

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

**Summary of Meeting¹
May 18-19, 2022**

The National Advisory Neurological Disorders and Stroke (NANDS) Council was convened for its 216th meeting on May 18-19, 2022, 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 18, 2022: 1:00 p.m. to 6:08 p.m. for the review and discussion of program development, needs, and policy; and
Closed: May 19, 2022: 1:00 p.m. to 5:20 p.m. for the consideration of individual grant applications.

Council members present:

Dr. Allan Basbaum	Dr. John Maunsell
Dr. Amy Brin	Dr. Louise McCullough
Dr. Robert Brown Jr.	Ms. Eileen Murray
Dr. S. Thomas Carmichael	Dr. Gina Poe
Dr. Nita Farahany	Dr. Ekemini Riley
Dr. Aaron Gitler	Dr. Timothy Ryan
Dr. Arnold Kriegstein	Dr. Sameer Sheth
Dr. Claudia Lucchinetti	Dr. N. Edwin Trevathan
Dr. Kenneth Maynard	Ms. Christin Veasley

Ex officio members present:

Dr. David Brody
Dr. Christopher Bever, Jr.

Council Roster (Attachment 1)

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

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

Dr. Bodo Stern, Chief Strategic Initiatives, Howard Hughes Medical Institute
Dr. Marina Picciotto, Editor in Chief, The Journal of Neuroscience

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.

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 216th meeting of the National Advisory Neurological Disorders and Stroke Council.

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

Dr. Robert Finkelstein

Approval of Council Minutes—Dr. Finkelstein requested, and the Council voted approval of the February 2-3, 2022, Council meeting minutes.

The following future Council meeting dates were confirmed:

Wed & Thurs, September 7-8, 2022
Wed & Thurs, February 1-2, 2023
Wed & Thurs, May 31, 2023-June 1, 2023
Wed & Thurs, September 6-7, 2023
Wed & Thurs, February 14-15, 2024
Wed & Thurs, May 15-16, 2024
Wed & Thurs, September 4-5, 2024

Expedited Review Process – Each Council round, a subset of Council members approves applications 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 Tom Carmichael, Claudia Lucchinetti, and Sameer Sheth for handling this responsibility for this meeting and the fiscal year. For the current Council round, 149 applications were eligible to be expedited. A portion of these awards already have been issued, and the others will be issued after Council.

Extramural Announcements

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

III. Report of the Director, NINDS

Dr. Walter Koroshetz, Director, NINDS

Leadership Changes—Dr. Norman E. “Ned” Sharpless stepped down as Director of the National Cancer Institute (NCI) in April. Principal Deputy Director Dr. Douglas R. Lowy was named NCI Acting Director. The search for a new NIH Director is ongoing.

Budget—The federal budget approved in March increased the NINDS base budget to \$2.082 billion, a 3.3 percent increase over fiscal year (FY) 2021 that is in line with other Institutes. In addition, NINDS received funds totaling \$182.9 million from the Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN®) Initiative and \$270.3 million from Helping to End Addiction Long-termSM (HEAL) Initiative and will manage \$274.7 million from the

National Institute on Aging (NIA) Alzheimer's Disease-Related Dementias (AD/ADRD). With these new resources, NINDS will maintain a payline at the 14th percentile.

The FY2022 Appropriations Bill strengthens the ability of NIH to address harassment in its funded activities by requiring that any removals and disciplinary actions be reported within 30 days to NIH. This bill ensures that NIH is made aware of the reason for disciplinary actions when there are concerns of harassment, bullying, retaliation, or hostile working conditions. The [reporting requirement](#) becomes effective July 8, 2022.

Advanced Research Projects Agency for Health (ARPA-H)—The FY2022 budget includes \$1 billion for three years to fund ARPA-H, a new agency that will report directly to the Secretary of Health. ARPA-H will complement, not duplicate, NIH programs; its mission is to benefit the health of all Americans by catalyzing health breakthroughs that cannot readily be accomplished through traditional research or commercial activity. ARPA-H will support transformative, high-risk, high-reward research to speed application and implementation of health breakthroughs; build capabilities and platforms to revolutionize prevention, treatment, and cures in a range of diseases; rapidly move use-driven ideas to tangible solutions for patients; and, through critical solutions or incentives, overcome market failures.

Researching COVID to Enhance Recovery (RECOVER)—The [RECOVER Initiative](#) aims for rapidly improving understanding of and ability to predict, treat, and prevent post-acute sequelae of COVID, which include neurologic problems with concentration, memory, pain, autonomic dysfunction, and sleep disorders. To date, approximately 3,000 individuals have been enrolled in cohorts, 60 million electronic health records are available for scanning, and a repository with 50+ types of tissue has been established. NIH has issued a [Research Opportunity Announcement](#) seeking proposals for clinical trials that test a range of interventions and use diverse methods to address symptoms, symptom clusters, and underlying mechanisms of pathobiology. Early trials may target symptoms, but over time mechanistic trials will focus on the underlying biology.

