NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS

ADVISORY COUNCIL

May 19 and 20, 2022

National Institutes of Health

Bethesda, Maryland

MINUTES

The National Deafness and Other Communication Disorders Advisory Council (NDCDAC) convened on May 19 and May 20, 2022, via videoconference at the National Institutes of Health (NIH) in Bethesda, MD. Dr. Debara L. Tucci, Director, National Institute on Deafness and Other Communication Disorders (NIDCD), served as Chairperson. In accordance with Public Law 92-463, the meeting was:

Closed: May 19, 2022, 10:00 a.m. to 12:00 p.m. for review of individual grant applications; and

Open: May 19, 2022, 1:00 p.m. to 3:38 p.m. and May 20, 2022, from 10:00 a.m. to 12:48 p.m., for the review and discussion of program development needs and policy.

Council members in attendance[1]:

Dr. Emily Buss
Dr. Laurel Carney
Dr. Nirupa Chaudhari
Ms. Vicki Deal-Williams
Dr. Ruth Anne Eatock
Mr. Richard Einhorn
Dr. Carol Espy-Wilson
Dr. Lisa Goffman
Dr. Andy Groves
Dr. Argye Hillis
Dr. Robert Hillman
Ms. Barbara Kelley
Dr. Anil Lalwani
Dr. Cynthia Morton
Dr. Dan Sanes
Dr. Ben Strowbridge
Dr. Margaret Wallhagen

Council Members Absent:
Ms. Lynne Murphy Breen

Ex-Officio Council Members in attendance:
Ms. Christa Themann (CDC)
Dr. Jeremy Nelson (DOD)
Dr. Judy Schafer for Dr. Lucille Beck (VA)

The complete Council roster can be found in Appendix 1.
NIDCD staff and other NIH staff in attendance list can be found in Appendix 3.

[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. This procedure applies only to individual discussion of an application and not to "*en bloc*" actions.

CLOSED SESSION May 19, 2022

Call to Order and Opening Remarks ..... Dr. Debara L. Tucci

The meeting was called to order by Dr. Tucci, Director, NIDCD, who expressed appreciation to the entire Council for their service and advice.

Council Procedures..... Dr. Becky Wagenaar-Miller

Procedural Matters

Dr. Becky Wagenaar-Miller discussed important procedural matters, including requirements imposed by the Government in the Sunshine Act and the Federal Advisory Committee Act. The necessity of members to avoid any conflict of interest and the need to maintain confidentiality concerning the proceedings and materials related to the closed portion of the meeting. Dr. Wagenaar-Miller announced that the Council meeting would be closed for consideration of grant applications during the morning session and would be open to the public at approximately 1:00 p.m. via Videocast.

Council Consideration of Pending Applications ..... Dr. Judith Cooper and Staff

Research Project Grant Awards

Consideration of Applications: On the Council's agenda was a total of 101 investigator-initiated R01 grant applications; 83 applications had primary assignment to NIDCD, in the amount of $32.5 million first-year direct costs. It is anticipated that, of the applications competing at this Council, NIDCD will be able to award grants to R01 applications scoring up through the 14th percentile.

Special Program Actions

1. NIH Mentored Clinical Scientist Research Career Development Award (K01): The Council voted to support of one application.
2. NIH Mentored Patient-Oriented Research Career Development Award (K23): The Council voted to support of one application.
3. NIH Pathway to Independence Award (K99/R00): The Council voted to support three applications.
4. Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Postdoctoral Career Transition Award to Promote Diversity (K99/R00): The Council voted to support one application.
5. Enhancing NIDCD's Extramural Workforce Diversity through Research Experiences (R25 Clinical Trial Not Allowed): The Council voted to support one application.
6. NIH Support for Conferences and Scientific Meetings (R13): The Council voted to support one application.
7. NIH Research Enhancement Award (R15): The Council voted to support one application.
8. NIH Exploratory/Development Research Grant Award (R21): The Council voted to support six applications.
9. NIDCD Early Career Research (ECR) Award (R21): The Council voted to support six applications.
10. NIH Small Business Technology Transfer Grant (STTR): The Council voted to support two Phase I (R41) applications.
11. NIH Small Business Innovation Research Awards (SBIR): The Council voted to support one Phase I (R43) application.
12. NIH Small Business Innovation Research Awards (SBIR): The Council voted to support one Phase II (R44) application.

13. SBIR/STTR Commercialization Readiness Pilot (CRP) Program Technical Assistance and Late-Stage Development (SB1, Clinical Trial Not Allowed): The Council voted to support one application.
14. RFA-HD-22-008 Autism Centers of Excellence: Networks (R01): The Council voted to support co-fund of one application.
15. PAR-22-002 - Collaborative Research in Computational Neuroscience (CRCNS) NSF Innovative Approaches to Science and Engineering on Brain Function (R01): The Council voted to support three applications.
16. PAR-21-303 – Mobile Health: Technology and Outcomes in Low- and Middle-Income Countries (R21/R33 – Clinical Trial Optional): The Council voted to support one application.
17. PAR-21-319 – Global Brain and Nervous System Disorders Research Across the Lifespan (R21 Clinical Trial Optional): The Council voted to support one application.

OPEN SESSION – May 19, 2022

Opening Remarks ..... **Dr. Tucci**

Dr. Tucci welcomed additional staff and visitors to the open session of the meeting which was available to the public from the NIH Videocast website. (https://videocast.nih.gov/watch=45315)

Council Introduction

Dr. Tucci invited each council member to introduce themselves to begin the meeting.

Consideration of Minutes of the Meeting of January 28 & 29, 2022

Dr. Tucci called the members' attention to the minutes of the January 28 and 29, 2022 meeting of the NDCDAC. The minutes were approved as written.

Confirmation of Dates for Future Council Meetings

Dates for the Council meetings through September 2024 have been established. A list of these meetings was distributed to the Council members and posted on the NIDCD website prior to this meeting. The next meeting of the Council is scheduled for Thursday September 8, 2022, and Friday, September 9, 2022.

[*Executive Secretary Note: The September 2022 council meeting will be hybrid and held on Thursday, September 8, 2022, and Friday September 9, 2022. Check the NIDCD Council website for meeting specifics.]*

NIDCD Director's Report ..... **Dr. Tucci**
NIH Updates: ARPA-H
Dr. Tucci reminded the council of the creation of a new federal research agency – The Advanced Research Projects Agency for Health, or ARPA-H, and how plans for this new agency are beginning to crystalize.

ARPA-H provides a platform for propelling use-driven, high-impact biomedical and health research.
The draft mission is: "To benefit the health of all Americans by catalyzing health breakthroughs that cannot readily be accomplished through traditional research (such as NIH), or commercial activity." She stressed the last part is a key point to be able to do make health breakthrough that cannot be done currently.

ARPA-H will support transformative, high-risk, high-reward biomedical and health research to:

- embrace a sense of urgency, to speed application and implementation of breakthroughs at various levels – from molecular to the societal – so that they serve all people

- build capabilities and platforms that are broadly applicable across a range of diseases/conditions to revolutionize how we prevent, treat, and cure them

- focus on converting use-driven ideas – those ideas with a direct application – into solutions for patients quickly

- help to overcome market failures through creative solutions, incentives, de-risking

Dr. Tucci indicated that ARPA-H will leverage an approach that was pioneered at the Defense Advanced Research Projects Agency (DARPA) and that has been applied in other areas of research and development. She explained that ARPA-H is being created as a distinct entity within NIH that will have the autonomy, independence, resources, and authorities to tackle some of the biggest challenges facing human health. The Director of ARPA-H is a presidential appointee and will report to the HHS secretary. ARPA-H will draw on knowledge, expertise, and ongoing activities of NIH, maximizing scientific collaboration and synergy and minimizing duplication of scientific and administrative effort.

Echoing many elements of the DARPA model, ARPA-H will be centered around ensuring risk tolerance – or acceptance – and instilling a sense of urgency, nimbleness, and innovation. ARPA-H is linked to NIH to draw on the vast knowledge, expertise, and infrastructure there; however, it will remain a distinct and autonomous organization. In order to do that, ARPA-H will seek to:

- bring on the most innovative people with the most novel ideas, that will form robustly diverse and collaborative teams

- equity will be considered an essential element of ARPA-H, and will be key to its internal practices, including hiring, and in the programs it supports, and the awards that are made

- be nimble and lean in administering its organization, business processes, and scientific portfolio, and inject a sense of urgency, operating under time-bound principles for both programs and the tenure of the people

- be open and transparent about these processes and approaches and engage stakeholders across a wide range of sectors and disciplines, early and often

- promote independence and accountability, reinforced by ambitious milestones and metrics, and

- seek to have bold programs, with the acceptance that not all will be successful, but could offer outsized impact and return on investment

Starting in the summer of 2021, the Office of Science and Technology Policy and NIH published a commentary in *Science* outlining a vision for ARPA-H, and held information sessions, meetings with different organizations, and convened 16 listening sessions (with over 5100 participants) to get feedback from stakeholders, including patient advocacy groups, industry, and scientific professional organizations.

