**NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS
ADVISORY COUNCIL
May 18–19, 2023
National Institutes of Health
Bethesda, Maryland**

MINUTES

The National Deafness and Other Communication Disorders Advisory Council (NDCDAC) convened on May 18–19, 2023, via videoconference at the National Institutes of Health (NIH) in Bethesda, MD. Dr. Debara L. Tucci, Director, National Institute on Deafness and Other Communication Disorders (NIDCD), served as Chairperson. In accordance with Public Law 92-463, the meeting was:

Closed: May 18, 2023, from 11:00 a.m. to 1:00 p.m., for the review and discussion of program development needs and policy; and

Open: May 18, 2023, from 2:00 p.m. to 4:55 p.m. and May 19, 2023, from 9:00 a.m. to 11:46 a.m. for the review and discussion of program development needs and policy.

Council members in attendance[1]:

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

Ad hocs in attendance:
  Ms. Katherine Bouton
  Dr. Daniel Merfeld
  Dr. Melinda Pettigrew
  Dr. Susan Thibeault

Ex-officio members in attendance:
  Dr. Judith Shafer
  Dr. Jeremy Nelson
  Ms. Christa Themann

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

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[1] For the record, it is noted that members absent themselves from the meeting when the Council is discussing applications (a) from their respective institutions or (b) in which a real or apparent conflict of interest might occur. This procedure applies only to individual discussion of an application and not to *en bloc* actions.

CLOSED SESSION May 18, 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 2:00 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 1:00 pm.

OPEN SESSION May 18, 2023

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

Dr. Tucci, director of NIDCD, called the meeting to order. She expressed appreciation to the entire Council for their service and advice.

Council Introduction

Dr. Tucci invited each Council member to introduce themselves.

Consideration of Minutes of the Meeting of February 2–3, 2023

Dr. Tucci called the members' attention to the minutes of the February 2–3, 2023, meeting of the NDCDAC. The minutes were approved as written.

Confirmation of Dates for Future Council Meetings

Dates for the Council meetings through September 2024 have been established. A list of these meetings was distributed to the Council members and posted on the NIDCD website. The next meeting of the Council will be hybrid on September 14–15, 2023. The meeting scheduled for January 25–26, 2024, will be virtual. Subsequent meetings will be hybrid and are scheduled for May 16–17, 2024, and September 12–13, 2024.

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

Nomination of Director of NIH

President Biden has announced the nomination Dr. Monica Bertagnolli as the next director of NIH. Dr. Bertagnolli joined NIH as director of the National Cancer Institute in October 2022. She will undergo Senate confirmation hearings. In the meantime, Dr. Lawrence Tabak will continue to serve as acting director.

Appointment of NIDCD Clinical Director

Dr. Joshua Levy is the new clinical director of NIDCD. He was previously an associate professor of otolaryngology and associate vice chair of research at Emory University School of Medicine, Department of Otolaryngology–Head and Neck Surgery. Dr. Levy will oversee NIDCD's Clinical and Translational Research Program conducted in the NIH Clinical Center and will also head NIDCD's new Sinonasal and Olfaction Program with the potential to advance treatment for patients.

Inaugural NIDCD Director's Seminar Series

A seminar series, "Advancing the Science of Communication to Improve Lives," will be launched on June 28, 2023, with a session by FDA Commissioner Dr. Robert Califf, titled "Technologies and Marketplace Innovations to Improve Health Care Access and Outcomes." Dr. Califf has been a partner with NIDCD in developing regulations for over-the-counter hearing aids. After his remarks, five NIH institute directors will engage in a discussion. The goal with the new lecture series is to highlight the science and strategic goals for the NIDCD scientific and stakeholder communities and for the wider NIH community.

NIDCD Strategic Plan: NIH-Wide Cross-Cutting Priorities

Two components of the NIDCD strategic plan for 2023–2027 are strengthening research training and career development and reinforcing a culture of scientific workforce diversity, equity, inclusion, and accessibility. Early career support is essential in fostering future career success, especially for women and racial and ethnic minorities. The competition for research dollars, however, means that experienced investigators are more likely to receive funding. In recognition of this, in 2016 NIH launched the Next Generation Research Initiative (NGRI) to promote earlier research independence. This initiative is targeted at early-stage investigators (ESIs), defined as those who are within 10 years of their terminal degree and who have not competed successfully for substantial NIH independent funding, and new investigators (NIs) who have no substantial prior NIH funding as a principal investigator (PI). This pool is more likely to include a larger percentage of women and racial and ethnic minorities. NIH is highly invested in this program and NIDCD is highly committed to working toward the initiative's goals. There are many predictors of success for ESIs, including publications during training, advanced degrees, didactic coursework, training in research skills, and mentorship. Efforts in these areas will be discussed in more detail during the meeting.

Updates on NIDCD ESIs .... **Dr. Susan Sullivan**

Dr. Sullivan provided an update on how NIDCD is supporting ESIs.

- To meet the goals set out by NGRI, NIH is striving to fund 1,100 new ESIs per year. To facilitate these efforts, greater emphasis has been placed on tracking ESIs and generating reports to show how individual institutes and centers (ICs) are supporting NGRI. NIH is following NIs, at-risk investigators, and established investigators.
- At-risk investigators are those who had prior funding from NIH but are at risk of not getting substantial funding in the following fiscal year (FY) when their NIH award ends and so are at risk of losing NIH funding altogether.
- A final category of investigators is those who are established investigators with at least one future year of funding at the start of the FY.
- The benefit of NI and ESI status is that reviews of R01 applications are clustered so that applicants are judged against investigators at the same career stage. Another benefit is that

summary statements are prioritized for release.

- At NIDCD, there is a special second-level review process so that if an ESI's application is deemed meritorious but does not fall within the automatic payline, the ESI is invited to write a letter to NIDCD that is shared with the Council. These letters are discussed in the closed session of council along with the application to recommend whether funding is warranted. There are also special funding opportunities uniquely targeted to NIs and ESIs.
- Funding rates per FY provided by NIH show that for three of the past four years, NIDCD has been in the top half of institutes for funding ESIs. In 2021, NIDCD ranked second for funding rates for ESIs. NIDCD funding for at-risk PIs is also consistently within the top half of institutes, ranging from 28.5% to 40.9%. NIDCD funding for new PIs is generally lower, but in three of the past four years, NIDCD has been in the top 50%. For funding of established PIs, NIDCD rates range from 33% to 38%.
- Comparisons of NIDCD funding rates with those of NIH overall show that NIDCD and NIH have similar funding rates overall, with NIs having lower rates and established PIs having the highest funding rates. Comparisons of NIDCD funding rates for ESIs with established investigators show that NIDCD is doing better than NIH in closing the gap between ESIs and established investigators.
- Data about funding of research project grants (RPGs), such as R21s and R15s, show that NIDCD has a high success rates (25%) compared with NIH (19%). Overall, these data show that NIDCD has a strong record in supporting the goals of NGRI.

Additionally, there are several new NIDCD initiatives that are targeted toward NIs and ESIs.

- [RFA-DC-23-001](#) supports workforce diversity for NIs and ESIs, including those who are underrepresented in the health sciences. Preliminary data are optional for this grant, and applications are reviewed in-house by the scientific review branch. Dr. Kelly King is the NIDCD contact for this program.
- The [Katz ESI Research Program](#) supports innovative projects by ESIs when they want to change their research direction. Preliminary data are not allowed in this program, but applicants must explain and justify how the proposed research direction is new to them. These applications are reviewed by the Center for Scientific Review (CSR) and clustered for discussion with other Katz R01 applications. Dr. Amy Poremba is the NIDCD contact for this program.

Discussion

- Dr. Eatock asked whether the data comparing the percentage of ESIs who were funded and established investigators who were funded represent the number of grants or the number of investigators. Dr. Sullivan said that the funding rates are "person" metrics, which means the numbers will not differ whether someone has one grant or five grants. Dr. Eatock said it would also be interesting to see the percentage of grants going to each category.
- Dr. Espy-Wilson asked whether there was a breakdown showing the percentages of men, women, and underrepresented minorities. Dr. Sullivan said this specific data set is focused on career stage, but another report from the NIH Office of Extramural Research addresses diversity issues and showed that of applicants for Type 1 R01-equivalent grants, very few were from Black investigators. This has been a trend from 2010 to 2022. However, there are some promising findings: The numbers of Black applicants and awardees and Hispanic applicants and awardees have gone up since 2010. The numbers are still low but are increasing. The gaps in funding rates for Hispanic and Asian investigators compared with Whites are narrowing, though there is still a substantial gap between the numbers of Black investigators and White investigators. More data need to be looked at over time.

Funding Success ....**Dr. Bracie Watson**

Dr. Watson provided a history of the NIDCD early career research (ECR) grant program.

