NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS

ADVISORY COUNCIL

September 9 & 10, 2021

National Institutes of Health

Bethesda, Maryland

MINUTES

The National Deafness and Other Communication Disorders Advisory Council (NDCDAC) convened on September 9 & September 10, 2021 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: September 9, 2021: 10:00 a.m. to 12:00 p.m. for review of individual grant applications; and

Open: September 9, 2021: 1:00 p.m. to 3:25 p.m. and September 10, 2021 from 10:00 a.m. to 11:58 a.m., for the review and discussion of program development needs and policy.

Council members in attendance[1]:

Dr. Nirupa Chaudhari
Dr. Ruth Anne Eatock
Mr. Richard Einhorn
Dr. Carol Espy-Wilson
Dr. Lisa Goffman
Dr. Argye Hillis
Dr. Robert Hillman
Ms. Barbara Kelley
Dr. Cynthia Morton
Ms. Lynne Murphy Breen
Dr. Dan Sanes
Dr. Ben Strowbridge

Council Members Absent:
None

Ad-Hoc Council Members in attendance:

Dr. Emily Buss
Dr. Laurel Carney
Ms. Vicki Deal-Williams
Dr. Andrew Groves
Dr. Anil Lalwani
Dr. Margaret Wallhagen

Ex-Officio Council Members in attendance:
Ms. Christa Themann
Dr. Lakeisha Henry
Dr. Judy Schafer

[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.

NIDCD employees present during portions of the meeting:

Mr. Christopher Adams
Dr. Kathy Bainbridge
Dr. Laura Cole
Dr. Judith Cooper
Dr. Lisa Cunningham
Dr. Janet Cyr
Mr. Hoai Doan
Dr. Nancy Freeman
Ms. Maria Garcia
Mr. Howard Hoffman
Dr. Andrea Kelly
Dr. Lisa Kennedy
Dr. Kelly King
Dr. Eliane Lazar-Wesley
Ms. Mimi Lee
Dr. Chuan-Ming Li
Dr. Trinh Ly
Dr. Castilla McNamara
Dr. Roger Miller
Dr. Elyssa Monzack
Mr. Christopher Myers
Mr. Eddie Myrbeck
Mr. Eric Nunn
Dr. Hua Ou
Dr. Amy Poremba
Dr. Mary Purucker
Dr. Kausik Ray
Dr. Alberto Rivera-Rentas
Ms. Cathy Rowe
Dr. Elka Scordalakes
Dr. Lana Shekim
Dr. Kathy Shim
Dr. Melissa Stick
Dr. Susan Sullivan
Ms. Nanette Stephenson
Dr. Debara Tucci
Dr. Becky Wagenaar-Miller
Dr. Bracie Watson
Ms. Ginger Webb
Mr. Tim Wheeles
Mr. Eric Williams
Ms. Kelli Van Zee
Mr. Baldwin (Buck) Wong
Dr. Shiguang Yang

Other federal employees present during portions of the meeting:

Dr. Biao Tian, CSR
Dr. Brian Scott, CSR
Dr. Maribeth Champoux, CSR
Dr. John Bishop, CSR
Dr. Alexei Kondratyev, CSR
Ms. Felice Harper, CIT
Mr. Alex Papadapolis, TV OPS
Ms. Tina Baker, Captioner
Dr. Avi Nath, NINDS

Other non-federal guests present during portions of the meeting:
Dr. Shelly Chadha, WHO

The complete Council roster is found in Appendix 1.

CLOSED SESSION September 9, 2021

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. Rebecca Wagenaar-Miller

Procedural Matters

Dr. Rebecca 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 even any appearance of a conflict was stressed, as was 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 116 investigator-initiated R01 grant applications; 105 applications had primary assignment to NIDCD, in the amount of $41.5 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 13th percentile.

Special Program Actions

1. NIH Mentored Clinical Scientist Research Career Development Award (K01): The Council recommended support of one application.
2. NIH Mentored Clinical Scientist Research Career Development Award (K08): The Council recommended support of two applications.
3. NIH Mentored Patient-Oriented Research Career Development Award (K23): The Council recommended support of two applications.
4. NIH Pathway to Independence Award (K99): The Council recommended support of two applications.
5. NIH Support for Conferences and Scientific Meetings (R13): The Council recommended support of one primary application and support of one secondarily assigned application.
6. NIH Research Enhancement Award (R15): The Council recommended support of one application.
7. NIH Exploratory/Development Research Grant Award (R21): The Council recommended support of six applications.
8. NIDCD Early Career Research (ECR) Award (R21): The Council recommended support of nine applications.

9. Clinical Research Center Award (P50): The Council recommended support of one application.
10. NIH Small Business Technology Transfer Grant (STTR): The Council recommended support of one Phase I (R41) application.
11. NIH Small Business Innovation Research Awards (SBIR): The Council recommended support of one Phase II (R44) application.

OPEN SESSION - September 9, 2021

Opening Remarks ..... Dr. Debara L. Tucci

Dr. Debara L. 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=42559)

Consideration of Minutes of the Meeting of May 20 & 21, 2021

Dr. Tucci called the members' attention to the minutes of the May 20 & 21, 2021 meeting of the NDCDAC. The minutes were approved as written.

Confirmation of Dates for Future Council Meetings

Dates for the Council meetings through September 2023 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 January 27, 2022 and Friday, January 28, 2022.

[*Executive Secretary Note: The January 2022 council meeting will be virtual and held on Thursday, January 27, 2022, and Friday January 28, 2022. The tentative plans are to start the meeting at 10:00 a.m. on each day.*

Introducing New Members

Each September we welcome new members to the advisory council. This September we welcomed the following members:

Dr. Emily Buss is a Distinguished Professor and Vice Chair for Research in the Department of Otolaryngology-Head and Neck Surgery at University of North Carolina - Chapel Hill. Her research interests are focused on investigating the perception of sound in human listeners. She is involved in a wide range of studies of human hearing including normative studies in both children and adults, as well as experiments on the effects of hearing loss in listeners who make use of hearing aids or cochlear implants. Dr. Buss has received continuous grant funding by the NIH since 1996 and has also received funding from the Hearing Research Consortium. She has been a frequent reviewer for journals such as *Acoustical Society of America*. Dr. Buss is an external mentor for a grant awarded to Boys Town National Research Hospital and she has served many years as a grant reviewer for NIH. She has published many articles, papers, books, and has several oral presentations and/or abstracts.

Dr. Laurel Carney is a Professor in the Department of Biomedical Engineering and Neuroscience, with a joint faculty appointment in the Department of Electrical Engineering at University of Rochester. Her research interests include combining neurophysiological, behavioral, and computational modeling techniques towards the goal of understanding neural mechanisms underlying the perception of complex sound. The main focus of her research is on hearing in listeners with normal hearing ability. She also has interest in applying results from the laboratory to the design of physiologically based signal-processing strategies to aid listeners with hearing loss. Dr. Carney has patents in the area of signal processing and has been funded by NIH since 1991. In the past she was funded by Whitaker Foundation, NOHR Research Awards and NSF. She has been an active member of grant review panels at NIH. She is Section Editor for *Hearing Research* and has received honors including the David T. Kearns Faculty Mentoring and Teaching Award. She is a frequent lecturer nationally and internationally and is widely published.