Dr. Tucci explained that the fiscal year 2022 omnibus appropriated $1B to be available over 3 years to launch ARPA-H and provided for:

- a presidentially appointed director

- flexible hiring and compensation authority

- award flexibilities and

- the HHS secretary may transfer ARPA-H within HHS

She indicated that since the appropriations

- the Secretary transferred ARPA-H to NIH

- the ARPA-H Director will directly report to the HHS Secretary
- the President requested $5B in the FY 23 budget to initially fund ARPA-H

NIH Updates: All of Us

Turning to another innovative NIH program, Dr. Tucci provided an update on the *All of Us* research program. In March 2015, the NIH formed the Precision Medicine Initiative Working Group of the Advisory Committee to the Director. The group concluded its work in September 2015 with a detailed report that provided a framework for setting up the *All of Us* Research Program.

This research program is an ambitious effort to gather health data from one million or more people living in the United States to accelerate research that may improve health. With over 490,000 participants currently enrolled, it is well on its way to building one of the most diverse health databases in history. Participants are asked to take online surveys, share their electronic health record and may be asked to give blood and urine samples or have physical measurements taken.

All of Us is part of a new era in which researchers, health care providers, technology experts, community partners, and the public work together to develop individualized health care. The Researcher Workbench allows the data to be used to learn how biology, lifestyle, and environment affect health and ultimately find ways to treat and prevent disease. Dr. Tucci indicated that NIH will be providing additional *All of Us* funding opportunities soon and that future council meetings will include more about this program.

NIH Updates: Diversity, Equity, Inclusion and Access

During the month of May, we celebrate and focus on diversity, inclusion, and leadership to advance the Asian American (AA) and Native Hawaiian, and Pacific Islander (NHPI) communities. This year, as expressed in the statement: “We are not a monolith,” our attention turns to better understanding the diversity of this community. When we categorize AA and NHPIs as a single group, it masks the diversity of languages, cultures, and customs of the many countries and regions that are represented. In fact, this monolithic view of AA and NHPIs also makes it difficult to understand the disparities within the AA and NHPI communities from education level to socioeconomic status.

NIDCD, along with the broader NIH community, continues to address issues in healthcare disparities, scientific workforce diversity, and discrimination that impact the AA and NHPI community.

NIDCD Updates

NIDCD and the National Institute on Aging (NIA) hosted a webinar on April 7, 2022. The purpose of the webinar was to highlight basic and translational research on communication disorders in Alzheimer’s Disease and Related Dementias supported through the collaborative efforts of NIDCD and NIA. Dr. Tucci explained that NIDCD and NIA have a long-standing interest on research on age-related hearing loss and also on balance disorders in older adults. These interests have resulted in joint Funding Opportunity Announcements on these topics. NIA also funded administrative supplements to NIH grantees to study Alzheimer’s disease and related dementias, and this webinar highlighted NIDCD grantees who were supported under that effort. Dr. Tucci shared a large list of distinguish speakers that presented on the state-of-the-science on animal models and on human studies. The webinar can be viewed by visiting the NIH Videocast https://videocast.nih.gov/watch=44829.

On Friday, May 13, 2022, NIDCD held a symposium celebrating the career of Carter Van Waes, M.D., Ph.D., clinical director of the NIDCD and chief of the NIDCD Head and Neck Surgery Branch, Tumor Biology Section. The day-long symposium highlighted the impact Dr. Van Waes has had on the NIDCD clinical program and the critical contributions he has made to head and neck cancer research. Dr. Tucci indicated that Dr. Van Waes is retiring in July and that recruitment is underway for his replacement. She expressed her thanks and stated that

she will miss his leadership and his clinical expertise. (NOTE: The celebration was not recorded.)

Dr. Tucci then finished her report with an update and discussion of the NIDCD Strategic Plan. The draft themes and goals of the new strategic plan were posted on the NIDCD website for public comment. The draft was shared with all NIDCD grantees and professional and scientific organizations that have interest in NIDCD's mission.

The draft plan has six overarching scientific themes. Under each theme, there are at least three goals that correspond to the theme. NIDCD developed these themes and goals in conjunction with input from the scientific community last year. The draft themes and goals are based on an assessment of the research areas that present the greatest scientific opportunities and address the greatest public health needs over the next 5–10 years for hearing, balance, taste, smell, voice, speech, and language.

1. Capitalize on advances in basic research to enhance our understanding of normal function and disordered processes
2. Develop and improve model systems to inform research
3. Promote a precision medicine approach to prevention, diagnosis, and treatment
4. Translate and implement scientific advances into standard clinical care
5. Facilitate use of best practices in biomedical data science
6. Harness advanced technology to improve prevention, diagnosis, and treatment

In addition to the themes, NIDCD will be addressing several NIH cross-cutting priorities:

- Research Training and Career Development
- Scientific Workforce
- Workforce Diversity
- Global Health
- Women's Health

She encouraged individuals to submit comments on the draft by May 31, 2022 by going to the NIDCD web page.

Budget Report .....Dr. Tucci

The budget report is usually given by Mr. Eric Williams, the Chief Budget Officer at NIDCD. He had an emergency, so Dr. Tucci continued with the Budget Report on his behalf. President Biden signed the current spending bill which gives NIH/NIDCD a budget. There have been four continuing resolutions this year before this budget. The final enacted budget is $514.9 million which represent a 3.4% increase in funding. Dr. Tucci mentioned that noncompeting awards are fully funded.

The breakdown of the budget shows what NIDCD spent in FY 2021 compared with the operating plan of spending for FY 2022. Most of the funding in the Research Projects is for non-competing awards followed by competing awards. The next line item is the Small Business set aside funds (SBIR/STTR). These funds must be spent on small business applications. The next line is the Research Centers, followed by Individual and Institutional Training grants, R & D Contracts, Intramural Research and Research Management and Support.

Dr. Tucci showed slides that provide a view of the success rates for funding across the NIH compared with the NIDCD. The graphs indicate that NIDCD success rates are above the NIH success rates for both Research Project Grants and the Fellowship program.

Report of the Division of Scientific Programs ..... Dr. Judith Cooper

Dr. Judith Cooper, as Division of Scientific Programs director, presented an update on NIDCD diversity, equity, inclusion, and accessibility (DEIA) activities. She began with an update from the NIDCD DEIA Implementation Committee. In January she provided a response to many of the recommendations in the Advisory Council Diversity Workgroup report. Actions and activities are continuing at a good pace across the institute.

This committee is representative of the various parts of NIDCD, and all share a commitment to change in DEIA issues and are working to address many of those issues raised in the Council Diversity Workgroup report. Members of the committee include Dr. Tucci, Dr. Lisa Cunningham, Dr. VanWaes, Dr. Wagenaar-Miller, Dr. Melissa Stick, Dr. Susan Sullivan, Dr. Elyssa Monzack, Ms. Joanne Karimbakas, Mr. Mark Lucano, and Mr. Tim Wheeles.

Dr. Cooper highlighted three activities that NIDCD has undertaken in response to the Council Diversity Workgroup report:

- The webinar entitled, “Extramural Opportunities to Enhance the Diversity of NIDCD’s Research Workforce (R25)” held in February, was led by Dr. Alberto Rivera-Rentas, our training officer, and Ms. Karimbakas, Chief of Office of Health Communication and Public Liaison. The webinar provided an overview of new extramural opportunities to enhance the diversity of NIDCD’s research workforce. The overview was followed by a live question and answer session with NIDCD staff. This program was recorded and was posted on the NIDCD website, for those unable to watch live, and for those future applicants as they come to learn about this program.
- The National Black Association for Speech-Language and Hearing held its annual convention in March and 3 NIDCD staff made two different presentations, to reach out to this membership, and familiarize them with NIDCD. The next convention will be in the spring in Washington DC, and there is already a group of NIDCD staff who are interested in again presenting and connecting with this group.
- The summer pilot program for high school and undergraduate students from diverse backgrounds was in direct response to the report’s urging that NIDCD do more to reach out to high school and undergraduates from diverse backgrounds. This pilot was offering investigators supported by an NIDCD R01 a chance to involve such individuals in their lab/clinic and research for a summer experience. Applications have been reviewed and 7 awards have been made, to investigators from all of the NIDCD mission areas, to allow these students a first research opportunity. Dr. Cooper explained that NIDCD will be considering next steps in determining success and the future of this activity.