- Starting in 1990, NIDCD had a small grant program targeted solely to NIs, which was an award of $25,000 for two years. The goal of the program was to help NIs compete for awards. Since then, changes have been made to the size of the grants and the numbers of years eligible. The application budget was increased, and eligibility was modified. This operated as the NIDCD small grant program (R03s). In 2016, the activity code was changed for consistency with the budget size, but it is a continuation of the same program. These grants are now known as the NIDCD ECR awards, and the funding is different from the NIH R21 program in that these are restricted to individuals and clinical scientists who are in the process of transitioning to an independent research career. The goal remains the same: to help individuals collect sufficient preliminary data for a subsequent R01 application. Their projects may be hypothesis-driven, or they may be milestone-driven allowing for secondary data analysis.
- The focus of the ECR awards must be on one of the NIDCD mission areas: hearing and balance, taste and smell, or voice, speech, and language. Eligibility is for no more than seven years from the date of the applicant's terminal degree. Postdoctoral fellows are eligible, and mentor letters are required. Years spent in clinical training are excluded, and extensions are possible under extenuating circumstances. Applicants must not have served as a project director (PD) or PI on any research project grant (RPG), and multiple PI applications are allowed if all PIs meet the ECR R21 eligibility criteria. Preliminary data are not required but should be included in the application materials if available.
- The budget for ECR awards is up to $125,000 per year for direct costs, and the duration is limited to three years. Applications are reviewed by the Communications Disorders Review Committee.
- A review of applicants from FY 2017 to FY 2022 shows the distribution by program areas. Voice, speech, and language consistently lead, followed by hearing and balance, then taste and smell. The average number of applicants per year is 91, with a median of 93 and a maximum of 106. The smallest number of applicants was 66, which was in 2021, in the middle of the COVID-19 pandemic, and numbers are starting to rise again.
- The ECR R21 success rates by FY were 24.2% in 2017 and 38.6% in 2022, with an average success rate of 29.7, comparable to rates under the previous iteration of this award.
- The rate of ECR R21s that subsequently resulted in R01 awards is difficult to ascertain. In the old R03 small grant mechanism, 30% to 40% went on to successfully complete an R01 application. In 2017, of 24 ECR awards, 8 went on to successful apply for an R01—a rate of 33.3%. In 2018, there was a 40% success rate. The numbers went down in 2020, 2021, and 2022, but the ECR applications awarded in those years are still in effect. When those timelines expire, there is hope that the numbers of R01 applications will be similar to those in 2017 and 2018.
- Broken down by institute, the vast majority of ECR R21 to R01 conversions were from NIDCD. This seems to point to good success for the program. ECR funding comes at a critical career point for individuals who are starting to end postdoctoral experiences and for individuals who are beginning early tenure-track faculty positions. Project funding helps these individuals focus their research directions and get sufficient preliminary data to apply for an R01 application. The individuals funded for the current awards will continue to be tracked for success measures.

Dr. Watson thanked Lisa Kennedy, Robert Powell (Information Systems Management Branch), and Cathy Rowe (Policy and Planning Branch) for their help in compiling the data.

Discussion

- Dr. Chaudhari asked whether there was a requirement for U.S. citizenship for ECR eligibility. Dr. Watson said that eligibility is ascertained by the university submitting the application.
- Dr. Eatock asked whether the program had any goals that were not being met or any future wish lists. Dr. Watson said it would be ideal for all awardees to apply for R01s, but that is not feasible, because the correct metric for R01s is constantly changing. The goal is to help make R01 applications possible for everyone. Some people use the ECR grants as a first step to an R01 application, but not everyone needs an ECR award to get an R01. An analysis several years ago showed that individuals who had an ECR and went on to apply for an R01 had a slight edge, but that may not be statistically significant.
- Dr. Wallhagen asked about R01 equivalence and if there was something else these individuals apply for besides an R01. Dr. Watson responded that he does not have any data on that.

NIDCD Training and Mentoring...**Dr. Emily Buss**
Dr. Alberto Rivera-Rentas

Dr. Tucci introduced Dr. Buss to talk about preparing a successful fellowship application and Dr. Rivera-Rentas to talk about NIDCD training programs.

Preparing a Successful Fellowship Application: Can We Do More to Support Diversity?

Dr. Buss said she graduated with a Ph.D. in 1987 and applied for a postdoctoral fellowship at the University of North Carolina, where she joined the faculty in 2001. As vice chair for research and a mentor, she has done a lot of thinking about what it takes to create a good fellowship application and how best to support diversity. She urges her students to take advantage of opportunities offered by NIDCD.

The steps to prepare a successful fellowship application are to identify funding sources, write a proposal, and submit an application. It has typically been assumed that the quality of the application is the sole criterion for receiving funding, but other factors come into play earlier. The idea of applying for funding in the first place requires confidence and a sense of belonging and a mentor that suggests this. Applicants have to have a vision in mind and a sense of confidence that the process will work for them.

Knowing which mechanism to apply for can also be overwhelming, and the terminology can be confusing. Writing of this type involves a style unfamiliar to many people, and the process of writing and revising a proposal many times can be arduous and requires a strong sense of purpose and persistence. Dr. Buss recommends that applicants work closely with their institutions sponsored research office from the earliest steps of the process, which can be challenging for any trainee but especially for those underrepresented in the biomedical fields with few mentors and those from under resourced institutions who do not handle many grants.

NIDCD is already making efforts to support diversity. Dr. Tucci authored an article in *Ear and Hearing* that describes some of the efforts. NIDCD has online resources and informational sessions at conferences, targeted grants, sample grant applications, and support for building institutional expertise. Together, these steps are a substantial commitment to increase the diversity of the extramural workforce.

She focused on what more can be done to help with the first steps, submitting an application and building persistence. She identified a few key factors to focus on including creating more

opportunities for one-on-one discussions with program staff, coordinating with professional societies to develop programming potentially partnering with individuals who were recently on an NIH study section, and collecting data on applicant experience regarding resources, information that was lacking and suggestions for support.

Discussion

- Dr. Chaudhari said it was a good idea to extend beyond what the program officers. She suggested a webinar available on an ongoing basis that features a panel of recent awardees and recent reviewers. Dr. Tucci said that those ideas are under consideration, and that NIDCD has a number of webinars already online.
- Dr. Eatock asked whether there was a way that postdoctoral applicants could get a sense of the review process. She expressed that individuals can be taught how to do good science, but they need to experience study section to understand how to write a careful and concise proposal. Dr. Wagenaar-Miller responded that there are some mock review sessions including one by NIH Center for Scientific Review (CSR) that is available online.
- Dr. Sanes commented that one-on-one, in-person meetings are more substantive and useful than webinars. He stated that the National Science Foundation (NSF) staff have a sign-up at conferences to meet with individuals and suggested that for conferences that NIH staff attend they could publish a sign-up online in advance of the meeting for individuals to book a meeting. Dr. Wagenaar-Miller also said that NIDCD participates in the yearly NIH Virtual Grants Conference where program staff are available for individual meetings. She commented that these are very underutilized, and Dr. Buss suggested that these be better publicized.
- Dr. Hillis said that NINDS staff do a two-day preconference before the American Neurological Association for recent K recipients and trainees with speakers focused on issues these individuals need to transition to an RPG. She suggested that NIDCD consider doing something similar to conferences attended by NIDCD trainees such as ASHA and bring together trainees, NIDCD staff and successful R01 awardees for mentorship.
- Ms. Deal-Williams commented that ASHA has a series of programs on robust research mentoring but that people from groups that are underrepresented in the biomedical fields are not applying for these programs at the same level as others. Programs need to look not only at individuals but at the process itself and the system
- Dr. Groves said there are ways to help mentors within institutions by providing them with tools and examples of good training plans. It would be helpful to leverage more resources externally.
- Dr. Espy-Wilson said it is important to consider taking the information to places where underrepresented people are.

Overview of NIDCD Research Training Program Portfolio

Dr. Rivera-Rentas provided an overview of NIDCD training officer, training, and career development opportunities from high school through programs for experienced investigators.

- Institutional research training programs offered by NIH and NIDCD cover undergraduates through new and junior investigators. NIDCD programs in this category include R25s that support mentoring networks to enhance diversity in research and workforce diversity in research, enhance clinician-scientists' participation in research, and provide research pathways for otolaryngology residents and medical students.
- Individual research training programs sponsored by NIDCD include an F32, which is a postdoctoral research dissertation fellowship for audiologists interested in pursuing a Ph.D., and a K01 for career development for postdoctoral audiologists. Additional programs include those sponsored by NIH with NIDCD participation. One worth noting is the extramural loan

repayment programs focusing on clinical research and pediatric research. Last year, this program was expanded by NIH to include health disparities research and research in emerging areas critical to human health.