Dr. Andrew Groves is a Professor and the Vivian L. Smith Endowed Chair in Neuroscience in the Department of Neuroscience and Molecular and Human Genetics and Director in the Graduate Program in Development, Disease Models and Therapeutics at Baylor College of Medicine. His research interests focus on understanding the development, evolution, and regeneration of the inner ear. Dr. Groves' lab pursues an understanding of developmental processes to address why the sensory tissue of the cochlear fails to regenerate after damage, and to identify genes involved in hereditary deafness. Dr. Groves has received grant funding from NIH since 1992 and he has received funding from the Department of Defense and the Hearing Health Foundation. He has served on many editorial boards such as *Scientific Reports* and *Developmental Biology*. He has been involved in many grant reviews and is widely published. He was a member of and served as chair of the NIDCD Board of Scientific Counselors from 2013-2018.

Dr. Anil Lalwani is Professor and Vice Chair for Research and Director, Division of Otology, Neurotology and Skull Base Surgery and Co-Director at Columbia Cochlear Implant Program at the Department of Otolaryngology-Head and Neck Surgery at Columbia University Vagelos College of Physicians and Surgeons. His research interests include cochlear implantation, middle ear implants, chronic ear disease, cholesteatoma, facial nerve disorders, otosclerosis, superior semicircular canal dehiscence, glomus tumors, cerebellopontine angle tumors, skull base surgery, and gamma knife therapy. Dr. Lalwani has previously focused on identifying genes that are critical for hearing through the use of molecular genetic and molecular biologic methods and developing and investigating gene transfer technology for the treatment of hearing disorders. Dr. Lalwani is considered one of the leading ear surgeons in the country. Dr. Lalwani has received years of grant funding from NIH. He has received honors and awards including American's Registry's America's Most Honored Professional and Castle Connolly Medical Ltd: *America's Top Doctors* (19th Edition). He is a member of many professional organizations such as American Neurotological Society. He serves on several editorial boards including Hearing, Balance and Communication (Associate Editor: Neuro-otology). Dr. Lalwani is widely published and has been a grant reviewer at NIH and an ad hoc reviewer for journals.

Ms. Vicki Deal-Williams is Chief Staff Officer for Multicultural Affairs at the American Speech-Language-Hearing Association (ASHA). Her professional interests include developing organizations and programs to educate, inspire and engage members. She is an advocate for the underserved and underrepresented. She is recognized for the co-development of, and for

sustaining the ASHA national office environment and culture. The ASHA workplace was named "Top Workplace" by the Washington Post, and as a "Great place to work" by Washingtonian Magazine. She is a facilitator of change, exploring opportunities for enhancement, identifying contributing factors in conflict and resistance, developing process/system improvement strategies, and establishing and implementing appropriate solutions. Ms. Deal-Williams has many affiliations including member, American Speech-Language-Hearing Association. She is frequently invited to present and is widely published.

Dr. Margaret (Meg) Wallhagen is Professor of Gerontological Nursing and Director of the John A. Hartford Center of Gerontological Nursing Excellence at the University of California, San Francisco. Her research interests include gerontology and chronic care management. Her focus is on how older individuals and their families manage chronic illness as well as changes that occur with age. She has explored issues related to informal caregiving, diabetes, and successful aging, but for the last several decades has focused specifically on hearing loss. She was involved in a four-year longitudinal study of the experience of hearing loss in older adults and their partners. Currently, she is doing a study on the benefits of integrating a screening and educational protocol into the primary care setting to promote better access to care and treatment. She is a member of many professional organizations such as American Nurses Association. She is an editorial board member for the journal *Research in Gerontological Nursing*. Dr. Wallhagen was appointed to the Board of Trustees at Hearing Loss Association of America. She received several honors and awards including the Helen Nahm Research Lecture Award and has contributed to numerous publications.

Dr. Rebecca (Becky) Wagenaar-Miller is our new NIDCD director of the Division of Extramural Activities. In this role, Dr. Wagenaar-Miller serves as the executive secretary of the NDCDAC. Dr. Wagenaar-Miller will lead a team that develops, implements, and disseminates NIDCD extramural review and grants management policies and procedures. She will also oversee the Grants Management Branch, the Scientific Review Branch, and staff within the DEA.

Dr. Wagenaar-Miller earned a Ph.D. in cancer biology from the Vanderbilt University School of Medicine. She completed a research fellowship at NIH's National Institute of Dental and Craniofacial Research (NIDCR) and a postdoctoral research fellowship in Vanderbilt's Department of Cancer Biology. She published numerous peer-reviewed articles on cancer biology prior to beginning her career in extramural research policy at NIH.

Dr. Wagenaar-Miller's experience guiding extramural research policy spans multiple NIH institutes and offices. She previously served as deputy director of the Division of Extramural Activities at the National Institute of Mental Health (NIMH), where she supported NIMH extramural research; supervised grants management and extramural review; and served as the executive secretary for the NIMH's advisory council. Prior to that, she was chief of the Extramural Policy Branch within the NIMH's DEA, directing all activities related to extramural research policy. During this time, she also co-chaired an NIH extramural committee that developed new review criteria focused on streamlining processes and reducing the administrative burden of multi-component funding opportunity announcements. Prior to NIMH, Dr. Wagenaar-Miller served as the acting director of the Office of Extramural Research Policy and Operations, and operations chief of the Office of Extramural Research Policy and Operations, at the NIH's National Institute of Allergy and Infectious Diseases (NIAID) and served as a scientific review officer within the NIH's NIDCR.

She replaces Dr. Craig Jordan, who retired from NIDCD last month. Dr. Wagenaar-Miller was able to join the NIDCD in July, so that there was an overlap between her start date and Dr. Jordan's retirement, which helped to provide for a smooth transition.

NIDCD Director's Report.....Dr. Tucci

Staffing Update: Dr. Tucci discussed the recruitment of a Chief Diversity Officer and indicated that it is a priority for NIDCD to help carry out many of the new programs and initiatives that have been recommended by the Council Working Group and by an internal NIDCD working group on Diversity, Equity and Inclusion. She stressed that NIDCD is very committed to the establishment of new programs to develop and support a diverse workforce and have many exciting ideas to work with. However, current NIDCD staff – while passionate about these issues – do not have the capacity to manage a large-scale program envisioned, will need someone in a senior position who can lead these efforts.

The NIH is currently working out hiring mechanisms and we hope to be able to proceed with recruitment before the end of the calendar year.