Next, Dr. Cooper presented some new on areas on the NIDCD website to aid potential applicants. First was called “Building A Diverse Scientific Workforce”. This website was developed by Ms. Karimbakas and her team, which is an effort to level the playing field for all potential applicants, especially those more junior investigators from perhaps more low-resource institutions. Second, she highlighted an area entitled “How to Apply for a Grant”, which includes an area focusing on “Sample Grant Applications”. As of the meeting there had been almost 500 hits on this site. Consideration is being given about additional grant mechanisms (such as SBIRs or the Early Career Researcher program) that could be highlighted.

Since January, several grant solicitations related to DEIA have been issued and several of these NIDCD has led or co-sponsored. Dr. Cooper reported that the NIDCD Research Opportunities for New Investigators to Promote Workforce Diversity was published as RFA-DC-23-001. This is an R01 funding opportunity which was developed and lead by Division of Scientific Program staff Dr. Kelly King, Dr. Janet Cyr, and Dr. Sullivan, and by Dr. Stick and Dr. Wagenaar-Miller in the Division of Extramural Activities. This initiative, which will be peer reviewed by a special NIDCD review committee, has as its purpose to solicit applications that propose

independent research projects that are within the scientific mission areas of NIDCD. This program is intended to support Early Stage and New Investigators from diverse backgrounds, including those from groups underrepresented in the health-related sciences. A unique aspect of this opportunity is that no preliminary data is required with hope of leveling the playing field and encouraging applications from individuals who might not be ready to submit traditional R01 applications. There are 4 submission dates for this Request for Applications (RFA). To get the message out, beyond the standard appearance in the NIH Guide to Grants and Contracts, NIDCD has reached out to current investigators, historically black colleges and universities (HBCUs) and minority serving institutions (MSIs), as well as to investigators who have submitted to NIDCD in the past two years but have been unsuccessful. There already has been a great deal of interest in this announcement, and NIDCD is hopeful for a robust response.

Dr. Cooper highlighted the NIDCD participation in the following two RFAs for RADx-UP:

- RADx-UP - Social, Ethical, and Behavioral Implications (SEBI) Research on Disparities in COVID-19 Testing among Underserved and Vulnerable Populations (U01 Clinical Trial Optional), RFA-OD-22-005
- RADx-UP Community-Engaged Research on Rapid SARS-CoV-2 Testing among Underserved and Vulnerable Populations (U01 Clinical Trial Optional), RFA-OD-22-006

NIDCD is also participating in two Notices of Special Interest (NOSIs)

- Administrative Supplements to Recognize Excellence in Diversity, Equity, Inclusion, and Accessibility (DEIA) Mentorship, NOT-OD-22-057
- Increasing Uptake of Evidence-Based Screening in Diverse Populations Across the Lifespan, NOT-OD-22-075

Finally, Dr. Cooper summarized other activities and issues that the NIDCD Committee wants to highlight:

1) In June, NIDCD will hold a virtual Boot Camp for our Diversity Scholars (that is recipients of diversity supplements in FY21), a program mentioned in January with Dr. Rivera-Rentas providing an NIH 101 and an opportunity to ask questions.
2) There are in the works NOSIs and FOAs across NIH that NIDCD will be considering participating in.
3) NIDCD is in the process of hiring a Chief Diversity Officer. The ad was posted, the search has closed, and a committee is reviewing applications, and interviews should be scheduled in the months ahead.
4) In September, as part of the annual report from Dr. Cunningham, the director of the NIDCD Division of Intramural Research, you will hear about DEIA efforts in that division.
5) And finally, the Implementation Committee is continuing to explore strategies which might enhance diversity and mentoring in NIDCD research and clinical awards.

Involving Deaf and Hard of Hearing Individuals in Science and Research .....Dr. Tilak Ratnanather
Dr. Poorna Kushalnagar

Dr. Tucci welcomed Dr. Tilak Ratnanather and Dr. Poorna Kushalnagar to discuss efforts to involve deaf and hard of hearing individuals in science and research. Dr. Ratnanather presented on “Thirty years of scientists and clinicians with hearing loss in NIDCD research areas.” He pronounced that the thirty years since the inception of NIDCD have seen a dramatic growth in the numbers of trainees with hearing loss in NIDCD research areas together with the emergence of a critical mass of principal investigators with hearing loss. On average, 35 papers in NIDCD research areas have been produced by these researchers. Dr. Ratnanather indicated that factors accounting for these statistics include the following: vertical and horizontal mentoring, self-advocacy, technology (hearing and assistive) with an overall philosophical emphasis on “all for one, one for all.” He also explained that broadly speaking, imposter syndrome, isolation, ignorance and invisibility are the four challenges facing anyone from underrepresented minorities in STEMM (Science, Technology, Engineering, Mathematics, and Medicine). He stressed that new ways for addressing privacy and outreach are needed. He discussed how an analysis of summer research experiences for college students with hearing loss indicate that disproportionate funding goes to a subset of ~120- 150 students at specialty tertiary institutions when in comparison there are at least 500K students with hearing loss at mainstream colleges. He suggested

that funding should be targeted for outreach and expanded to trainees using listening and spoken language at institutions with very high research activity, Research 1 (R1), institutions as well as training audiologists and speech and language pathologists, gap-year and medical students. He went on to state that with regards to the latter group, the pipeline for training otologists with hearing loss is unfortunately leaky with interview questions revealing unconscious bias that need to be corrected. Finally, he discussed ideas for diversifying, replicating and expanding the STEMM-HEAR (STEMM opportunities for trainees with Hearing loss to Engage in Auditory Research) pipeline.

In this talk, Dr. Kushalnagar describes efforts to involve Deaf and Hard-of-Hearing (HH) individuals in science and research. Her talk began with her history and journey from a fellowship awardee (F31) to her current U01 funding and concluded with recommendations on furthering support and inclusion of Deaf/HH individuals in the development of a diverse scientific community. She discussed some of the hardships and challenges that she encountered along the way including limited interpreting services and lack of interpreters with a strong knowledge of science, lack of mentors who were women, individuals of color or individuals who were Deaf/HH. She explained how she focused on building her own network of support. Dr. Kushalnagar explained that one big challenge faced by researchers who are Deaf/HH is in the expense to pay for interpreters and finding funding that covers those vital services. She provided numerous suggestions for expanding inclusion of Deaf/HH individuals as both researchers and particants in research. Dr. Kushalnagar ended her talk by expressing her enthusiasm for both NIDCD and NIH and the growing commitment to intersectionality and diversity within the fields of science.

Discussion
Dr. Tucci inquired about programs that Dr. Kushalnagar, as chief research officer, is working on to increase research capacity for faculty at Gallaudet University. Dr. Kushalnagar discussed efforts to provide more grant writing support and workshops on research fundamentals for training of students as there is a real shortage of qualified individuals who are Deaf/HH to perform research. She also discussed plans for a research summit to bring Deaf/HH signing researchers to the university to discuss issues and challenges as well as to develop a network of collaborators and mentors to students.

Dr. Laurel Carney asked about resources or guidance to provide support for doctoral students related to DEIA. Dr. Ratnanather mentioned that the University of Rochester website has resources to help investigators mentor someone in lab and there are a lot of websites about accessability that came out at the beginning of the pandemic. Dr. Kushalnagar indicated that Association of Medical Professionals with Hearing Losses (AMPHL) has a nice resource list for individuals interested in going into the healthcare profession and a mentoring program to match individuals with similar hearing loss or interests. She also indicated that NIDCD previoulsy had efforts related to this and encouraged NIDCD to rejuvenate this resource.

Mr. Richard Einhorn asked about resources for increasing accessability for environments for training medical professionals with hearing loss such as in operating rooms or during grand rounds. Dr. Ratnanather discussed advances in the fields and apps that are available now to enable this but that one needs to consider potential issues with projecting or recording sensitive patient information. Dr. Tucci followed up to ask if the virtual environment has made grand rounds any easier or more accessible. Dr. Ratnanather responded that the technology has improved dramatically especially with automatic captioning although human captioning is still much quicker and potentially more accurate. Dr. Kushalnagar commented on some of the drawbacks and challenges faced with virtual meetings. She indicated that a virtual platform like zoom is very heavily audio based where the image with the interpreter shifts around when new people speak or raise their virtual hand which creates barriers for sign language users.