Accelerating Access to Critical Therapies Act for Amyotrophic Lateral Sclerosis (ACT for ALS)—NIH received a \$25 million appropriation to launch implementation of the ACT for ALS, which includes a Department of Health and Human Services (HHS) program to allow people with ALS who are ineligible for clinical trials to receive investigational drugs or biological products under expanded access. The bill limits the drugs to those who are in Phase 3 FDA-approved clinical trials sponsored by a small business. A Funding Opportunity Announcement ([FOA](#)) has been issued to encourage grant applications for research using data from expanded access.

NIH Data Sharing Policy—Effective [January 25, 2023](#), grant applications must submit a data management and sharing plan outlining how scientific data and metadata will be managed and shared, taking into account any potential restrictions or limitations. Program directors must approve plans prior to funding. The [policy](#) is designed to ensure that rigorous data from government-funded research are available for others to investigate and analyze. Next steps include making the data findable and useful through optimization of common data elements, metadata, and standards. Dr. Koroshetz noted the importance of sharing null data to inform future research efforts. The Trans-NIH BioMedical Informatics Coordinating Committee maintains a list of [NIH-supported data repositories](#).

New R01 Mechanism to Promote Workforce Diversity—The National Institute on Drug Abuse (NIDA), National Institute of Mental Health, and NINDS issued [PAR-22-181](#), which solicits R01

grant applications within the scientific mission of participating Institutes and Centers (ICs) and is intended to support [new](#) and [at-risk](#) investigators from diverse backgrounds, including those underrepresented in the health-related sciences. Between 2016 and 2020, only 6 percent of applicants and only 5 percent of awardees were from underrepresented groups (Black, Hispanic, American Indians and Alaska Natives, and Native Hawaiian and other Pacific Islander).

Fundamental Neuroscience (FN)—FN is the basic research that provides a foundation for the research achieving the NINDS mission—seeking essential knowledge about the brain and nervous system and using that knowledge to reduce the burden of neurological disease. NINDS efforts to support FN have included issuing a [Request for Information](#) to solicit ideas on how to advance FN research (response deadline extended to September 1) and establishing a Council Working Group to review current NINDS practices, obtain stakeholder feedback, and give recommendations to the NANDSC.

Clinical Trials Networks—Dr. Koroshetz acknowledged members of the NINDS Clinical Trials Evaluation Working Group; NINDS staff; and leaders of StrokeNet and NeuroNEXT, two NINDS clinical trial networks that will be recompeting. Key recommendations from the Evaluation Working Group include proactively identifying priorities; monumentally improving pre-award and review efficiency; and strengthening regular network evaluation and timely improvement.

Recent and Upcoming Meetings—The [Brain Attack Coalition Virtual Symposium](#) on Inequities in Access & Delivery of Acute Stroke Care (March 17–18) focused on changing healthcare systems to expand availability of timely acute stroke care. Recommendations arising from the [Alzheimer’s Disease-Related Dementias Summit](#) (March 22–23) will be presented during the September NANDSC meeting. The NINDS Office of Programs to Enhance Neuroscience Workforce Diversity is hosting an [OPEN Stage webinar](#) series for people interested in understanding how to navigate the NIH system. [The NINDS Workshop on Catalyzing Communities of Research Rigor Champions](#) (May 23–24) will focus on creating a culture that prioritizes quality and rigor of science. The 17th Annual [NIH Pain Consortium Symposium: Pain Management Through the Lens of Whole Person Health](#) (June 1–2) is the annual meeting of the trans-NIH group of Institutes that work in pain. The 8th Annual [BRAIN Initiative® Meeting: Open Science, New Tools](#) (June 21–22) will feature new devices and science. The 2022 [NINDS Nonprofit Forum](#) (July 19–20) will bring together 70 advocacy organizations that represent patients and caregivers.

Platform for Future Council Meetings—Dr. Koroshetz noted that the Institute has gained firsthand experience with virtual meetings and solicited feedback from Council on the optimal balance between virtual, hybrid, and in-person meetings.

IV. Discussion of Director’s Report

Council discussed the pros and cons of virtual, hybrid, and in-person meetings. It was generally agreed that Council should hold at least one in-person meeting each year, with consideration about the topics best covered in person, such as strategic changes and weighty subjects where it is important to hear from every member.

V. Update on the NINDS Intramural Research Program (IRP)

Dr. Nina Schor, Deputy Director, NINDS, Acting Scientific Director, NINDS IRP

Dr. Schor described steps to prepare for new leadership of the NINDS IRP. The process began with taking stock of IRP resources; asking people to dream beyond what the IRP is to what it can be; and engaging with faculty and trainees to set expectations for a new leader, highlighting the IRP team's ability to provide input into the process. A space audit was conducted to show candidates what is available not only for their own research program but also for expanding the program via recruitment and staffing changes. replacement of people in the program.

While working to identify the right leader for IRP, Dr. Schor sought to revive optimism. She described a core ideal program designed to ensure increased civility and collegiality among neuroscientists at NINDS as well as new affinity and special interest groups, the BEACON career advancement program for nurses, and the Porter Neuroscience Book Club.

Final candidates for IRP Scientific Director are coming for in-person visits where they will meet with junior faculty trainees, senior faculty, and lab and office staff. Candidates include men and women with MD/PhDs and PhDs and broad research interests, leadership experience, and a dedication to mentoring and training as well as to diversity, equity, inclusion, and accessibility. Dr. Koroshetz will make the final selection.