Susan Dambrauskas who has headed the NIDCD Office of Health Communication and Public Liaison has left the NIH and a search for her replacement is beginning. This office is important because, as the name implies, they manage and facilitate our public outreach activities with all outside the NIH, particularly through our website which is undergoing significant revision. NIDCD has updated many of its webpages, including those focused on training.

One of the goals of the NIDCD intramural program in the Clinical Center has been to improve our infrastructure for clinical care and clinical research. Towards that end, NIDCD is currently recruiting for two important positions. The first position, Branch Chief for Neurotology, is wrapping up the search.

The second search is for a Director of the Otolaryngology Clinic in the Clinical Center. That person would be charged not only with directing our service's clinical activities, but also with developing more collaborations with other services and our own research protocols that take advantage of the rich intellectual environment of the NIH. This search is ongoing and council members are urged to encourage a colleague who would excel in this environment to apply.

Last, Dr. Carter VanWaes will retire in June of 2022, and NIDCD will likely initiate a search for the position of Clinical Director in January of next year.

Council Activities: NIDCD is thankful for the Council's advisory role, and Dr. Tucci expressed her appreciation of Council's participation in past and current activities:

- Drs. Nirupa Chaudhari and Dan Sanes are serving as the Council liaisons in helping the **NIDCD develop a new strategic plan**.
- Drs. Lisa Goffman and Fan-Gang Zeng, a former council member, led the **Council Working Group on Diversity and Inclusiveness** and presented a preliminary report at the May 2021 advisory council meeting. The institute received the Working Group's final report this summer and we are currently reviewing the recommendations in the report with plans for implementation.

- Council participated in a presentation and discussion on the **impact of COVID-19 on the scientific community** at the May 2020 advisory council meeting. The discussion was moderated by Drs. Ruth-Anne Eatock, Sandra Gordon-Salant, John Carey, and Robert Hillman, resulting in contributions that were implemented by NIDCD and NIH on ways to support the extramural research community during the pandemic.

During the past 18 months, Council members have helped to lead three NIDCD working groups that have provided important information to the institute:

- Dr. Carey led a working group to advise on **human temporal bone** research and research infrastructure.
- Drs. Cynthia Morton and Sanes participated in an October 2020 workshop on **Otitis Media (OM) in Early Childhood**. Workshop participants identified major gaps in our understanding of OM that present opportunities for novel and continued research. The group has also noted important barriers to progress in the field, in clinical and basic research, and in translation of research to the clinic.
- NIDCD continues a long-standing collaboration with the Lawrence Livermore National Labs to develop a new generation of implantable electrodes. Novel fabrication techniques are needed to develop automated, precise, microfabrication of implantable devices, such as cochlear implants for individual with hearing loss and vestibular implants for individuals with balance disorders, that will function for the lifetime of a patient. To this end, NIDCD provides funding support for the Implantable Microsystems Group at the Lawrence Livermore National Laboratory to develop precise and rapid construction micromachining techniques and construct arrays of microelectrodes suitable for recording and stimulating neural tissue. Dr. Zeng currently participates on this working group, which is ongoing.

NIDCD continues to participate in numerous trans-NIH initiatives, and Dr. Tucci highlighted examples of just a few of these efforts.

BRAIN Initiative: NIDCD-supported scientists continue to capitalize on funds from the Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN) Initiative. The BRAIN Initiative is aimed at revolutionizing our understanding of the human brain. Former NIDCD advisory council member, John Ngai, Ph.D., is serving as the director. Dr. Christoph Schreiner presented an update of the BRAIN Initiative at the May 2019 advisory council meeting, and Dr. Sanes currently serves as the NIDCD representative to the BRAIN Initiative Multi-Council Working Group.

Interagency Autism Coordinating Committee: Dr. Cooper and Dr. Tucci serve on this federal advisory committee which is mandated by Congress to coordinate Autism Spectrum Disorder (ASD)- related activities across the U.S. Department of Health and Human Services. NIDCD supports additional research to improve the lives of people with ASD and their families, especially research on children with ASD who have limited speech and language skills.

RADx-rad: NIH launched a series of initiatives to address challenges related to the COVID-19 pandemic, including the Rapid Acceleration of Diagnostics or RADx. NIDCD is playing a large role on the RADx-Radical or RADx-rad initiative, which supports new non-traditional approaches to address gaps in COVID-19 testing. Four initial projects funded by the RADx-rad initiative that

were awarded to NIDCD grantees are designed to enhance the use of chemosensory testing as a COVID-19 screening tool.

Ensuring Research Support During the Pandemic: NIDCD joined NIH in taking steps to allow flexibility and options so grantees could sustain their research and prioritize safety for themselves, their lab members and research participants during the pandemic. Some of the actions undertaken by NIH and NIDCD include:

- Delayed the start dates of some awards to accommodate lab closures.
- Approved no-cost extensions as well as modifications of existing protocols to allow telehealth/virtual intervention approaches.
- Encouraged grantees to shift research focus to other activities or convert in-person activities to virtual, when appropriate to focus on safe conduct of research.
- Extended eligibility period of some early career applicants.
- Permitted continued payment of salaries on research grants despite lab closures and increased clinical responsibilities during pandemic.
- Allowed a one-page update with preliminary data as post-submission materials for applications.
- Allowed early career scientists whose career trajectories have been significantly impacted by COVID-19 to request (paid) grant extensions – F, K, and ECR (R21) grantees.

ARPA-H: Dr. Tucci then briefly covered ARPA-H. ARPA-H stands for the Advanced Research Projects Agency for Health and was conceived as an agency similar in some ways to DARPA, which is an agency in the Department of Defense (Defense Advanced Research Projects Agency) which is charged with developing new, innovative, transformative technological advances. DARPA is responsible for development of GPS, weather satellites, the personal computer, and the internet, among other advances that we take for granted today.

To improve the U.S. government's capabilities to speed research that can improve the health of all Americans, President Biden is proposing the establishment of the ARPA-H. Included in the President's FY2022 budget as a component of the NIH with a requested funding level of $6.5B available for three years, ARPA-H will be tasked with building high-risk, high-reward capabilities (or platforms) to drive biomedical breakthroughs—ranging from molecular to societal—that would provide transformative solutions for all patients. The White House's Office of Science and Technology Policy (OSTP, headed by Dr. Eric Lander) and the NIH hosted 15 listening sessions to extensively engage a broad set of stakeholders on the proposed ARPA-H throughout the month of July and into August. On July 26, 2021, Dr. Tucci was accompanied by the directors of the National Eye Institute and the National Institute of Dental and Craniofacial Research at a listening session with advocates for Research on diseases in these mission areas. Representatives from the Hearing Loss Association of America, the American Academy of Otolaryngology-Head and Neck Surgery, and the American Speech-Language-Hearing Association gave brief comments during that session.

Clinical Trials: The pandemic has brought to light the challenges that the country faces in addressing major public health needs in a comprehensive and expeditious manner. Especially

early in the pandemic, results were reported from trials that were often underpowered, had design flaws such as lack of appropriate controls, or did not recruit study participants that reflect the diversity of the country's population. This was all done in an effort to get effective treatments to patients faster, but ultimately did not serve the public need.

