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

Summary of Meeting[1]
February 2-3, 2022

The National Advisory Neurological Disorders and Stroke (NANDS) Council was convened for its 215th meeting on February 2-3, 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: February 2, 2022: 1:00 p.m. to 5:36 p.m. for the review and discussion of program development, needs, and policy; and
Closed: February 3, 2022: 1:00 p.m. to 4:00 p.m. for the consideration of individual grant applications.

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

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

Ad Hoc present:
Dr. Robert Brown

Council Roster (Attachment 1)

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

[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.

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

Kathy Sedgwick, NOVA Research Company
Dr. Karen Johnston, University of Virginia
Dr. Barbara Vickrey, Icahn School of Medicine at Mt Sinai
Dr. Richard Ruddick, Optimal Brain Health Consultants

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 215th meeting of the National Advisory Neurological Disorders and Stroke Council.

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

Approval of Council Minutes—Dr. Finkelstein requested, and the Council voted approval of the September 9-10, 2021, and the November 26, 2021, Council meeting minutes.

The following future Council meeting dates were confirmed:

Wed & Thurs, May 18-19, 2022
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

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, 148 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. Koroshetz summarized recent leadership changes at NIH. Dr. Lawrence A. Tabak is Acting Director of NIH. A former Director of the National Institute of Dental and Craniofacial Research, he has been NIH Principal Deputy Director since 2010. Dr. Tara A. Schwetz is Acting Principal Deputy Director.

Funding— NIH is operating under a Continuing Resolution (CR), which is set to expire on February 18. NINDS has conducted an analysis toward maintaining funding at the 14th

percentile despite challenges related to budgetary uncertainty and fluctuating outyear costs. If the CR continues, maintaining this payline will require strong steps such as deferring high-priority program and bridge awards, postponing the launch of expensive grants such as clinical trials (CTs) until FY2023, and trimming outyear costs for all grants.

NINDS attempts to, whenever possible, maintain a stable funding payline for extramural researchers. Over the past ten years, the payline has been relatively stable, fluctuating between the 14th and 16th percentiles. Most of the large funding increases in recent years were designated by Congress for specific initiatives such as the National Institute on Aging (NIA) Alzheimer's Disease-Related Dementias (AD/ADRD) program, the Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN®) Initiative, and the Helping to End Addiction Long-term℠ (HEAL) Initiative.

Discussion
Dr. Koroshetz asked Council to consider whether the 14th percentile "line in the sand" is the right strategy and what other metrics (e.g., number of awards, number of investigators) should be tracked to guide policy decisions.

Council members discussed how the NINDS payline approach compares with those of other Institutes, along with the ratio of modular to non-modular grants.

Pain Research Funding—Dr. Koroshetz summarized the outlook for FY2022 pain research funding opportunities. In multiple proposed budgets, Congress has indicated a desire to increase the NINDS budget for pain research by $43 million. NINDS has issued several Notices of Special Interest (NOSIs) for most aspects of the NINDS pain portfolio, including migraine and headache, pain mechanisms, technologies for investigation of pain and pain circuits, and development of pain treatment devices. In addition, proposed budgets include $135 million for HEAL efforts to improve pain management. HEAL has issued Funding Opportunity Announcements (FOAs) for training and career development, myofascial pain, health equity in pain, and mapping of integrated innervation of joint and surrounding tissues.

Post-acute Sequelae SARS-CoV-2 Infection (PASC)—To date, NIH has obligated $500 million to support the RECOVER Initiative: Researching COVID-19 to Enhance Recovery. This ambitious project aims at understanding the biological drivers of persistent effects of COVID-19 (e.g., fatigue, muscular weakness, cognitive disturbance) and will involve a national study population of diverse research volunteers, a large electronic health record cohort, and an autopsy cohort.

The Future of Work at NINDS—Throughout the pandemic, NINDS staff demonstrated their commitment to advancing the Institute's mission despite many challenges. NINDS is reimagining and restructuring the intersection of the workforce, workplace, and the work based on the telework experience during the COVID-19 pandemic. A hybrid work environment is planned for administrative staff.

Amyotrophic Lateral Sclerosis (ALS) Research—In December 2021, President Biden signed the Accelerating Access to Critical Therapies Act for ALS (ACT for ALS), which establishes a public-private partnership, including the U.S. Food and Drug Administration (FDA) and NIH, to focus on advancing regulatory science and research to support and accelerate development and review

of drugs for ALS. The Act authorizes $100 million per year for FY2022 through FY2026 and establishes a program to fund research that uses expanded access data from individuals not otherwise eligible for clinical trials.