Once a new director is on site, IRP faculty will help that individual succeed. Even as the new scientific director is inaugurated, developing junior members' leadership abilities and planning for succession will begin.

Dr. Schor highlighted recent accomplishments of IRP faculty: Dr. Antonina Roll-Mecak received the Biochemical Society's International Award. Honorary memberships have been awarded to Drs. Rebecca Gottesman and Michael Ward (American Society for Clinical Investigation), Drs. Bryan Traynor and Daniel Reich (Association of American Physicians), and Daniel Reich (Henry G. Kunkel Society). Drs. Avi Nath and David Sibley are now Fellows of the American Association for the Advancement of Science. Dr. Michael O'Donovan is a new Scientist Emeritus, and Drs. Jeffrey Smith and Mark Hallett made valedictory presentations to the NIH Boards of Scientific Counselors. Drs. Sadhana Jackson, Mark Wagner, and Desmond Brown have been named NIH Distinguished Scholars; Dr. Derek Narendra has been named a Lasker Clinical Research Scholar; and Dr. Quan Yuan has been named a Tenured Senior Investigator. Dr. Ben Free has transitioned from project management to program management.

Discussion

Council members asked about interaction between basic and clinical scientists. Dr. Schor described several opportunities for such interactions, such as inviting basic scientists to attend the clinical grand rounds currently held via Zoom and including a 15-minute data blitz of unpublished data at the start of every faculty meeting. These activities have sparked collaborations. In addition, a small grant mechanism supported by the intramural budget supports teams that are working at the interface between a clinical problem and a scientific observation.

VI. Special Council Review (SCR) Policy Update

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

Dr. Finkelstein provided background on the NIH SCR policy, which requires Council to approve new research applications from Principal Investigators (PIs) whose annual NIH support exceeds \$1 million in direct costs (DC). Individual ICs can modify the SCR process, but their rules must be at least as stringent as those of NIH. The policy came about as a way for more people to become actively engaged in research. Another important consideration is that the mentoring and training environment in a lab and quality or rigor of its research are affected when an investigator devotes minimal effort to overseeing a grant.

In 2017 NANDSC approved a revised NINDS policy that includes the new application in calculating a PI's NIH support and establishes an SCR payline at half of the general NINDS payline (i.e., currently, the 7th percentile). Exceptions to the current policy include training and career development, conference, and research resource applications; applications to initiative supported by congressionally directed funds (e.g., AD/ADRD, BRAIN[®] HEALSM, CounterACT, Small Business Innovation Research [SBIR] and Small Business Technology Transfer [STTR]); and applications involving "inherently costly" research (e.g., clinical trials, non-human primate studies).

In light of new NIH/HHS emphasis on total costs (TC) as a funding metric and the increased cost of research, NIH updated its [SCR policy](#) this year. The 2022 policy threshold changed from \$1 million DC to \$2 million TC. Dr. Finkelstein noted that \$1 million DC is approximately \$1.5 million TC. The proposed [update to the NINDS SCR policy](#) increases the SCR threshold from \$1 million DC to \$2 million TC including the pending new application.

As a result of not funding applications, the [previous NINDS SCR policy](#) "saved" an average of \$6.3 million per year; the proposed policy would save approximately \$3.8 million per year. Funds generated through SCR can be used to help maintain or increase the payline or promote a more diverse workforce.

Discussion

Council members noted that using TC instead of DC puts PIs at some institutions at a disadvantage, and they discussed the need to increase the scientific community's awareness of the SCR policy. Council supported using the savings to bring diverse scientific perspectives into the workplace and suggested a focus on creative ways to support early-stage investigators with first-time renewals.

VII. HEAL Initiative Update and Council Discussion

Dr. Linda Porter, Director, Office of Pain Policy, NINDS

Dr. Michael Oshinsky, Program Director, Division of Neuroscience, NINDS

Dr. Porter presented an overview of the U.S. public health crisis of chronic pain, including new data from the National Health Interview Survey on the public impact of pain. More women than men have chronic and high-impact chronic pain; more rural than urban dwellers report chronic pain; and the prevalence of chronic and high-impact chronic pain increases with age.

To date, \$2 billion has been spent on pain research: more than 600 projects, 26 programs, 50 states, and 50 FOAs. [Funded projects](#) have moved from discovery through preclinical development (e.g., [Preclinical Screening Platform for Pain](#), diagnostic biomarkers) and clinical trials to implementation and dissemination.

Dr. Porter provided updates on the Phase 2 [Early Phase Pain Investigation Pain Network](#), the [Back Pain Consortium](#) Pain Management [Effectiveness Research Network](#), [Hemodialysis Opioid Prescription Effort](#), [PRagmatic and Implementation Studies for the Management of Pain](#), and [Integrative Management of chronic Pain and OUD \[Opioid Use Disorder\] for Whole Recovery](#). HEAL also supports awards that aim to ensure an expanded, enduring, diverse pool of highly trained clinical pain research scientists and that promote patient engagement, diversity, and inclusion. Other important components of the initiative are harmonization of patient-reported pain outcomes data (e.g., pain intensity, physical functioning, depression, anxiety), and secondary analyses.