- NIDCD sponsors two diversity-targeted programs, both R25s. One supports mentoring programs, and one enhances extramural workforce diversity through research experiences, ranging from undergraduate to new and junior investigator levels. Multiple institutions can work together to seek these grants and collaborate. An additional component of these offerings is mentoring mentors as well as students. NIDCD participation in NIH programs includes support of predoctoral and postdoctoral fellowships, loan repayment programs, and support for research excellence.

The NIDCD research training portfolio includes a total of 33 programs. There are two research training programs, five R25 programs, six National Research Service Awards (NRSAs), 10 programs supporting mentored career development (K awards), six administrative supplement awards, and four loan repayment programs. The programs are continuing to grow and Dr. Rivera-Rentas welcomed Dr. Jaclyn Schurman as a new research training officer that will be responsible for the fellowships.

Dr. Rivera-Rentas provided an overview of the success rates for the awards.

- The total number of trainees in the NRSA T32 program from 2012 to 2022 was 1,734; 61% (1,054) of these were predoctoral, and 39% (680) were postdoctoral.
- From 2013 to 2022, there were 543 NRSA fellows. There was an average success rate of 55% for F30s, 37% for F31s, and 38% for F32s, compared with the NIH averages of 39%, 27%, and 27%, respectively. For the mentored research programs (the K awards) during the same time frame, there were 149 awards, with similar success rates for NIDCD and NIH.

Dr. Rivera-Rentas provided an overview of outreach events held via live webinars that are also recorded for on-demand viewing.

- There was a training webinar for NIDCD clinical scientists interested in R25 funding; it has received more than 300 views.
- Another webinar was focused on diversity-targeted programs and included tips for writing effective applications; it has gotten more than 600 views.
- A webinar covering predoctoral fellowships has had 103 views, and one on postdoctoral fellowships has had 44 views.
- The next webinar will be held on September 27, 2023, and will provide an overview of all mentored research career development (K award) programs.

Dr. Rivera-Rentas announced a request for information (RFI) on recommendations for improving NRSA fellowship review. The proposed changes to the review criteria of fellowship applications are intended to:

- Allow peer reviewers to better evaluate each applicant's potential and the quality of the scientific training plan without undue influence from the sponsor's or institution's reputation.
- Ensure that the information provided in the application is aligned with the restructured criteria and targeted to the fellowship candidate's specific training needs.

More information about the RFI would be provided later in the meeting.

Dr. Rivera-Rentas thanked his colleagues and opened the floor for questions and discussion.

Discussion

- Dr. Chaudhari commented that she had listened in to a few of these webinars and asked if they were available on demand. Dr. Rivera-Rentas confirmed that they are and that they are used by a lot of training programs with new trainees.
- Dr. Buss said that the presentation offered an impressive array of opportunities and wondered whether there was a simplified chart that would match a reader's level of education or career with the available or appropriate opportunity. Dr. Rivera-Rentas said that in addition to links to the webinars with descriptions of who is eligible for what awards, there are tabs on the website and FAQ pages that provide guidance and coaching around the appropriate institute to apply to, because there is significant overlap with NIDCD and other NIH institutes such as NICHD, NIMH, and NIA. He encourages all trainees to send him their aims so that he can advise them on if NIDCD is the appropriate home for their application.
- Dr. Strowbridge asked whether there was information about what percentage of the applicants take advantage of the coaching that is offered. Dr. Rivera-Rentas said that the website provides growing amounts of information and that he is receiving fewer individual emails.

Three Stories About How NIDCD Supports Training and Mentoring .... Dr. Ross Williamson
Dr. Jamila Minga
Dr. Elizabeth Peña

Dr. Tucci introduced three guest speakers to talk about their research and how NIDCD has supported their training or mentoring.

Dr. Ross Williamson

Dr. Williamson is an assistant professor of otolaryngology at the University of Pittsburgh School of Medicine. His research focuses on how the auditory system is connected to the rest of the brain (e.g., how a sound might elicit a motor response or an emotional reaction).

As a postdoctoral student, Dr. Williamson learned from his mentor, Dr. Daniel Polley at Harvard University, how to research and conduct experiments and applied for and received an F32 award that allowed him to study cell connectivity. He then applied for and received an R21 that enabled him to study anatomical work that found that cell outputs extend far beyond the traditional auditory system. He highlighted that this work was carried out at his laboratory by Megan Arnold, who received an NIDCD supplement that has allowed her to pursue an M.D. and a Ph.D. at the University of Pittsburgh. He said that the R21 he initially received set the stage for his subsequent work, and he received his first R01 in 2022, which is allowing his lab to use state-of-the-art recording and optical techniques to study how single cells rapidly change their response properties across learning to represent discrete perceptual categories.

Dr. Williamson said mentoring was vital to his career development, which was not traditional in that he was educated outside of the United States and does not consider himself a neuroscientist. He believes that mentoring relationships are dynamic, reciprocal, and personal, not one-size-fits-all. Someone's background and lived experience dictate what they know or do not know about a system, and a mentor's role is not simply to advise someone about how to conduct science but also to train them to achieve their goals and dreams. Mentors need to teach mentees how to write and speak about their work so they can successfully apply for NIH grants. A lot of factors go into a mentor–mentee relationship, and Dr. Williamson makes a point to address these factors at his laboratory by setting up a mentoring agreement, which involves discussing expectations on the part of the mentor and the mentee, helping define goals and establish honest communications.

Dr. Williamson said that academics are not trained to be mentors. Mentorship can be taught. He also emphasized that enforcing strict postdoctoral time limits can disadvantage nontraditional students. He changed fields and needed more time, and he urged NIDCD to consider changing those criteria.

Dr. Jamila Minga

Dr. Minga is an assistant professor of head and neck surgery and communication sciences, an assistant professor in neurology, and a member of the Center for Cognitive Neuroscience at Duke University School of Medicine whose research focuses on adult neurogenic communication disorders after stroke and stroke rehabilitation outcomes. She currently has a K23 award from NIDCD. She spoke about her NIH and NIDCD supported advances in research on right hemisphere language production. Communication is ubiquitous and essential to every aspect of life, so when communication is disordered, as it is after 80% of right hemisphere strokes, it has a significant and functional impact on people's lives. Apragmatism is a disorder in conveying and/or comprehending meaning or intent through linguistic, extralinguistic, and/or paralinguistic modes of context-dependent communication. The linguistic domain of apragmatism is historically underrepresented and not wholly understood, but Dr. Minga believes there are ways to quantify and characterize the disorder in clinically meaningful ways. This has been the focus of her NIH-funded work.

Dr. Minga was awarded an NIH diversity supplement in 2017 to work on the development of a shared database for collecting information about right hemisphere damage (RHD). Since its start the [RHDBank](#) has been cited in more than 20 publications, and the consortium includes 19 countries. It is the largest repository of language samples dedicated to RHD. Dr. Minga's lab has collected more than 70 data sets. With the diversity supplement and additional support from NIH's Building Interdisciplinary Research Careers in Women's Health ([BIRCWH](#)) award, Dr. Minga has been able to characterize language use patterns. She has identified question use as one pragmatic aspect of communication using two RHDBank tasks. The tasks generated around question use revealed that adults with RHD asked fewer questions overall, which is a significant finding, and means that one pragmatic aspect of language use is measurable and may be used for diagnostic purposes.

The study of question use led to the development of the right hemisphere framework for asking questions. The framework involves brain processes that are important to question asking, including recognizing the need for information, generating inferences about that need, and integrating that information into a polar question (i.e., one with a yes-or-no answer). Deficits within any three of these processes can hamper the frequency of question use for social engagement.

After six consecutive applications, Dr. Minga also received a loan repayment award. With this award and a pilot award from NIMHD, she was able to study a hypothesis about whether race mediates question asking in patients with RHD. The sample included 16 Black women and 16 White women, with half of each surviving a single stroke in the right hemisphere. The findings showed that Black women asked 59% fewer questions than White women did. NIH funding has allowed for these studies, which are important, because not only does brain damage affect question asking, but race also influences one pragmatic aspect of language use.

Now, as a K23 awardee, Dr. Minga is planning to expand her work to move beyond behavioral descriptions of what happens after right hemisphere stroke to look at associations with the lesion to learn more about communication. Research funding support has also allowed her to develop a strong relationship with the RHD community. She has co-produced a documentary about the disorder and is involved in the RHD community to increase education and visibility of RHD survivors. She thanked her mentors for allowing her to explore this area of research. She has applied for 11 funding opportunities, both initial and resubmitted, and has received funding for 3, for a 27% success rate.

