

**NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS
ADVISORY COUNCIL
September 14–15, 2023
National Institutes of Health
Bethesda, Maryland**

MINUTES

The National Deafness and Other Communication Disorders Advisory Council (NDCDAC) convened on September 14–15, 2023, at the National Institutes of Health (NIH) in Bethesda, MD. Dr. Debara L. Tucci, director of the National Institute on Deafness and Other Communication Disorders (NIDCD), served as Chairperson. In accordance with Public Law 92-463, the meeting was:

Closed September 14, 2023, from 9:00 a.m. to 12:00 p.m. for review of individual grant applications and September 15, 2023, from 9:00 a.m. to 9:40 a.m., for report from Board of Scientific Counselors; and

Open September 14, 2023, from 1:00 p.m. to 4:20 p.m. and September 15, 2023, from 10:00 a.m. to 11:50 a.m., for the review and discussion of program development needs and policy.

Council members in attendance¹:

Dr. Emily Buss	Dr. Argye Hillis
Dr. Nirupa Chaudhari	Ms. Barbara Kelley
Ms. Vicki Deal-Williams	Dr. Anil Lalwani
Dr. Ruth Anne Eatock	Ms. Lynne Murphy Breen
Dr. Carol Espy-Wilson	Dr. Dan Sanes
Dr. Lisa Goffman	Dr. Ben Strowbridge
Dr. Andy Groves	Dr. Margaret Wallhagen

Council members absent:
None

Pending Members:

Ms. Katherine Bouton	Dr. Susan Thibeault
Dr. Daniel Merfeld	

Ex officio members:

Dr. Judith Shafer	Ms. Christa Themann
Dr. Jeremy Nelson	

Subject Matter Experts:

Dr. Jay Gottfried	Dr. Jose Pena
Ms. Kimberly Kuman	Dr. Larry Trussell

The complete Council roster can be found in Appendix 1.

The list of NIDCD staff and other NIH staff in attendance 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 September 14, 2023

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. 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 115 investigator-initiated R01 grant applications; 100 applications had primary assignment to NIDCD, in the amount of \$38.3 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 Research Scientist Development Award – Research and Training (K01): The Council recommended support of two applications.
2. NIH Mentored Clinical Scientist Research Career Development Award (K08): The Council recommended support of three applications.
3. NIDCD Research Career Enhancement Award for Established Investigators (K18): The Council recommended support of one application.
4. NIH Mentored Patient-Oriented Research Career Development Award(K23): The Council recommended support of two applications.
5. NIH Pathway to Independence Award (K99/R00): The Council recommended support of one application.
6. NIDCD's Mentored Research Pathway for Otolaryngology Residents and Medical Students (R25 - Clinical Trial Not Allowed): The Council recommended support of one application.
7. NIH Support for Conferences and Scientific Meetings (R13): The Council recommended full support of one application, one application for one year and co-fund one dual application.
8. NIH Research Enhancement Award (R15): The Council recommended support of two applications.

9. NIH Exploratory/Development Research Grant Award (R21): The Council recommended support of seven applications.
10. NIDCD Early Career Research (ECR) Award (R21): The Council recommended support of five applications.
11. NIH Small Business Innovation Research Awards (SBIR): The Council recommended support of two Phase II (R44) applications.
12. NIDCD Hearing Healthcare for Adults: Improving Access and Affordability (R21/R33 Clinical Trials Optional): The Council recommended support of one application.
13. Central and Peripheral Control of Balance in Older Adults (R01 Clinical Trial Optional): The Council recommended support of one application.
14. NSF/NIH Collaborative Research in Computational Neuroscience (CRCNS) (R01): The council recommended support of three applications.
15. Mobile Health: Technology and Outcomes in Low- and Middle-Income Countries (R21/R33 Clinical Trial Optional): The council recommended support of one application.

Dr. Tucci adjourned the closed session at 12:00 pm.

OPEN SESSION September 14, 2023

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

Dr. Tucci called the meeting to order.

Council Introduction

Dr. Tucci invited each Council member, including the pending members, ex officio, and subject matter experts, to introduce themselves.

Consideration of Minutes of the Meeting of May 18–19, 2023

Dr. Tucci called the members’ attention to the minutes of the May 18–19, 2023, meeting of the NDCDAC. The minutes were approved as written.

Future Council Meetings

Dates for the 2024 NDCDAC meetings are January 25–26 (virtual), May 16–17 (in-person), and September 12–13 (in-person). Dates for the 2025 Council meetings are January 23–34 (virtual), May 15–16 (in-person), and September 4–5 (in-person). Members are to inform the Council executive secretary of major conflicts for any of the dates.

NIDCD Director’s Report Dr. Tucci

Fiscal Year (FY) 2024 Appropriations

Dr. Tucci began by stating that the FY 2024 government budget, which would begin October 1, 2023, has not been approved. She covered three possible outcomes: (a) Congress will pass the budget, (b) Congress will not pass the budget but will pass a continuing resolution, or (c) the government will shut down, which would prohibit NIH employees from working. NIDCD expects to receive relatively flat funding for the next two years as the Senate is proposing a small increase to NIH's budget and the House of Representatives is proposing a cut to NIH's budget. More budget information will be presented tomorrow.

Retirements and New Selections

Dr. Tucci said that Dr. Patricia Brennan, director of the National Library of Medicine, has announced her retirement. Dr. Brennan has contributed tremendously to NIH. Dr. Jeanne M. Marrazzo was selected as the new director for the National Institute of Allergy and Infectious Diseases, and she will begin this role in October 2023. Dr. Gayla L. Poling was selected as chief research audiologist for the NIDCD Audiology Unit.