The issue of clinical trial (CT) stewardship has been of great concern to the NIH for many years, and these considerations were behind the CT Stewardship reforms that were instituted in 2016.

These reforms included:

1) Quality and Rigor: CT-specific funding opportunity announcements (FOAs), Good Clinical Practice training for all Principal Investigators (PIs) and Key Personnel, protocol templates for grant applications, guiding principles for Institute/Center (IC) management and oversight of trials

2) Transparency: Dissemination of NIH-funded CT information (Clinical Trials.gov)

3) Efficiency: Single Institutional Review Board (IRB) requirement for multi-site studies

Given that we are now 5 years after the 2016 reforms have been implemented, and the recent challenges highlighted by the pandemic, Dr. Collins requested that a task force be convened across the NIH to assess the impact of these reforms and consider any opportunities that we may have to improve our CT infrastructure. The work of the task force is ongoing, and Dr. Tucci was named co-chair of this task force.

The NIDCD has an expanding Clinical Trials program that is led by Dr. Trinh Ly, with the recent addition of Dr. Mary Purucker who was most recently at National Center for Advancing Translational Sciences (NCATS). NIDCD is currently considering how best to provide the support that our investigators need to develop trials that impact patient care, and how best to monitor progress of those trials over time.

Part of this discussion is that resources exist outside of the NIDCD that we may be able to leverage, such as NCATs programs including the Clinical and Translational Science Awards (CTSA) Program which funds programs in 60 institutions across the country, and the NCATS Trial Innovation Network (TIN) which is designed to support trial design, recruitment, and completion.

Dr. Tucci indicated that a big priority for her and for NIDCD staff has been to develop mechanisms to support the training and retention of clinician scientists in the NIDCD mission workforce. Data show that the clinician scientist workforce is becoming ever scarcer. However, data also show that when grant applications are submitted by clinician scientists, they have a very good rate of success in being funded.

This year, NIDCD released 3 new programs aimed at supporting development of this workforce. These were presented by our training officer, Dr. Alberto Rivera-Rentas, at a recent Council meeting. The first listed program is intended to support otolaryngology resident and medical student research training and will eventually replace the T32 mechanism for training these specific populations. The second and third listed programs are intended to support national or multi-institutional mentoring and research training networks for clinician scientists working not just in otolaryngology but in all our NIDCD mission areas, and for clinicians including but not limited to MDs.

Ending Structural Racism in Biomedical Research: NIH is committed to 1) Creating and maintaining a work environment that is free of racism, discrimination, harassment, and other inappropriate behaviors; and 2) Identifying and removing any barriers that may perpetuate structural racism that exclude people of color from professional advancement and leadership opportunities at NIH. Dr. Tucci shared information on NIH's and NIDCD's major ongoing efforts towards achieving diversity, equity, and inclusion in the scientific research community and within NIH/NIDCD's workforce:

- **NIDCD Extramural Working Group:** NIDCD convened this internal group to focus on increasing diversity engagement and the research pipeline for NIDCD's extramural research program. We dissolved this group after the NDCDAC Working Group on Diversity and Inclusiveness was established.
- **NDCDAC Working Group on Diversity and Inclusiveness:** Drs. Goffman and Zeng co-chaired this group, and they presented a draft report at the May 2021 advisory council meeting. The draft report included five 'Identified Needs' and associated 'Proposed Solutions.'
- **Diversity Catalysts:** This trans-NIH committee was established to facilitate implementation and evaluation of diversity, equity, and inclusion strategies within and across NIH institutes and centers. The committee has developed 3 tools: 1) a recruitment search protocol to identify qualified scientific researchers from diverse backgrounds, 2) an implicit-bias education module to create awareness of implicit bias and reduce its impact, and 3) a prototype career-development conference for early-career scientists from diverse backgrounds.
- **NIH Anti-Racism Steering Committee:** This trans-NIH committee has over 400 members consisting of staff across the NIH. It was established to redress issues regarding policies and procedures that lead to racism.
- **UNITE Initiative:** This is an NIH-wide effort committed to ending racial inequities across the biomedical research enterprise. It is composed of five high-level committees with representatives from all 27 NIH ICs who are passionate about addressing diversity, equity, and inclusion. Each committee is represented by a different letter of the UNITE acronym and has a specific, targeted focus.
- **NIDCD DIR Committee for Diversity, Equity, and Inclusion:** This NIDCD committee advises the NIDCD scientific director on diversity, equity, and inclusion issues specific to our intramural research program.
- **NIDCD Diversity Working Group:** Established earlier this year, this NIDCD working group is helping to coordinate the institute's diversity efforts. It will work with NIDCD leadership to propose how the basic tenets of diversity, inclusion, equity, and respect could be better realized within NIDCD. The Working Group will specifically address how to increase and showcase diversity at all levels within the Institute and explore and implement opportunities to improve inclusion, equity, and respect, and foster an informed community that is welcoming to everyone.

NIDCD staff involved in this Diversity Working Group include Dr. Elyssa Monzack and Mark Lucano as Co-Chairs, and Cathy Rowe as Executive Secretary for the group. Subcommittees include:

- Recruiting led by Dr. Melanie Barzik
- Continued Training and Education led by Dr. Kelly King
- Equity and Inclusion led by Ms. Lisa Portnoy
- Engagement/Outreach/Communications led by Mr. Baldwin Wong
- Accountability led by Ms. Lynne Penn

In addition, efforts have begun to develop a trans-NIH working group to develop an **NIH-wide strategic plan for diversity, equity, inclusion, and accessibility**. Mr. Mark Lucano is serving as NIDCD's representative on this effort.

The NIDCD Diversity Working Group is the only internal trans-NIDCD committee and can integrate suggestions from the Advisory Council and from DIR, as well as provide specific policy recommendations for the Institute that no one Division or trans-NIH group can. There is good synergy across the co-chairs, the subcommittee leads, and the other staff representatives that help to avoid redundancy and to integrate suggestions.

Dr. Tucci indicated that the working group recently presented to her and other NIDCD leadership 10 recommendations. NIDCD leadership is considering these recommendations along with the recommendations suggested by the Advisory Council's diversity and inclusiveness working group.

NIDCD recently published two Funding Opportunity Announcements (FOAs) that use the **R25** grant mechanism to encourage scientific workforce diversity. The overarching goal of the R25 program is to support educational activities that encourage individuals from diverse backgrounds, including those from groups underrepresented in the biomedical and behavioral sciences, to pursue further studies or careers in research.

- PAR-21-185, **Mentoring Networks to Enhance Diversity in NIDCD's Extramural Research Workforce**. This FOA will support creative educational activities with a primary focus on Mentoring Activities and welcomes programs aimed at improving the caliber of mentorship.
- PAR-21-186, **Enhancing NIDCD's Extramural Workforce Diversity through Research Experiences**. This FOA will support creative educational activities with a primary focus on Research Experiences. The proposed research experiences may be targeted to undergraduates, graduate students, postdoctorates or early to mid-career faculty and should be designed to extend their research skills, experiences and knowledge base.