The NIH Common Fund's Accelerating Leading-edge Science in ALS (ALS^2) initiative supports high-risk, high-reward ALS-related research that will transform knowledge of the disease. Four new awards were made in FY2021. NINDS is embarking on a strategic planning effort to accelerate research on the biology underpinning ALS toward optimizing clinical research, improving quality of life of those living with ALS, and identifying collaboration and partnership opportunities. NINDS has issued a request for information (RFI) to inform its strategic planning in ALS.

Fostering Fundamental Neuroscience (FN) Research at NINDS—FN is the foundation for public- and private-sector progress in prevention and treatment of all neurological disorders and maximizing brain health. The Fundamental Neuroscience Taskforce is identifying ways to enhance basic neuroscience and stimulate more FN applications. Responses to an NINDS Request for Information (RFI) are due by June 1, 2022.

Commitment to End Racism within NIH and Science Communities—NIH efforts to advance diversity, equity, inclusion, and accessibility (DEIA) include the NIH UNITE, a multipronged effort to address structural racism and racial inequity in biomedical research; the strategic plan for FY2022–2026 drafted by Dr. Marie Bernard, Chief Officer for Scientific Workforce Diversity (COSWD); and NIH Institute and Center (IC) racial and ethnic equity plans (REEPs). REEPS will focus on sustained and measurable behavior change across all dimensions of ICs. The NIH-wide DEIA strategic plan applies to the entire internal and external NIH workforce and will serve as a blueprint for current and future activities in the broad DEIA space. UNITE recommendations are currently looking at: increasing career opportunities for under-represented groups; identifying and changing NIH processes and policies contributing to inequities in extramural funding; building and sustaining research capacity at minority-serving institutions; promoting extramural institutional culture change in support of inclusivity and equity.

Led by Dr. Michelle Jones London, the NINDS Office of Programs to Enhance Neuroscience Workforce Diversity (OPEN) coordinates NINDS diversity activities with a focus on increasing applications from underrepresented groups, identifying and rooting out bias in peer review and other aspects of funding decisions, and openly developing and tracking metrics. The K01-NINDS Faculty Development Award to Promote Diversity in Neuroscience is an OPEN program that supports a sustained 5-year period and career development toward accelerating independent research careers of tenure-track faculty. Of the 29 K01 awards made from 2009 through 2017, all have submitted R01 applications, 17 have received R01s, and several are pending review. Most BRAIN® FOAs require applicants to submit a plan for enhancing diverse perspectives (PEDP). NINDS plans to include similar language in some of its FOAs.

The NIH Common Fund's Faculty Institutional Recruitment for Sustainable Transformation program aims to enhance and maintain cultures of inclusive excellence in the biomedical research community. The NIH First Cohort Hiring Program is expected to fund 12 awards over the next 3 years; 2021 awards have been announced, and a second round is forthcoming.

Brain Attack Coalition Symposium: Inequities in Access and Delivery of Acute Stroke Care—An acute stroke care symposium (March 17–18) will bring together diverse teams of public health and stroke experts with a goal of improving stroke systems of care by increasing equity in access to efficient, effective treatments and improving outcomes for all affected populations during any stage of care.

Dr. Koroshetz noted that Dr. Richard Benson, Director, NINDS Office of Global Health and Health Disparities, would be presenting the NINDS Health Equity Strategic Plan during the meeting.

Environmental Drivers of Neurological Disorders—Dr. Koroshetz noted the need to understand environmental contributions to impaired function of the nervous system. NIH is exploring the possibility of launching an Office for Environmental Research that would be tied to current toxicology efforts. An RFI is planned to obtain input on challenges and opportunities for collaborative, interdisciplinary research among neuroscientists and environmental health scientists across NIH Institutes, Offices, and Centers (IOCs).

IV. Discussion of Director's Report

BRAIN® is holding review orientations to ensure that reviewers understand how to evaluate how diverse perspectives will improve the science within the five scorable areas. The PEDP itself will not be scored. Dr. Ngai noted that progress reports will be reviewed for evidence of plan effectiveness. Council members noted that the symptoms of long COVID and myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS) are quite similar; they recommended collaborating or coordinating efforts of researching COVID to enhance recovery (RECOVER) and ME/CFS research centers.

