NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS ADVISORY COUNCIL
May 16, 2024
National Institutes of Health
Bethesda, Maryland

MINUTES

The National Deafness and Other Communication Disorders Advisory Council (NDCDAC) convened on May 16, 2024, at the National Institutes of Health (NIH) in Bethesda, Maryland. Dr. Debara L. Tucci, Director, National Institute on Deafness and Other Communication Disorders (NIDCD), served as Chair.

In accordance with Public Law 92-463, the morning session of the meeting from 9:00 a.m. to 10:36 a.m. was closed for review of individual grant applications and open from 12:13 p.m. to 4:21 p.m. for the review and discussion of program development needs and policy.

Council members in attendance:[1]

Ms. Katherine Bouton
Dr. Emily Buss
Dr. Nirupa Chaudhari
Dr. Carol Espy-Wilson
Dr. Lisa Goffman
Dr. Andy Groves
Dr Argye Hillis
Dr. Anil Lalwani
Dr. Dan Merfeld
Ms. Lynne Murphy Breen
Dr. Susan Thibeault
Dr. Margaret Wallhagen

Ex-officio Council members in attendance:

Dr. Jeremy Nelson
Ms. Christa Themann

Subject matter experts in attendance:

Dr. Yale Cohen
Dr. Jay Gottfried
Ms. Kimberly Kuman
Dr. Mario Svirsky
Dr. Laurence Trussell

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

[1] 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 16, 2024

This portion of the meeting was closed to the public in accordance with the determination that it was concerned with matters exempt from mandatory disclosure under sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., and section 1009(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. §. § 1001- 1014)

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

The meeting was called to order at 10:00 am by Dr. Debara Tucci, Director, NIDCD, who expressed appreciation to the entire Council for their service and advice.

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

Dr. Becky Wagenaar-Miller discussed 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 12:00 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 160 investigator-initiated R01 grant applications: 151 applications had primary assignment to NIDCD, in the amount of $68.299 million first-year direct costs. It is anticipated that, of the applications competing at this Council, NIDCD will be able to award grants to R01 applications scoring up through the 14th percentile.

Special Program Actions

1. NIH Mentored Clinical Scientist Research Career Development Award (K08): The Council recommended support of one application.

2. NIH Mentored Patient-Oriented Research Career Development Award (K23): The Council recommended support of two applications.

3. NIH Pathway to Independence Award (K99/R00): The Council recommended support of two applications.

4. BRAIN Initiative Advanced Postdoctoral Career Transition Award to Promote Diversity (K99/R00): The Council recommended support of one application.

5. Enhancing NIDCD's Extramural Workforce Diversity through Research Experiences (R25): The Council recommended support of two applications.

6. NIDCD's Mentoring Networks to Enhance Clinician-Scientists' Participation in Research (R25): The Council recommended support of one application.

7. NIDCD's Mentored Research Pathway for Otolaryngology Residents and Medical Students (R25 - Clinical Trial Not Allowed): The Council recommended support of one application.

8. National Cancer Institute Youth Enjoy Science Research Educations Program (R25): The Council recommended support of one application.

9. NIH Support for Conferences and Scientific Meetings (R13): The Council recommended support of two applications and co-fund of one application.

10. NIH Research Enhancement Award (R15): The Council recommended support of two applications.

11. NIH Exploratory/Development Research Grant Award (R21): The Council recommended support of seven applications.

12. NIDCD Early Career Research (ECR) Award (R21): The Council recommended support of five applications.

13. NIH Small Business Technology Transfer Grant (STTR): The Council recommended support of one Phase I (R41) application.

14. NIH Small Business Innovation Research Awards (SBIR): The Council recommended support of two Phase I (R43) applications and one Phase II (R44) application.

15. STrengthening Research Opportunities for NIH Grants (STRONG): Structured Institutional Needs Assessment and Action Plan Development for Resource Limited Institutions (UC2): The Council recommended support of one application.

Dr. Tucci adjourned the closed session at 10:36 a.m.

OPEN SESSION – May 16, 2024

Opening Remarks .....Dr. Tucci

Dr. Tucci called the open session to order at 12:13 p.m. She welcomed viewers to the open session and noted that this meeting would be videocast live and available to NIH staff and the public for one year from the NIH VideoCast website at National Deafness and Other Communication Disorders Advisory Council May 2024.

