Kate Nicholson
	Dr. Roy Sillitoe

Council Roster (Attachment 1)

NINDS employees and members of the public in attendance (Attachment 2)

The meeting was held virtually via NIH Videocast and Microsoft Teams.

OPEN PORTION OF THE MEETING

Call to Order and Opening Remarks
Dr. Walter Koroshetz, Director, NINDS

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

Dr. Koroshetz welcomed Council members, visitors, and staff to the 228th meeting of the National Advisory Neurological Disorders and Stroke (NANDS) Council.

Report of the Director, Division of Extramural Activities, NINDS
Dr. Andrea Meredith, Director, Division of Extramural Activities, NINDS

A. Approval of Council Minutes — Dr. Meredith requested and Council voted to approve the May 14-15, 2025, and August 7, 2025, Council meeting minutes.

B. The following future Council meeting dates were confirmed:

Wednesday and Thursday, February 11-12, 2026
Wednesday and Thursday, May 20-21, 2026
Wednesday and Thursday, September 9-10, 2026
Wednesday and Thursday, February 10-11, 2027
Wednesday and Thursday, May 19-20, 20207
Wednesday and Thursday, September 8-9, 2027

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

NIH Policy Changes – Dr. Meredith reviewed a number of NIH policy changes. Recent policy updates included the centralization of peer review at the Center for Scientific Review (CSR), changes to foreign subawards, a limit of six applications per calendar year, a cap on allowable publication costs, and increased use of human biology-based methodologies. There was also prohibition of applications substantially developed using artificial intelligence (AI). Policy changes were underway to simplify and streamline processes for notices of funding opportunities (NOFOs), including the centralization of funding announcements to grants.nih.gov, the elimination of Notices of Special Interest (NOSIs), and the introduction of "Highlighted Topics" as a mechanism for announcing research priority areas by Institute.

Report of the NINDS Director and Discussion
Dr. Walter Koroshetz, Director, NINDS

NINDS 75th Anniversary – Dr. Koroshetz announced that this was the last Council meeting of NINDS's 75th year and thanked everyone who had made the 75th anniversary a success.

NIH and NINDS Leadership Changes – Dr. Koroshetz reviewed NIH and NINDS leadership changes. CSR Director Dr. Noni Byrnes retired, and Dr. Bruce Reed will serve as the Acting CSR Director. At NINDS, Dr. Ann Poduri , Deputy Director, departed NINDS, and Dr. Amy Adams will serve as Acting Deputy Director, . At the NINDS Division of Neuroscience, Dr. Ling Wong will serve as Acting Deputy Director, Dr. Patrick Bellgowan as Acting Associate Director, and Dr. Marie Gill as Acting Chief of Staff. Dr. Shanta Rajaram will serve as the Acting Deputy Director of the Division of Extramural Activities. Dr. Koroshetz announced that a number of NINDS staff were moving to CSR. The hiring freeze at NIH was extended through mid-October 2025.

NINDS News – Dr. Koroshetz talked about the Restoring Gold Standard Science Executive Order and noted that the NINDS Office of Research Quality, which has promoted research rigor for many years, will support NIH Director Dr. Jayanta Bhattacharya's priority to advance research replicability across NIH. Dr. Koroshetz said that NINDS would not publish fixed paylines going forward but would instead take a more flexible funding approach such as a greater focus on peer review. He provided a brief overview of Dr. Bhattacharya's research priorities and funding approaches across NIH.

Dr. Koroshetz talked about NINDS's commitment to investigator-led research and peer review, accelerating the translation of basic research into patient use and treatments, cultivating a future workforce of neuroscience researchers, and eliminating health disparities in neurologic diseases. He encouraged people to participate in peer review and pursue careers in neuroscience research to help achieve these goals.

Dr. Koroshetz announced that NIH was seeking public input about limiting allowable publishing costs, for which responses were due by September 15, 2025. He provided more information about the new NIH policies that limited applicants to six applications per year, the prohibition of substantial use of AI in applications, and the NIH priority to promote human-based research approaches.