V. NINDS Health Disparities Strategic Planning Process and Working Group Recommendations

Dr. Richard Benson, Program Director, Office of Global Health and Health Disparities (OGHHD), NINDS
Dr. Karen Johnston, Harrison Distinguished Teaching Professor of Neurology; Associate Vice President for Clinical & Translational Research, Office of the Vice President for Research; Director, Translational Health Research Institute of Virginia, University of Virginia
Dr. Edwin Trevathan, Amos Christie Chair in Global Health, Vanderbilt Institute for Global Health, Vanderbilt University Medical Center

Dr. Benson outlined the process for developing a comprehensive plan to guide research investments over the next 5 to 10 years. The process, a collaboration between the NINDS OGHHD and the Office of Science, Policy, and Planning, included establishment of an NANDS Steering Committee and working group subcommittees, a systematic literature review, an RFI to obtain stakeholder input, a portfolio analysis, and the HEADWAY Workshop. Responses to the RFI were received from across the country as well as urban and sub-urban areas. NINDS acknowledges better outreach should be done in the future to obtain responses from rural regions. Each subcommittee incorporated its findings and recommendations into separate manuscripts for publication in a special issue of *Neurology*.

Dr. Johnston presented results of the mortality and portfolio analyses. The mortality analysis estimated that 29,986 U.S. deaths from neurological disease (2010–2019) would have been averted had non-Hispanic black Americans experienced the same mortality rates as non-Hispanic white Americans. The portfolio analysis showed that between FY 2016 and FY 2020, NINDS funded 58 new research projects that had health equity components for approximately $30.6 million. The majority of these were observational projects and concentrated in a few disease areas (i.e., stroke, and ADRD). A peak in projects funded in 2019 was attributed to a partnership between NINDS and the National Heart, Lung, and Blood Institute to co-fund projects.

Dr. Trevathan presented recommendations for NANDSC approval prior to wide dissemination:

1. **Increase health equity research funding** across all neurological disease areas to identify/validate approaches to eliminate disparities; identify/define how social determinants of health (SDOH), structural racism, and provider bias drive inequity; and increase minority participation in clinical trials.
2. **Develop priority areas to address specific SDOH-related questions across the lifespan**, with the goal of developing multidisciplinary, targeted interventions, co-created with patients, families, and community stakeholders, to address adverse childhood experiences (ACEs) and other SDOH that are uncovered in the clinical setting.
3. **Prioritize the assessment, screening, measurement, and interventions on SDOH** and develop guidelines for researchers and clinicians to conduct needs assessments on the burden of SDOH in their clinical settings and their capacity to screen for and address SDOH in research using accepted screening tools and common data.
4. **Prioritize evaluation of the most relevant and impactful interventions** for addressing the drivers of economic instability (poverty, housing, food insecurity, employment) and the impact on neurological health.
5. **Develop and validate SDOH-informed instruments** to promote detection and assessment of neurological disorder health disparities (HD) specific to diverse populations vulnerable to HD.
6. **Involve the *community* early. Specify early community engagement in FOAs and include it in reviewers' evaluations.**
7. **Require reporting of *community* engagement strategies** in all NIH funded research submitted to peer-reviewed journals**. *Specify the importance of engaging with underrepresented communities in FOAs and in reviews of applications*.**
8. **NINDS should fund a range of research efforts aimed at increasing understanding of, identifying, and implementing effective strategies to address *community* distrust of science and scientists.**
9. **NINDS should fund qualitative research targeting at-risk populations** to better understand how they make health decisions (before the inception of a disease), how they prefer to receive health information, and what motivates them to make healthy behavioral changes that may prevent the future onset of neurological disease.
10. **Build and disseminate curricula that address challenges in community-based participatory research.**
11. **Include best practices in partnering with *community* organizations as part of health inequity research training.** These activities may include mentoring from experienced community health workers and others who can help ensure that research activities have optimal potential to benefit the communities of interest.

12. **Allocate funding to support a network of partnerships** between research-intensive institutions and historically minority colleges and universities to allow exchange of health equity research ideas, cultural sensitivity awareness, and access to minority investigators and communities.
13. **Support career development for minority junior investigators through multiple mechanisms** (e.g., Diversity Supplements, K-awards).
14. **Require Certificate of Completion following completion of key training activities;** embed health disparities training in all career development and training grant applications; and develop culturally aware mentoring programs or incorporate cultural sensitivity training into planned or existing programs.
15. **Create a new NINDS funding mechanism to promote health equity research** aimed at not only underrepresented minority (URM) investigators interested in this line of work, but also at non-URM scientists, who are solely interested in conducting health equity research but also in developing opportunities to train both URM and non-URM junior investigators who are developing academic careers in health equity research.
16. **Provide funding and logistical support for grantsmanship workshops for trainees from underrepresented backgrounds.** Proactively track and invite trainees with appropriate backgrounds who have not yet secured competitive research funding.
17. **Emphasize interventional research as a major component of training programs** for scientists (of all backgrounds) focused on health inequities research.
18. **Prioritize developing SDOH-informed instruments, national HD neurological disorder disease surveillance, and a centralized neurological disorder HD database.** Build infrastructure to generate and validate harmonized national surveillance of neurological disease progression among HD-vulnerable populations across the lifespan. This will support the development of early detection and prevention strategies, appropriate assessment instruments, and prompt evidence-based care.