Council Introduction

Dr. Tucci invited Council members to introduce themselves to begin the meeting.

Consideration of Minutes of the Meeting of January 25–26, 2024

Dr. Tucci called the members' attention to the minutes of the January 25–26, 2024, meeting of the NDCD Advisory Council in the Electronic Council Book; she asked whether there were any additions or corrections to these minutes. Hearing none, she deemed the minutes accepted as written.

Confirmation of Dates for Future Council Meetings

Dr. Tucci pointed out the future meeting dates through 2025: September 12–13, 2024 (in person), January 23–24, 2025 (virtual), May 8–9, 2025 (in person), and September 4–5, 2025 (in person). She asked members to check their calendars and notify council organizers of any potential conflicts.

NIDCD Director's Report: Diversity in the NIDCD Scientific Workforce

Dr. Tucci provided a high-level view of workforce diversity. Underrepresented minorities (URM) in the NIH-supported research include Black/African Americans, Hispanics/Latinos, American Indians/Alaska Natives, and Native Hawaiians/Pacific Islanders. NIDCD supports fewer URM than NIH overall in all award categories, but sometimes the differences are quite small. There was considerable variability in the NIDCD data on the success rate for awards to URM because of the small number of awardees. For fiscal years (FYs) 2015–2023, the R01 success rate for URM for NIDCD awards is higher than for non-URM NIDCD awards (nearly 50% versus a little more than 45%). Several mechanisms have been put in place to enhance workforce

diversity at NIDCD including the R25 diversity-focused programs. Dr. Tucci highlighted the Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) program, which is administered by the National Institute of General Medical Sciences, and indicated that investigators within the NIDCD portfolio have been part of this program. NIDCD is developing a Diversity Scholar Cohort and will be hosting an inaugural diversity scholar workshop on October 24–25, 2024. This workshop will encompass 64 scholars and eight faculty mentors. The scholars will engage in professional development activities meant to help them advance to the next stage in their careers.

Dr. Tucci pointed out that there is an NIH Data Book, which allows users to view statistics on NIH funding trends. She also described the NIH Common Fund Program, which supports clinical research in primary care settings. Because health is declining most sharply among the underserved and underrepresented, the program plans to establish a primary care-focused clinical research network that will engage underrepresented communities. The program is currently in its pilot phase; it will eventually transition to an institute at NIH.

Research at the Intersection of Translational Science .....Dr. Joni Rutter

Dr. Tucci introduced Dr. Rutter, who has served as the Director of the National Center for Advances Translational Sciences (NCATS) since 2022. NCATS supports research to make the translational process more effective and efficient, which in turn increases the speed of research. Dr. Rutter has collaborated with government, academia, industry, and nonprofit organizations to foster NCATS programs.

Dr. Rutter said that all NCATS work is in the translational space rather than basic science. Specifically, the center works in the pipeline between research and preclinical studies, so that new treatments can reach people faster. Most of the preclinical work occurs in the intramural program, and most of the clinical work (i.e., clinical trials) occurs in the extramural program. NCATS tries to address multiple hurdles in the translational pipeline. For instance, only about 5% of therapeutics can be used for rare diseases. On average it takes 10 to 15 years for a newly identified compound to move through the entire pipeline of the research phase, and then another 10 years or so for the drug to arrive in people's medicine cabinets. Additionally, the entire process has a 90% failure rate, with most of those failures occurring in Phase II or III of clinical research.

NCATS takes on projects that try to de-risk this pipeline through four key strategies: understanding what is similar across diseases to spur multiple treatments, developing models that better predict reactions to treatments, enhancing clinical trials to more accurately reflect the patient population, and leveraging real-world data and data science to address public health needs.

NCATS' mission is to "turn research observations into health solutions through translational science." It has three goals: more treatments (increase the number of treatable diseases from 5% to 25%), increased inclusivity (benefit all people), and more speed (diagnostics and therapeutics reach people twice as fast).

NCATS collaborates with multiple entities (.gov, .edu, .org, and .com). Often, an organization will come to NCATS with a specific problem in the pipeline that needs addressing. One example of this is an investigational new drug (IND) approval from the Food and Drug Administration (FDA). NCATS has collaborated on more than 50 IND applications. The outside organizations provide the subject matter expertise. The work done at NCATS is primarily on platform and assay development to improve the therapeutic pipeline.