Chief Diversity Officer Year in Review

Dr. Tucci said that NIDCD's first chief diversity officer, Dr. Cendrine Robinson, has been in the position for one year. Dr. Robinson has coordinated and led several efforts, such as identifying opportunities to advance science in notices of funding and working with the internal NIDCD workforce to address diversity, equity, inclusion, and accessibility (DEIA).

NIDCD Director's Seminar Series

Dr. Tucci next covered the new NIDCD Director's Seminar Series which was established to further educate the research community and promote NIDCD's strategic plan. The next seminar will be October 25, 2023, from 10:00 to 11:30 a.m. ET at NIH Building 31/6C (Room A/B) or virtually via NIH Videocast. Dr. Adam Resnick will present "From Datasets to Data Platforms to Data Ecosystems: The Emerging Landscape of Collaborative Cross-Disease Discovery and Accelerated Clinical Translation." This presentation will cover precision medicine and biomedical data science with discussion led by Dr. Geoffrey Ginsberg, chief medical and scientific officer for the *All of Us* Research Project.

Introduction to Repository Models for Data Sharing Anup Mahurkar

Dr. Tucci introduced Mr. Anup Mahurkar, executive director of software engineering and information technology at the University of Maryland Institute for Genome Sciences. His areas of expertise include bioinformatics, tool development, large-scale analysis systems, database design, high-throughput computing architecture, and application development. Mr. Mahurkar has helped NIDCD determine its data science resource needs.

Mr. Mahurkar said that his latest efforts have been in building repositories for biomedical and genomic data at the University of Maryland. His presentation will cover data sharing, data repository models, and data standards.

Data Sharing

[NIH defines data sharing](#) as "the act of making scientific data available for use by others (e.g., the

larger research community, institutions, the broader public), for example, via an established repository.” Data sharing is done for scientific and policy decisions reasons.

Policies, such as the 2023 Data Management and Sharing Policy, have established the expectation of maximized effort for the appropriate sharing of scientific data. Scientific data includes unpublished data, but laboratory notebooks and peer reviews are some of the sources of data that do not need to be shared.

More than 130 specialized repositories have been made, and [a list of repositories](#) are maintained by the Trans-NIH BioMedical Informatics Coordinating Committee.

Data Repository Models

Data is the largest base building block that supports a DIKW (data, information, knowledge, and wisdom) pyramid, and repositories can be made at each of the three steps that lead up to wisdom. The main desirable characteristics for a repository are unique persistent identifiers, long-term sustainability, and the metadata the repository will support. Clear use guidance, security, and a common format are some additional desirable characteristics. Human data repositories need fidelity to consent, plans for a breach, and more.

Repository types include institutional (e.g., Harvard Dataverse), generalist (e.g., Dryad, Vivli, Mendeley Data), specialized (e.g., disease- or domain-specific [the National Institute of Dental and Craniofacial Research (NIDCR) FaceBase resource for craniofacial researchers]), or data-specific (e.g., National Center for Biotechnology Information [NCBI] Sequence Read Archive [SRA]) repositories and data ecosystems (e.g., *All of Us* Research Hub and the National Cancer Institute’s Cancer Research Data Commons), which help researchers access multiple repositories in one place. Each repository type has its own pros and cons.

Data Standards

Repositories need to have data standards to provide valuable metadata for a community. Data standards help a researcher find data in repositories based on similar characteristics and outcomes and make data findable, accessible, interoperable, and reusable.

Data standards can be employed for information such as clinical variables, assay types, and data modalities. The standards can be implemented with controlled lists or terminologies, ontologies, and common data elements for clinical data.

Enabling Data-Intensive Translational Research in Dental, Oral, Craniofacial, and Related Disorders and ConditionsDr. Lu Wang

Dr. Tucci introduced Dr. Wang, the translational genomics research branch director for the Translational Genetics and Genomics Program at NIDCR. Dr. Wang said that she would discuss NIDCR’s data science strategy working group and how NIDCR has facilitated the evolution of their data repository, [FaceBase](#).

Data Science Strategy Working Group

The NIDCR data science strategy working group’s 12 members are experts from academia and

industry. With regular meetings and two listening sessions in July 2023, the working group’s goal is to make recommendations for a well-informed and well-reasoned data science strategy to enable NIDCR to realize the potential of data science in advancing the full translational continuum of dental, oral, and craniofacial (DOC) research; reducing health disparities; and improving oral and overall health. The group’s recommendations are pending.

FaceBase

NIDCR’s FaceBase began in 2009 and is now a community-driven central resource of craniofacial development and malformation data. It is a public data repository that features self-curation, data housed “in the cloud,” artificial intelligence (AI)/machine learning (ML)/deep learning (DL) data readiness, CoreTrustSeal certification, permanent identifiers, links to external resources, and more.

The dental, oral, and craniofacial (DOC) data in the repository is generated from molecular, cellular, genomic, and imaging technologies from multiple organisms. Most of the data is available via open access; potentially identifiable data is available via controlled access. FaceBase office hours are available for investigators who want to use the repository.

Examples of data in FaceBase are craniosynostosis data for mouse, human, and zebrafish; orofacial clefting data for mouse and human; and an audiogram clinical assays example dataset. The FaceBase team would be happy to talk to groups about how the repository may be used.

Discussion..... Dr. Susan Thibeault

The following discussion questions were posed to the Council:

How should NIDCD solicit input from its community regarding data sharing and standards?

Dr. Thibeault asked whether NIDCD should use grants or a working group to establish standards. Dr. Tucci said that standards are necessary in order to have interoperability of data. Mr. Mahurkar said there are two trains of thought for establishing data standards: (1) ask investigators for data management and sharing plans to then create a survey that can determine what and where data would be deposited and (2) create a working group that looks at repositories and recommends them to NIDCD.