NINDS Budget – Dr. Koroshetz said that fiscal year (FY) 2026 would begin on October 1, 2025. The President's FY 2026 budget called for a 40 percent reduction across NIH. However, the Senate and House budgets for NINDS were similar to FY 2025 with small increases to targeted programs. A new NIH policy called for FY 2025 multiyear grants to receive a single upfront payment rather than a year-by-year budget, which would decrease the number of grants funded. The Senate aimed to limit the impact of this policy by requiring that NIH fund the same number of investigators in FY 2025 as FY 2024. Dr. Koroshetz said that NINDS was asked to upfront fund 50 percent of its FY 2025 grants—although this did not decrease the number of FY 2025 funded grants, he anticipated a decrease if the policy continued in FY 2026. Dr. Koroshetz also noted that, despite administrative delays, NINDS staff was able to fund nearly 93 percent of its FY 2025 funds to date.

NINDS Highlights – Dr. Koroshetz highlighted other NINDS events. Former United States Representative Jennifer Wexton spoke about her journey with progressive supranuclear palsy (PSP) at the 2025 NINDS Nonprofit Forum, which she accomplished using AI-powered voice technology. Dr. Koroshetz noted that NINDS funds research on PSP and AI technologies. He also recognized the winners of the 2025 NINDS Early-Career Rigor Champions Prize, the new amyotrophic lateral sclerosis (ALS) Knowledge Portal, and the NIH Autism Data Science Initiative. He thanked partner organizations for their support during the NINDS 75th Anniversary celebrations and highlighted their upcoming symposiums. He also announced that NINDS would host a number of events at Neuroscience 2025 in November.

Discussion of Director's Report

Council members debated the advantages and disadvantages of upfront funding for multiyear grants and the potential benefit of reducing grants to three years instead of five. Although upfront funding is an efficient way to fund grants, the disadvantages may include a lack of

flexibility to adapt to shifting priorities, the potential that fixed funding may be insufficient for rising costs of research or new technologies, a hard expiration date without a mechanism to continue research if needed (e.g., delays from unforeseen circumstances such as a global pandemic), and an overall decrease in accountability. Council members expressed interest in providing more formal input about the benefits and liabilities of this funding approach.

A Council member asked how non-payline grant decisions would be made. Dr. Koroshetz answered that an application that might not have scored well under a NOFO or other funding announcement might be awarded through peer review under the Highlighted Topic mechanism. Another Council member asked for clarification on the move toward human-based research. Dr. Koroshetz said that there would be an emphasis on non-animal models, but the policy was not meant to prohibit the use of animal models. Rather, the science should drive which model to use and researchers who use animal models would have to provide justification. He also noted that future study sections would be trained in or include experts on human-based methodologies. A Council member asked whether the Food and Drug Administration (FDA) had received the same guidance on the use of non-animal based models, expressing concern about the implications for preclinical studies. Dr. Koroshetz answered that the policy shifts were likely aligned across both agencies.

A Council member expressed concern about how research priorities were identified and asked whether the diseases that NINDS prioritized would be deemphasized going forward. Dr. Koroshetz said that Dr. Bhattacharya's research priorities represented a small subset of what NIH focused on, and that there was no suggestion that any other disease area would receive less attention. Another Council member noted that the BRAIN 21st Century Cures Act budget had doubled and asked whether there was a certain priority area within that program that the administration was interested in. Dr. Koroshetz answered that funding schedules were set when the 21st Century Cures Act was first passed, and the increase was therefore not related to a new policy or priority area.

ADRD Summit

Dr. Amber McCartney, Scientific Project Manager, NINDS, Division of Neuroscience
Dr. Kate Possin, ADRD Summit 2025 Chair, John Douglas French Alzheimer's Foundation Endowed Professor, University of California San Francisco

Dr. McCartney provided Council with an annual update on activities across NINDS that support the National Plan to Address Alzheimer's Disease, an initiative mandated by the National Alzheimer's Project Act (NAPA). Goal 1 of the National Plan directs NIH to regularly convene summits, including the NIH Alzheimer's Disease-Related Dementias (ADRD) Summit. The ADRD Summit is held in collaboration with the National Institute on Aging (NIA) and brings together scientists, clinicians, patient advocates, caregivers, patients, and other individuals with lived experience to review scientific progress and develop recommendations to guide future NIH research. The recommendations are then published for public comment, presented to Council for approval, and submitted to the Department of Health and Human Services (HHS) and the NAPA Council for inclusion in the next iteration of the National Plan.