Dr. Tucci highlighted the NIH Common **Fund's Faculty Institutional Recruitment for Sustainable Transformation (FIRST) program** which aims to enhance and maintain cultures of inclusive excellence in the biomedical research community. "Inclusive excellence" refers to cultures that establish and sustain scientific environments that cultivate and benefit from a full range of talent. NIH aims to facilitate institutions in their building a self-reinforcing community of scientists, through recruitment of a critical mass of early-career faculty who have a

demonstrated commitment to inclusive excellence. The program also seeks to have a positive impact on faculty development, retention, progression, and eventual promotion, as well as develop inclusive environments that are sustainable. The initial awards are in the process of being announced, and the NIDCD is considering options for how we might support our academic community through this program.

The BRAIN Initiative has implemented a new requirement that will require applicants to submit a "Plan for Enhancing Diverse Perspectives" (PEDP) as part of the grant application. When a PEDP is required, applications submitted without such a plan will be considered incomplete and will be withdrawn prior to peer review. Evaluation of the applicant's PEDP will be made during peer review as part of the scorable criteria and during programmatic review and will be used to inform funding decisions. The goal is to encourage investigators, institutions and organizations, and the research community broadly to consider how diverse perspectives advance the proposed study aims and are integral to the research performed. With the publication of this requirement, future NIH FOAs can use the language and intent from the BRAIN announcements. This is a big step forward that will help lead all of NIH forward on diversity in research.

NIDCD Budget Report ..... Mr. Eric Williams

NIDCD's Budget Officer, Mr. Eric Williams, presented information on the current and previous fiscal year budgets. He shared the NIDCD's 2021 Budget Operating Plan as compared against the FY 2020 final allocation. The FY2021 budget benefits from a $8 M increase. That increase is largely applied to growth in Training Grants and mandatory increases to Intramural Research and Research Management and Support. He indicated that FY 2022 would likely start on a continuing resolution which sets funding at the FY 2021 enacted level. Proposals by the President and House both point to significant growth at NIH to support COVID-related activities as well as, across-the-board increases. These proposals if enacted would result in budget increases for NIH of 5-10 percent. Caution abounds because many factors play into the budget, including the likelihood that the Secretary of HHS will transfer funds from NIDCD's appropriation to support child-care/medical operations on the southern border.

[A copy of the slides Mr. Williams used for this budget presentation is included in Appendix 2]

The World Report on Hearing and WHO .....Dr. Kelly King
Actions for its Implementation Dr. Shelly Chadha

Dr. King provided a brief summary of NIDCD's collaborations with the World Health Organization (WHO) since the World Health Assembly passed a resolution to promote ear and hearing care globally in 2017. Following this review, Dr. Shelly Chadha, technical officer and lead, Ear and Hearing Care programme, WHO, was introduced. Dr. Chadha's presentation covered the recently released World Report on Hearing and WHO planned actions for its implementation. Discussion

Discussion

Dr. Tucci asked Dr. Chadha to talk more about barriers to implementing hearing care programs and the integration of hearing care into universal health platforms. Dr. Chadha expressed her belief that human resources constitute the biggest challenge as there is limited availability of qualified ear, nose, and throat (ENTs), audiologists, speech language pathologists, and hearing

aid technicians across the world. She pointed out that the World Report on Hearing expands on this and she stressed there needs to be a focus on training. Dr. Chadha explained that these individuals could be considered under the umbrella of universal health coverage. Dr. Tucci pointed out that the lack of trained individuals is not just in under-resourced countries but also within the U.S.

Dr. Sanes asked who would first recognize hearing loss in children around the world. Dr. Chadha responded that parents are often the first to recognize or suspect hearing loss in a child which is why it is important to empower parents by giving them information about what to do if hearing loss is suspected. She also indicated that outside the house, teachers would have a large role in identifying suspected hearing loss in school age children.

Dr. Ruth Ann Eatock asked about role models from the public health perspective in wealthier nations and in under-resourced nations. Dr. Chadha indicated that the report provides a sample of good practices in a wide range of countries.

Dr. Richard Einhorn asked about what is being done about stigma associated with hearing loss. Dr. Chadha stated that the literature on stigma related to hearing loss is very limited and is being explored in the Lancet Commission on Hearing Loss.

Dr. Cynthia Morton inquired about congenital cytomegalovirus (CMV) infection and newborn hearing loss. Dr. Chadha stated that CMV is one important cause of congenital hearing loss but that not enough countries are taking CMV infections serious enough to address the problem.

Dr. Espy-Wilson asked about concerts and headphones use as they contribute to hearing loss and asked if there is a difference with ear buds or over the ear headphones. Dr. Chadha indicated that both concerts and headphones contribute to hearing loss, but people attend concerts for a short duration, but headphone use is often for extended time over multiple days. She also described findings from a recent paper that demonstrated ear buds cause a marked increase in the pressure within the ear canal which increases the possibility of more damage but that more studies are needed on the question.

Dr. Chaudhari asked about engagement of technology companies on this problem. Dr. Chadha summarized the WHO Make Listening Safe initiative that was launched in 2015 to address this. She indicated that the WHO has been engaging with technology companies since 2015 and other stakeholders to develop features to reduce the risk of hearing loss.

Strategic Plan Update.....Dr. Laura Cole
Dr. Nirupa Chaudhari, Dr. Dan Sanes

Dr. Laura Cole updated Council members on the NIDCD 2022-2027 Strategic Plan development. NIDCD hosted a Virtual Strategic Plan Kickoff meeting on July 12, 2021. Dr. Tucci informed kickoff attendees about NIDCD's new strategic planning process, and how they could contribute to the strategic plan by submitting their best forward-thinking ideas. NIDCD received over 122 ideas from 116 people, including both those who attended the kickoff, and those who learned about the request for ideas from colleagues. NIDCD analyzed all of the ideas and will consider them when we develop the strategic plan.

Dr. Cole described next steps, which include a December 2021 Virtual Idea Generation meeting, where a diverse group of participants representing all of the NIDCD Mission areas will

determine the agenda by pitching forward-thinking ideas to be discussed with other experts at the meeting. The Council then heard from NDCDAC Liaisons Drs. Chaudhari and Sanes, who gave their perspectives on NIDCD's strategic planning process and on the December idea generation meeting and reminded Council that they are welcome to provide feedback and suggest ideas. Drs. Chaudhari and Sanes will provide the Advisory Council with another update at the January 2022 meeting.

Discussion
Ms. Vicki Deal-Williams inquired about the extent to which diversity, equity and inclusion will be addressed across the priorities. Multiple council members discussed the use of a template and potential modifications.