Where should NIDCD start the process of building a repository?

Dr. Thibeault asked where NIDCD should begin its repository strategy. Should it focus on one specific area (e.g., genetics, behavioral data) or on a broader area? Should NIDCD use an ecosystem repository or tag onto existing repositories?

Dr. Tucci asked whether NIDCD could leverage existing databases or needs a repository for data not currently available. Dr. Goffman commented that she relies on an open science framework for behavioral data and the open science preliminary piece where experimental plans and data are entered.

Dr. Wang said that NIDCD can use the open science framework, but data quality and appropriate sharing of identifiable data need to be considered; NIDCR has learned about these aspects from its

grantees. FaceBase has more than 40 datatypes, one of which is behavioral research data. An agnostic data model allows a hybrid data repository to fill in the gaps between generalist and specialist repositories to accommodate data sharing.

Should NIDCD build its own repository?

Dr. Thibeault said that NIDCD researchers are currently required to deposit their data in repositories, so she wondered why NIDCD would need its own repository.

Dr. Chaudhari said that she is not a data scientist, but she has seen repositories that cannot talk to each other because of different formats and data entry, so a central NIDCD repository with consistent formatting would be beneficial.

Dr. Tucci said that data standards would support data interoperability and reusability.

Dr. Goffman suggested that NIDCD remain flexible in how it approaches a repository, because of the diverse work the institute does.

Should all data be treated equally?

Dr. Sanes said that data standards would be difficult to establish because of the many ways data is collected, such as with several various types of videos, microphones, and sampling rates. Raw data would need standardized readouts, and too much time would be spent standardizing data when technology evolves quickly.

Dr. Espy-Wilson replied that researchers need diversity in data, such as for a deep learning algorithm that uses data from multiple microphone channels. A data standard for high sampling rates would be needed.

Dr. Wang said that data standardization needs to consider the life cycle of data collection and embrace the diversity derived from advances in technology. NIDCR considers both areas for its data standards.

Should high-value datasets be treated differently?

Mr. Mahurkar said that high-value datasets, such as the data in the *All of Us* Research Program, have transformed the genomics field. He asked whether NIDCD could identify an area for a high-value dataset, and he said that data standards are needed for data's collection and definition for use in machine learning algorithms.

General Comments

Dr. Lalwani suggested that, once the questions around data and its standards are settled, NIDCD fund training grants to relay this information to students.

Dr. Espy-Wilson said that she had to become a visiting scholar in order to access medical data; to prevent such challenges, she suggested that institutional review boards include the ability for data to be shared with other researchers in the field. Dr. Tucci said that database privacy concerns are a major issue.

Closing Thoughts

Dr. Thibeault suggested that a task force be established to consider and determine what needs to be done to establish an NIDCD repository.

Meaningful Outcome Measures in Adult Hearing Health Care: A New Partnership with the National Academies..... Dr. Kelly King

Dr. Tucci introduced Dr. Kelly King, an NIDCD program officer, who shared information about the new initiative between NIDCD and the National Academies of Sciences, Engineering, and Medicine (NASEM) to determine standard outcomes that are meaningful to both the individual and the clinician while being standardly applied in adult hearing health care. The outcome measures are needed to establish which of the many new interventions improve the lives of people with hearing loss and determine the quantitative and qualitative aspects of that improvement. Current outcome measures, such as audiogram tests, are not a great proxy for how a patient feels about their hearing or the patient's satisfaction with interventions.

The National Academies are private, nonprofit institutions that provide expert advice on some of the most pressing challenges facing the nation and world. NASEM uses a proven study process that begins with defining a study, followed by opening the call for nominations to a committee that meets and deliberates. Committee members' biographies and the final report are shared with the public.

Dr. King reviewed the committee's lengthy statement of task. When robust evidence is lacking or absent, the committee is encouraged to make recommendations based on sound scientific reasoning in the context of the current health care environment.

The [Meaningful Outcome Measures in Adult Hearing Health Care](#) project timeline covers the next 18 months, and a final report is expected by spring 2025.

Discussion

Dr. Buss said that she hopes the same recommendations can be generated for children. Dr. King agreed, saying that if this project is successful, it can be a model for other mission areas and applications.

Ms. Kelley congratulated Dr. King for making this project happen.

From Pandemic to Practice: COVID-19 and the Case for Universal Smell Testing.....Dr. Valentina Parma

Dr. Tucci introduced Dr. Valentina Parma, assistant director and assistant member, Monell Chemical Senses Center and chair of the [Global Consortium for Chemosensory Research](#) (GCCR) Dr. Parma began by saying that COVID-19 exposed gaps in preparedness for medical care. Recent innovations have enabled population screening for the smell function, and implementing routine smell testing will lead to breakthroughs in various areas of health care, including nutrition, mental health, and brain health.

Smell Loss and COVID-19

One study found that [self-reported loss of smell was the best predictor of having COVID-19](#). Another study found evidence of a [causal relationship between COVID-19 and loss of smell](#). The loss of smell in patients with COVID-19 is normally slowly regained within two weeks; however, some patients have persistent loss of smell for years. [Patients have reported a reduced quality of life](#) due to loss of smell, which can also affect [nutrition and social behavior](#). Distorted smell, known as parosmia, changes how patients experience life.