Dr. Nirupa Chaudhari wondered if institutions develop partnerships with other institutions across the country to decentralize training for research staff and to develop tools for reaching, supporting and training students. Dr. Ratnanather and Dr. Kushalnagar agreed that this could be helpful. Dr. Kushalnagar discussed her own experience and suggested that partnerships and collaborations could work well if the Deaf/HH individuals have a home institution and travel as needed for a complimentary training experience. Dr. Rivera-Rentas indicated that the new NIDCD R25 program allows for partnerships such as this.

Changes to NIH Data Management and Sharing Policies ..... Dr. Mike Lauer

Dr. Mike Lauer discussed NIH's new data management and sharing policies which is in the implementation process. He also shared that this was a team effort and recognized Dr. Lyric Jorgenson along with several other colleagues for their efforts.

Dr. Lauer began by explaining that data sharing is not a new idea and the idea that government funded research researchers. He provided a history and timeline of the policies dating back to 2003 and indicated that this was expanded with the 21st Century Cures Act, passed with overwhelming bipartisan support in December 2016, which contains a provision that states that the NIH Director has the authority to require data sharing for all grants recipients. The original policies apply to grants that receive more than $500 thousand a year. He also discussed the 2014 genomic data sharing and the 2016 requirements regarding required registration and reporting of clinical trials. Dr. Lauer explained the policy developed as a result of the 21st Century Cures Act was put out for public comment and a variety of working groups were consulted in development of the policy which will be implemented beginning in January of 2023.

Dr. Lauer covered the two basic requirements of the policy. The first is that with any grant application that involves the likely generation of data there needs to be a plan that describes data management and data sharing submitted with the application. Part two is that once that plan is approved it becomes a condition of awards and grant recipients will be expected to be compliant with their own plan. This will be applicable to all NIH funded research. He went on to explain some general principles including that the default practice should be the data sharing is maximized, and that data sharing should be done in a responsible way that includes protection of privacy rights and confidentiality as well as observance of all applicable laws and regulations and policies.

The plan, as Dr. Lauer explained, will be submitted with the application and consist of two parts, a brief description of the plan and the budget justification section as NIH recognizes that data sharing has a real cost associated with it. He indicated that the plan will usually be viewed as administrative item for staff assessment and not ordinarily part of peer reviewers. Once the plan has been agreed upon, it will be incorporated into the terms and conditions of the award and monitored over time.

One of the biggest questions relates to what data needs to be shared. Dr. Lauer explained that NIH uses a definition of scientific data which is scientific data is recorded factual material to validate research findings. He acknowledged that what exactly that is depends upon the research that is being done. Data sharing does not include laboratory notebooks, case report forms for epidemiology studies or trials or physical objects. The general idea is that data should be available at the time of publication and for those data that do not get published they should be made available at the end of an award. Dr. Lauer covered the many resources available including the 'Open Mike' blog, webinar, FAQs and draft guidance and discussed plans for additional guidance.

Dr. Lauer concluded by reiterating that data sharing has long been expected including at the highest levels of government. The new policy raises the level and extends the depth of data sharing beginning with implementation in January of 2023. He encouraged applicants to pay attention to NIH activities regarding data sharing and to visit the NIH website for more information.

Discussion

Dr. Tucci asked about how academic institutions incentivize data sharing. Dr. Lauer discussed the publications of peer review articles focused on data resources in journals. These articles describe what that data looks like and how to get to it, and then this is something that should be rewarded on the part of academic leadership. He also discussed assigning a digital object identifier (DOI) to data sets in a repository so that it can be connected, just like a publication does, to track how data are being used. This could allow a researcher to demonstrate how the data they produced are used by other people.

Dr. Cynthia Morton stated that she is a member of the American Society of Human Genetics and that the genetics community is strongly behind data sharing. She asked whether Congress might step in at some point and weigh in. Dr. Lauer focused on what congress has done in passing a law that said that the NIH Director is authorized to require data sharing and commented on some of his observations regarding sharing data.

Dr. Tucci asked Dr. Lauer to discuss how plans will be reviewed by staff in a consistent manner. Dr. Lauer responded that NIH will largely be following a list of elements that were put out when the policy was released back in October of 2020. He indicated that NIH is developing tools for staff to make it straightforward for staff to review these plans. He also discussed how some organizations have put together a data management template based on the policy the NIH policy released in October of 2020. Additionally, he indicated that a number of libraries are also developing resources and that he feels it is likely that many of the plans will look similar with well-described required elements based on these templates.

Open Session – May 20, 2022

Director's Greeting ..... Dr. Tucci

Dr. Tucci welcomed additional staff and visitors to the open session of the meeting which was available to the public from the NIH Videocast website. (https://videocast.nih.gov/watch=45315)

CSR Pilots ..... Dr. Bruce Reed

Dr. Bruce Reed provided an update on CSR pilots and discussed peer review at CSR. He discussed what CSR understands about bias and peer review at the NIH and what CSR is doing to combat it. Dr. Reed began with summarizing some literature on peer review at the NIH. The 2011 publication by Dr. Donna Ginther showed that African Americans scientists are substantially less likely to be awarded an R01 compared to white counterparts. This basic observation was replicated and extended in multiple papers and demonstrates a substantial funding gap, on the order of fifty percent. Dr. Reed explained that at the NIH overall, there is a close relationship between review outcomes and funding decisions, driving people to look for potential bias in peer. Looking for potential causes, it was noted that applications from African Americans scientists are concentrated in a small number of topics as determined by looking at a large batch of NIH applications and using natural language processing to grouped applications into topic clusters. It was observed that just 15 topics accounted for over 50% of the applications that come from black scientists. A publication by Hoppe and colleagues observed that the award rates differ four-fold across these different topics and basically, the award rates for topics favored by black applications, are relatively low and topic choice alone accounted for over 20% of the NIH funding gap. An assumption from these finding was that reviewers seemed to prefer certain topics over others, but one important variable was not considered, the individual NIH Institute or Center (IC) award rate. He showed data from a 2021 paper from Dr. Mike Lauer and colleagues using the same dataset that Hoppe used. He noted that African Americans preferred topics are primarily funded by ICs with relatively low funding rates and that this explains the topic choice effect. Applications on African American preferred topics had similar review outcomes as other topics demonstrating that there was no evidence of reviewer bias on the basis of topic choice,

Dr. Reed then discussed analysis of any potential identity-based biased in peer review. The NIH CSR published an anonymization study (Nakamura 2021) that used three sets of real NIH applications with 400 R01 applications from black PIs and comparator sets of 400 R01 applications from matched white PIs on review relevant features and 400 R01 applications from random white PI applicants. Applications were redacted to remove indicator of personal identity and institutional affiliation. Then the standard format and redacted versions underwent simulated peer review and reviewers were asked also to guess the PI race, gender, and name after they completed their reviews. Dr. Reed highlighted a couple of key findings. First, redaction reduced the accuracy of reviewers' guesses of PI race for black but not for white applicants. Second, redaction made scores worse for white applicants but not for black applicants. Third, overall, the applications from white PIs did score better than those from black PIs, and redaction did not eliminate that difference but did reduce it by approximately one-half. Dr. Reed postulated that one explanation for this could be halo effect. He explained that halo effect is the situation of the glow of a big name leads the reviewer to give overly good scores which benefits senior, well-established PIs who are predominantly non-Hispanic white PIs. This suggests voting bias on the basis of PI or institutional reputation which tends to favor well-established non-Hispanic white PIs. This could explain the findings seen in the redaction pilot where scores got worse after redaction. Dr. Reed explained that this could be particularly important at the NIH because two of the five legally required review criteria, investigator and environment, could be impacted by this phenomenon.

Dr. Reed explained that CSR has taken multiple steps to combat bias, especially reputational bias in peer review at NIH. He discussed several initiatives that are underway including a partially blinded review process. CSR has begun a three-year pilot, in conjunction with the Common Fund, looking at the review of the NIH Director's Transformative Research Awards. This RFA gets a large number of applications on a huge range of science and is reviewed using an editorial board format with initial pool of applications winnowed down to small set of finalists through a series of steps. Those initial steps prior to the meeting, the whole process of winnowing down to the finalists, is done without information about who or where the application comes from. The RFA requires the applicants write the abstract, specific aims and research plan, in a way that makes it extremely difficult to identify who or where it comes from. It is only at this last stage of full peer review when key decisions or judgments about the importance and quality of the science have already been made, that the identity of the institution and PI are revealed. Dr. Reed indicated that CSR is halfway into this pilot and an external contractor has started to look at the preliminary data.