Discussion

Council members suggested investing in existing, underfunded health disparities/health equity work, especially for those who already have tools and study populations in hand. Comments included the need to educate study sections on trial design to intentionally consider health equity; eligibility criteria should not exclude individuals with comorbidities to ensure health equity is taken into account; Council members proposed using funding mechanisms that promote workforce diversity.

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

VI. Triennial Inclusion Report: Inclusion of Women and Minorities as Participants in Clinical Research

Dr. Richard Benson, Program Director, Office of Global Health and Health Disparities, NINDS

Dr. Benson presented the inclusion report mandated by the Public Health Service Act that ensures inclusion of women and minorities in all NIH-funded clinical research and requires clinical trial designs to provide information about differences between sex/gender, race, and/or ethnicity.

Dr. Benson displayed total inclusion for enrollment records (IERs) for clinical research reported between FY2019 and FY2021. He noted that during this period, there were no significant changes in the ratios of individuals identified as white, black/African American, Asian, Native Hawaiian/Pacific Islander, American Indian/Native American, multi-race, and unknown race. There were no real changes in enrollment based on sex/gender. In 2020, Phase III clinical research included clear engagement in enrolling Hispanic subjects compared to other years due to enrollment of Hispanics in a study in Peru.

The 2021 data by age distribution showed significant enrollment of children (less than 18 years) compared with two adult age groups: 18–64 years and 65 years and older.

Strategies to increase inclusion of women and minorities include working with peer review; program staff monitoring and grants management oversight; continued training of NINDS staff; program staff support to investigators (presubmission); Network-specific Minority Recruitment and Diversity Committees (i.e., NeuroNEXT and StrokeNet); and establishment of a Division of Clinical Research workgroup that discusses best practices in inclusion and community engagement techniques.

Discussion
Council members suggested providing inclusion data corrected for disease-associated prevalence. This is of particular relevance to stroke studies, for which eligibility criteria should reflect higher incidence among older ages and women.

A motion to approve the Triennial Inclusion Report was made, seconded, and carried.

VII. Report of the Clinical Trials Networks Evaluation Working Group of the NANDS Council: NeuroNEXT and NIH StrokeNet
Dr. Barbara Vickrey (Co-chair), Professor and Chair, Icahn School of Medicine at Mt. Sinai
Dr. Richard Rudick (Co-chair), Optimal Brain Health Consultants

Dr. Vickrey introduced the evaluation working group that was charged with assessing processes and outcomes for the two NINDS clinical research networks: NeuroNEXT and StrokeNet. The group focused on identifying areas for improvement in the design of the next iterations of these programs with consideration of the following: the extent to which the programs are meeting their goals and collaborating with and benefitting the research community.

Dr. Rudick presented the working group recommendations focused on proactively identifying priorities and improving pre-award review efficiency.

Proactively identify priorities. Network proposal review is entirely reactive and does not provide guidance to the community on high-priority unmet needs or systematic identification of therapeutics with high scientific promise. Recommendations to address this include:

1. Implement a multi-stakeholder process to prioritize studies that meet high-priority unmet needs and have high scientific promise.
2. Issue specialized FOAs for identified priorities to guide investigators.
3. Leverage this approach to advance use of innovative study designs and methods such as platform and virtual trials and use of promising emerging technologies.

4. initiate at least two pediatric trials per network.

Monumentally improve pre-award/review efficiency. The median time from initial proposal to budget activation was very long 925/957 days for NeuroNEXT and 405/612 days for StrokeNet. Notably, success rates were 5.5 percent for NeuroNEXT and 9.0 percent for StrokeNet. Network staff and applicants spent substantial time conducting internal network review and planning of proposals that were never initiated. Recommendations to address this include:

1. Shorten time from initial study concept receipt to Notice of Grant Award by at least 50 percent.
2. Move peer review for significance and impact earlier in the process, to mitigate resources used in the planning.
3. Consider alternatives to reviewing trials as separate grant applications through regular study sections as is done by NCI and in Early Phase Pain Investigation Clinical Network (EPPIC-Net).