Dr. McCartney noted that NINDS manages approximately 10 percent of NIH appropriations for Alzheimer's disease (AD) and ADRD—a budget that has increased by six-fold since 2015. NINDS is committed to researching multiple etiologies and has led several major ADRD research programs, such as the FTD Natural History study, the NIH Center for Alzheimer's and Related Dementias (CARD), and the VCID Center Without Walls for small vessel cerebrovascular disease. NINDS also funds large scale implementation studies, which have been critical for developing tools to detect mild cognitive impairment and dementia in primary care settings. Additionally, NINDS-funded biomarker research has helped scientists better understand pathogenesis and stratify patients for clinical studies and diagnosis.

Dr. McCartney invited researchers to submit investigator-initiated applications and thanked NINDS and NIA staff, the scientific community, partners, and Council members Dr. Jin-Moo Lee and Dr. Hank Paulson for their contributions.

Dr. Possin talked about the projected increase of dementia in the United States from 6.5 million today to 13 million by 2060, highlighting the critical need for prevention and intervention research to offset this projection. Federal and non-federal panelists convened at the ADRD Summit 2025 to refine past and develop new recommendations to address the most critical research needs. The Summit focused on nine topic areas: multiple etiology dementias (MED), which was further subdivided into basic and clinical discovery, discovery implementation, limbic predominant age-related TDP-43, post-traumatic brain injury AD/ADRD, and the impact of the exposome; health disparities; vascular contributions to cognitive impairment and dementia (VCID); dementias with Lewy bodies; and frontotemporal dementias (FTD).

Participants in each of the nine sessions considered the most urgent needs and developed recommendations that represent high-priority national research pathways, which are outlined in the ADRD Summit 2025 Report. Summit participants also identified several themes cross-cutting the nine topic areas, such as the importance of accelerating implementation science, promoting real-world impact for patients and families, embracing the complexity of AD/ADRD, harnessing digital innovation, advancing biomarker development, and fostering inclusive and equitable access to care. Dr. Possin emphasized the importance of sustained investment, strategic prioritization, and a shared commitment to moving discovery from bench to bedside.

Council members expressed enthusiasm for the report. A Council member asked whether there specific examples of how people with lived experience contributed to the development of the recommendations. Dr. Possin said that people with lived experience provided significant input to the session focused on discovery implementation, suggesting that more effort was needed in prevention research. Other Council members suggested greater attention to gender disparities and genetic risk factors.

Council members voted to accept the ADRD Summit 2025 Report.

Somatic Cell Genome Editing (SCGE) Program
Dr. Timothy LaVaute, Program Director, NINDS, Division of Neuroscience

Dr. LaVaute provided an update on the NIH Common Fund's Somatic Cell Genome Editing (SCGE) Program, which was launched in 2018 to accelerate the development of safe, effective genome

editing therapies for genetic disorders. The SCGE Program exemplifies the Common Fund's mission to support bold, cross-cutting science that fosters multidisciplinary collaboration and supports high-risk, high-reward ideas. Common Fund programs are also milestone-driven, time-limited, and designed to develop broadly useful tools and resources for the research community. Dr. LaVaute emphasized that the SCGE program was selected as a Common Fund initiative because of its potential to transform treatment for a wide range of genetic diseases, create new tools and resources to support the research community and future innovation, and advance genome editing tools into safe and effective therapies.

Dr. LaVaute reviewed Phase 1 of the SCGE program, which focused on building the foundation for moving therapeutic genome editing into clinical settings. A major hallmark of Phase 1 was its replication and validation process, which required confirmation of research findings before advancing to larger animal studies. Key highlights from Phase 1 included the refinement of base editing technology, which enables precise single-base changes in DNA with reduced off-target effects, and the creation of prime editing, which is a next-generation technology for precise DNA insertions and deletions. Another major milestone was the engineering of adeno-associated virus capsids capable of crossing the blood-brain barrier—ushering in new opportunities for treating neurological disorders.