Global Consortium for Chemosensory Research

The GCCR was formed to address what happens to the sense of smell and taste in patients with COVID-19. The organization has more than 700 members from 71 countries, so it can collect data from diverse locations. One Consortium study found that [asking patients about their ability to smell](#) on a scale from 0 to 100 could discriminate between patients with COVID-19 and patients with other disorders with an accuracy of 71%. Another self-survey could predict by 10 days [COVID-19 surges](#) that could overwhelm intensive care units. However, self-reported measurements of smell loss [underestimate the true prevalence of smell loss by 27%](#), which prompts the need for a universal test, particularly in children.

Smell Tests

Before the COVID-19 pandemic, standardized smell tests were cumbersome and costly to administer. The [RADx[®] Radical](#) (RADx-rad) award asked for new, rapid tests to detect chemosensory issues in COVID-19. Four solutions that attempted to set data standards emerged: the ArOMa-T and Aromha tests, which use cards to test smell; the hard candy test, which is conducted with actual hard candy; and the SCENTinel test, developed by Dr. Parma and others, which uses a card with a single odor.

Dr. Parma shared that the [SCENTinel 1.1 card has 94% accuracy](#) in discriminating between people with anosmia and people with normosmia, but the test's ability to detect COVID-19 has been more limited because of the virus' variants; approximately 70% of patients with the Delta variant lose their sense of smell, compared with 30% of those with the Omicron variant. SCENTinel's high specificity makes it good at determining when a patient does not have Omicron COVID-19, but the test is less successful in determining when a patient does have it.

Smell as a Sentinel

Dr. Parma presented evidence for regular testing of smell for reasons beyond COVID-19, such as mental, nutritional, metabolic, and brain issues. Smell loss is one of the strongest predictors of 5- and 10-year mortality in the United States, but only 20.3% of patients discuss smell or taste loss with their provider. Since the pandemic began, 50 million people have experienced smell loss, with 5% to 10% still suffering from it.

Theme 4 of the [2023–2027 NIDCD Strategic Plan](#), “Translate and implement scientific advances into standard clinical care,” includes smell testing. More providers should discuss loss of smell and taste with their patients, and smell should be measured as regularly as blood pressure, eyesight, and other metrics. This notion is supported by the Smell and Taste Association of North America (STANA), and regular smell monitoring will be discussed at the Towards Universal Chemosensory Testing conference taking place in Philadelphia, PA, November 5–7, 2023.

Discussion..... **Dr. Ben Strowbridge**

Dr. Strowbridge agreed that regular smell testing is needed, but that was not clear before the COVID-19 pandemic.

Dr. Chaudhari asked whether there are other qualities that change among the different variants of COVID-19. Dr. Parma did not see changes other than the reduced frequency of smell loss with Omicron, but she said that more monitoring is needed to detect differences. The best data available for the prevalence of smell disorders is from the 2013 and 2014 National Health and Nutrition Examination Survey, but smell and taste testing has not been added since the COVID-19 pandemic began, so there is limited data for evaluating the impact of smell loss and dysfunction.

Dr. Levy, NIDCD clinical director, said that COVID-19 brought the world's attention to the field of chemosensory testing. He asked what challenges face chemosensory care. Dr. Parma said that lack of awareness about smell loss is still an issue, so self-reporting is not a reliable metric. Instead, a metric is needed to highlight historical and longitudinal changes in smell. Issues with a person's sense of smell can begin 10 years before a diagnosis of Parkinson's disease, so a test that detects changes in smell would be beneficial. As more therapeutic options for diseases become available, Dr. Parma would like the medical community to be ready to use a rapid smell test to monitor for conditions that could begin with smell loss.

Dr. Gottfried asked whether investigators have looked at interactions between COVID-19 and other autoimmune olfaction disorders. Dr. Parma responded that she did not know of that research but suggested that an olfactory database with screening measures could be matched with electronic health records to study whether smell loss can predict diseases. Databases would provide critical mass information.

Dr. Pena asked whether certain smells could be used to detect Alzheimer's disease or Parkinson's disease. Dr. Parma said that she does not know of specific smells used to detect certain diseases; this question has been studied, but the sense of smell is very complicated. Peanut butter or spices can be used for some tests.

Ms. Bouton asked what the provider response to the 20.3% of patients who reported their smell loss was. Her experience is that primary care providers do not screen for hearing loss, so she asked how providers will be educated about screening for loss of smell. Dr. Parma said that this is an important issue. Data collected from 6,000 patients and caregivers found that most providers did not know about smell loss or told their patients not to worry about it. Aside from some training materials aimed at ear, nose, and throat physicians, most textbooks do not have much information about smell. More training is needed, but without a cure for smell loss, it is difficult to generate interest. Patients want to receive validation about smell loss, and nutrition and mental health counseling could support patients' quality of life without curing their loss of smell. Including smell testing in a series of clinical trials could identify a subgroup of patients who need a different level of support for smell loss, but that data is not currently being collected. Nutrition, mental health, and neurodegenerative disorders are solid places to start smell testing.

Ms. Kelley said that her mother, who lost her sense of smell and taste after a bad cold, never regained her sense of smell, which compromised her quality of life, and her doctor dismissed her concerns. Ms. Kelley asked about the correlation between smell and pregnancy. Dr. Parma said that there is a correlation between smell and pregnancy, but it is not experienced by every pregnant woman. The sense of smell and its loss affects social and relationship connections. Dr. Parma would

like providers to provide validation to patients who lose their sense of smell.

Remarks from Retiring Members.....
Dr. Ruth Anne Eatock
Ms. Barbara Kelley
Dr. Dan Sanes
Dr. Ben Strowbridge

Dr. Tucci said that she began at NIDCD at the same time as the four retiring Council members. She has enjoyed working with them, and she thanked them for their advice and wisdom.

Dr. Eatock thanked the Council for the opportunity to serve. She gave several examples of how NIDCD has supported research that has been impactful in her career. NIDCD's training grants have been beneficial to younger researchers, and Dr. Eatock feels that NIDCD will be rewarded by its sustained investments.