Dr. Porter outlined [funding programs](#) for FY2023, including Chronic Pain Management in Rural Populations, Pain Management in Sickle Cell Disease, Coordinated Approaches to Pain Care in Health Care Systems, and Multilevel Interventions to Reduce Harm and Improve Quality of Life for Patients on Long-Term Opioid Therapy.

Dr. Oshinsky gave an update on HEAL-supported research focused on accelerating discovery and preclinical development of nonaddictive pain treatments. This includes development of small molecules, biologics, and devices for effective pain treatment, from target identification and validation ([RFA-NS-22-034](#)) through Phase I trials, as well as screening and testing platforms, tissue chips, and optimization research.

Ten NIH Institutes including NINDS participate in the three-phase [Pain Therapeutics Development Program](#) that includes a planning grant ([RFA-NS-21-029](#)), team research for initial therapeutics discovery ([RFA-NS-22-052](#)), and development ([RFA-NS-21-010](#)). The HEAL Restoring Joint Health and Function to Reduce Pain Consortium ([RFA-AR-22-009](#)) aims to facilitate identification of key receptors and mediators that induce joint pain. The Program to Reveal and Evaluate Cells-to-gene Information that Specify Intricacies, Origins, and the Nature of Human Pain Network is building comprehensive datasets of molecular signatures, cell types, and cellular function phenotypes or signatures that underlie human pain signal transduction, transmission, and processing, by using primary human tissues and cells ([RFA-NS-22-018](#) and [RFA-NS-22-021](#)); the datasets can be mined by those doing therapeutics development studies. [Translating Discoveries into Effective Devices to Treat Pain](#) supports clinical trials and basic science studies that seek to develop and translate next-generation medical devices for pain diagnosis and treatment. The [Development of Therapies and Technologies Directed at Enhanced Pain Management](#) FOA uses a small business set-aside to advance development and commercialization of therapies and technologies aimed at improving pain measurement and treatment.

The [National Center for Advancing Translational Sciences \(NCATS\) HEAL Portfolio](#) includes 65 projects. Three open NCATS HEAL FOAs are emergency awards: Translational Science Career Enhancement Awards ([PAR-22-058](#)), the New Innovator Award ([RFA-TR-22-013](#)), and Early-Stage Discovery of New Pain and OUD Targets Within the Understudied Druggable Proteome ([RFA-TR-22-011](#)). NCATS also supports developing investigational drugs for clinical testing.

Dr. Oshinsky highlighted two success stories for early HEAL-funded optimization projects. The first is completion of a [Phase 1a Clinical Trial for use of EC5026](#) as a nonaddictive opioid alternative for neuropathic pain. The second is a collaboration and license agreement to [advance Nav1.7 inhibitors](#) for treatment of pain.

Dr. Oshinsky presented three HEAL concepts, which do not require a formal NANDSC vote.

Concept 1: Integrated Basic and Clinical Research in Pain

Michael Oshinsky, Division of Neuroscience

The proposed concept would employ an RM1 interdisciplinary team science mechanism to pursue bold, impactful, and challenging research to increase understanding of biological underpinnings of specific human pain conditions and enable innovative reverse translational approaches.

Concept 2: Development and Validation of Animal Models and Outcome Measures for Pain

Michael Oshinsky, Division of Neuroscience

The proposed concept would employ an R01 mechanism for developing and validating non-rodent mammalian models of pain with translational potential for testing therapeutics.

Concept 3: Embedded Entrepreneur Supplement Program

Michael Oshinsky, Division of Neuroscience

The proposed concept would provide a supplement mechanism to support business development activities and add business management expertise in SBIR- and STTR-funded small businesses working in the pain space.

Discussion

Council members expressed enthusiasm for the proposed concepts, particularly the entrepreneur supplement that will bring in the business acumen required for success.

VIII. Initiatives Requiring Concept Clearance

AD/ADRD FOA Concepts

Roderick Corriveau, NINDS AD/ADRD Program Lead, Division of Neuroscience

Dr. Corriveau presented an overview of the NIA and [NINDS collaboration on AD/ADRD](#) funding opportunities, paylines, and the triennial summits that shape ADRD research priorities. NIA leads the NIH response to the National Plan, and NINDS leads support for Lewy body dementia, frontotemporal degeneration, and vascular contributions to cognitive impairment and dementia (VCID) as well as the ADRD planning summits. He outlined the ADRD FOA development process: from concept development to discussion and leadership input to bringing concepts to NANDSC for approval.

The following three ADRD FOA concepts are proposed for FY2023 and FY2024.

1. ALL (FY 23), Cellular and Molecular Mechanisms of Prion-Like Aggregate Seeding, Propagation, and Neurotoxicity in AD/ADRD *Lead: Dr. Daley*
2. VCID (FY24), Anti-amyloid Efficacy in Populations with Vascular Risk Factors of Cognitive Impairment and Dementia *Leads: Drs. Hommer and Wright*
3. ALL (FY24), Neuropathological Assessment of TBI-related Neurodegeneration and Neurocognitive Decline *Lead: Dr. Umoh*

Council voted to approve the above (items 1–3).