Other recommendations.

1. Strengthen internal and external community engagement
2. Increase attention to and resourcing for patient recruitment, especially from underrepresented groups
3. Set explicit goals to address diversity, equity, and inclusion and include resources to achieve them
    a. Set an explicit goal to achieve a distribution of study participants, investigators, trainees, and staff that each reflect at least the proportions of individuals from non-White groups by race and of Hispanic ethnicity per the 2020 census
4. Enhance workforce development, readiness, and retention
    a. Establish specific expectations & deliverables for Fellows programs
5. Strengthen regular network evaluation and timely improvement

The working group raised two additional considerations for NINDS: revisiting the Institute's approach to organizing support for CTs: 1) Does it make sense have One network for stroke trials (across the development spectrum) and one network for all other neurological conditions (focused largely on phase 2 studies). 2) Clarify whether studies to advance CT tools and methods are within the scope of the two networks.

Discussion

Council members commented about support for research coordinators who are critical to CT enrollment, broadening stakeholders to include end-users of data generated by trials, ensuring resources are set aside for training in authentic and meaningful community engagement, and the practicalities around pediatric trials in stroke.

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

A motion was made to approve the StrokeNet and NeuroNEXT clinical trials concept. Reissuance details will be presented to Council in the future. The motion was seconded and carried.

VIII. BRAIN® Initiative Update

Dr. John Ngai, Director, NIH BRAIN® Initiative

Dr. Ngai presented an overview of the BRAIN® Initiative budget, which includes funds from the 21st Century Cures Act that are projected to reach $5.8 billion through 2026, and highlighted recent Initiative efforts. The BRAIN® Initiative approach to advancing excellence through inclusivity is built on three pillars: training the next generation of scientific leaders (e.g., diversity-focused training awards), engaging new partners (e.g., a capacity-building RFA), and fostering inclusive research environments via a Plan for Enhancing Diverse Perspectives (PEDP) requirements in nine BRAIN FOAs.

The BRAIN® Initiative's neuroethics strategy emphasizes proactive, ongoing assessment of the neuroethical implications of the development and application of BRAIN-funded tools and neurotechnologies. BRAIN® efforts to integrate neuroethics into science include the Neuroethics Working Group, neuroethics guiding principles, topical workshops, and funded neuroethics research. For example, the January 2022 neuroethics working group meeting included a session on ethical challenges in implanted neural device research with human participants. A workshop series on post-trial responsibilities is planned for mid-2022.

Dr. Ngai provided an update on three large projects that will transform neuroscience: a comprehensive atlas of human brain cells, tools to complete a microconnectivity map of an entire mammalian brain, and tools for precision access to identified cell types to enable interrogation and modulation of neural circuits.

Recent BRAIN®-supported research advances include a cell census and atlas of the mammalian primary motor cortex, a mouse and marmoset study of engineered adeno-associated virus capsid variants, a study of intracranial brain stimulation in a patient with depression, and an assessment of intracranial electrophysiology in patients with Obsessive-Compulsive Disorder (OCD).

Dr. Ngai announced several upcoming workshops and the 8th Annual BRAIN® Initiative Meeting. A searchable database of FOAs is available at https://braininitiative.nih.gov/funding/funding-opportunities.

Discussion
Council members expressed interest in seeing proteomic studies incorporated into BRAIN® databases.

IX. Initiatives Requiring Concept Clearance (IRP)

Supporting Team Science at NINDS
Karen David, Division of Neuroscience

This proposed concept, would employ an RM1 mechanism to support interdisciplinary collaborations from 3-6 MPIs to achieve a common goal/solve a defined problem. The RM1 will require a Team Management Plan and provide resources for managing and coordinating team science. It will also require a *Plan for Enhancing Diverse Perspectives* (PEDP) similar to the BRAIN® initiatives. NINDS will support RM1 projects that challenge existing paradigms,

overcome long-standing roadblocks to progress, and/or develop new synergies among different scientific fields.

Council voted to approve moving forward with this concept.

AD/ADRD FOA Concepts
Rod Corriveau, Division of Neuroscience

Dr. Corriveau explained the NIH commitments and workflow for AD/ADRD research. NIA leads the NIH response to the National Plan, and NINDS leads support for Lewy body dementia (LBD), frontotemporal degeneration (FTD), and vascular contributions to cognitive impairment and dementia (VCID), as well as the ADRD planning summits. NINDS and NIA collaborate closely on funding opportunities. He described the ADRD FOA development process from concept development through discussion and leadership input and bringing the concepts to NANDSC for Council approval vote.