The SCGE program is currently in its Phase 2, which builds on these advances and shifts from an emphasis on tool and resource development towards translation to clinical settings through preclinical and Investigational New Drug (IND)-enabling studies. Dr. LaVaute noted that Phase 2 projects address a wide range of conditions, including genetic hearing loss. neonatal metabolic disorders, retinal disease, and neurodegenerative and neurodevelopmental disorders. Phase 2 also prioritizes engagement with regulatory agencies such as the FDA. SCGE investigators work proactively and transparently with FDA, and most have at least one FDA submission. FDA, in turn, applies the insights it receives from SCGE investigators to help shape regulatory policy.

Dr. LaVaute emphasized that close collaboration with FDA has accelerated progress. He shared the story of a young child born with carbamoyl phosphate synthetase (CPS1) deficiency. Within seven months, SCGE investigators advanced a personalized therapy from discovery to IND submission. After receiving the treatment, the child quickly showed remarkable improvement with no major side effects. Dr. LaVaute acknowledged the dedication of these investigators, as well as the many NIH staff and investigators who contribute to the SCGE program.

Discussion

Council members expressed enthusiasm for the extraordinary advances from this initiative. A Council member asked whether there were any concerns that might slow down progress. Dr. LaVaute answered that bumps in the road were unpredictable, but inevitable. However, there are therapies currently on the market that have much greater potential for mutagenic effects than genome editing. He therefore hoped there would be some tolerance for the inevitable bumps. He also expressed hope for sustaining the program and its success going forward. Another Council member asked whether Dr. LaVaute could envision the initiative moving beyond correcting therapies for rare genetic disorders and into treatment. Dr. LaVaute said that industry is moving toward such therapies for conditions such as heart, Alzheimer's, and sickle cell diseases. There would be greater potential for addressing these broader diseases as the barriers and costs

for drug approval decrease. A Council member asked whether the SCGE program was considering applications related to transferrin-mediated permeation across the blood-brain barrier. Dr. LaVaute said that other NINDS funding mechanisms were available for that technology, but noted that SCGE did hold a prize competition for identifying delivery methods for crossing the blood-brain barrier.

Initiatives for Concept Clearance
Dr. Meredith said there was one reissue concept for approval.

Concept 1: Funding Opportunity to Investigate Novel Therapeutic Interventions and Testing Strategies for Neurological Disorders Including to Treat, Modify and Prevent the Development of Epilepsy (for ETSP). *Lead: Dr. Brian Klein, Program Director, Epilepsy Therapy Screening Program (ETSP), Division of Translational Research.*

The Council voted to approve this proposed concept.

IX. Adjournment

The open session of the meeting was adjourned at 5:30 p.m. on Wednesday, May 14, 2025

CLOSED PORTION OF THE MEETING

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. Councilmembers were reminded that materials furnished for review purposes and discussion during the closed portions of the meeting are considered privileged information. All Councilmembers 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 Councilmember, the Councilmember must respond that he/she is not permitted to discuss the application. Any inquiry should be referred to Dr. Andrea Meredith 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 412 research career development and institutional training grant applications with primary assignment to NINDS, and 223 of them (54 percent) were scored in the amount of $16 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 $3.9 million (61 grants).

Research Project and Center Awards – The Council reviewed a total of 1872 research project and center applications with primary assignment to NINDS, and 1,065 of them (57 percent) were scored/percentiled in the amount of $468.6 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 $53.9 million (132 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 Council approved three Javits nominations at this meeting: Ryan Hibbs, Ph.D. (University of California, San Diego), J. Marc Simard, M.D., Ph.D. (University of Maryland), and Jennifer Whitwell, Ph.D. (Mayo Clinic).

Small Business Innovation Research and Small Business Technology Transfer Award Programs* – The Council reviewed a total of 196 Small Business Innovation Research (SBIR) and Small Technology Transfer Award (STTR) grant applications with primary assignment to NINDS, and 131 of them (67 percent) were scored in the amount of $64.3 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 $7 million (14 grants).

*pending re-authorization of SBIR/STTR authority

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

XI. Adjournment

The meeting was adjourned at 11:30 a.m. on Wednesday, September 3, 2025.

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

Andrea Meredith, Ph.D.
Executive Secretary
National Advisory Neurological Disorders and Stroke Council
Director, Division of Extramural Activities

National Institute of Neurological Disorders and Stroke

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.