Diverse and Neurotypical Brain Donation Concept

Daniel Miller, Division of Neuroscience

The proposed multi-IC Concept for an FOA aims to address two of the top challenges of human brain tissue banking: (1) achieving donor diversity across all axes of human variation and all disease types; and (2) accessing neurotypical tissue for understanding normal human brain function and for use as a comparator for disease-focused studies. The initiative would support implementation of a two-pronged strategy: outreach and engagement with partners active in underserved communities and collaborations between brain banks and sites of tissue collection (e.g., medical examiners, organ procurement organizations).

Council voted to approve the proposed concept.

Additional Concepts

1. PAR: NIH Countermeasure Against Chemical Threats (CounterACT): Basic and Early Translational Research on Chemical Threats that Affect the Nervous System *Lead: Dr. Spriggs*
2. PAR: Early Stage and Established Biomedical Data Repositories (DR) or Knowledge Bases (KB) *Lead: Dr. Bellgowan*
3. RFA: Extracellular RNA Sequencing Research Resource for the Accelerating Medicines Partnership® Parkinson's Disease (AMP®PD) *Lead: Dr. Babcock*
4. NIDA and NINDS Research Opportunities for New and "At-Risk" Investigators to Promote Workforce Diversity (R01 Clinical Trial Optional) *Lead: Dr. Jones-London*
5. RFA Reissue: PAR-19-220: Clinical Trial Readiness for Rare Neurological and Neuromuscular Diseases (U01 Clinical Trial Not Allowed) *Lead: Dr. Talley*
6. RFA Reissue: RFA-NS-21-020: Research Program Award (R35 Clinical Trial Optional) Outstanding Investigator Award *Lead: Dr. Talley*
7. RFA Reissue: RFA-NS-20-003: Education Program on Translational Devices *Lead: Dr. Hudak*
8. RFA Reissue: PAR-21-209: NIH Countermeasures Against Chemical Threats (CounterACT) Early Stage Investigator Research Award *Lead: Dr. Caporello*
9. Contract: Preclinical Screening Platforms for Pain: Renewal and Recompete Contract for Award in 2024 *Lead: Dr. Iyengar*

Council voted to approve all of the above (items 1–9).

IX. Open-Access Publishing Discussion

Dr. Amy Adams, Division Deputy Director, Scientific Management and Operations, NINDS

Mr. Jerry Sheehan, Deputy Director, National Library of Medicine (NLM)

Dr. Bodo Stern, Chief of Strategic Initiatives, Howard Hughes Medical Institute (HHMI)

Dr. Marina R. Picciotto, Editor-in-Chief, The Journal of Neuroscience

Dr. Ekemeni Riley, Managing Director, Aligning Science Across Parkinson's (ASAP) and Member, NANDSC

Dr. Adams shared background on policies designed to ensure that federally funded research results are readily accessible to the public.

Mr. Jerry Sheehan, Deputy Director, National Library of Medicine (NLM)

In 2008, the [NIH public access policy](#) went into effect in accordance with Division G, Title II, Section 218 of [PL 110-161](#) (Consolidated Appropriations Act, 2008). In 2013, the White House Office of Science and Technology Policy issued a [policy memorandum](#) requiring most federal agencies to ensure that publications and data resulting from federally funded research were freely available to the public within one year of publication. Since then, online publishing and pre-publishing has expanded even as major funders have issued policy changes. The past two years have seen an urgent, immediate need for access to COVID-19 data.

Mr. Sheehan presented on the NIH policy from the perspective of the NLM. The estimated overall policy compliance rate is about 90 percent. PubMed Central (PMC) contains 1.3 million NIH-supported articles, accounting for 17 percent of the PMC archive and 42 percent of article views annually. NLM also supports data discovery via links to associated data. About 40 percent of materials in PMC have supplementary data.

In March 2020, NLM launched public access in support of the COVID-19 response, collaborating with more than 50 publishers and societies to provide immediate access. As of May 2022, the literature includes 400,000 publications.

In June 2020, NLM launched an [NIH preprint pilot](#) to test viability of making preprints discoverable in PMC and PubMed databases, starting with preprints result from NIH-funded COVID-19 research. Preprint status is clearly indicated, to distinguish such publications from peer-reviewed content.

Results of a survey indicate that providing preprint information has not eroded trust in NLM resources. NLM is interested in understanding why about 40 percent of preprints accumulated since 2020 remain preprint-only (i.e., have not been released from a peer-reviewed publication).

Dr. Bodo Stern, Chief of Strategic Initiatives, Howard Hughes Medical Institute (HHMI)

Dr. Stern gave an overview of the new [HHMI open-access policy](#) that requires immediate open access that enables free and immediate access and reuse. The policy aligns with Plan S formulated by cOAlition S—26 international organizations including charitable organizations (i.e., Gates, Wellcome Trust, HHMI, ASAP), the World Health Organization, and national funders from Africa, Canada, Europe, the European Commission, and the United Kingdom. The core feature of Plan S is an open license that authors can apply (1) to the journal article version of record, which involves publication fees paid to journals that have fully adopted an open access business model, or (2) to the author's manuscript with sufficient copyright to share on PMC. HHMI asks scientists to sign an agreement to ensure that they retain rights to share their article.