Next, Dr. Reed provided an update on CSR's advisory council working groups focused on the review criteria themselves, one for research project grants (RPGs) and one for clinical trial applications. These workgroups were focused on reducing the burden on reviewers and improving the quality of review. The major recommendation was to reorganize the current five scored review criteria, into three factors. The three factors being 1) the importance of the science,2) feasibility and rigor, and 3) the investigators and environment. The idea behind organizing things into these factors is to clearly focus reviewers' attention on the crucial judgments they need to make about each application. Additionally, this structure lends itself to having those critical judgments made, without -- at least separately from this information and judgment about the investigators and environment. It lends itself to that sort of multi-stage partially blinded review process that is utilized for the Director’s Transformative Research Awards.

Dr. Reed then discussed CSR efforts to reduce bias through enhanced training. He summarized the training and highlighted its goal of raising awareness and providing tools to mitigate bias. To date, CSR has invited over 15,000 reviewers to take this training shortly in advance of review meetings and almost 11,000 have completed it. Surveys of participants found that respondents indicated that the training helped them in identifying potential bias in review and more comfortable in intervening when they see bias. CSR has made it easier for people to report bias when they see it through the establishment of a bias reporting e-mail that goes to the CSR associate director for workforce diversity.

Dr. Reed ended his presentation with an update on efforts that CSR is taking to make study sections more diverse. He discussed efforts aimed at raising collective awareness among staff on the critical importance of diversity and link between diversity and excellence in review. He talked about the significant effort that CSR

puts into building up databases and search tools to bring in new sources of potential reviewers. This allows for searching the vast NIH database of everybody who has ever submitted a grant application for specific expertise and various other characteristics. He also acknowledged the need to look beyond NIH and discussed efforts to increase the pool of potential reviewers including the CSR early career reviewer program and through recommendations from institutes, professional societies and minority interest groups. CSR has been able to add 11,000 names of people funded by other agencies, such as NSF, DOD, CDC, or some major private foundations and overall has added 24,000 names to this sort of core NIH database.

Discussion

Dr. Emily Buss inquired if the simulated review study was analyzed by the demographic of the reviewer and if so, were there any results showing that individuals from under resourced institutions were less likely to ding an application from an under resourced applicant. Dr. Reed indicated that analysis was not able to be performed as that kind of information on the reviewers was not available.

Dr. Argye Hillis expressed her appreciation of this kind of investigation into the source of the bias to attempt finding solutions. Dr. Andy Groves commented that he recently completed the CSR bias training course and found it very helpful, entertaining and thought provoking.

While he was pleased to see that taking this training is empowering people to speak up more, he inquired what was being done to empower SROs to intervene, if no one else does. Dr. Reed acknowledged the importance of everybody in the review meeting having an active role in this and that CSR has invested a lot in both really helping SROs think about the ideas and concepts behind it and making sure that they understand that they have a very appropriate role in intervening themselves directly.

Dr. Ruth Anne Eatock commented on the strong requirements by current study sections for expertise and asked about the working groups thoughts if that the new efforts to reduce bias might result in review panels that lack that deep expertise. Dr. Reed reiterated that expertise is the core requirement for anybody to serve on a study section and that they have to have expertise that's appropriate to the range of applications that are being reviewed within that panel. He acknowledged that this can be a very complicated discussion and commented that there are two main types of expertise that need to be balanced, spot on expertise where reviewers closely understand the sciences, methodological pitfalls and so forth to assess rigor and feasibility, and individuals with a range of perspectives to assess importance and significance of the proposed research.

Dr. Ben Strowbridge asked about the future of Special Emphasis Panels (SEPs) and if there is any difference in problems reported between SEPs and standing panels. Dr. Reed acknowledged that until recently, CSR did not pay as much attention to diversity on SEPs but has recently increased its focus in this area. He commented that he does not see SEPs going away because there are a variety of reasons that standing panels are unable to fill all the needs. Dr. Chaudhari commented that from her experience as both a reviewer and study section chair that it seems like SROs tend to pick people who are very close to the field of a particular application, and this might be a potential area for retraining. Dr. Reed agreed that this could be beneficial, and that SROs are encouraged to get outside of their normal reviewers. Dr. Chaudhari then asked about how to correct for topic choice and institute funding lines. Finally, she agreed that the topic choice accounting for 20% of the funding gap is significant but wanted to know what the cause of the rest of it was. Dr. Reed indicated that reputational bias accounts for part of the funding gap and works in both directions, it can be positive for the big names and big-name institutions and can be negative for the less-known people in the smaller less-known institutions. He discussed Dr. Ginther’s work and the two main issues, pipeline issues and the role of citation, citation metrics, and connection to social networks in science.

Ms. Vickie Deal-Williams wanted to explore the definition of expertise, and if there is any possibility of adding the consideration of variables like the extent to which an individual PI might bring alternatives to what would be deemed traditional scientific expertise. She commented that things like lived experience might contribute to the success and feasibility of a project. Dr. Reed stated that it was an interesting point especially as one thinks about the review of fellowship applications. Looking at what qualifies people, such as they went to an elite

school, end up in an elite lab, sort of all these things, but those are not the only people who have the potential to be fabulous scientists. You have other people who have not had those same advantages and their experience has been more complicated. In evaluating fellowship applications NIH needs to find a way to consider that a broader view of what that person brings and what their qualifications are.

Dr. Carol Espy Wilson echoed what others pointed out that expertise is really hard thing to judge and figure out how to change. She commented that she has seen first-hand in study section meetings where a well-funded investigator submitted an application that was not well written, and on the face of it would not have gotten funded but because of the reputation of the person and, you know, the history they have had, it was funded. She stressed that this happened even though some of the panel spoke up but were overruled in the scoring decision. She encouraged NIH to work at changing the funding levels for topics that are of interest to African Americans as some of the areas are things where there is bias in health care.

Report of the Director Division of Extramural Activities ..... Dr. Wagenaar-Miller

Dr. Wagenaar-Miller provided an overview of peer review at NIDCD. She began by thanking Dr. Stick and Dr. Andrea Kelly from the NIDCD Scientific Review Branch for their assistance with the presentation. She provided some background on the regulations and policies that apply to peer review to illustrate the framework that NIH works within. She the discussed multiple factors that are considered in developing or updating a review roster and covered the three main categories – authority in the field, diversity, and the types of science to be reviewed in the applications. She discussed efforts by NIDCD scientific review officers (SROs) to expand the pool of potential reviewers including the use of several different databases, professional materials such as conference programs, public directories, and university webpages, as well as suggestions from colleagues. She stressed the strategic job of balancing of multiple factors when recruiting reviewers including many that can limit an SROs ability to recruit the ideal reviewer.

Dr. Wagenaar-Miller detailed the applications reviewed at NIDCD or at CSR. NIDCD-managed review meetings mainly focus on applications to Request for Announcements (RFAs), the early career R21, career, training, fellowship, all complex grants such as program project and all cooperative agreement applications while CSR generally manages the review of everything else. This results in approximately 30% of grants each round are reviewed at NIDCD review meetings and 70% at CSR review meetings.

Dr. Wagenaar-Miller expressed that NIDCD is working to increase the diversity in the peer review meetings – including diversity of the scientific perspective, demographics, career stage and review experience. She showed data on the breakdown of women and minorities serving as NIDCD peer reviewers which demonstrates NIDCD's long-standing commitment to diversity of perspective. The NIDCD standing committee (Communication Disorders Review Committee or CDRC) has a significantly higher percentage of women than average CSR standing committee and NIDCD is about equivalent with CSR for women serving on SEPs. The NIDCD peer reviewers range from 19-29% minority for appointed standing committee members, 4-19% for temporary members of the standing committee and 16-21% for SEP members. She acknowledged that there is more that needs to be done and stated that this is a priority for NIDCD. She highlighted ongoing NIDCD peer review outreach and training efforts that fall into inter-related areas of recruitment and education at conferences, webinars as well as reviewer self-nomination. She provided examples of ways in which SROs are recruiting from adjacent fields to expand the reviewer pool. She discussed efforts to promote bias awareness training. Dr. Wagenaar-Miller also discussed multiple efforts by NIDCD staff to educate applicants and reviewers through conferences and webinars. Links to these webinars are available on the NIDCD website to increase the accessibility of the information regardless of ability to attend the conference. Dr. Wagenaar-Miller concluded by acknowledging that even with all of these efforts, qualified reviewers are still missed. She discussed a recently launched webform to allow individuals to self-nominate for NIDCD peer review meetings and efforts to disseminate this form widely to reach as many perspective reviewers as possible.