Dr. Rutter gave examples of how NCATS collaborates in the drug development process. In one such case, it worked with Oricula Therapeutics on a drug to prevent an antibiotic-induced hearing loss. NCATS has a memorandum of understanding with NIDCD to develop preclinical activities that will eventually be moved into clinical activities supported by NIDCD. Also, NCATS has robotic systems to develop new ways to look at disease models. The robots can analyze cell cultures and look at more variables than when this analysis is done manually by a person. NCATS can take cells to create tissue chips, which has led to a partnership with NASA. The chips are sent into outer space to observe the results, which can be used to understand diseases on earth. NCATS is developing cell-derived, three-dimensional models to understand rare diseases. A

particularly prominent area involves using models to understand gene therapies before they are applied to actual patients. NCATS is also using the NIH Common Fund's Complement Animal Research in Experimentation (Complement-ARIE) program to speed the development, validation, and use of human-based methodologies by adding in a computer data component (e.g., digital twins).

Dr. Rutter said that to expand benefits for all people, NCATS has created the Clinical & Translational Science Awards Program (CTSA) program. It is designed to turn science into health faster, promote partnerships and collaborations, address health disparities, promote training/career support, and nurture translational science. More than 60 institutions across the country are part of the CTSA program, which permits a national response to public health crises (e.g., the opioid epidemic, COVID-19).

Dr. Rutter explained that the CTSA Trial Innovation Network (TIN) focuses on operational innovation, operational excellence, and collaboration. This network enables innovation and recruitment around clinical trials; it can also help design trials and disseminate results.

Dr. Rutter pointed out three researchers in CTSA leadership who would be relevant to the work of NIDCD: Dr. Jay Piccirillo, Dr. Marian Hansen, and Dr. Jareen Meinzen-Derr. She also mentioned Dr. Matthew Bush, who transformed telehealth in the state of Kentucky and the Appalachian region; he also focused on ways for children with hearing issues to be treated by the clinical community.

Dr. Rutter said the CTSA has enabled electronic health records (EHRs) to be studied more broadly by the research community. Specifically, NCATS has attempted to harmonize EHRs, Centers for Medicare & Medicaid Services (CMS) data, social determinants of health data, and mortality data into a single model, known as the National COVID Cohort Collaborative (N3C) data enclave. This enhances interoperability. N3C has produced data to answer public health questions about COVID-19, showing that Paxlovid works and would have saved lives if had been used more broadly during the pandemic. The goal now is to expand N3C beyond COVID-19 to analyze other conditions.

Dr. Rutter said that the other NCATS flagship program focuses on rare diseases. Most of its work here takes place through the Rare Diseases Clinical Research Network. Patient advocacy groups are funded and have a seat at the table as part of this network, which has resulted in 12 new drug approvals to date.

Dr. Rutter briefly mentioned the Tracking Acquisition of Language in Kids (TALK) Initiative. NCATS is collaborating with NIDCD and several other institutes on this initiative.

Dr. Rutter then discussed speeding up therapies (NCATS' third goal) by first describing gene-targeted therapy approaches. Of these, somatic cell gene editing (SCGE) is the farthest from clinical trials, but it is a fast-moving field. There is an NIH Common Fund prize challenge of $1 million for researchers who can develop targeted genome editing for hard-to-reach places, such as the brain.

Dr. Rutter described the Accelerating Medicines Partnership (AMP) Bespoke Gene Therapy Consortium (BGTC), which is meant to enhance the generation of vectors for gene therapy. The goal is to move the results of this research into the clinical setting. The program is working with the FDA and NIDCD. Dr. Rutter described the portfolio being supported by this program, which is to build better vectors for the future. NCATS has also developed a BGTC Regulatory Playbook with guidance on how to get a gene therapy through the regulatory pipeline. Although the vectors on which BGTC focuses will probably change, the consortium will be able to apply what it has learned regarding how to get these types of delivery vehicles through the regulatory process.

Dr. Rutter said that NCATS is studying diseases that have no commercial interest (e.g., orphan drugs, rare pediatric diseases). The fact that the government is doing the research means that all results can be published. This is an effort to democratize these gene therapy activities.