The following ADRD FOA Concepts are proposed for FY2023:

1. ADRD, Adverse Childhood Experiences, and Social Determinants of Health Ancillary Studies of Existing Longitudinal Cohorts *Lead: Dr. Hommer*
2. Early-Stage Therapy Development for ADRD *Lead: Dr. Roof*
3. Pragmatic Clinical Trials in Community Settings to Decrease or Prevent VCID Outcomes, Including in Populations that Experience Health Disparities *Lead*: *Dr. Benson*
4. Postmortem Neuropathology, Cellular, and Molecular Analyses, Including Ex-Vivo Imaging, to Assess the Significance of Human TBI and VCID AD/ADRD-Relevant Imaging and Clinical Findings During Life *Leads: Drs. Umoh and Faraco*
5. Impact of the Microbiome Gut-Brain Axis on ADRD *Lead: Dr. Jett*
6. Training Award to Promote Cross-Training in the Fields of TBI in AD/ADRD *Leads: Drs. Umoh and Faraco*
7. Connecting Machine Readable Digital Human ADRD Neuropathological Library Platforms for Advanced Analytics *Lead:* Dr. *Umoh*
8. Somatic Cell Genome Editing for ADRD *Lead: Dr. Lavaute*
9. COVID-19 Related Revisions to NINDS ADRD Human Subjects Cooperative Agreement Programs *Lead: Dr. Wright*
10. Using Multimodal Biomarkers to Differentially Diagnose ADRDs for Clinical Trials *Leads: Drs. Babcock and Taylor-Burds*
11. Blood Brain Barrier Response to Antibodies Targeting Beta-Amyloid *Lead: Dr. Corriveau*
12. Treatments for Lewy Body Dementias & Frontotemporal Degeneration - Exploratory Clinical Trial (Related to RFA-NS-21-008) *Lead: Dr. Babcock*
13. Reissue: Functional Validation of Novel Targets in ADRD (Re-issue RFA-NS-19-015) *Lead: Dr. Laeng*
14. Reissue: Structural Biology of Alzheimer's Disease Related Dementias Proteinopathies (Re-issue RFA-NS-18-015) *Lead: Dr. Cheever*

Additional Concepts

15. Reissue: Mechanisms, Models, Measurement and Management in Pain Research (R01) CT Optional *Lead: Dr. Mohapatra*

16. Reissue: PAR-19-220: Clinical Trial Readiness for Rare Neurological and Neuromuscular Diseases (U01 Clinical Trial Not Allowed) *Lead: Dr. Nuckolls*
17. Reissue: RFA-NS-21-020: Research Program Award (R35 Clinical Trial Optional) Outstanding Investigator Award *Leads: Drs. Owens and Schaefer*
18. Reissue: RFA-NS-20-003: Education Program on Translational Devices *Lead: Dr. Ashmont*
19. Reissue: PAR-21-209: NIH Countermeasures Against Chemical Threats (CounterACT) Early-Stage Investigator Research Award *Leads: Drs. Jett and Spriggs*

Council voted to approve all of the above (items 1–19).

Intramural Scientific Director Search Update
Nina Schor, Deputy Director, NINDS

Dr. Schor provided an update on the search for the next NINDS Scientific Director. Of 21 applicants, 24 percent are women, 24 percent are Asian, 10 percent are Hispanic, and 5 percent are black. About half of the applicants are PhDs, 15 percent are MDs, and 30 percent are MD/PhDs. Semi-finalists are being interviewed. A short list of finalists will be handed off to Dr. Koroshetz by the end of February.

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 338 research career development and institutional training grant applications with primary assignment to NINDS, and 205 of them (61 percent) were scored in the amount of $18.6 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 $9.3 million (99 grants).

Research Project and Center Awards – The Council reviewed a total of 1,440 research project and center applications with primary assignment to NINDS, and 838 of them (58 percent) were scored/percentiled in the amount of $283.8 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 $74.5 million (249 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: Richard Huganir, Ph.D. (John Hopkins University), and Mark Baccei, Ph.D. (University of Cincinnati).

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 93 of them (60 percent) were scored in the amount of $44.9 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 $8.4 million (12 grants).