The first day of the meeting was adjourned at 3:25 p.m. on Thursday, September 9.

OPEN SESSION September 10, 2021

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. Dr. Tucci welcomed 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=42561).

Report of the Division of Intramural Research (DIR)..... Dr. Lisa Cunningham

NIH policy requires that the National Advisory Council for each institute review the activities of their respective intramural program once a year. Dr. Lisa Cunningham, Scientific Director of NIDCD's Division of Intramural Research, presented the 2021 report.

Dr. Lisa Cunningham introduced herself and provided her background and experience. She has a background in audiology and received her Ph.D. in Neuroscience from the University of Virginia. In 2011 she joined NIDCD and in April 2021, became the NIDCD Scientific Director (SD). Her research at NIH is focused primarily on hair cell degeneration and hearing loss in the mature ear that is caused by ototoxic drugs. She is developing strategies to safeguard hearing in humans receiving ototoxic drugs, guided by the knowledge developed from her basic science studies examining the molecular mechanisms that underlie the death and survival of sensory hair cells.

Dr. Cunningham was preceded by Dr. Andrew Griffith, the NIDCD Scientific Director from 2009 until 2020. Dr. Griffith is now Senior Associate Dean for Research at University of Tennessee Health Science Center in Memphis. Dr. Thomas Friedman became Acting Scientific Director from June of 2020 until April of 2021. Dr. Cunningham thanked Dr. Friedman for his outstanding job during the pandemic which was a very difficult time to lead DIR. He demonstrated outstanding leadership and focused on the safety and wellness of NIDCD faculty and trainees. The Intramural Chief of Staff is Dr. Monzack who also serves as the NIDCD intramural Training Director. Dr. Cunningham expressed her appreciation of Dr. Monzack's leadership in the office of the Scientific Director. The Chief Administrative Officer is Ms. Penn. Ms. Penn has been in her position for over 10 years and is also very experienced with the administrative leadership in DIR.

The NIDCD Intramural investigators include two Tenure-Track Investigators, Dr. Clint Allen and Dr. Catherine Weisz and seven tenured investigators, Dr. Friedman, Dr. Bechara Kachar, Dr. Katie Kindt, Dr. Matthew Kelley, Dr. Van Waes, Dr. Doris Wu, and Dr. Cunningham. The Otolaryngology Surgeon Scientist Program includes three members: Dr. Wade Chien, Dr. Michael Hoa and Dr. Nyall London. NIDCD has a new faculty member, Dr. Nadia Biassou, who is a neuroradiologist and combines functional imaging and artificial intelligence to study cognitive behavior such as auditory language processing. Her primary appointment is to the NIH Clinical Center. In addition, the NIDCD intramural program has three investigators who are Scientists Emeriti, Dr. Richard Chadwick, Dr. Dennis Drayna and Dr. Barry Horwitz.

Oversight for the Intramural program is provided by the Board of Scientific Counselors (BSC). Dr. Paul Manis serves as Chair of the BSC. The BSC currently includes eight members, all prominent researchers, including several past Advisory Council members. A complete list of the BSC roster can be found here: https://www.nidcd.nih.gov/about/board-scientific-counselors/roster. The intramural labs are evaluated every four years on a rotation and this year, the Board will meet in November to review the labs of Dr. Cunningham and Dr. Chien.

The Intramural labs are also undergoing a “Blue-Ribbon Panel” review which is a review process put in place by the NIH Office of Intramural Research and Led by the Institute Director, through which extramural experts weigh in on what resources are needed to provide the greatest opportunities for scientific advancement in the Intramural Research Program. The last formal review of DIR was in 1998 and there was a smaller review in 2014 that resulted in an “Intramural Review and Long-Term Planning Report”. Dr. Cunningham expects the Blue-Ribbon Panel to complete their work sometime in October 2021 and looks forward to exploring ways to implement their recommendations.

DIR holds an annual Principal Investigator Retreat with all Intramural Investigators and Staff Scientists, which has historically been a mix of scientific and administrative discussions. This year the retreat will facilitate a strategic planning discussion focused on scientific priorities for DIR, including how best to foster an innovative culture, create opportunities for collaboration, and translate basic science discoveries into clinical therapies. These discussions will be held in December, allowing for the discussions to be guided by the Blue Ribbon Panel Report.

Dr. Cunningham provided a SARS-CoV-2 impact update. Initially, the number of staff who remained on site was limited to those with a role of caring for animals, patients and facilities. Beginning in June 2020, individuals whose work could not be completed remotely were allowed on site, but only in a limited amount due to the 50% building occupancy restriction at NIH. In July 2020, the staff allowed on site expanded to include those whose work was difficult to complete remotely, which was an improvement, but the 50% restriction continued. NIDCD is awaiting guidance from NIH leadership as to when the rest of the staff may return. Dr. Cunningham met with every member of DIR to check in and assess pain points and understand how people were doing. Approvals have been given for appointment extensions for trainees at all levels, as well as Tenure-Track Investigators. Maximum telework and leave flexibility have been extended to all personnel. Trainees have been encouraged to take advantage of the expanded wellness programs, resilience training programs and support groups provided by the NIH Office of Intramural Training and Education (OITE).

Dr. Cunningham highlighted NIDCD’s EARssentials course, which was held for the eighth time in July 2021. In 2021 the course format was a virtual discussion series via Zoom, where participants first watched recorded lectures and then participated in live discussion groups. The

online platform allowed for more than 75 pre-registered participants from 18 states in the U.S. and Puerto Rico and 17 countries around the world. Dr. Hertzano provided a virtual workshop on the "gEAR" resource that is used for genomics data and Dr. Isabelle Roux led a virtual mouse genetics laboratory session.

This summer DIR hosted interns virtually through the NIH Summer Internship Program (SIP), which was cancelled in 2020 due to the pandemic. Two of NIDCD's six summer interns were from diversity-focused OITE subprograms (the Community College Summer Enrichment Program (CCSEP) and the College Summer Opportunities to Advance Research (CSOAR) program). Dr. Cunningham expressed her excitement about expanding NIDCD participation in SIP in the future.

Dr. Cunningham concluded her presentation with a discussion of her vision for moving DIR forward. She described the NIDCD mission to conduct outstanding basic, translational and clinical research training in normal and disordered processes of communication with a focus on hearing and balance. She also described her own vision which is that DIR will have a transformative impact on lives through continuous innovation in research, research training, and therapy development. She noted that DIR is too small to cover all the mission areas of the NIDCD and advisory reviews support that DIR maintain a focus on hearing and balance. Finally, Dr. Cunningham described her own values that underlie her vision for DIR. She noted that if there are the right people in place and they have access to the right kinds of support, DIR will foster innovation, collaboration and excellence in its scientific work. It is important that DIR fosters an open collaborative and inclusive culture with a focus on diversity, integrity, innovation, and accountability.