Ms. Kelley recalled the establishment of NIDCD in 1989. She was honored to be part of the Council and to represent the community of people with hearing loss. She has enjoyed learning about other areas addressed by NIDCD, which she has seen positively affect individuals.

Dr. Sanes said that the NIDCD program staff should know how highly they are thought of by the community at large.

Dr. Strowbridge appreciated meeting the NIDCD staff behind the grants he received. He indicated that the olfaction community is happy with what NIDCD is doing. He remarked that the intersection of all the senses will require multidisciplinary studies.

Dr. Tucci thanked the Council members and presenters. She adjourned this session of open council at 4:00 p.m.

BSC Closed Session – September 15, 2023

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

The meeting was called to order by Dr. Tucci, Director, NIDCD, at 9:00 am who expressed her appreciation to the entire Council for their service and advice.

Council Procedures Dr. Becky Wagenaar-Miller

Dr. Wagenaar-Miller briefly reminded Council of the procedures of this special closed session and that the meeting would move into Open Session at approximately 11:00 a.m.

Board of Scientific Counselors Report Dr. Lisa Cunningham

Dr. Tucci welcomed Dr. Lisa Cunningham, Director of NIDCD's Division of Intramural Research. As stipulated by law, each institute must provide annually to its National Advisory Council an overview of the Intramural Research Program. The overview includes reports of the Board of Scientific Counselors (BSC), and the responses of the Scientific Director. This presentation is informational only and Council members are not asked to recommend approval or disapproval of the reports or to modify them in any way. However, the Council may make recommendations to the Director, NIDCD regarding such research on the basis of the materials provided.

Dr. Cunningham presented Reports of the BSC regarding the review of three intramural laboratories. She then presented her response to the reports and responded to questions from Council.

[Executive Secretary Note: During the BSC presentation, attendance was restricted to the Council members, the Executive Secretary and a few senior NIDCD administrators.]

Dr. Tucci adjourned the BSC Closed Session at 9:40 am.

OPEN SESSION September 15, 2023

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

Dr. Tucci called the meeting to order at 10:00 am and announced the agenda. She introduced the NIDCR director of intramural research, Dr. Cunningham.

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

Intramural Investigators

Dr. Cunningham reviewed the list of NIDCD intramural investigators, which includes two new members: Dr. Ronna Hertzano and Dr. Joshua Levy. Dr. Levy is the new NIDCD clinical director, who will guide the development of intramural clinical trials in NIDCD's mission areas and conduct research on sinonasal and olfactory disorders. Dr. Hertzano's research focuses on understanding the regulatory signaling cascades that lead to inner ear development and developing therapeutics to prevent hearing loss. Dr. Gayla Poling is the new chief of the NIDCD audiology unit, and her research

focuses on developing diagnostic approaches for early detection and prevention of hearing loss as well as advancing the development and use of clinical audiologic databases.

Dr. Cunningham reviewed the members of the 2023 NIDCD Board of Scientific Counselors (BSC).

NIDCD DIR Updates

Dr. Cunningham provided updates for recommendations made by the 2021 Blue Ribbon Panel's review of the NIDCD intramural research program (IRP). One update is that the Innovation Award was established by the Office of the Scientific Director; this competitive award is meant to incentivize high-risk and high-impact projects, and Wade Chien, M.D., was the award's first recipient in 2023. Another update is the completion of the first phase of an NIH-wide clinical database of hearing and balance function.

Diversity

NIDCD's intramural diversity efforts have included identifying a diverse pool of qualified applicants to the NIH Postbaccalaureate Intramural Research Training Award program for consideration by NIDCD intramural labs; three fellows from the pool were selected by NIDCD labs in 2023.

EARssentials Course

The 10th Annual [EARssentials](#) course was well attended by in-person and online participants.

Summer Internship Program

NIDCD hosted 10 summer interns who were supported with regular meetings with the NIDCD training director, NIH resources for deaf and/or hard-of-hearing trainees, and the NIH Office of Intramural Training and Education.

Discussion

Dr. Gottfried asked to learn more about the BSC. Dr. Cunningham said that the BSC is the means by which intermural investigators have their research programs evaluated by experienced extramural scientists with expertise in NIDCD mission areas. The BSC reviews tenure-track investigators every three years and senior tenured investigators every four years.

Dr. Eatock complimented the EARssentials course. Dr. Cunningham said that EARssentials meets the need for courses that are available to everyone.

Dr. Buss asked about how to implement a summer research experience at her extramural laboratory. Dr. Cunningham said that NIH centrally supports the [Summer Internship Program](#) (SIP) and collects applications through its portal. Dr. Elyssa Monzack, the deputy scientific director for NIDCD's Intramural Research Training and Career Development Program, may be contacted for further information. Dr. Monzack said that there are thousands of applicants, but researchers who have a particular student in mind who has an interest in an NIDCD mission area should email her.

Dr. Chaudhari asked what percentage of high school and undergraduate college interns are local or regional to the NIH campus. Dr. Monzack suggested asking the NIH SIP office for an exact

percentage, but students are provided with a relocation allowance to help them move to attend the summer program, and some students live locally.

An Introduction to All Things Intramural Dr. Nina Schor

Introduction to the NIH IRP

Dr. Tucci introduced Dr. Schor, deputy director for NIH Intramural Research Program (IRP). Dr. Schor said that her office is an amalgamation of the 23 institutes and centers that have IRPs; the authority for each intramural program lies with its respective institute, scientific, and clinical directors.