X. Adjournment
The meeting was adjourned at 4:00 p.m. on Thursday, February 3, 2022.

NINDS employees present for portions of the meeting included:

Open Session:

DeAnna Adkins
Ram Arudchandran
Kari Ashmont
Taryn Aubrecht
Hibah Awwad
Debra Babcock
Julia Bachman
Kelly Baker
Linda Bambrick
Amy Bany Adams
Elena Barnaeva
Jennifer Barnes
Patrick Bellgowan
Richard Benson
William Benzing
Thomas Bleck
Marci Bollt
Carolyn Bondar
Naomi Booker
Francesca Bosetti
Chris Boshoff
Giulia Bova
Ryan Calabrese
Roger Campbell
Emily Caporello
Stacey Chambers
Chi Chang
Maria Charlier
Denise Chatman
Bo-Shiun Chen
Daofen Chen
Ben Churn
Robin Conwit
Janice Cordell
Rod Corriveau
Devon Crawford

Diana Cummings
Charles Cywin
William Daley
Sara Dauber
Karen David
Vedangi Desai
Neel Dhruv
Anthony Domenichiello
Adele Doperalski
Denise Dorsey
Argenia Doss
Kristin Dupre
Anahid Ebrahimi
Debbie Eng
Judy Fabrikant
Christina Fang
Carlos Faraco
Robin Felder
Bob Finkelstein
Jane Fountain
Megan Frankowski
Natalie Frazin
Alissa Gallagher
Lina Garcia
Shannon Garnett
Hermon Gebrehiwet
Maryam Ghaleh
Marie Gill
Paul Girolami
Jordan Gladman
Jim Gnadt
Kalynda Gonzales Stokes
Maureen Gormley
Rogers Gross II
Amelie Gubitz
Clint Guin
Mohamed Hachicha
E Haley
Joseph Hall
Maureen Hambrecht
Adam Hartman
Brandon Hartsell
Brian Haugen
Jane Hettinger
David Higgins
Rebecca Hommer
Mir Ahamed Hossain
Nina Hsu
Eric Hudak
Xan Humphries
Smriti Iyengar
Scott Janis
Lyn Jakeman
Sophia Jeon
David Jett
Karen Johnston
Michelle Jones-London
Barbara Karp
Cory Kelly
Brenda Kibler
Eunyoung Kim
Jenny Kim
Yasmin Kloth
Jim Koenig
Stephen Korn
Walter Koroshetz
Kranthi Kotha
Sahana Kukke
Pascal Laeng
Christine Lam
Nick Langhals
Crystal Lantz
Dr. Lataisia Jones
Timothy LaVaute
Crystal Lee
Miriam Leenders
Catherine Levy
Nina Lichtenberg
Erica Littlejohn
Cara Long
Rosa Lopez
Stephanie Lowenhaupt
Codrin Lungu
Quynh Ly
Tim Lyden
Heidi Matos Galicia
Marguerite Matthews
Amber McCartney

Linda McGavern
Barbara McMakin
Carolina Mendoza-Puccini
Daniel Miller
Stephanie Mitchell
DP Mohapatra
Karen Molina
Marilyn Moore-Hoon
Jill Morris
Paul Myers
John Ngai
Cristina Nigro
Glen Nuckolls
Jiaqi O'Reilly
Ana Olariu
Oreisa O'Neil-Mathurin
Jiaqi O'Reilly
Nia Pree
Tatiana Pasternak
Michele Pearson
Mary Ann Pelleymounter
Marlene Peters-Lawrence
Erna Petrich
Leah Pogorzala
Linda Porter
Pragya Prakash
Rebecca Price
Carlo Quintanilla
Shamsi Raeissi
Shanta Rajaram
Ranga Rangarajan
Yogendra Raol
K. Paul Rezaizadeh
Robert Riddle
Sarah Robinson-Schwartz
Becky Roof
Cheryse Sankar
Joel Saydoff
Alisa Schaefer
Nina Schor
Lindsey Scott
Paul Scott
Kathy Sedgwick
Kelly Sheppard
Beth-Anne Sieber
Shai Silberberg
Adissa Silue
Mario Skiadopoulos
Shardell Spriggs
Natalia Strunnikova
Abhi Subedi
Maripierre Surpris
Christine Swanson-Fischer
Brooke Sydnor
Elizabeth Sypek
Edmund Talley
Amir Tamiz
Beverly Tarrant
Anna Taylor
Felecia Taylor
Carol Taylor-Burds
Shruthi Thomas
Christine Torborg
Delany Torres
Natalie Trzcinski
Eric Tucker
Alexander Tuttle
Lauren Ullrich
George Kwabena Umanah
Nsini Umoh
Ursula Utz
Nasim Vahidi
Joanna Vivalda
Cheryl Wall
Laura Wandner
James Washington
Anne-Sophie Wattiez
Keith Whitaker
Matthew White
Vicky Whittemore
Shellie Wilburn
Ling Wong
Clint Wright
Xiing Yin
Ariel Zane
Ran Zhang