Although HHMI scientists strongly supported open access, initial backing for a mandate was mixed due to concerns about the ability to publish in specific journals or about a possible negative impact on trainee careers. Implementation challenges include policy complexities and high open-access fees.

Dr. Stern asserted the need to make the publishing itself more open, by promoting a flipped publishing process: publication followed by review, similar to the preprint process. Rigor and relevance are signaled through transparent, post-publication review and curation. This approach would end the rejection-resubmission cycle and eliminate high publishing costs, waste of reviewer and author resources, publication delays, and demoralizing effects on trainees. The flipped process is already operating with eLife, peer-review services, and grassroots organizations such as ASAPbio. Journals need to commit to conducting peer review the way eLife is doing it.

Dr. Marina R. Picciotto, Editor-in-Chief, The Journal of Neuroscience

Open access can be promoted as rights retention, thus building a coalition of funders and society publishers to create a process and business model and rewarding open science by recognizing refereed preprints as peer-reviewed articles.

Dr. Picciotto presented her perspectives as a neuroscientist and editor-in-chief of *The Journal of Neuroscience*, a hybrid journal that offers full open access after 6 months and complies with Plan S. Authors own full copyright of their work and are encouraged to submit to bioRxiv at any time before or during submission.

Delivery of scientific information to the public is complex. Peer review adds value, and blinded peer review is a way to guarantee that those with privilege do not receive extra credit from reviewers. The *Journal* has been published by the Society for Neuroscience for 41 years and offers incredible editorial freedom because of an incredible investment in peer review. Curation also adds value; being selected by members of their field as well as professional editors enhances the careers of trainees. Peer review and curation are costly and take time. According to Dr. Picciotto, the main goal of public access should be to maximize access while allowing for the time and value of peer review.

Who should pay for peer review? For journals, library subscriptions play a substantial role. By moving to fully open access, peer-review costs would be borne by authors or governments and funding agencies via negotiated agreements. The *Journal* is negotiating a pilot agreement with UK funders to absorb the costs and allow British authors to publish fully via open access immediately. It is unclear whether NIH would adopt similar agreements.

NIH could assist scientific publishing reform by granting full copyright to authors and giving a creative commons license to use all materials published for other scientific work after peer review. The current mix of early posting on preprint servers followed by formal peer review and curation by journals and availability on government archives after publication has already had an impact; it facilitated faster dissemination of scientific information. bioRxiv has been essential in getting information to other scientists and the public. Sharing unreviewed data leads to problems in public perception of science.

Some of the open-access publishing policies being proposed do not solve some major problems in the current system. For example, post-publication peer review has its own challenges. Scientists will not review unless invited and recognized for it, which has a cost. The experiment is interesting, but the scale is small and made possible by well-funded organizations. Increasing choice for authors and supporting innovation from eLife and funding bodies such as HHMI have made a difference in what is thought to be acceptable.

Dr. Ekemeni Riley, Managing Director, Aligning Science Across Parkinson's (ASAP) and Member, NANDSC

Dr. Riley presented her perspective as a leader of ASAP, which is a member of cOAlition S and has implemented some of the policies that group pioneered. The five key components of the [ASAP Open Science Policy](#) mandate immediate, free, online access upon publication with grantees retaining copyright via license for unrestricted reuse; posting of manuscripts in an preprint repository upon submission to a journal; research outputs deposited in publicly accessible repositories and cited in the publication; appropriate attributions to ASAP-funded work; and utilization of the ASAP Research Output Management System (ROMS) for tracking within the virtual grantee platform. ASAP covers article processing fees for grantees and allows publication in hybrid journals.

ASAP supports open science to facilitate rapid, free exchange of scientific ideas, ensuring that the research ASAP funds can be leveraged for future discoveries. ASAP holds that science is based on collaboration; for science to function effectively, research data must be made open, and the ultimate value of data often cannot be predicted. Citing recent changes in the open science landscape (e.g., NIH policy requiring a data-sharing plan in grant applications, NASA designation of 2023 as the Year of Open Science, and [National Academies' Toolkit for Fostering Open Science Practices](#)), Dr. Riley noted how open science extends the principles of openness to the whole research cycle and how ASAP practices open science—from data collection and processing through data storage, publications, and distribution to reuse.

Currently, ASAP-supported articles include 46 preprints, which have led to 26 original research publications. Compliance checks are made at different points in the cycle. The ROMS platform houses information—from submitted proposal and progress reports to resources generated (datasets, bioinformatics tools, cell lines, viral vectors, plasmids, animal models)—available to everyone in the ASAP network. Ultimately, all these resources will be made available to the broad neuroscience community.

Dr. Riley described ASAP's assessment of open science e.g.: Are resources findable and accessible? Is discovery being accelerated? Is ASAP helping change the culture of open science?

Discussion

Presenters and Council members discussed who bears the costs of independent reviews in the current model (i.e., philanthropic organizations), the costs associated with peer review, the value of peer review for publication quality, the inadequacy of the publication allowance in a 5-year grant, and potential role that NIH can play in supporting open science.

Editors agree that their role is in appraising and reviewing content. Participants suggested that journals should move away from publishing to serve as reviewers and curators.