Dr. Rutter also described data science efforts, particularly in the context of how existing therapies might be applied to new conditions. One strategy involves the app CURE ID, which offers a way to crowdsource how existing therapies are being used for new diseases. NCATS started this for COVID-19, expanded it to

included monkeypox, and is now looking into how to expand the app into rare diseases. Another strategy involves NCATS' large catalogue of screening compounds, 3,000 of which are FDA-approved. If one of these compounds looks promising for another disease, then safety issues are already known because of prior approval; this reduces, by years, the amount of time needed to develop a successful therapy. Another strategy involves developing partnerships between NCATS and biotechnology/pharmaceutical companies. Finally, there is the strategy of the NCATS biomedical data translator, which contains 150,000 data sources for machine learning (ML); this enables testing of the types of drugs that might effectively treat a particular disease. Dr. Rutter ended with an example of a physician using the translator analysis to treat a little girl with an approved high blood pressure medication for a rare condition called SHINE (sleep disturbances, hypotonia, intellectual disabilities, neurological disorders, and epilepsy) syndrome which resulted in noticeably improved motor abilities, as reflected in her artwork.

Discussion

Dr. Tucci asked what are the big challenges and opportunities for the CTSA program. Dr. Rutter said that there are logistical challenges in visiting more than 60 sites within a year because the visits would have to be more frequent than weekly. There are also time challenges because 20% are awarded on a yearly basis, so different sites are at different stages in their awards cycles. Collaborative institutional awards facilitate actions such as creating the EHR resource. There is also a TIN liaison within each of the 60 hub institutions, which can provide access to TIN resources. An association meeting and a programmatic meeting take place each year and provide an opportunity to bring everyone together. NCATS also wants to leverage the strengths of individual institutions; it relies on the institutions to manage themselves. The steering committee, which meets every two weeks, consists of 10 to 12 representatives, and each of whom has their own steering committee meetings with nearby hubs in their region (called a pod) and brings this feedback to the larger committee.

Dr. Wallhagen, who noted that most of the translational work focused on drugs, asked about non-drug treatments with a focus on implementation science. Dr. Rutter said that there is a digital health technology group focused on this area. The CTSA also works with the practice-based research networks on a wide variety of issues, such as how to work with EHRs. And NCATS wants to understand the burdens on the primary care community. It addresses a variety of nontherapeutic issues within the clinical space.

Dr. Svirsky asked about devices and nerve stimulation specifically as a non-therapeutic example. Dr. Rutter said she did not know whether anyone in the CTSA was working on this specifically, but she thought that it would be interesting. She said she would investigate whether the University of Washington, the University of Cincinnati, or the University of Iowa is researching these issues.

Ms. Kuman, a patient advocate, said that she appreciated that patient advocates had a seat at the table. In her consortium, the researchers are respectful of the patient advocacy role. Dr. Rutter said that NCATS is trying to ensure patient voices in other areas that it supports as well.

Dr. Chaudhari said that she was interested in nutrition and wondered whether the primary care network is the right home for this topic or NCATS. There are large populations that need education on this topic. Dr. Rutter said that nutrition would be more diffuse than the CTSA program, but there might be opportunities to collaborate with other parts of NIH, such as the Office of Nutritional Research, on topics such as maternal health. Dr. Rutter said that 3-D printing could be applied to food, which could be thought of as medicine for rare diseases.

Dr. Tucci thanked Dr. Rutter for the presentation.

NIDCD Clinical Trials Program .....Dr. Trin Ly

Dr. Tucci introduced Dr. Ly to talk about the NIDCD clinical trials program.

Dr. Ly provided background on the scope of work that the NIDCD clinical trials teams manages especially as it relates to higher-risk clinical trials. She introduced the clinical trials team staff. Dr. Ly and Dr. Samah Jafari are the medical officers and the main contacts for clinical trial-related questions. Dr. Steven Hirschfeld is a

volunteer with significant as a medical officer and in clinical trials. Dr. Castilla McNamara works on conflict of interest, clinical trials contacts, and informed consent. Dr. Chuan-Ming Li is a statistician who works with U01 teams and provides advice on statistical analysis plans.

The clinical trials team has three core responsibilities: consultation and guidance to extramural investigators and staff; management of clinical trial operations; and technical expertise and oversight for higher-risk clinical trials. Among the activities for consultation are policies and requirements, risk determination, determinations for clinical trials and basic experimental studies involving humans (BESH), funding opportunities, and evaluation of trials that cost more than $500,000 per year in direct costs. Management of clinical trial operations involves creating U01 and R01 funding opportunities, managing the NIDCD clinical trials website, developing clinical trials standard operating procedures (SOPs), and managing and overseeing the NIDCD Data and Safety Monitoring Board (DSMB). For high-risk clinical trials, the clinical trials team provides support on protocol and informed consent development as well as trial implementation.