Discussion
Dr. Wallhagen asked if the full focus of the intramural program was on basic science. Dr. Cunningham answered that NIDCD DIR is focused on hearing and balance within the NIDCD mission areas but is not entirely basic research. She indicated that investigators with clinical expertise are part of DIR and that she is working hard to build a program that will allow NIDCD to build therapies by translating the basic science discoveries into clinical trials.

Dr. Chaudhari asked if there are plans to add one or more labs in other mission areas and Dr. Tucci encouraged Dr. Cunningham to talk about joint hires with other Institutes at NIH. Dr. Cunningham responded that NIDCD is waiting to hear from the Blue Ribbon Panel about expanding into other mission areas. She also indicated that there are a lot of opportunities for joint hires with other institutes that could have cross-cutting expertise such as in neuroscience.

Report of the Division of Scientific Programs .....Dr. Cooper
Dr. Cooper introduced statistician Dr. Hua Oh, the newest employee of the Division of Scientific Programs (DSP) and presented "The Report on the Division of Scientific Programs" at NIDCD. She discussed three topics:

1. Notices of Special Interest (NOSIs)
2. Concept clearance
3. Recent supplement activities that DSP has overseen

Notice of Special Interest (NOSI) are an avenue that NIH is utilizing in place of Program Announcements (PAs) to inform potential applicants that NIDCD is interested in a particular topic and would like to see more research in this area. DSP has the option to develop their own NOSI or sign on to NOSIs developed by other Institutes/Centers and add wording specific to

NIDCD's mission.
Examples of both include:

- NIDCD Health Disparities and Inequities Research (Dr. King)
- Improving Patient Adherence to Treatment and Prevention Regimens to Promote Health (Dr. Lana Shekim)
- Simulation Modeling and Systems Science to Address Health Disparities (Mr. Howard Hoffman)
- Developing and Testing Multilevel Physical Activity Interventions to Improve Health and Well-Being (Dr. Cooper)

Concept Clearance
DSP is required by NIH to present any ideas, renewals of previous activities, plans for new directions to the NDCDAC before proceeding with development of a FOA. A broad description is provided. Council concurred with the following concept:

- Create new research opportunities for individuals from diverse backgrounds at all career stages to increase the number of investigators from diverse backgrounds, including under-represented minorities (URM) and individuals with disabilities and encourage self-identification.

Discussion
Dr. Wallhagen asked how NIDCD would define a diverse background. Dr. Cooper indicated that NIDCD would follow the NIH definition of diversity which includes a variety of categories including individuals with hearing loss.

Dr. Espy-Wilson commented that the Council Diversity Workgroup recommended that these applicants receive a review and discussion of their application. Dr. Cooper responded that NIDCD is looking into a number of ways to address the review of these applications but she cautioned that investigator-initiated R01 applications reviewed by CSR would not have any special review accommodations.

Ms. Deal-Williams commented that NIDCD should look at the requirements for the program and whether are potential barriers for individuals from diverse backgrounds to participate. Dr. Cooper responded that we have a couple of new programs that provide mentoring for individuals who are at less experienced institutions to develop the skills needed to be competitive for an NIH grant.

Dr. Wagenaar-Miller called for a vote to approve the concept. The concept was approved unanimously.

Administrative supplements
Dr. Cooper discussed administrative supplements made to active NIDCD awards and provided some examples of reasons supplements might be supported. She also described how other Institutes and Centers may have additional funds to provide supplements to NIDCD Investigators that may overlap with their research fields. Likewise, NIDCD issues supplements for new, one-year opportunities. Some examples covered include:

- Supplements for research training or career development awards whose projects had been significantly affected by COVID-19. At the end of FY21, 27 supplements were awarded, worth approximately $472,000.
- The Alzheimer's-focused administrative supplements for NIH grants that currently are not focused on Alzheimer's disease through the National Institute on Aging (NIA). NIA

funded 12 supplements to awards from NIDCD in response to this call for supplements. Dr. Cooper introduced Dr. Roger Miller and Dr. Amy Poremba to present on two administrative supplement programs led and coordinated by NIDCD staff: Data Science and the Temporal Bone.

Dr. Miller highlighted three NOSIs that were released in the Spring of 2021, e.g. NOT-OD-21-089, NOT-OD-21-091, and NOT-OD-21-094 by the NIH Office of Data Science Strategy (ODSS) to catalyze new capabilities in biomedical data science across all ICs at NIH. NIDCD and ODSS staff performed administrative reviews of these supplement applications and ultimately 9 awards were made with funds from the ODSS. An additional 11 awards were made with NIDCD funds to ensure efforts to build strategic partnerships for data science were supported across all NIDCD mission areas.

Dr. Poremba highlighted one NOSI that was released in the Summer of 2021, NOT-DC-21-004, by NIDCD to provide supplements to currently existing R01s, U01s, or R21s for equipment to digitize previously processed temporal bone tissue. She discussed how the digitally scanned temporal bone sections will be used to start a widely accessible database of available temporal bone tissue sections from a variety of clinical cases and normal subjects with at least 20x resolution. These online temporal bone sections can be analyzed at individual researchers' desktops rather than having to always access the tissue slides one at a time with a microscope while using slides that have to be physically sent between laboratories. The goal of the supplements is to pilot a way to speed up and improve access to this valuable resource. Six supplement applications were administratively reviewed by NIDCD staff and three awards were made.

Discussion
Ms. Barbara Kelley commented that the Hearing Loss Association of America community is very excited about this and that she would encourage the community to support this.

Dr. Chaudhari suggested that NIDCD website be updated to remind people that the repository needs donations.

Neurological Manifestations of Long-Haul COVID .....Dr. Avindra Nath

Dr. Avindra Nath a physician from the National Institute of Neurological Disorders and Stroke spoke about the neurological implications of COVID with an emphasis on long covid.

Dr. Nath presented some historical context of infectious diseases impact on humans and compared the uncertainty, loss and change in biomedical research during the AIDS epidemic of the 1980s to what we are seeing today with SARS-CoV-2. He discussed the multiple variants of SARS-CoV-2 including Delta and Mu and then moved into the neurological complications. These complications can be broadly classified into two groups - the acute phase and the post-viral phase. He explained that after recovery from the acute phase, a number of immune-mediated manifestations can occur over weeks and months. Dr. Nath indicated that he would discuss select complications including multi-system inflammatory syndrome in children (MIS-C) and long-haul COVID in adults which mimics chronic fatigue syndrome. He discussed a rat model of a different coronavirus (OC43) that utilized a fluorescent tagged virus to track the virus after inoculation. He stated that this has not yet been shown for SARS-Cov-2 but indicated that it remained a concern due to the structures that OC43 traveled to and possible involvement of multiple nerves. Dr. Nath presented on several publications detailing clinical presentation of

SARS-CoV-2 infection including vertigo, tinnitus, and vascular injury. He showed images of significant brainstem pathology and blood vessel involvement and disruption of the blood-brain barrier even though virus could not be detected in the brain. Dr. Nath presented some finding on SARS-CoV-2 and MIS-C. He explained that these patients can present with encephalopathy but generally respond to treatment with corticosteroids or intravenous immunoglobulins (IVIg). Dr. Nath discussed two recently published papers on long covid in adults which indicate that if symptoms persist beyond 3 months, that there is little chance of recovery and that it is worse in women. He also discussed a publication that stratified symptoms at onset with recovery and found that individuals with more severe symptoms at onset persist much longer. Some of the persistent symptoms that patients experienced were tinnitus, dysautonomia, cognitive and mood disorders, He noted that while many of these symptoms are similar to complications from other respiratory illnesses, the psychiatric manifestations associated with SARS-CoV-2 infection are greater than other respiratory illnesses. He discussed reports of increased presence of cerebral spinal fluid monocytes which produce a lot of cytokines and macrophages in the brain as driving the long covid symptoms. Dr. Nath discussed possible treatment options including anti-virals and immune suppression.