NLM has experimented with linking to open peer reviews associated with journal articles; as other journals move in that direction, NLM can provide a platform that reflects such change. NIH has played a significant role in moving toward open science. When the public-access policy was implemented in 2008, there was concern about undermining the current models of publishing and claims that only scientists need access. Today, considerable evidence attests

that publishing has survived; many people within and beyond the scientific community access the literature.

Addressing issues of equity and inclusion in research and the scientific workforce, it is critical to ensure that there is a path to publication.

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

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

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

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

Research Training and Career Development Programs – The Council reviewed a total of 382 research career development and institutional training grant applications with primary assignment to NINDS, and 227 of them (59 percent) were scored in the amount of \$21.8 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 \$7.9 million (90 grants).

Research Project and Center Awards – The Council reviewed a total of 1,482 research project and center applications with primary assignment to NINDS, and 864 of them (58 percent) were scored/percentiled in the amount of \$351.6 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 \$73.8 million (263 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

two Javits nominations at this meeting: Manisha N. Patel, Ph.D. (University of Denver-Colorado), and Surachai Supattapone, M.D., Ph.D., D.Phil. (Dartmouth College).

Small Business Innovation Research and Small Business Technology Transfer Award Programs

– The Council reviewed a total of 126 Small Business Innovation Research (SBIR) and Small Technology Transfer Award (STTR) grant applications with primary assignment to NINDS, and 84 of them (67 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 \$6.6 million (14 grants).

XI. Adjournment

The meeting was adjourned at 5:20 p.m. on Thursday, May 19, 2022.

NINDS employees present for portions of the meeting included:

Open Session:

DeAnna Adkins
Ram Arudchandran
Taryn Aubrecht
Debra Babcock
Julia Bachman
Linda Bambrick
Amy Bany Adams
Elena Barnaeva
Kiara Bates
Patrick Bellgowan
Richard Benson
Karrah Benson
William Benzing
Victoria Bitzer-Wales
Marci Bolt
Carolyn Bondar
Naomi Booker
Francesca Bosetti
Jeremy Brown
Erin Bryant
Ryan Calabrese
Emily Caporello
Maria Charlier
Denise Chatman
Thomas Cheever
Daofen Chen
Bo-Shiun Chen

Ben Churn
Rod Corriveau
Devon Crawford
Charles Cywin
William Daley
Sara Dauber
Karen David
Vedangi Desai
Neel Dhruv
Alicia Diggs
Anthony Domenichiello
Adele Doperalski
Argenia Doss
Kristin Dupre
Anahid Ebrahimi
Debbie Eng
Judy Fabrikant
Christina Fang
Carlos Faraco
Robin Felder
Cassandra Fields
Robert Finkelstein
Nhi Floyd
Megan Frankowski
Natalie Frazin
Alissa Gallagher
Lina Garcia
Shannon Garnett

Hermon Gebrehiwet
Maryam Ghaleh
Marie Gill
Jordan Gladman
Jim Gnadl
jasmine grandy
Brooks Gross
Mohamed Hachicha
Joseph Hall
Maureen Hambrecht
Kristina Hardy
Adam Hartman
Brian Haugen
Jane Hettinger
David Higgins
Rebecca Hommer
Mir Ahamed Hossain
Nina Hsu
Eric Hudak
Smriti Iyengar
Lyn Jakeman
Scott Janis
David Jett
Michelle Jones-London
Cory Kelly
Brenda Kibler
Jenny Kim
Yasmin Kloth
Jim Koenig
Stephen Korn
Walter Koroshetz
Kranthi Kotha
Sahana Kukke
Pascal Laeng
Christine Lam
Nick Langhals
Crystal Lantz
Timothy LaVaute
Miriam Leenders
Catherine Levy
Rosa Lopez
Codrin Lungu
Quynh Ly
Tim Lyden

Ernie Lyons
Candice Martin
Heidi Matos
Eugenia McAllister
Amber McCartney
Linda McGavern
Barbara McMakin
Carolina Mendoza-Puccini
Mirela Milescu
Daniel Miller
Stephanie Mitchell
DP Mohapatra
Karen Molina
Marilyn Moore-Hoon
Alphonso Morgan
John Ngai
Cristina Nigro
Glen Nuckolls
Ana Olariu
Oreisa O'Neil
Jiaqi Oreilly
Michael Oshinsky
Dave Owens
Alexander Papadopoulos
Tatiana
Michele Pearson
Mary Ann Pelleymounter
Leah Pogorzala
Linda Porter
Carlo Quintanilla
Shamsi Raeissi
Shanta Rajaram
Ranga Rangarajan
Yogendra Raol
Alva Recinos
K. Paul Rezaizadeh
Robert Riddle
Sarah Robinson Schwartz
Becky Roof
Joel Saydoff
Alisa Schaefer
Nina Schor
Lindsey Scott
Paul Scott

Kathy Sedgwick
Beth-Anne Sieber
Shai Silberberg
Adissa Silue
Shardell Spriggs
Rukma Sripathi
Natalia Strunnikova
Abhi Subedi
Tao Sun
Maripierre Surpris
Christine Swanson-Fischer
Elizabeth Sypek
Amir Tamiz
Anna Taylor
Carol Taylor-Burds
Michael Tennekoon
Shruthi Thomas
Christine Torborg