She is one of two funded researchers with a focus on RHD, and she implored the Council to develop more opportunities for RHD research, which would allow others to forge novel paths of inquiry. She said the Council should continue to fund and enhance access to funding for individuals underrepresented in biomedical research.

Dr. Elizabeth Peña

Dr. Peña is associate dean of faculty development and diversity and professor at the School of Education at the University of California, Irvine. She currently has an R01 award from NIDCD and has received an administrative supplement, diversity supplements, and R21, K23, and K08 awards.

Dr. Peña said that half the world is bilingual. That percentage increases to 68% if multilingual people are included. In the United States, one third of children under the age of 9 have exposure to more than one language, and up to one 10th have developmental language disorder (DLD). DLD is one of the most common childhood disorders and is associated with greater risk for reading disability, math disability, mental health issues, and underemployment. PubMed lists 29,200 papers on DLD published since 1944. For context, there are more than 70,000 papers on autism. If "bilingual" is added to the search term "DLD," there are 749 papers. A lot of myths surround bilingualism and DLD, and these myths have consequences. Children are not automatically delayed if they have exposure to more than one language. Bilingualism does not cause DLD. Children with DLD can become bilingual, and monolingualism is not a cure for DLD.

Dr. Peña's work focuses on ways to accurately identify DLD in bilingual children. NIDCD is currently funding her work on how to use English to identify DLD in bilingual children by using a tailored item set that is targeted at children's expected mastery level, exposure and experience, and typology of their other language. Spanish–English bilingual children and Vietnamese–English bilingual children are being studied, as the typologies of these languages are very different. With the supplement, the work will also include Cantonese and Mandarin speakers.

Dr. Peña's role as a mentor includes teaching an undergraduate class on bilingualism. Only one third of these students are education majors, and the rest have a range of majors, including science and humanities. When asked why they are taking the class, many say they themselves are bilingual and had been misdiagnosed as having DLD when they were younger.

Dr. Peña said three main components of mentoring are important for her:

- Expertise - Students bring expertise with them. This needs to be recognized and emboldened within them. Mentees might know something that the mentor does not; together, everyone can learn more.
- Belonging -Mentees, especially students from minority communities, need a sense of belonging. They need a place away from home to form community. A science laboratory is a place where they can both be with people who are like them and learn from people who are not. It needs to be a safe place for them to try things out, give support, make connections, and forge relationships independent of the mentor.
- Contributing - Mentees are often the first in their families or communities to achieve what they are achieving, and they are often working in cultural isolation. Many have a deep need to return or give back to their communities. A mentor needs to help mentees identify whether and how they want to do that.

Dr. Peña was fortunate to be selected to complete training at the Center for the Improvement of Mentored Experiences in Research. This program uses case studies to help mentees solve problems

and consider different strategies to use in different scenarios. As part of the NIH mentoring program, Dr. Peña is working with two postdoctoral students to learn this curriculum and bring it to the laboratory setting. Meetings are held once a month, with doctoral students mentoring undergraduate students. Discussions help uncover the "hidden curriculum" in a safe space. There are two aspects to mentoring: the instrumental aspect, which involves career counseling and skills development; and the psychosocial aspect, which includes emotional supports, attitudes, behaviors, and values. Research shows that faculty are not as good at psychosocial mentoring as they are at instrumental mentoring. Students, especially first-generation students, need mechanisms to support network mentoring. Faculty will become better researchers when they work in collaboration with undergraduates, graduates, and postdoctoral students.

Discussion

- Dr. Thibeault noted that when one is writing P32s and R25s applications that they have to note that mentors are receiving training, but this is not yet required for F31s and F32s. Dr. Thibeault asked whether this is going to be a requirement. Dr. Tucci responded that she agreed but that these are NIH-wide programs, so NIDCD has little control over the requirements. Dr. Rivera-Rentas said mentor training is not part of the review criteria, which are focused more on the applicant's track record. The request for information on modifications to the fellowship review criteria would be a great way to provide NIH with feedback about incorporating the mentoring philosophy.
- Dr. Merfeld said the idea of a mentor has often been the traditional professor with experience, and although he had good mentors who were senior to him, he also had peer-to-peer mentors who were invaluable. Dr. Minga responded that she had similar experiences with different mentors serving different purposes in her development and positioning in academia, including peers who helped her culturally and mentors at different institutions. Dr. Peña said she works with junior faculty and tells them they need at least three mentors: a near peer who is doing what you are trying to do, a senior mentor with a broad overview of the whole path, and someone not in their department or institution who has an outside perspective. Dr. Williamson also commented and said he still reaches out to his old mentors, senior advisors, and lots of peers who are in close communication with each other. Mentoring circles have been created among certain institutions that widen the circle of support.

Dr. Tucci adjourned for the day at 4:55 p.m.

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

Dr. Tucci, director of NIDCD, called the meeting to order at 9:00 am. She introduced Dr. Dr. Helen Tager-Flusberg, professor in the Department of Psychological and Brain Sciences at Boston University and the Departments of Anatomy and Neurobiology and Pediatrics at Boston University School of Medicine. Dr. Tucci welcomed Dr. Tager-Flusberg who together with Dr. Judith Cooper, deputy director of NIDCD, to present on a recent NIDCD webinar on minimally verbal (MV)/non-speaking individuals with autism.

Highlights from the NIDCD Webinar

Dr. Cooper shared information about a January 24–25, 2023, workshop on MV/non-speaking individuals with autism. NIDCD has a long history of focusing on autism and the communications challenges and needs of autistic individuals of all ages. Research has tended to focus on communication profiles, effective behavioral interventions, and alternative and augmentative communication approaches. In 2009, Dr. Cooper had a conversation with a mother with minimally verbal child with autism who pointed out that this subgroup was neglected in terms of research and challenged NIH to do more. As a result, NIDCD created a planning committee. In April 2010, a multidisciplinary workshop was held focusing on children with autism spectrum disorder (ASD) who have not developed functional verbal language by age 5. The purpose of the workshop was to address who these children were, what characterizes them, and how best to assess and assist them.

After the workshop, NIDCD activities and the research community overall shifted their foci to include the publication of numerous funding opportunities, highlight research needs in the strategic plan, and publish key papers. There was a summary presentation at a meeting of all the NIH directors that described the interest in this area, and applications for funding began to be submitted. These initial activities provided the basis for examination of what is now known about MV/non-speaking ASD individuals and what challenges remain. The January 2023 workshop was the result of this examination.

The process of developing the webinar took a year and included discussion with leading researchers in the field, Dr. Tager-Flusberg and Dr. Connie Kasari, to identify research needs and directions and determine areas of focus for intervention. The webinar, which was broadcast publicly, opened with a panel of people with varying perspectives on what research they thought was most needed for this population. These panelists included a self-advocate, a college student, a sibling, a researcher, a professor, a parent, and a speech-language pathologist. Speakers then covered novel intervention approaches, innovative research design, and meaningful outcomes. The workshop ended with reflections from two MV individuals and a researcher and a summary of research opportunities and next steps.

Reviews from webinar participants have generally been positive. The NIDCD website posted a summary of the meeting, the agenda, the list of participants, and participant-suggested publications. A full recording of the workshop is also available for viewing. A notice of special interest (NOSI) has been published, promoting language and communication in MV/non-speaking individuals with autism. Also, several NIDCD staff have met with MV individuals and related federal agencies to explore opportunities and shared interests related to this population. Additional activities related to the recommendations will be discussed during the September Council meeting.

Research Directions for Interventions to Promote Language and Communication

Dr. Tager-Flusberg discussed research directions that might guide the development of new interventions to promote language and communication. The focus on language in autism, instead of on autism per se, is important, because language ability is the single most important predictor of long-term outcomes for autistic individuals. Only those individuals who have developed advanced and fluent language skills have a chance to live independently. Language is the foundation of literacy and all forms of learning and is integrally linked to social communication.

One of the primary reasons there has been so little work on MV individuals with autism is that they are challenging to assess on multiple levels. The more language a child acquires, the fewer challenging behaviors develop. All forms of language, including alternative and augmentative communications, foster social and cognitive development, but what parents aspire for their child to acquire is spoken language.

A prospective study (Talbot et al., 2015) shows that delays in language are among the first signs of autism. Almost 60% of children whose parents expressed concerns about language development when their children were 12 months of age were later diagnosed with ASD. This is far more than the other core symptoms of ASD (i.e., repetitive and restrictive behaviors, and social communication).

Problems in language appear very early. Developmental trajectories show that at 10 to 12 months of age, differences appear in both expressive and receptive language and result in poor outcomes by the age of 4 years. There is enormous heterogeneity of language outcomes in autism. About 25% of the population have no language impairment by the time they reach school age, 45% are verbal but have some language impairment, and 30% are still MV/non-speaking by school age.