Other federal employees present for portions of the meeting included:

Jonathan Bennett, CIT
Rob Folson, CIT

Closed Session:

DeAnna Adkins
Ram Arudchandran
Kari Ashmont
Taryn Aubrecht
Hibah Awwad
Debra Babcock
Julia Bachman
Kelly Baker
Linda Bambrick
Amy Bany Adams
Elena Barnaeva
Jennifer Barnes
Andrea Beckel-Mitchener
Patrick Bellgowan
Richard Benson
William Benzing
Victoria Bitzer-Wales
Marci Bollt
Carolyn Bondar
Naomi Booker
Francesca Bosetti
Chris Boshoff
Giulia Bova
Jeremy Brown
Ryan Calabrese
Roger Campbell
Emily Caporello
Stacey Chambers
Chi Chang
Maria Charlier
Denise Chatman
Thomas Cheever
Bo-Shiun Chen
Daofen Chen
Ben Churn
Robin Conwit
Janice Cordell
Rod Corriveau
Devon Crawford
Diana Cummings
Charles Cywin
William Daley
Sara Dauber
Karen David
Neel Dhruv
Sara Dodson
Anthony Domenichiello
Adele Doperalski
Argenia Doss
Kristin Dupre
Anahid Ebrahimi
Debbie Eng
Judy Fabrikant
Christina Fang
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Carlos Faraco
Robin Felder
Cassandra Fields
Bob Finkelstein
Nhi Floyd
Jane Fountain
Megan Frankowski
Lina Garcia
Hermon Gebrehiwet
Maryam Ghaleh
Marie Gill
Jordan Gladman
Jim Gnadt
Kalynda Gonzales Stokes
Maureen Gormley
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Amelie Gubitz
Mohamed Hachicha
Joseph Hall

Maureen Hambrecht
Adam Hartman
Brandon Hartsell
Brian Haugen
Janet He
Jane Hettinger
Rebecca Hommer
Mir Ahamed Hossain
Nina Hsu
Xan Humphries
Smriti Iyengar
Scott Janis
Lyn Jakeman
Carole Jelsema
Sophia Jeon
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Li Jia
Lataisia Jones
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Brian Klein
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Sahana Kukke
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Nick Langhals
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Timothy LaVaute
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Quynh Ly
Tim Lyden
Heidi Matos Galicia
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Amber McCartney
Linda McGavern
Barbara McMakin
Carolina Mendoza-Puccini
Mirela Milescu
Daniel Miller
DP Mohapatra
Karen Molina
Marilyn Moore-Hoon
Jill Morris
Paul Myers
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Shamsi Raeissi
Shanta Rajaram
Ranga Rangarajan
Yogendra Raol
K. Paul Rezaizadeh
Ryan Richardson
Robert Riddle
Becky Roof
Cheryse Sankar
Joel Saydoff
Alisa Schaefer
Nina Schor
Lindsey Scott
Shalini Sharma
Smita Sharma
Beth-Anne Sieber
Shai Silberberg

Adissa Silue
Mario Skiadopoulos
Shardell Spriggs
Natalia Strunnikova
Abhi Subedi
Maripierre Surpris
Christine Swanson-Fischer
Brooke Sydnor
Elizabeth Sypek
Edmund Talley
Amir Tamiz
Anna Taylor
Carol Taylor-Burds
Michael Tennekoon
Shruthi Thomas
Christine Torborg
Delany Torres
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Nasim Vahidi
Joanna Vivalda
Laura Wandner
Anne-Sophie Wattiez
Sam White
Vicky Whittemore
Shellie Wilburn
Ling Wong
Clint Wright
Xiing Yin
Ariel Zane
Ran Zhang

Other federal employees present for portions of the meeting included:

Carole Jelsema, CSR
Aleksey Kazantsev, CSR
Suzan Nadi, CSR
Delia Olufokunbi Sam, CSR
Sarah Robinson Schwartz, NIH OD
Elyse Schauwecker, CSR
Lauren Taupenot, CSR

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

__4/29/2022__
Date

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

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

4/29/2022

Date

Walter J. Koroshetz -S

Digitally signed by Walter J. Koroshetz -S
Date: 2022.04.29 12:17:09 -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.