Delany Torres
Natalie Trzcinski
Lauren Ullrich
George Umanah
Nsini Umoh
Ursula Utz
Nasim Vahidi
Joanna Vivalda
Laura Wandner
Samantha White
Alan Willard
Sarah Woller
Ling Wong
Clinton Wright
Xiling Yin
Ariel Zane

Other federal employees present for portions of the meeting included:

Jerry Sheehan

Closed Session:

DeAnna Adkins
Mir Ahamed
Ram Arudchandran
Taryn Aubrecht
Debra Babcock
Julia Bachman
Kelly Baker
Linda Bambrick
Amy Bany Adams
Elena Barnaeva
Patrick Bellgowan
Richard Benson
William Benzing
Victoria Bitzer-Wales
Carolyn Bondar
Naomi Booker
Francesca Bosetti
Chris Boshoff
Giulia Bova
Jeremy Brown
Erin Bryant

Ryan Calabrese
Roger Campbell
Emily Caporello
Stacey Chambers
Chi Chang
Maria Charlier
Denise Chatman
Thomas Cheever
Daofen Chen
Bo-Shiun Chen
Ben Churn
Janice Cordell
Rod Corriveau
Devon Crawford
Diana Cummings
Charles Cywin
William Daley
Sara Dauber
Vedangi Desai
Neel Dhruv
Alicia Diggs

Sara Dodson
Anthony Domenichiello
Adele Doperalski
Argenia Doss
Kristin Dupre
Anahid Ebrahimi
Samuel Edwards
Debbie Eng
Judy Fabrikant
Christina Fang
Carlos Faraco
Cassandra Fields
Robert Finkelstein
Jane Fountain
Megan Frankowski
Lina Garcia
Hermon Gebrehiwet
Maryam Ghaleh
Marie Gill
Jordan Gladman
Jim Gnadl
Jasmine Grandy
Brooks Gross
Mohamed Hachicha
Joseph Hall
Maureen Hambrecht
Kristina Hardy
Adam Hartman
Brandon Hartsell
Brian Haugen
Janet He
Jane Hettinger
Rebecca Hommer
Nina Hsu
Eric Hudak
Smriti Iyengar
Lyn Jakeman
Scott Janis
David Jett
Li Jia
Michelle Jones-London
Cory Kelly
Brenda Kibler
Jenny Kim
Eunyoung Kim
Brian Klein

Jim Koenig
Stephen Korn
Walter Koroshetz
Arnold Kriegstein
Sahana Kukke
Pascal Laeng
Christine Lam
Mark Langer
Nick Langhals
Crystal Lantz
Timothy LaVaute
Miriam Leenders
Catherine Levy
Erica Littlejohn
Cara Long
Rosa Lopez
Codrin Lungu
Quynh Ly
Tim Lyden
Ernie Lyons
Heidi Matos
Marguerite Matthews
Amber McCartney
Linda McGavern
Carolina Mendoza-
Puccini
Mirela Milesescu
Daniel Miller
Stephanie Mitchell
DP Mohapatra
Marilyn Moore-Hoon
Jill Morris
John Ngai
Cristina Nigro
Glen Nuckolls
Ana Olariu
Oreisa O'Neil
Jiaqi O'Reilly
Michael Oshinsky
David Owens
Tatiana Pasternak
K. Paul
Michele Pearson
Mary Ann Pelleymounter
Marlene Peters
Erna Petrich

Leah Pogorzala
Kevin Powell
Pragya Prakash
Rebecca Price
Shamsi Raeissi
Shanta Rajaram
Ranga Rangarajan
Alva Recinos
Robert Riddle
Becky Roof
Tim Ryan
Cheryse Sankar
Joel Saydoff
Alisa Schaefer
Nina Schor
Sarah Robinson
Schwartz
Lindsey Scott
Paul Scott
Nilkantha Sen
Shalini Sharma
Beth-Anne Sieber
Shai Silberberg
Maryann Sofranko
Shardell Spriggs
Natalia Strunnikova
Abhi Subedi
Tao Sun
Maripierre Surpris
Christine Swanson-
Fischer
Brooke Sydnor
Elizabeth Sypek

Edmund Talley
Amir Tamiz
Anna Taylor
Carol Taylor-Burds
Michael Tennekoon
Shruthi Thomas
Jacek Topczewski
Christine Torborg
Delany Torres
Natalie Trzcinski
Eric Tucker
Lauren Ullrich
George Umanah
Nsini Umoh
Ursula Utz
Nasim Vahidi
Mad Vahidi
Joanna Vivalda
Laura Wandner
Anne-Sophie Wattiez
Keith Whitaker
Samantha White
Vicky Whittemore
Sarah Woller
Ling Wong
Clinton Wright
Xiling Yin
Ariel Zane
Ran Zhang

Other federal employees present for portions of the meeting included:

Carole Jelsema, CSR
Aleksy Kazantsev, CSR
Suzan Nadi, CSR
Delia Olufokunbi Sam, CSR
Elyse Schauwecker, CSR

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

8/17/2022

Date

**Walter J.
Koroshetz -S**

Date



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

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

 Digitally signed by Walter J.
Koroshetz -S

Date: 2022.08.15 10:34:22 -04'00'

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.