Clinical trials are managed through a risk-based approach. Risk is analyzed through the lens of complexity, safety, impact, and fiscal investment. Trials with direct costs of more than $700,000 per year are considered high risk. NIDCD has two separate funding opportunities dedicated to support clinical trials. The R01 mechanism is for low-risk clinical trials, which are managed by program officers. Higher-risk trials are funded through the U01 mechanism, and the review of these applications are coordinated by the NIDCD Scientific Review Branch. Currently, voice, speech, and language are the focus of most clinical trials, with more R01 trials than BESH. The U01 mechanism also supports clinical trials in hearing and balance; taste and smell; and voice, speech, and language. Early feasibility/Phase I and Phase II trials are ongoing now, with Phase III trials anticipated. Some of the interventions being studied include devices, drugs, dietary, and behaviors. The trials span all of the NIDCD's mission areas.

Dr. Ly presented a slide of the NIDCD's work on U01 clinical trials, including steps to reduce safety risks. She did not go into the details of the slide but emphasized how the Program Officers engage in stewardship to promote safety. In the application phase, critical elements for planning are in the funding opportunity. When funded, NIDCD works closely with high-risk studies' teams on protocol and informed consent development, pre-implementation preparation, and implementation and monitoring. NIDCD works constantly with teams to identify gaps/challenges and provide solutions.

The NIDCD clinical trials team is working to achieve the institute's mission of improving lives by creating effective and accessible treatments. To advance safe and beneficial research interventions and put them into practice, NIDCD published an updated U01 Notice of Funding Opportunity (NOFO) on October 23, 2023, that focuses on selecting the most appropriate primary endpoint(s), recruiting underrepresented populations to promote inclusion and diversity, and completing clinical trials successfully in a timely manner. To achieve these goals, applicants must now justify their primary endpoints as valid/reliable, clinically relevant, and accepted by regulatory authorities and the clinical community. These issues must be assessed by reviewers. The NIDCD is asking for recruitment and retention plans with proactive strategies to include underrepresented populations, as well as sustained community engagement; reviewers must address these issues in their assessment of applications. To ensure successful timely completion, the human subjects research component can be awarded on a capitation basis, and trials should be managed by appropriate statisticians, data managers, and coordination staff. Investigators will be required to include a trial management plan—including a risk management plan, a strategy to address fiscal and logistical issues, and a plan for project closure—to manage issues and optimize resources. A timeline with milestones, to include enrollment targets negotiated at the time of the award, is also requested. NIDCD has developed a webpage called "Steps Prior to Implementation" that provides investigators with information on all that needs to be done in the year before participants are enrolled, which includes a link to the NIDCD pre-implementation table. The table emphasizes the need for high-quality and valid results.

In the future, NIDCD would like to have more of a focus on the quality, rigor, and integrity of trials. To that end, the institute hopes to strengthen U01 study teams in the areas of project quality and data management. NIDCD is working on developing guidance on the Phase III clinical trials that it supports. This guidance will ensure appropriate fiscal stewardship of these larger trials, provide transparency on criteria needed to justify these trials, help with trial planning, and be relevant for Phase II investigators.

Discussion

Dr. Tucci thanked Dr. Ly for her presentation and acknowledged the hard work that she does in working with applicants on their projects. Dr. Tucci asked the council how many resources for developing clinical trials are available at their home institutions and when they would reach out to Dr. Ly and her team for advice.

Dr. Goffman said that there is continued confusion about BESH trials. Dr. Ly responded that the R01 opportunity was developed to include the BESH trials to decrease confusion between clinical trials and BESH and prevent researchers from being penalized for applying to the wrong funding opportunity.

Dr. Lalwani said that there is a CTSA resource for clinical trials at his institution, Columbia University, but it is hard to access. He liked that the CTSA had one go-to resource available and said that he would refer members of his department to Dr. Ly and her team. Dr. Ly said that she is looking forward to receiving the relevant CTSA document from Dr. Rutter. She and her team are not directly involved, but they do refer investigators to work with their CTSA. She said that more work could be done to develop clearer and more helpful instructions on how to make the connection with the CTSA.