Discussion
Dr. Argye Hillis asked about long term deficits in taste and smell. Dr. Nath indicated that anosmia is the most common symptom impacting 60% of individuals by self-report and 80-90% of individuals by testing. He indicated that most recover but that some do not and progress further to parosmia. He explained that the virus affects the nasal mucosa and not the olfactory nerve due to the lack of ACE-2 receptor on the nerve.

Dr. Stonebridge asked about the projections from the olfactory bulb and if other viruses result in a similar phenotype. Dr. Nath indicated that they see this for other coronaviruses, and it has been speculated for SARS-CoV-2 but not demonstrated even though the pathology shows the area is impacted in patients infected by SARS-CoV-2.

Dr. Chaudhari mentioned trials ongoing for retraining olfactory system that might be useful for individuals suffering from parosmia.

Dr. Lakeisha Henry asked if Dr. Nath could comment on olfactory retraining and platelet-rich plasma treatment. Dr. Nath asked other individuals to comment, and Dr. Susan Sullivan responded that there have not yet been strong clinical trials testing to determine if retraining can be effective. She stressed that most individuals who experience defects in smell as a result of SARS-CoV-2 infection recover on their own, so these trials are needed to definitively demonstrate a benefit of retraining.

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

Dr. Wagenaar-Miller presented the report of the Division of Extramural Activities (DEA). She highlighted the interim actions that NIDCD grants management staff have performed since May council including extensions with funds to fellows and early career researchers in response to NOT-OD-21-052. Dr. Wagenaar-Miller highlighted several recent NIH notices including NOT-OD-21-180, NOT-OD-21-179, NOT-OD-21-169, and NOT-OD-21-135. She highlighted the upcoming NIH Virtual Seminar and encouraged researchers and administrators at all levels to attend. Dr. Wagenaar-Miller concluded by introducing two new DEA staff, Mr. Jamar Hill who joined as an Extramural Support Assistant and Ms. Cheyenne Socre who joined as a Travel

Planner. She thanked all of the DEA staff for helping with her transition to NIDCD and for keeping science moving forward.

Approach to NIDCD Extramural Clinical Trials **Dr. Trinh Ly**

Dr. Ly from the Division of Scientific Programs presented the approach NIDCD developed for the oversight of extramural clinical trials. The NIDCD Clinical Trials staff provide support for clinical trials across all NIDCD's mission areas: Hearing, Balance, Taste & Smell, Voice, Speech, and Language. The broad scope of NIDCD clinical trials include the evaluation of drug, dietary, device, and behavioral interventions. The core responsibilities of the NIDCD Clinical Trials team are to provide clinical trials consultation and guidance to extramural investigators and staff, manage the U01 clinical trials operations, and provide technical expertise and oversight for funded U01 clinical trials. The NIDCD has a risk-based approach to clinical trials and determines risk based on the complexity, safety, impact, and fiscal investment of each trial.

NIDCD utilizes the U01 Cooperative Agreement mechanism where the NIDCD Medical Officer serves as the Project Scientist and has substantial involvement for high-risk trials. The operations of the U01 clinical trials are overseen by the NIDCD Clinical Trials team who work in partnership with the study team. In a separate role, the NIDCD Program Officer has programmatic oversight of the U01 grant award. For high risk U01 clinical trials, the NIDCD Clinical Trials team has been striving to establish a more systematic approach to ensure key elements and activities are addressed across all U01 clinical trials. These include the utilization of the NIH-FDA protocol template. the institution of pre-implementation requirements prior to the initiation of enrollment, and the establishment of NIDCD's first internal independent Data and Safety Monitoring Board. These and other efforts are to ensure the NIDCD clinical trials are designed and implemented with rigor, well executed with integrity, and participants are safe and protected throughout the trial.

Adjournment

The meeting was adjourned at 11:58 a.m. on September 10, 2021.

Certification of Minutes

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

1

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

Debara L. Tucci, M.D., M.S., M.B.A.
Acting Chair
National Deafness and Other Communication Disorders Advisory Council

Director
National Institute on Deafness and 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)

Chairperson
Debara L. Tucci M.D., Director
National Institute on Deafness and Other Communication Disorders
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Ex Officio

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HENRY, LaKeisha R., M.D, FACS
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COLLINS, Francis S., Ph.D., M.D.
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Executive Secretary

WAGENNAR-MILLER, Becky, Ph.D.
Director, Division of Extramural Activities
National Institute on Deafness and Other
Communication Disorders
Bethesda, MD 20892

NIDCD Council Budget Report

Eric Williams, Budget Officer
NIDCD Advisory Council Meeting
September 9, 2021

National Institute on Deafness and Other Communication Disorders (NIDCD)

FY 2020 vs FY 2021 Operating Plan

(Dollars in thousands)

	FY 2020 Final Allocation		FY 2021 Operating Plan*	
Budget Mechanism	*Number*	*Amount*	*Number*	*Amount*
Research Projects				
Noncompeting	622	$264,153	588	$261,500
Admin. Supplements	55	$5,841	38	4,087
Competing	180	$76,119	162	78,500
Subtotal	802	$346,113	750	344,087
SBIR/STTR	31	$15,538	26	15,492
Subtotal, RPG's	833	$361,651	776	359,579
Research Centers	6	$15,228	6	15,514
Other Research	80	$10,687	90	12,008
Total Research Grants	919	$387,566	872	387,101
Individual Training	133	$6,494	150	8,079
Institutional Training	158	$8,307	158	8,788
R & D Contracts	40	$22,886	40	22,860
Intramural Research		$42,763		45,000
Research Mgmt. & Support		$22,671		24,750
TOTAL		$490,687		$496,578
Lapse		$5		

*Projected

National Institute on Deafness and Other Communication Disorders (NIDCD)

FY 2022 Budget Outlook

(Dollars in thousands)

- FY 2019 Enacted: $474,404
- FY 2020 Enacted: $490,692
- FY 2021 Enacted: $498,073

FY 2022

- House Mark-up: $522,758
- President's Budget: $511,792