Speech-language interventions include a wait-and-see approach. Interventions are offered only when a child has experienced significant delays. For MV/non-speaking children, those interventions are not effective.

Two research directions address these issues:

- Identify personalized and more targeted interventions for MV autistic children and adults and learn more about the underlying mechanisms and systems.
- Develop innovative preemptive interventions targeting speech and language in infants.

There is no adequate answer to the question of why MV children do not acquire spoken language. It may be that they have an impaired understanding of intentional communication/joint attention, symbolic deficits, an intellectual disability, impaired imitation and motor skills, or impaired auditory processing. In a study of predictors of expressive language in MV ASD individuals that included analyses of a child's ability to initiate behavioral regulations using nonverbal communication, initiate joint attention, or respond to joint attention, as well analyses of play, imitation, cognition/IQ, and age, the factors that had the highest predictive value for development of expressive language were play, imitation, and cognition. Of those, motor imitation was found to be the single highest predictor. In a study of 90 children 4 to 7 years old, half of whom were MV, a correlation between fine motor skills as reported by parents and language intelligibility to outside researchers in MV ASD individuals was found.

In terms of receptive language, a study of 1,600 MV children and adolescents 5 to 18 years old was designed to measure age-appropriate receptive skills. Almost every child was found to be below the expected range for their age. Although receptive language abilities were significantly better than expressive language abilities in MV ASD individuals, they were still found to be close to age level. A small number of children had better receptive skills than expressive skills, and those children need to

be further identified. The fact remains, however, that the single best predictor of who has better receptive than expressive language is motor skills.

Speech motor impairments were examined in more detail in a study of 60 children diagnosed with childhood apraxia of speech (CAS), which is a rare neurological disorder that impairs speech movement precision and consistency. CAS was found in 25% of the children, and another 25% were found to have no speech motor impairment. One third of the children had some form of speech disorder but did not meet the stringent requirement for CAS, and some of the children did not produce any speech sounds and therefore could not be coded.

In the same sample of children, severity and types of speech motor deficit were coded for specific features, some of which are related to articulation and some of which are related to pronation or the respiratory system. There was wide variability in the results, but most impairments were in articulatory speeches, such as vowel precision, intelligibility, and consistency. From these studies, it appears that CAS accounts for at least some MV ASD children.

Auditory processing is another area of research. Many autistic children have significant auditory sensitivity and show a variety of behaviors that demonstrate this sensitivity. One study coded the percentage of time that MV ASD children engaged in auditory and visual behaviors compared with verbally fluent ASD children. The results showed the same number of visual behaviors in both groups. In MV children, however, far more auditory sensitivities were found. The percentage of time that a child engaged in those behaviors was correlated negatively with receptive language. The more time the children covered their ears, for example, or complained about sound, the worse their receptive language skills were.

Neural markers for auditory processing problems were examined in these same children. Electroencephalography (EEG) was used to capture brain function in MV individuals as they listened to a tone, which was then interrupted by an occasional deviant tone. The amplitude of the brain response to the deviant tones was found to be smaller in children with more auditory sensory behaviors.

There is more room for research in all these areas, and new tools are suitable for studying brain responses in younger children.

Dr. Kasari has developed a play-based intervention called JASPER (Joint Attention, Symbolic Play, Engagement & Regulation). In a randomized controlled study, half the group received JASPER plus a speech-generating device (SGD), and half received JASPER alone. When JASPER was combined with SGD, there was significant improvement in social communicative language in 5- to 8-year-old children. This indicates that play and imitation combined with a device that bypasses the speech motor impairment is an important combined intervention.

The scientific community is beginning to unravel the multiple factors that contribute to MV ASD. Future directions should include identifying profiles for each individual child and tailoring interventions to map onto their strengths and weaknesses.

There is a strong case for preemptive interventions that include studying early development in infants at risk for autism. One such study is recruiting infants with an older sibling diagnosed with ASD. These infants have a 20% chance of developing ASD. They are recruited for the study soon after birth and are being followed until the age of 24 to 36 months, when they can be given diagnostic outcomes. This allows for study before the onset of delays to determine whether an infant is vulnerable to developing a neurodevelopmental disorder and comparison with infants with no familial

risk.

Factors studied include speech vocalization at 12 months, as reported by parents. Infants eventually diagnosed with ASD had fewer vocalizations at 12 months than those at low risk for ASD or those with high risk who did not develop ASD. At 6 to 36 months of age, infants later diagnosed with ASD have significantly lower Mullen language scores.

Looking at brain functioning allows for the capture of differences in this group of high-risk infants. Baseline EEG is collected for two minutes. Developmental trajectories of resting EEG show that the brains of high-risk infants, regardless of their outcome, have lower power in each spectral band of the EEG. This finding can be used to predict which infants end up with a diagnosis of ASD and can also be used to predict language development. High alpha waves on the EEG at the age of 3 months were found to correlate with language development at 12 months, with poorer expressive language found in infants who had reduced frontal high alpha power at 3 months. Studies about how the brain responds to speech at 6, 9, and 12 months have found that amplitudes at 9 months predicted later language ability, but only in high-risk infants.

Differences in how the brain is organized for language in high-risk ASD infants have also been studied. By 12 months, the brains of high-risk infants who later develop ASD are organized differently from those of low-risk infants or those at high risk who do not develop ASD. The brains of infants who later developed ASD showed the highest reduced laterality and the lowest functional connectivity.

The early roots of language impairment are evident in the first year of life. Brain functioning, both resting and in response to speech, differs in high-risk infants. It is important to use EEG and behavior to identify the infants who are at highest risk for language delay and provide interventions that can take advantage of increased plasticity and learning potential in infants.

One future project called Promoting Early intervention Timing and Attention to Language (PETAL), supported by NIDCD, will be a study of infants at risk for ASD starting at 6 months of age. Resting EEG will be used to assess language, behavior, and the brain. The families recruited for the study will be low-income, and the EEG will be performed in their homes. A standard set of activities that promote motor skills and focus on language will be provided. At the age of 9 months, 12 months, or 15 months, infants will either continue with those activities or be given a specialized intervention consisting of JASPER and the Babble Boot Camp. This will focus more directly on speech development at a time when babies are beginning to babble. Outcomes will be captured at 24 months to determine what, if any, differences are found with intervention and which infants benefitted most from early intervention.

Dr. Tager-Flusberg thanked her collaborators and NIDCD for funding support and opened the floor for questions and discussion.

Discussion

- Dr. Chaudhari asked whether there were plans to do cognitive measures in PETAL that would be as independent as possible from measures of symbolic development. Dr. Tager-Flusberg said there were plans to use Mullen Scales of Early Learning to capture cognitive and motor development, but the project planners did not want to overwhelm the families and infants. Dr. Chaudhari clarified that she meant whether cognitive measures would be used in the evaluation stage of the study, not as an intervention, and she was wondering whether linguistic advancements would have a programming effect on other cognitive functions. Dr. Tager-Flusberg said there is evidence that socialization is more advanced in MV children if they have

better receptive language skills. Inferences that language contributes to socialization but not the other way around, for which longitudinal data are necessary, can be made.

- Ms. Bouton wondered whether children who wear headphones or put their hands over their ears have been tested for hyperacusis. Dr. Tager-Flusberg said that they had and that many MV children have intense sensitivity to sound, but at the same time, children with ASD may love the sound of the washing machine, so rather than defining their sensitivity to sound as hyperacusis, the term "atypical response to sound" is preferred.
- Dr. Sanes asked whether there was any sense of how these children learn or respond to treatment on a daily basis (e.g., whether there was any consolidation of progress made on one day or they returned to the same "place" the next day). Dr. Tager-Flusberg said she has not studied that, but perhaps clinicians have more information.
- Dr. Hillis commented that the MV children she has known that do well have had very intensive therapy (e.g., with a live-in speech pathologist), which typically only wealthy families can afford.
- Dr. Goffman asked whether there were any studies of motor skills in children who were not MV and how those skills may predict ASD.
- Dr. Chaudhari asked about a previous study that focused on accents and found that infants recognized a diversity of different sorts of syllables but that those syllables not represented in the infants' home language become unrecognizable. This seems connected to the findings describing the fact that infants at high risk for developing ASD continue to recognize syllable differences, as though they are retaining a very young version of syllable recognition. Dr. Tager-Flusberg responded that it was the hypothesis of that study—that children with ASD would continue to show signs of distinguishing between similar syllables—but no evidence of that was found.

Budget Report .... Mr. Eric Williams

Mr. Williams presented the budget report showing the operating plan for Q1 of FY 2023 compared with the actual numbers for FY 2022.