Dr. Schor said that there is an effort to increase the diversity of the intramural workforce. As of 2022, 44% of the workforce was female, 9% was Black, and 9% was Hispanic.

Dr. Schor described the differences between intramural and extramural research, each of which has pros and cons. The main difference is that intramural funding is awarded for a principal investigator's entire research portfolio, while extramural funding is awarded for individual projects. Intramural funding is reviewed every four years, and extramural funding is reviewed every five years.

Career development opportunities in the NIH IRP include the [Stadtman Tenure-Track Investigator Program](#), the [Lasker Clinical Research Scholars Program](#), the [Distinguished Scholars Program](#), and the [Independent Research Scholar Program](#). Dr. Schor's office supports these opportunities.

Introduction to the NIH Office of Intramural Research (OIR)

Dr. Schor leads the OIR, which has six employees who help oversee a broad array of areas for NIH research: research policy, compliance, appointments and promotions, DEIA and faculty affairs, training, technology transfer, and intramural communications. Each area has many subcomponents.

Discussion

Dr. Chaudhari said that she appreciates Dr. Schor's emails to the extramural community. Dr. Schor said that she enjoys writing her column for the OIR newsletter.

Dr. Strowbridge asked whether OIR thinks more about a potential tenure-track investigator's work that could not be done in a university or the investigator's work to expand knowledge in a mission area. Dr. Schor said that OIR's career development programs think carefully about the complementary nature of an investigator's expertise and their environment, but the ultimate appointment decision is made at the institute IRP level. NIH institutes vary in what drives their hiring decisions. OIR has a vision for NIH research and how it interacts with research outside of NIH that Dr. Schor in turn sells to each institute's directors, who have the resources to act on the vision.

Dr. Cunningham said that the NIDCD IRP seeks to hire investigators whose research includes a uniquely intramural component, such as first-in-human or longitudinal studies. The BSC comments on the extent to which research is uniquely intramural, and resources are allocated based on those comments.

Dr. Eatock asked whether Dr. Schor or NIH is developing strategies to address the postdoctoral shortage in IRPs. Dr. Schor said that her office is taking several steps to address the issue, such as

inviting postdoctoral fellows from unconventional places and planning to provide a living wage that is standardized across institutes. There is a working group in the NIH Advisory Council to the Director that brainstorms ideas to address the issue and will publish a final report soon. Institutions need to be accountable for investigators' career development, such as by providing a mentor and a career development plan.

Dr. Eatock said that NIDCD has a center for career choice and support, and she suggested that the aforementioned NIH working group establish career support guidelines for institutes. Dr. Schor agreed, saying that NIH should ask institutes to provide proof of their commitment to career development and resources for postdoctoral personnel; however, if it makes this a requirement, NIH will need to consider equity across institutes.

Dr. Chaudhari said that NIDCD has career development and mentoring offerings for postdoctoral and graduate students. Training for these offerings could be transportable, and she suggested that there be a training for trainers. Dr. Schor said that more of these resources, including the [Becoming a Resilient Scientist lecture series](#) and a webinar series for tenure-track investigators that instructs them on promotional activities such as preparing for site visits, are publicly available.

Budget Report..... Mr. Eric Williams

Mr. Williams presented the budget report showing the operating plan for Q4 of FY 2023 compared with the actual numbers for FY 2022. NIDCD's budget grew \$20 million between FY 2022 and FY 2023, with much of that money going to grant programs, preparation for the next two years, and growing DIR so that it is on par with other institutes.

Mr. Williams said that, because of the large noncompeting research project base, the budget community needs to manage the \$20 million growth without reducing the competing research project portfolio. The noncompeting base (such as R01s and R21s) is the largest part of the NIDCD budget, so it needs to be kept relatively stable to maintain a robust competing program. The stability strategy, despite an expected flat budget between FY 2024 and FY 2025, is to balance multiyear-funded projects with projects funded with one-year dollars. Competing grants may be funded with around \$80 million.

Congress has promised a 5.0% to 5.5% pay raise for federal employees, so some contracts have been prefunded to absorb the upcoming pay raises.

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

Dr. Cooper introduced the newest members of the Division of Scientific Programs: Dr. Jaclyn Schurman, a research training officer for fellowship programs, and Dr. Lisa Kopf, a program officer in the voice and speech program.

Report of the Division of Extramural Activities (DEA).....Dr. Becky Wagenaar-Miller

Dr. Wagenaar-Miller introduced two new DEA staff members: Nadine Bikim, a travel planner, and Zsa Zsa Young, an extramural support assistant.

Dr. Wagenaar-Miller provided updates about new NIH notices for policies and requirements. First, per the changes in the small business innovation research (SBIR) and small business technology transfer

(STTR) foreign disclosure requirements ([NOT-OD-23-139](#)), grant applicants will need to disclose all funded and unfunded relationships with foreign countries for all owners and all senior key personnel in the application. Awardees are responsible for monitoring relationships with foreign countries of concern post-award and must submit an updated disclosure form to report any changes.

Generative Artificial Intelligence (AI) is prohibited for the NIH peer-review process ([NOT-OD-23-149](#)). Uploading or sharing content or original concepts from an NIH grant application, contract proposal, or critique to online generative AI tools violates the NIH peer review confidentiality and integrity requirements. By signing security, confidentiality, and nondisclosure agreements, reviewers are acknowledging that they did not use generative AI technologies (e.g., natural language processors, large language models) for analyzing and formulating peer review critiques for grant applications and research and development contract proposals.

Review integrity and bias awareness training ([NOT-OD-23-156](#)) will be required for NIH reviewers, effective at the May 2024 Council round. The training will need to be completed every three years.