BRAIN Update ..... Dr. John Ngai
Dr. Amy Poremba
Dr. Merav Sabri
Dr. Roger Miller
Dr. Alberto Rivera-Rentas
Dr. Andrea Beckel-Mitchener

Dr. John Ngai

Dr. Tucci introduced the Director of the Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN) Initiative, Dr. John Ngai and welcomed him to discuss the innovative work of the BRAIN Initiative. Dr. Ngai began by covering the history of the program and its mission to revolutionize understanding of the human BRAIN. The NIH BRAIN Initiative involves ten institutes and centers, of which NIDCD is one. The BRAIN 2.0 report, issued in 2019 by working groups commissioned by the NIH Director's advisory council, acts as the strategic plan that guide all the BRAIN efforts. Dr. Ngai highlighted a few major findings from the report.

Dr. Ngai covered the history of funding for the BRAIN Initiative including how the anticipated large increase in funding from the 21st Century Cures Act in 2023 enables the launch of large projects as inspired by the BRAIN 2.0 report. He discussed the need for a parts list and wiring diagram of the brain, a way to interrogate and modulate brain circuits to understand how the brain ultimately works and how to fix it when it does not. The parts list, an atlas or census of cell types in the brain, understanding of their properties and a wiring diagram of the connectomic properties provides information about what the circuits of the brain look like and are needed to begin to test hypotheses about how these circuits function. This is a huge challenge as the human brain comprises on the order of 86 billion neurons and an equivalent number of non-neuronal cells including those in inflammatory responses. The overall goal of the BRAIN 2.0 transformative projects is to change the trajectory of neuroscience research by providing new tools and resources that can be used to study neural circuits across the brain and do so at depth and scale. Dr. Ngai provided an update on the three transformative projects 1) comprehensive brain cell atlas shifting emphasis from mouse to the human and non-human primate brain, 2) whole brain microconnectivity project to develop tools necessary to generate a wiring diagram of mammalian brains, and 3) tools for gaining precision to modulate neural circuits from the basic discovery side but also to eventually provide the foundation for precision gene therapies.

Dr. Ngai then highlighted BRAIN Initiative research by NIDCD investigators and the great alignment of missions between the BRAIN Initiative and the NIDCD. The BRAIN Initiative is by design disease or system agnostic but that does not exclude the development of some great tools based on IC specific needs. Investigators are the leading edge of developing tools in a variety of areas including investigating circuits and computation underlying auditory processing and vestibular function, understanding principles of speech and language, illuminating the mechanisms of chemosensation, and the development of next generation sensory and sensorimotor neural prosthesis. Dr. Ngai commented that he continues to work on the olfactory system and that a lot of great science is going on at NIDCD that is synergistic with the BRAIN Initiative.

One of the projects highlighted involve the olfactory system and COVID. Soon after the COVID pandemic hit, people had noticed an association of anosmia with patients who developed the symptoms of SARS-CoV-2 infection, or COVID. This intriguing association raised question about the broader ramifications of COVID on the underlying cause and the patient's health and recovery, specifically effects on nervous system. A study by Dr. Ngai and Dr. Bob Datta approached this by asking on which cells in the peripheral olfactory system are receptors (ACE2) and spike proteases (TMPRSS2) for SARS-CoV-2 expressed. Single cell RNA sequencing of mouse olfactory epithelium, human olfactory epithelium and human olfactory bulb was used to look for *Ace2* and *Tmprss2*. These two molecules, critical for SARS-CoV-2 entry, were found to be expressed in the sustentacular support cells and horizontal basal cells but not in the olfactory sensory neurons. He stated that this was initially controversial but indicated that this has since validated by additional studies.

Dr. Ngai then moved to a recent publication by Dr. Stavros Lomvardas' lab in *Cell* looking at how SARS-CoV-2 infection could be causing anosmia. Single cell RNA sequencing showed a rapid downregulation of olfactory receptors genes and of key genes encoding signaling molecules in the signaling cascade in both hamsters as well as humans. They found the effect of SAR-CoV-2 infection result in non-cell-autonomous disruption of

nuclear architecture that is required for high level olfactory receptor expression and olfactory sensory neurons. These finding may have implications not only for COVID but also with neurodegenerative disorders including Parkinson's and Alzheimer's disease.

Next, Dr. Ngai discussed a publication in *Cell* from Dr. Eddie Chang's lab looking at the processing of speech in humans. They used cortical recordings and stimulation across human auditory cortex to determine how information is processed across these regions and how cues in the speech signal are mapped across the entire auditory cortex. They found through response latency and receptor field analyses that the information is not processed serially but in parallel across various regions of the primary and non-primary auditory cortices which argues against simple hierarchy of cortical processing. Direct stimulation of either auditory cortex or regions in the superior temporal gyrus (STG) provide evidence that the primary auditory cortex is neither necessary nor sufficient for speech perception. They found stimulation in STG caused disruption in patient's ability to hear and repeat a word that was given.

Dr. Ngai then pivoted to a publication in *Nature* from Dr. Krishna Shenoy and Dr. Jaimie Henderson on the development of brain-computer interfaces as neural prostheses. They used recordings and interpretations of neural signals across electrodes placed in the brain to allow a paralyzed individual to communicate. This brain-computer interface could allow this patient to type 90 characters per minute with great accuracy by simply imagining the keystrokes of writing the letters themselves. Neural activity was recorded, a recurring neural network was used to learn activity associations between the imagined letters and the actual written letters, and then this was used to categorize each imagined key stroke based on changes in activity to cluster them and to allow the patient to literally type out words. This is remarkable way to interpret this information and turn it into a communication prosthetic device.

Dr. Ngai discussed the need to be mindful of the ethical, legal, societal implications when working with humans and developing technologies that can affect human brain function. He highlighted how the BRAIN Initiative has been diligent in incorporating these issues into what they do and that there is an active neuroethics working group that advises BRAIN on these issues. The working group has helped in developing guiding principles and the BRAIN Initiative has a team focused on these issues. Dr. Ngai ended his presentation by encouraging everyone to register for the upcoming 8th Annual BRAIN Initiative meeting.

Discussion

Dr. Tucci noted that funding bump in 2023 from the 21st Century Cures Act will be a challenge to develop programs are only for one year and asked what the plan is for spending within those constraints. Dr. Ngai indicated that while appropriations typically must be spent within each year, the 21st Century Cures Act allows for funds to be carried forward to the next one.

Dr. Strowbridge asked for Dr. Ngai's perspective on how the BRAIN Initiative funding connects to mainstream NIH funding. He described his initial concerns when the BRAIN Initiative began that it would draw people away from classic cellular mechanistic questions and that he received reassurances that the BRAIN Initiative would be separate funding and would expand the pool. Dr. Strowbridge went on to say that the BRAIN Initiative has had the effect of drawing so many people away and that few labs are working on the classic methods that are still going to be important for a long time. He expressed concern that some of these skills will be lost. He wanted to know if Dr. Ngai viewed the BRAIN Initiative as a separate mission or is the future connected to research areas traditionally funded by NIH institutes and centers. Dr. Ngai acknowledged the concern and stressed that the BRAIN Initiative focus is on enabling researchers to do experiments that they could not do before, and to help develop tools to do those studies.

Dr. Chaudhari followed up on Dr. Strowbridge's comment and asked if the BRAIN Initiative has come up with a way of tracking where traditional application have resulted from BRAIN Initiative-funded work or track utilization of the BRAIN derived technologies. Dr. Ngai responded that the efforts are currently underway to determine what metrics to use, how to measure and interpret them to understand what impact the BRAIN Initiative is having.

Dr. Meg Wallhagen commented that she is interested in what can be done to translate the findings into more clinically based practices. Dr. Ngai responded that there is an emphasis on both basic discovery and translation. There is a whole program for research opportunities in humans that looks to the extent possible in humans neural circuit function and relation to the behavior. He mentioned plans to step up a program in looking at synchronizing behavior and neural activity. He discussed work coming out of the cell census project, making a huge investment in characterizing, and organizing cell types in mammalian brains. Already the BRAIN Initiative Cell Census Network (BICCN) has resulted in the identification of human-specific cell types that are selectively vulnerable in Alzheimer's disease. He mentioned research using omics technologies profiling mid-brain dopamine neurons in humans and humans with Parkinson's disease as another example.

Dr. Dan Sanes emphasized that the BRAIN Initiative is constantly coming up with, examining, and discussing new initiatives and concepts. The Brain Behavior Quantification and Synchronization concept is aimed at developing new high-resolution tools and data science approaches to precisely quantify behaviors and synchronize them with brain activity data.