- The dollar amount for research projects for 2023 will probably decrease.
- NIH will provide additional noncompeting funding to subsidize grants for which NIDCD has obligations.
- The administrative supplement numbers will decrease as well.
- The number for competing research projects appears low compared with last year, but the funding from noncompeting projects and from administrative supplements will be rolled into that number, increasing it by several million dollars.
- The Small Business Innovation Research/Small Business Technology Transfer budget is formula-driven, based on the overall budget.
- Research center budgets are higher for 2023 than for 2022 because of additional centers.
- In the area of other research, there is steady growth in careers and in the R25 program. The training line will decrease because funds that were going into training are now dedicated to the R25 program.
- The number of fellowship applications is decreasing, so those funds will also decrease.
- The research and development program budget is staying the same.
- Intramural research and research management and support are priorities of the NIDCD program and are growing, so those funds will increase. Pay raises have also increased costs this year in this area.

NIDCD has consistently higher success rates with RPGs and with fellowships than the rest of NIH. A history of how NIDCD has been funded shows that the budget has consistently risen. However, the

budget for FY 2024 will stay the same as that for FY 2023. This creates several challenges because of pay raises, inflation, and competing grants that have already been awarded, but there are plans to remain flexible in as many ways as possible, such as by prefunding certain grants while funds are available.

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

- Dr. Wagenaar-Miller introduced Ruth Bonnerjee, who joined NIDCD in April as the travel planner for all extramural staff.
- An RFI to review criteria for RPGs was issued in December 2022 and closed in March 2023. The proposed changes would reduce the number of scored review criteria from five to two by combining "Significance" and "Innovation" into "Importance of the Research"; making "Approach" part of "Rigor and Feasibility"; and combining "Investigator" and "Environment" into "Expertise and Resource," which would not receive an individual score but would affect the overall impact score. The RFI had 780 individual responses, 30 responses from scientific societies, and 30 from academic institutions. The vast majority of responses were supportive of the proposed changes. There was agreement about collapsing the criteria. Some responses were in favor of keeping "Investigator" and "Environment" as scored criteria. A smaller number of responses proposed blinding or partially blinding the review process, but there was overall agreement about the need for stronger training resources for reviewers, study section chairs, and scientific review officers. NIH has convened a trans-NIH working group to look at implementing these changes and is now turning to review of the fellowship applications.
- There is some concern that some highly qualified applicants are not scoring well on fellowship applications due to the current review structure. An analysis of 6,000 fellowship applications found that a small number of institutions are submitting the vast majority of applications, raising a strong concern about bias toward well-funded labs and senior scientists. There are recommendations to revise the review criteria as well as the application. Key modifications are to focus on three key assessments: the potential of the applicant, the strength of the science, and the quality of the training plan. This will result in less bias by reducing the consideration of the sponsor and the reputation of the institution. Changes to the application include an emphasis on the applicants' scientific thinking, needs, and goals and a broader statement of qualifications. No grades are required/allowed for the application. Additionally, the application will place more emphasis on the sponsor's mentorship approach and plan for this student (not simply their track record), and letters of support will include targeted, trainee-specific questions. An optional statement of special circumstances to address situations that might have hindered the trainee's progress, such as harassment and the COVID-19 pandemic, will also be considered. An RFI open through June 23, 2023, is seeking additional community input about the proposed changes to the fellowship application. Dr. Wagenaar-Miller encouraged Council members and others to provide their comments. The NIH CSR has developed resources to clarify the application process. Information is available on the NIDCD funding page.
- There is another RFI on the clarification of animal activities that are exempt from Public Health Service (PHS) policy requirements. The 21st Century Cures Act directed NIH to conduct a review of applicable regulations and policies for the care and use of laboratory animals and to make revisions, as appropriate, to reduce administrative burden while maintaining the integrity and credibility of research findings and protection of research animals. The NIH Office of Laboratory Animal Welcome is seeking input on proposed clarifications of animal activities that are exempt from the PHS policy requirements for review by the Institutional Animal Care and Use Committee. Responses must be submitted by July 31, 2023.
- Dr. Wagenaar-Miller reminded the Council that with the expiration of the federal Public Health Emergency for COVID-19, NIH will no longer grant single-IRB exceptions for multisite

research. All exceptions that have been granted by NIH before May 11, 2023, will be effective for the duration of the research or the time they were granted, as indicated in the determination letters.

- Dr. Wagenaar-Miller reminded the Council that NIDCD is interested in having an expanded pool of peer reviewers. Anyone interested can nominate themselves by filling out an online form.

Dr. Tucci announced a break until 10:35 a.m. and on return introduced Dr. Patricia Flatley Brennan, the director of the National Library of Medicine (NLM).

Digital NIH: A Strategic Vision for Advancing Support Through Information Technology…………………………………………………………………...Dr. Patricia Flatley Brennan

Dr. Brennan said that NLM is a critical part of NIH, and she provided some history. NLM is older than NIH and began 200 years ago as an army officer's bookshelf. In 1956, the leadership of the military decided to transfer the materials to PHS. There are 65 miles of shelves from 10 centuries of medical writing. The responsibility of NLM is to preserve knowledge. In 1966, the U.S. Surgeon General assigned NLM to NIH. NLM is both an institute and a library. NIH is the creator of knowledge, and NLM is the storer of knowledge. In the late 1980s, the library became a repository of genomic data, and since 2000, NLM has become more of a 21st-century library, interconnecting knowledge and ideas across the world. It offers services that connect everyone with customized health information, including services for physicians and researchers (e.g., PubMed and Medline), biomedical tools (e.g., the Basic Local Alignment Search Tool and GenBank), consumer tools for health references, library resources, and health data standards.

Digital NIH is a document on the NLM website that is focused on innovation, technology, and computation for the future of NIH. Technology and scientific activities are inseparable. Science is driven by and changed by technology. When tools change, science changes, and vice versa. NIH requires new ways of doing business because the role of technology is changing. To achieve the promise of new technologies, new funding and governance models are needed. Digital NIH is a strategy that is an adaptive governance model aligning IC-specific technology investments with trans-NIH investments and its mission. It requires agreement about standards and priority setting. The first step in creating a readiness to change involved more than 400 NIH staff and 19 leading sector organizations.

Digital NIH involves a new, more enterprise-savvy approach to technology governance and decision-making that reflects holistic, integrated planning across NIH. The strategy aims to:

- Provide rapid computational processing, flexible data storage and retrieval, and advanced analytic functions to support scientific endeavors
- Enable all ICs to be at the forefront of rapid changes in science and technology
- Maximize operational efficiency of scientific processes and technologies
- Adopt innovative frameworks that deliver faster, more automated, and more cost-effective technologies

Dr. Brennan discussed the framework that has been created to address NIH's priorities not by looking at individual ICs but by looking at what is common across NIH—namely, extramural research management, intramural clinical and basic research, and administration and management. She highlighted the cross-cutting needs, such as security and workforce development and agile analytic tools to manage and shape the future of extramural research, intramural research, administration and management, and cross-cutting capabilities.

Implementing Digital NIH is a multiyear journey that will iteratively explore solutions over the next several years.

- Year 1 is focused on establishing infrastructure, developing a capabilities portfolio and roadmap, and beginning capability proof of concept.
- Year 2 is focused on collecting lessons learned, consulting capabilities portfolio and roadmap, and continuing subsequent capability proof of concepts.
- Year 3 is focused on roadmap refinement, spinning off full-scale projects, and integration into operations.
- Year 4 and beyond are focused on integration into operations and revision and vision of next phases.

Preparing for a September 2023 launch has involved finalizing implementation infrastructure, developing roadmaps, and submitting capability proof of concept.

To consider how NIDCD will bring the Digital NIH to life, the Council should consider three key areas:

- Treating technology as a mission-critical resource
- Applying new holistic and collaborative planning to give priority to innovative shared solutions
- Upholding the IC's ability to meet unique IC technology needs

This will require a culture change to:

- Evaluate existing technology solutions before new acquisitions or development can be pursued
- Serve as a center of excellence where technology or tools can benefit other ICs and the enterprise
- Work with implementation planning teams to identify stand-up capabilities over the next five years
- Enable powerful research through support of common architecture, standards, data interoperability, AI, machine learning, and process automation

Digital NIH is working closely with the Office of Data Science Strategy to develop a 2023 strategic plan for data science to ensure alignment. Digital NIH provides the infrastructure while the Office of Data Science Strategy provides the information that goes through the infrastructure.