There are NIH application instruction updates for data management and sharing (DMS) costs ([NOT-OD-23-161](#)). Costs associated with DMS are currently noted on the Research & Related (R&R) Budget Form as a single line item titled “Data Management and Sharing Costs,” but starting with applications with due dates of October 5, 2023, or later, NIH will no longer require the use of the single DMS cost line item.

Dr. Wagenaar-Miller reviewed the five open requests for information where NIH is seeking input. All of them are published in the NIH Guide for Grants and Contracts.

NIDCD is recruiting more reviewers for peer-review panels, offering a good opportunity for young and diverse reviewers. Nominations, including self-nominations, [are being accepted](#).

Closing Comments **Dr. Tucci**

Dr. Tucci thanked all of the participants and adjourned the meeting at 11:50 a.m.

I. Certification of Minutes

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

Rebecca A. Miller -S Digitally signed by Rebecca A. Miller -S
Date: 2024.04.04 15:06:06 -04'00'

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

Debara L. Tucci -S Digitally signed by Debara L. Tucci -S
Date: 2024.04.03 22:48:05 -04'00'

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

Director
National Institute on Deafness and
Other Communication Disorders

Brooke Sydnor
Council Assistant
NDCD Advisory Council

Appendices

Appendix 1—Roster

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Appendix 3—Attendance

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Roster

National Deafness and Other Communication Disorders Advisory Council

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

Chairperson

Debara L. Tucci, M.D., M.S., M.B.A.

Director

National Institute on Deafness and Other Communication Disorders

Bethesda, MD 20892

BUSS, Emily, Ph.D. Vice Chair of Research Professor of Otolaryngology/Head and Neck Surgery Chief, Division of Auditory Research University of North Carolina Chapel Hill, NC 27599	2025	GOFFMAN, Lisa, Ph.D. Professor and Nelle Johnston Chair Callier Center for Communication Disorders School of Behavioral and Brain Sciences University of Texas at Dallas Dallas, TX 75235	2024
CHAUDHARI, Nirupa, Ph.D. Professor of Physiology & Biophysics University of Miami School of Medicine Biological Sciences Division Miami, FL 33136	2024	GROVES, Andy, Ph.D. Professor Departments of Neuroscience and Molecular and Human Genetics Baylor College of Medicine Houston, TX 77030	2025
DEAL-WILLIAMS, Vicki, M.A., CAE Chief Staff Officer of Multicultural Affairs American Speech-Language-Hearing Association Rockville, MD 20850	2025	HILLIS, Argye Elizabeth, M.D., M.A. Professor of Neurology Johns Hopkins School of Medicine Baltimore, MD 21205	2024
EATOCK, Ruth Anne, Ph.D. Professor of Neurobiology Dean of Faculty Affairs Biological Sciences Division University of Chicago Chicago, IL 60637	2024	KELLEY, Barbara Executive Director Hearing Loss Association of America Rockville, MD 20852	2023
ESPY-WILSON, Carol, Ph.D. Professor of Electrical and Computer Engineering Institute for Systems Research University of Maryland, College Park College Park, MD 20742	2024	LALWANI, Anil, M.D. Professor and Vice Chair for Research Director, Division of Otolaryngology, Neurotology, & Skull Base Surgery Co-Director Columbia Cochlear Implant Center Columbia University Vagelos College of Physicians and Surgeons New York, NY 10032	2025

MURPHY BREEN, Lynne, J.D. 2024
Founder of Clear Title
Senior Underwriting and Agency
Counsel
Chicago Title & Commonwealth Land
Title (Fidelity National Financial)
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Ex Officio

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BECERRA, Xavier
Secretary
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THEMANN, Christa, M.S., CCC-A
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Hearing Loss Prevention Team
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National Institute for Occupational Safety
and Health
Cincinnati, OH 45226

Executive Secretary

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

Appendix 2

National Institute on Deafness and
Other Communication Disorders (NIDCD)
FY 2023 Operating Plan (Q4) vs FY 2022 Actuals
(Dollars in thousands)

Mechanism	FY2022 Actual		FY2023 Plan	
	Number	Amount	Number	Amount
<u>Research Projects</u>				
Noncompeting	581	\$264,766	582	\$263,314
Administrative Supplements	(71)	\$5,560	(65)	\$5,200
Competing	191	\$80,343	205	\$88,871
Subtotal, RPGs	772	\$350,669	787	\$357,385
SBIR/STTR	27	\$16,015	20	\$16,321
Research Project Grants	799	\$366,683	807	\$373,706
<u>Research Centers</u>				
Specialized/Comprehensive	6	\$15,318	7	\$18,487
Clinical Research	0	\$0	0	\$28
Biotechnology	0	\$0	0	\$0
Comparative Medicine	0	\$0	0	\$0
Res. Centers in Minority Instit.	0	\$0	0	\$0
Subtotal, Centers	6	\$15,318	7	\$18,515
<u>Other Research</u>				
Research Careers	58	\$8,884	66	\$10,732
Cancer Education	0	\$0	0	\$0
Cooperative Clinical Research	0	\$0	0	\$0
Biomedical Research Support	0	\$0	0	\$0
Minority Biomed. Res. Support	0	\$0	0	\$0
Other	33	\$7,298	45	\$8,930
Subtotal, Other Research	91	\$16,182	111	\$19,662
Total Research Grants	896	\$398,183	918	\$411,883
<u>Training</u>	<u>FTEPs</u>		<u>FTEPs</u>	
Individual	142	\$6,997	156	\$6,698
Institutional	153	\$9,631	154	\$8,982
Total, Training (FTEPs and Award Amount)	295	\$16,628	310	\$15,680
Research & Develop. Contracts	44	\$23,229	44	\$23,217
<i>SBIR/STTR (non-add)</i>	<i>(0)</i>	<i>(\$204)</i>	<i>(0)</i>	<i>(\$200)</i>
Intramural Research	56	\$52,588	64	\$56,800
Res. Management & Support	74	\$24,248	76	\$26,750
Total, Program Level		\$514,876		\$534,330