Dr. Amy Poremba

Dr. Amy Poremba introduced herself and the other staff who serve as the NIDCD representatives for the BRAIN Initiative and she thanked Dr. Sanes for his additional service on the BRAIN Initiative multi-council working group. Dr. Poremba introduced Dr. Merav Sabri and explained that she will split her time between the BRAIN Initiative and as a program officer for NIDCD focusing on higher olfactory and taste processing. She provided an update on how the BRAIN Initiative interacts with the NIDCD mission. She showed how BRAIN Initiative-supported reseach fits within the very broad NIDCD mission areas of taste and smell, voice speech and language, and hearing and balance. Looking back over seven years through 2021 approximately 10% of BRAIN Initiative awards are related to NIDCD mission areas. Over seven years BRAIN Initiative grants have covered all the NIDCD mission areas with the greatest number of awards in olfaction, primarily hearing and some balance in the second group, and speech followed by language and voice in the last category. The numbers are slightly larger for hearing and balance, in terms of dollars. Over the past seven years, chemical senses received more than $200 million in total funding, hearing and balance $143 million, voice speech and language with $93 million. That equals about $437 million total for the years 2014-2021. For comparison, each year NIDCD awards $85 million in new competing grants, plus $14 million for small business grants, total of about $100 million per year of our budget goes to newly awarded grants. She showed that in 2021, the BRAIN Initiative awarded $41 million in competing grants related to NIDCD mission areas which equals roughly 41% of what NIDCD typically spends in total for new awards each year. These dollars are adding to the NIDCD mission areas with technology to utilize and answer questions directly related to the NIDCD mission. She also discussed ways in which the BRAIN Initiative funding indirectly benefits NIDCD including the expansion of cutting-edge techniques applied to our mission areas and the applicability of some NIDCD mission-relevant model systems for study which bring new investigators to the field.

Dr. Merav Sabri

Dr. Sabri discussed outreach efforts and highlighted a virtual seminar with Dr. Maria Geffen of University of Pennsylvania and Dr. Sanes of New York University for potential applicants that are interested in learning about the NIH BRAIN program and funding opportunities. The seminar included presentations about the goals and priorities of the BRAIN program, various funding opportunities, the synergy between the BRAIN program and the NIDCD. In addition, talks from BRAIN grantees in the NIDCD space, Drs. Geffen, Stephen David, and Dima Rinberg highlighted their process of submitting a successful BRAIN application and the lessons they learned along the way. She highlighted a small subset of funding opportunities under the ‘circuits’ program that are cross-cutting across several NIDCD mission areas. She encouraged interested individuals to check out the recording of the seminar on Demystifying the BRAIN Initiative® Program: Guidance to Potential NIDCD Applicants and recent funding opportunities on investigating neural circuit function at cellular resolution and sub-second timescales and Brain Behavior Quantification and Synchronization. Dr. Sabri reminded applicants to keep in mind that each funding opportunity announcement is unique and includes a description of specific requirements and review criteria. She recommended that individuals read the funding announcement and pay attention to the details. She pointed out that each announcement includes contact information, and that

program staff would love to hear from individuals about ideas for a grant. Dr. Sabri concluded by highlighting a new NIDCD website, the BRAIN initiative and the NIDCD, developed in collaboration with the NIDCD Office of Health Communication and Public Liaison. This page includes information about funded applications, example awards, and links to active funding announcements.

Dr. Roger Miller

Dr. Roger Miller shared how the NIDCD portfolio on neuroprosthesis development synergizes with the BRAIN Initiative. He highlighted grants from Dr. Jamie Henderson and Dr. Krishna Shenoy at Stanford University and explained the technology of the BrainGate2 device. These studies are done under the early feasibility study program from the FDA and this type of investigative device exemption allows limited clinical use of a device in earliest stages of development. It allows investigators to evaluate different device designs for safety and functionality. The BRAIN Initiative award involves electrodes in the hand region, as Dr. Ngai illustrated in his presentation, while the NIDCD-supported award is designed to have arrays placed in different areas with a goal of a direct to speech brain-computer interface.

Dr. Miller then discussed another brain computer interface (BCI) that uses a different approach than the previous study. The SWITCH trial by Dr. Doug Weber uses a stent approach and he showed a diagram of the stent electrode into a blood vessel on the surface of the cortex but indicated the blood vessel could be anywhere. This is a very different approach to try to get neural activity to be modulated by the user to create an effective BCI. The goal of this award is for an interface to pick up discrete actions, such as menu selection, click, or zoom. An early feasibility study could follow from the UG3 award as the point of this UG3 award is to get all the preliminary data in place, submit and investigational device exemption (IDE) application to the FDA so human subjects studies can start.

These are two approaches for BCI to support communication and demonstrate synergy between the BRAIN Initiative and NIDCDs mission areas.

Dr. Alberto Rivera-Rentas

Dr. Rivera-Rentas, NIDCD research training officer and member of BRAIN team training, inclusion, and equity (TIE) presented an overview of BRAIN Initiative training. Team TIE supports everything about training including programs and workshops to increase awareness and to engage trainees. Dr. Rivera-Rentas highlighted the BRAIN Initiative training award programs at various career stages including for predoctoral students and postdoctoral trainees. He then discussed transition awards to promote diversity. These utilize several diversity categories (race, gender, ethnicity, disability, disadvantaged backgrounds) and he mentioned a few awards in various NIDCD mission areas. Dr. Rivera-Rentas closed out his presentation with information on diversity supplements for investigators who already have a BRAIN award to support recruiting of researchers from groups underrepresented in health-related research.

Dr. Andrea Beckel-Mitchener

Dr. Andrea Beckel-Mitchener, deputy director of the BRAIN Initiative, presented on the BRAIN Initiative's new plan for enhancing diverse perspectives. To support the best science through the BRAIN Initiative, the broadest perspectives in research must be supported and promoted. This is accomplished across a variety of parameters including transdisciplinary research with collaborations among neuroscientists as well as investigators from several different fields, career stage, individuals from diverse backgrounds, institution, and geographic distribution. The BRAIN Initiative is working to enhance diversity in all of these areas and key to that is recruiting and supporting funding individuals from diverse backgrounds such as those traditionally underrepresented in science including those from disadvantaged backgrounds and women. The institution type, a question raised earlier, is very important and the BRAIN Initiative is looking to engage different institutions and organizations in the research including everything from the research-intensive institutions that everybody is familiar with to undergraduate focused institutions, minority serving, and community based, as well as promoting partnerships with geographic and region natural heterogeneity.

Dr. Beckel-Mitchener presented data on funding within the BRAIN Initiative including information on how many women are funded across the portfolio as they are underrepresented in neuroscience research. She showed that the numbers are quite low for awards with women as the contact PI compared to NIH as a whole, but there does not seem to be a disparity in the awards that are made between men and women. The race and ethnicity data show that BRAIN Initiative awardees are slightly more diverse than NIH average, but these data are very noisy with a lot of unknowns which reduce confidence in the data. She presented on the composition of teams for multi-PI awards and most multi-PI teams consist of not underrepresented minority males. Additionally, most of the applications are submitted by and awarded to institutions that are located on the coast at highly resourced research-intensive institutions in California, New York, and Massachusetts.

Dr. Beckel-Mitchener discussed some steps that the BRAIN Initiative is taking to expand the diversity of researchers. She highlighted a targeted funding opportunities resource grant (U24) for facilities at minority-serving institutions (MSIs) and Institutional Development Award (IDeA)-eligible institutions. She then discussed a new requirement for a plan for enhancing diverse perspectives (PEDP) in BRAIN Initiative applications to promote inclusive research environments. The PEDP is part of the research strategy, main body of the grant, and requires a one-page summary to be included in the application. Importantly and new to the process is that the plan will be part of the scored application and considered when funding decisions are being made. The goal of the plan is to make more team more diverse. She explained that diverse perspectives are defined very broadly to include the people who do the research, who participate in research as part of a study population, and the places where the research is done. She highlighted a few potential strategies that an investigator might include in their application. She touched on inclusion of women, individuals from underrepresented groups, training or mentoring opportunities an investigator might promote, description of planned partnerships that enhance geographic heterogeneity, career enhancing opportunities for early or mid-career or trainees, opportunities to advance the transdisciplinary nature of the research, recruitment of diverse research participants, and outreach activities that may engage specific stakeholders such as educators, patient groups, patients, policymakers. Key elements of the PEDP include the timeline, milestones, benchmarks for the PEDP as well as approaches to discussing progress towards those goals. The PEDP should reflect careful consideration how these perspectives will benefit the project. Specific questions are included in each of the scored review criteria (significance, innovation, investigators, approach, environment) for all BRAIN Initiative funding announcements. She stressed that applications that do not include a PEDP are considered incomplete and are withdrawn. She also noted that investigators can ask for allowable expenses associated with the PEDP and its implementation. Dr. Beckel-Mitchener discussed the multiple dissemination approaches, materials and training to ensure applicants, reviewers and staff are informed about the PEDP. She also addressed plans for evaluation of the effectiveness of the PEDP to increase diversity within the BRAIN Initiative portfolio. She reiterated that diversity and inclusivity are integral to enhancing science and innovation.