The strategic plan for data science includes five goals:

- Capabilities to sustain NIH data management and sharing policy programs to enhance human derived data for research
- Programs to enhance human derived data for research
- New opportunities in software, computational methods, and AI
- Support for a federated biomedical research data infrastructure
- Strengthen a broader community of data science

Discussion

- Dr. Merfeld shared two stories that illustrated the importance of sharing the grant requirements in advance of the writing and the award, because the requirements sometimes change when the study starts. Dr. Brennan said that extramural research is essential to the future of science

and society, and the extramural community must be supported. Science moves fast, language is hard to transfer, and rules change fast too. There are efforts to clarify what it means to have oversight. NIH does not want to intrude. When someone receives an R01, they are given an opportunity to show their expertise; when oversight becomes too intrusive, NIH should be aware of that. At the same time, NIH must protect the rights of the people who participate in research studies.

Dr. Brennan asked the Council what they are thinking about ChatGPT and natural language AI generators.

- Dr. Strowbridge said the more data are shared, the more bots will be able to write R01s using the shared information.
- Dr. Brennan said that every step taken toward democratizing access to science has two sides to it: responsible use and opportunity. The role of responsible information communicators, such as NLM, is to help people build skills to understand and evaluate information. It is easier to teach people to generate knowledge than it is to evaluate accuracy and relevance of that knowledge. NLM can get information into the hands of people who can make good decisions around hard issues, and that will improve people's capacity to understand.
- Dr. Hillis said there are some ways that generative AI can reduce disparities among researchers, specifically for non-English speakers. Scientists have always been able to submit fraudulent data, but if there is transparency around when AI is used, that is good. AI cannot take responsibility for the content of a paper and cannot be an author, but it could improve the problem among investigators of the "rich getting richer," as investigators who know how to write grants continue to write and receive grants. AI could help people who do not have access to a mentor with grant-writing experience. Dr. Brennan said NLM works with journal editors, who set policies that NLM implements, such as the policy that ChatGPT cannot be an author, because it does not meet the ethical standards. However, ChatGPT has been cited as an author in some journals. A chain of accountability needs to be more firmly established.
- Dr. Groves asked whether there are AI detection tools that could be used to determine whether references are real. Dr. Brennan said that that is an interesting idea and that she will talk to the PubMed team about it. She encouraged Council members to look at the AI risk management program written by the National Institute of Standards and Technology to help with verification and create a chain of trust.

Tackling Acquisition of Language in Kids (TALK)………Dr. Judith Cooper and Dr. Holly Storkel

Dr. Cooper introduced TALK by saying that in FY 2023 congressional funding was set aside for research on developmental delays, including speech and language delays in infants and toddlers. The funding was followed by a letter from Senator Chuck Schumer of New York to the acting director of NIH. The letter noted that NIDCD is charged with this task and urged the institute to take the lead on this research. Senator Schumer specifically requested a focus on children who begin talking late in life ("late talkers") and requested longitudinal studies that were disease- or condition-agnostic. Additionally, he requested research-based evidence for parents, teachers, pediatricians, and other caregivers.

A team was formed to respond to this need, involving individuals from the Division of Scientific Programs, the Science Policy and Planning Branch, and the Division of Extramural. A total of five institutes at NIH with an interst in late talkers are working together on this.

- The group chose the name TALK and decided that immediate foci for the first year of funding were to award outstanding relevant projects immediately, create a supplement program,

develop an approach to address parents and pediatricians, and to create projects for possible FY 2024 funding.

The purpose of TALK is to:

- Advance understanding of why children with various conditions and/or risk factors start talking late
- Differentiate developmental trajectories that lead to better outcomes
- Evaluate the effectiveness of clinical approaches to improve outcomes
- Provide caregivers and professionals with the information they need to help late talkers grow and thrive in school and life

- The program has awarded four grants relevant to late talkers within two months of starting the initiative: two from NIDCD and two from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development. Supplements to relevant active awards were solicited through a new NOSI to alert the research community of this effort. Staff have been meetings with congressional staffers.

Dr. Storkel provided background on late talkers. For this initiative, a later talker is defined as anyone who does not meet development milestones for communication at 18 months for any reason. As many as 10% to 20% of children are late talkers. There are a variety of risk factors and conditions among this group, and outcomes are variable. Some children learn at a faster rate than their peers, and some continue to show delays. This raises critical practice issues because every service environment has limited resources to support these children. It is not known which children are on which pathway to start, so determining who needs how much of what and when is difficult.

Dr. Storkel highlighted the four applications that were awarded:

- PETAL, promoting early intervention timing and attention to language, taking a family-based approach
- Talking late in two languages, focusing on bilingual children
- Bilingual exposure following preterm birth, studying toddler language outcomes and cumulative risk factors
- Community viable family–school partnership intervention for children with social communication deficits in early childhood education

The goal of the NOSI was to look at some parent grants that were already funded but with a little more support, they could contribute to this initiative. The kinds of projects funded are those that would:

- Add language and communication measures to an existing grant
- Create the foundation for comparing growth across different conditions by adding a different population than was originally planned
- Augment analyses of trajectories by adding earlier or later points to an existing longitudinal study
- Create infrastructure for leveraging existing data to make it more readily available for analyses

There has been a lot of interest in the NOSI, and the community is ready to advance this initiative.

This initiative can move the field forward by focusing on:

- Developmental trajectories, which will help illuminate how children start in the same place but end up on different pathways. The initiative will help to determine how soon, how accurately, and with what information can those pathways be predicted.
- Translating research into practice, which involves developing, evaluating, disseminating, and implementing state-of-the-science information and evidence-based practices.
- Creating, adapting, or applying novel approaches to the study of late talkers to develop new and more effective ways of understanding and supporting them.

Discussion

- Ms. Deal-Williams said that this information and the information provided by Dr. Tager-Flusberg provide a compelling case for studying late talkers. This is all in the context of early intervention being critical. Having projects that focus on late talking will help science manage and answer many questions. The idea of the Babble Boot Camp suggests that there are things that could help jump-start development. One additional thought or caveat is that as this science is explored, what is happening needs to be described before a decision is made about what is wrong. Scientists and clinicians can make assumptions about what is typical instead of looking at what is happening. Is the child effectively communicating? Large-scale descriptive studies might provide a better picture of what is happening so that children are not categorized before they are described.
- Dr. Goffman said that this is a key period of plasticity and that interventions are essential. It is remarkable that predictions about outcomes of late talkers still cannot be made. The number of words spoken does not predict outcome. A deeper dive into this area is welcome.
- Ms. Murphy Breen asked about referrals and presenting criteria for referral. There is a low threshold for intervention. If there is a complex late talker, it is not yet known what is going on. She asked whether that is going to be addressed. Dr. Storkel said that the question was within the scope of the initiative, because there need to be both a better understanding about the pathways and about how to encourage people to share information and to understand what parents and professionals want to know. A parent cannot simply be told that nothing is wrong or that something is terribly wrong, but it needs to be determined how to convey nuance in a way that is comprehensible. Dr. Tucci said that that is one of the tasks charged to NIDCD by Senator Schumer's office: to help parents and pediatricians gain clarity about interventions and to make that information clear and accessible to the public.

Dr. Tucci adjourned the meeting at 11:46 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 15:06:49 -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 22:46:02 -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

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. — 2024 Professor and Nelle Johnston Chair Callier Center for Communication Disorders School of Behavioral and Brain Sciences University of Texas at Dallas Dallas, TX 75235
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. — 2025 Professor Departments of Neuroscience and Molecular and Human Genetics Baylor College of Medicine Houston, TX 77030
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. — 2024 Professor of Neurology Johns Hopkins School of Medicine Baltimore, MD 21205
EATOCK, Ruth Anne, Ph.D. Professor of Neurobiology Dean of Faculty Affairs Biological Sciences Division University of Chicago Chicago, IL 60637	2024	KELLEY, Barbara — 2023 Executive Director Hearing Loss Association of America Rockville, MD 20852
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. — 2025 Professor and Vice Chair for Research Director Division of Otology, Neurotology, & Skull Base Surgery Co-Director Columbia Cochlear Implant Center Columbia University Vagelos College of Physicians and Surgeons New York, NY 10032

MURPHY-BREEN, Lynne, J.D. 2024
Founder
Clear Title
Senior Underwriting and Agency
Counsel
Chicago Title & Commonwealth Land
Title (Fidelity National Financial)
Boston, MA 02110

SANES, Dan H., Ph.D. 2023
Professor
Center for Neural Science
New York University
New York, NY 10003

STROWBRIDGE, Ben W., Ph.D. 2023
Professor of Neuroscience
Departments of Neuroscience and
Physiology/Biophysics
Case Western Reserve University
School of Medicine
Cleveland, OH 44106

WALLHAGEN, Margaret I., Ph.D. 2025
Professor
Department of Physiological Nursing
University of California, San Francisco
San Francisco, CA 94143

Ex Officio

BECK, Lucille B., Ph.D.
Director
Audiology and Speech Pathology Service
Department of Veterans Affairs
Washington, DC 20422