**National Institute on Deafness and
Other Communication Disorders (NIDCD)**

FY2024 Budget Outlook

(Dollars in Thousands)

- FY 2020 Enacted: \$490,692
- FY 2021 Enacted: \$498,076
- FY 2022 Enacted: \$514,882
- FY 2023 Enacted: \$534,330

- FY 2024 CJ: **FLAT to FY 2023 Enacted**
- FY 2025: **Expect Flat to 1% Growth**

Strategy

- Challenging due to various inflations
- Close management of 1-year versus multi-year funded projects
- Maintain control of non-competing base
- Pre-funding to create flexibility

Appendix 3

**NIH Staff Present
Closed Session 1 Thursday 9/14/2023**

Christopher Adams	Jean McCaffery (CSR)	Nanette Stephenson
Aruna Behera	Roger Miller	Melissa Stick
Shivakumar Chittari	Christopher Myers	Holly Storkel
Laura Cole	Edward Myrbeck	Susan Sullivan
Judith Cooper	Stephanie Nagel Emmens (CSR)	Brooke Sydnor
Janet Cyr	Sonia Nanescu	Debara Tucci
Aurea De Sousa	Eric Nunn	Jean Verheyden
Hoai Doan	Matthew Oh (CSR)	Becky Wagenaar-Miller
Nancy Freeman	Amy Poremba	Bracie Watson
Maria Garcia	Kausik (Bobby) Ray	Tim Wheelles
Sara Hargraves (CSR)	Alberto Rivera-Rentas	Eric Williams
Rochelle Hentges (CSR)	Cathy Rowe	Shiguang Yang
Tanya Holmes	Merav Sabri	
Nichelle Johnson	Alena Savonenko (CSR)	
Andrea Kelly	Jaclyn Schurman	Other NIH Staff:
Lisa Kennedy	Elka Scordalakes-Ferrante	CART Captioner Lidia
Lisa Kopf	Brian Scott (CSR)	ASL Interpreter
Trinh Ly	Lana Shekim	
Barbara Mallon (CSR)	Katherine Shim	

**NIH Staff Present
Open Session 1 Thursday 9/14/2023**

Christopher Adams	Takushi Miyoshi	Melissa Stick
Kathy Bainbridge	Elyssa Monzack	Holly Storkel
Richard Chadwick	Christopher Myers	Susan Sullivan
Hui Cheng	Edward Myrbeck	Cathy Sung
Laura Cole	Sonia Nanescu	Brooke Sydnor
Judith Cooper	Eric Nunn	Debara Tucci
Janet Cyr	Hua Ou	Kerstin Valente
Hoai Doan	Lynn Penn	Becky Wagenaar-Miller
Nancy Freeman	Amy Poremba	Lizhen Wang
Tom Friedman	Lisa Portnoy	Bracie Watson
Maria Garcia	Kausik (Bobby) Ray	Tim Wheelles
Ronna Hertzano	Alberto Rivera-Rentas	Eric Williams
Nichelle Johnson	Cendrine Robinson	Shiguang Yang
Tanji Johnson	Heidi Rosvold-Brenholtz	
Paule Joseph (NIAAA)	Cathy Rowe	Other NIH Staff:
Andrea Kelly	Merav Sabri	CART Captioner Candice
Lisa Kennedy	Jaclyn Schurman	CART Captioner Lidia
Connie Latzko	Katherine Shim	ASL Interpreter Joshua Lane
Mimi Lee	Shirley Simson	ASL Interpreter Victoria
Wang Lu	Tresca Smith	ASL Interpreter Stephanie
Dina Lyon	Nanette Stephenson	ASL Interpreter Sam

**NIH Staff Present
Closed Session 2 Friday 9/15/2023**

Christopher Adams
Judith Cooper
Lisa Cunningham
Elyssa Monzack
Brooke Sydnor
Debara Tucci
Becky Wagenaar-Miller
Tim Wheelles
Other NIH Staff:
CART Captioner Lidia

**NIH Staff Present
Open Session 2 Friday 9/15/2023**

Christopher Adams	Castilla McNamara	Susan Sullivan
Kathy Bainbridge	Elyssa Monzack	Brooke Sydnor
Laura Cole	Christopher Myers	Debara Tucci
Judith Cooper	Edward Myrbeck	Becky Wagenaar-Miller
Lisa Cunningham	Sonia Nanescu	Bracie Watson
Janet Cyr	Eric Nunn	Tim Wheelles
Hoai Doan	Amy Poremba	Shiguang Yang
Betsy Driver	Kausik (Bobby) Ray	Zsa Zsa Young
Nancy Freeman	Cendrine Robinson	Jianliang Zhu
Maria Garcia	Cathy Rowe	
Myrica Guzeh	Merav Sabri	Other NIH Staff:
Nichelle Johnson	Jaclyn Schurman	CART Captioner Candice
Tanji Johnson	Lana Shekim	CART Captioner Edith/Edie
Joanne Karimbakas	Katherine Shim	CART Captioner Lidia
Andrea Kelly	Shirley Simson	ASL Interpreter Stephanie
Lisa Kennedy	Elka Scordalakes	ASL Interpreter Sam
Lisa Kopf	Nanette Stephenson	Broadcast Engineer Mike Burnham
Trinh Ly	Melissa Stick	Audio Video Engineer Bob Hamer
Dina Lyon	Holly Storkel	