Dr. Tucci concluded the meeting by thanking everyone for the discussion.

Certification of Minutes

We certify that, to the best of our knowledge, the foregoing minutes and attachments are accurate and correct.[2]

9/16/2022

/Rebecca Wagenaar-Miller/
Rebecca Wagenaar-Miller, Ph.D.
Executive Secretary
National Deafness and Other Communication
Disorders Advisory Council

9/16/2022

/Debara L. Tucci/
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National Deafness and Other Communication
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Director
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Other Communication Disorders

Ginger Webb
Council Assistant
NDCD Advisory Council

[2] These minutes will be approved formally by the Council at the next meeting on January 27 & 28, 2022, and corrections or notations will be stated in the minutes of that meeting.

Appendices

Roster
National Deafness and Other Communication Disorders Advisory Council

(Terms end on 5/31 of the designated year)

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Appendix 2

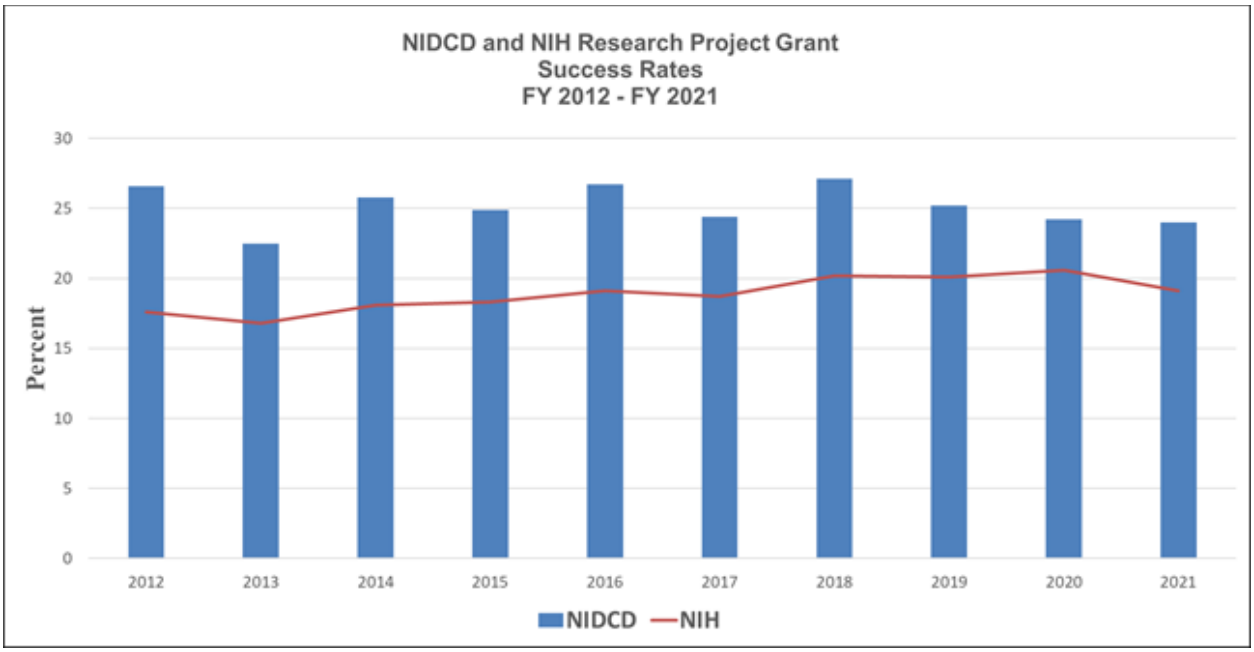
NIDCD Council Budget Report

Eric Williams, Budget Officer
NIDCD Advisory Council Meeting
May 19, 2022

National Institute on Deafness and Other Communication Disorders (NIDCD)
FY 2021 vs FY 2022 Operating Plan
(Dollars in thousands)

	FY 2021 Final Allocation		FY 2022 Operating Plan*	
Budget Mechanism	*Number*	*Amount*	*Number*	*Amount*
Research Projects				
Noncompeting	582	$256,482	590	$274,884
Admin. Supplements	60	$6,524	40	$2,000
Competing	180	$80,605	170	$75,088
Subtotal	762	$343,612	760	$351,972
SBIR/STTR	21	$15,492	22	$15,860
Subtotal, RPG's	783	$359,103	782	$367,832
Research Centers	7	$18,220	6	$15,243
Other Research	85	$12,048	93	$14,167
Total Research Grants	875	$389,371	881	$397,242
Individual Training	156	$7,359	155	$7,300
Institutional Training	157	$8,892	163	$9,665
R & D Contracts	43	$21,907	44	$25,635
Intramural Research		$44,747		$50,100
Research Mgmt. & Support		$24,297		$24,940
TOTAL		$496,574		$514,882
Lapse		$4		

*Projected


NIDCD and NIH Research Project Grant
Success Rates
FY 2012 - FY 2021
Percent
30
25
20
15
10
5
0
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
NIDCD
NIH

Appendix 3

NIH Staff Present
Closed Session

Christopher Adams	Mimi Lee	Nanette Stephenson
Kathy Bainbridge	Chuan-Ming Li	Melissa Stick
Tian Biao (CSR)	Trinh Ly	Susan Sullivan
Maribeth Champoux (CSR)	Castilla McNamara	Debara Tucci
Laura Cole	Roger Miller	Becky Wagenaar-Miller
Judith Cooper	Christopher Myers	Mitchell Wainberg
Janet Cyr	Edward Myrbeck	Bracie Watson
Hoai Doan	Eric Nunn	Ginger Webb
Emma Eggerman	Hua Ou	Tim Wheeles
Nancy Freeman	Amy Poremba	Eric Williams
Maria Garcia	Lisa Portnoy	Baldwin Wong
Rochelle Henteges (CSR)	Kausik (Bobby) Ray	Shiguang Yang
Howard Hoffman	Alberto Rivera-Rentas	
Roger Janz (CSR)	Cathy Rowe	
Nichelle Johnson	Merav Sabri	**Other NIH Staff:**
Tanji Johnson	Elka Scordalakes-Ferrante	Felice Harper (CIT)
Andrea Kelly	Brian Scott (CSR)	CART Captioner
Lisa Kennedy	Anu Sharman	ASL Interpreter Ella
Kelly King	Lana Shekim	ASL Interpreter Tierra Carter
Alexei Kondratyev (CSR)	Katherine Shim	
Eliane Lazar-Wesley		

NIH Staff Present
Open Session

Christopher Adams	Chuan-Ming Li	Nanette Stephenson
Kathy Bainbridge	Trinh Ly	Melissa Stick
Shaunna Bach (BRAIN)	Castilla McNamara	Susan Sullivan
Andrea Beckel-Mitchener (BRAIN)	Roger Miller	Debara Tucci
Laura Cole	Kristen Mullsteff	Becky Wagenaar-Miller
Judith Cooper	Christopher Myers	Mitchell Wainberg
Janet Cyr	Edward Myrbeck	Bracie Watson
Hoai Doan	John Ngai (BRAIN)	Ginger Webb
Emma Eggerman	Eric Nunn	Tim Wheeles
Nancy Freeman	Hua Ou	Eric Williams
Maria Garcia	Amy Poremba	Baldwin Wong
Howard Hoffman	Lisa Portnoy	Shiguang Yang
Nichelle Johnson	Kausik (Bobby) Ray	
Tanji Johnson	Bruce Reed (CSR)	**Other NIH Staff:**
Joanne Karimbakas	Alberto Rivera-Rentas	Jonathan Bennett (ORS)
Andrea Kelly	Cathy Rowe	Felice Harper (CIT)
Lisa Kennedy	Merav Sabri	Joy Jackson-Ferrar (ORS)
Kelly King	Elka Scordalakes-Ferrante	CART Captioner – Tina
Michael Lauer (OD)	Anu Sharman	ASL Interpreter Joshua Lane
Eliane Lazar-Wesley	Lana Shekim	ASL Interpreter Tierra Carter
Mimi Lee	Katherine Shim	ASL Interpreter Jolanta