BECERRA, Xavier
Secretary
U.S. Department of Health and Human
Services Washington, DC 20201

NELSON, Jeremy T., Ph.D.
Chief Scientist & Research Section Lead
DoD Hearing Center for Excellence
Defense Health Agency
Joint Base San Antonio-Lackland, TX 78236

TABAK, Lawrence A., D.D.S., Ph.D.
Acting Director
National Institutes of Health
Bethesda, MD 20892

THEMANN, Christa, M.S., CCC-A
Research Audiologist
Hearing Loss Prevention Team
Division of Applied Research and Technology
National Institute for Occupational Safety
and Health
Cincinnati, OH 45226

Executive Secretary

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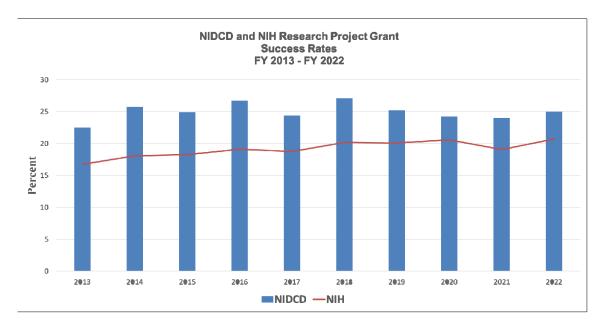National Institute on Deafness and Other
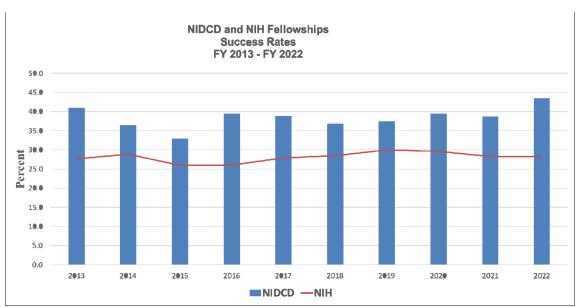Communication
National Institutes of Health
Bethesda, MD 20892

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

FY 2023 Operating Plan (Q1) vs FY 2022 Actuals
(Dollars in thousands)

Mechanism	FY2022 Actual		FY2023 Plan	
	Number	Amount	Number	Amount
Research Projects				
Noncompeting	581	$264,766	582	$268,925
Administrative Supplements	(71)	$5,560	(65)	$5,000
Competing	191	$80,343	193	$81,244
Subtotal, RPGs	772	$350,669	775	$355,169
SBIR/STTR	27	$16,015	27	$16,300
Research Project Grants	799	$366,683	802	$371,469
Research Centers				
Specialized/Comprehensive	6	$15,318	7	$18,434
Clinical Research	0	$0	0	$31
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	$18,465
Other Research				
Research Careers	58	$8,884	67	$10,746
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	42	$8,935
Subtotal, Other Research	91	$16,182	109	$19,681
Total Research Grants	896	$398,183	918	$409,615
Training	FTTPs		FTTPs	
Individual	142	$6,997	156	$7,854
Institutional	153	$9,631	154	$9,961
Total, Training (FTTPs and Award Amount)	295	$16,628	310	$17,815
Research & Develop. Contracts	44	$23,229	44	$23,500
SBIR/STTR (non-add)	(0)	($204)	(0)	($200)
Intramural Research	56	$52,588	64	$57,000
Res. Management & Support	74	$24,248	76	$26,400
Total, Program Level		**$514,876**		**$534,330**

National Institute on Deafness and
Other Communication Disorders (NIDCD)
FY 2013 – FY 2022 Success Rates (RPGs and F's)

NIDCD and NIH Research Project Grant
Success Rates
FY 2013 - FY 2022

NIDCD and NIH Fellowships
Success Rates
FY 2013 - FY 2022

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

FY2023 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 2023 Competing R01/U01 Budget
Payline: $16,000 per Council
HPP: $4,000 per Council

NIH Staff Present
Closed Session

Christopher Adams	Xinrui (Shinray) Li (CSR)	Katherine Shim
Aruna Behera (CSR)	Trinh Ly	Nanette Stephenson
Pablo Blazquez Gamez (CSR)	Castilla McNamara	Holly Storkel
Laura Cole	Roger Miller	Susan Sullivan
Judith Cooper	Christopher Myers	Brooke Sydnor
Janet Cyr	Edward Myrbeck	Debara Tucci
Hoai Doan	Stephanie Nagle Emmens (CSR)	Jean Verheyden
Nancy Freeman	Sonia Nanescu	Becky Wagenaar-Miller
Maria Garcia	Eric Nunn	Dawn Walker
Sara Hargrave (CSR)	Matthew Oh (CSR)	Bracie Watson
Rochelle Hentges (CSR)	Amy Poremba	Tim Wheeles
Howard Hoffman	Salma Quraishi (CSR)	Eric Williams
Tanya Holmes	Kausik (Bobby) Ray	Shiguang Yang
Nichelle Johnson	Alberto Rivera-Rentas	Thomas Zeyda (CSR)
Andrea Kelly	Cathy Rowe	
Alex Kazantsev (CSR)	Merav Sabri	**Other NIH Staff:**
Lisa Kennedy	Elka Scordalakes-Ferrante	ASL Interpreter Aleah Martinho
Kelly King	Brian Scott (CSR)	ASL Interpreter Lisa Schulman
Mimi Lee	Lana Shekim	Ryan Holofcener (ORS)

NIH Staff and Guest Speakers Present
Open Session Thursday 5/18, 2023

Christopher Adams	Roger Miller	Jean Verheyden
Reza Amanipour	Beatrice Milon	Becky Wagenaar-Miller
Angela Ballesteros	Jaylen Mumphrey	Dawn Walker
Erich Boger	Christopher Myers	Brianna Walters
Hui Cheng	Edward Myrbeck	Lizhen (Jenny) Wang
Julie Christensen	Sonia Nanescu	Bracie Watson
Laura Cole	Amy Poremba	Tim Wheeles
Judith Cooper	Lisa Portnoy	Eric Williams
Lisa Cunningham	Kausik (Bobby) Ray	Ningjin Wu
Janet Cyr	Alberto Rivera-Rentas	Michael Xydakis
Hoai Doan	Cendrine Robinson	Shiguang Yang
Kate Fernandez	Heidi Rosvold-Brenholtz	Jianliang Zhu
Nancy Freeman	Cathy Rowe	
Thomas Friedman	Merav Sabri	**Other NIH Staff:**
Maria Garcia	Susumu Sakamoto	Jonathan Bennett (ORS)
Tanya Holmes	Elka Scordalakes-Ferrante	CART Captioner Fran
Nichelle Johnson	Lana Shekim	ASL Interpreter Aleah Martinho
Tanji Johnson	Katherine Shim	ASL Interpreter Lisa Schulman
Joanne Karimbakas	Won Chul Shin	Ryan Holofcener (ORS)
Lisa Kennedy	Archana Shukla	
Kelly King	Christopher Shults	**Guest Speakers**
Zhengchang Lei	Shirley Simson	Jamila Minga
Joshua Levy	Nanette Stephenson	Liz Peña
Chuan-Ming Li	Susan Sullivan	Ross Williamson
Trinh Ly	Brooke Sydnor	
Castilla McNamara	Debara Tucci	

NIH Staff and Guest Speakers Present
Open Session Friday 5/19, 2023

Christopher Adams	Sonia Nanescu	Jean Verheyden
Kathy Bainbridge	Eric Nunn	Becky Wagenaar-Miller
Angela Ballesteros	Hua Ou	Dawn Walker
Hui Cheng	Amy Poremba	Bracie Watson
Hoai Doan	Lisa Portnoy	Tim Wheeles
Kate Fernandez	Kausik (Bobby) Ray	Eric Williams
Nancy Freeman	Cendrine Robinson	Ningjin Wu
Maria Garcia	Heidi Rosvold-Brenholtz	Michael Xydakis
Howard Hoffman	Cathy Rowe	Shiguang Yang
Tanya Holmes	Merav Sabri	Chris Zalewski
Nichelle Johnson	Elka Scordalakes-Ferrante	
Joanne Karimbakas	Lana Shekim	**Other NIH Staff:**
Lisa Kennedy	Katherine Shim	Jonathan Bennett (ORS)
Kelly King	Shirley Simson	CART Captioner Fran
Connie Latzko	Nanette Stephenson	ASL Interpreter Aleah Martinho
Chuan-Ming Li	Melissa Stick	ASL Interpreter Lisa Schulman
Castilla McNamara	Susan Sullivan	Ryan Holofcener (ORS)
Roger Miller	Cathy Sung	
Christopher Myers	Brooke Sydnor	**Guest Speakers**
Edward Myrbeck	Debara Tucci	Helen Tager-Flusberg