Dr. Tucci asked Dr. Ly to comment on the NIDCD DSMB and investigators putting together their own DSMB. Dr. Ly said that currently, there is only one NIDCD DSMB. All U01 clinical trials are required to have a DSMB, which are investigator coordinated and initiated. Discussions among NIDCD, program officers, and the chair of the institute's DSMB determine which studies should be sent to the NIDCD DSMB. The reasons for sending specific studies for NIDCD DSMB review vary, such as the risk or benefit to an investigator from experiencing a formal DSMB review which has benefited study teams in the past. NIDCD is trying to establish best practices across clinical trials because each investigator seems to design trials slightly differently and the NIDCD DSMB has been involved in setting these best practices.

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

Mr. Williams presented a table of the NIDCD's actual spending for fiscal year (FY) 2023 and the first-quarter plan for FY 2024. He said that there is a flat budget. For research projects, the noncompeting base for FY 2024 starts out large ($267,943 in FY2024), but this number will trend downward for projects that do not go full term. NIDCD hopes that the competing project numbers for FY 2024 are close to what they were for FY 2023 (183 in FY 2023 and 177 in FY 2024); this would be a great accomplishment on a flat budget with mandatory federal pay raises and inflation. For research centers, NIDCD is supporting six rather than seven P50 grants, which will save money. There has been growth in the R25 program—about $1 million in the first quarter so far, and this will grow even more because of great applications. There will probably be a little more money spent on individual training than there was last year. The line for institutional training in the budget shows a decrease in the amount of funds, but this is from funds saved from last year that could be used this year; however, the same number of institutions are still receiving funds. The research and development part of the budget has increased because of an increase in funds that have to be paid to NIH, programs that NIDCD has joined, and a large contract for clinical trials management. There has been an increase in intramural research, primarily because of increases in pay, taps, and assessments.

NIDCD's success rates for research project grants (RPGs) are about 5% higher than NIH's, and about 10% higher for fellowships.

Mr. Williams said that next year's budget may be fairly flat, with perhaps a slight adjustment for inflation. NIDCD is planning on ways to be cost-effective, such as by fully funding programs this year if feasible. The institute is maintaining funding on training and research and development contracts in case high-quality programs need support. Mr. Williams anticipates that for the FY 2024 competing R01/U01 budget, the payline may exceed the proposed $16 million per council because of the high quality of submitted applications (close to 20% are supported); as a result, the high program priority (HPP) estimate of $4 million per council may need to be adjusted to maintain a flat budget.

Dr. Tucci thanked Mr. Williams for his presentation and the excellent stewardship of NIDCD funds.

NIDCD Fellowships: Updates and Outreach Efforts..... Dr. Jaclyn Schurman

Dr. Tucci introduced Dr. Schurman and Dr. Rivera-Rentas, who provided general comments about the fellowship programs, and then introduced four R25 recipients: Dr. Lauren Calandruccio, Professor in the Department of Psychological Sciences at Case Western Reserve University; Dr. Rochelle Newman, Professor and Chair in the Department of Speech and Hearing Sciences at the University of Maryland; Dr. Jay Piccirillo, Professor of Otolaryngology, Medicine, Biostatistics, and Occupational Therapy at Washington University; and Dr. John Oghalai, Professor of Medicine at the University of Southern California.

Dr. Schurman, the research training officer for the fellowship program, described the NIDCD fellowship program, new training support and outreach efforts, and fellowship success rates. Dr. Schurman said that there are pre-application information sessions, which explain individual fellowship mechanisms, the application pathway (from receipt of application to review), and advice for a successful application. The next pre-application virtual webinar will be on June 26, 2024, from 2:00 p.m. to 3:00 p.m. ET.

Dr. Schurman described post-submission information sessions. These sessions discuss the application pathway in more depth (month by month), the post-review process (e.g., what the score and summary statement mean, when to contact Dr. Schurman on next steps, etc.), and the potential outcomes of applications (i.e., what to do for each scenario).

Dr. Schurman summarized the fellowship success rates from 2018 to 2023. The NIDCD success rates, based on type of funding mechanism, were 59.3% for F30, 36.9% for F31, and 39.5% for F32; the comparable figures for these funding mechanisms in NIH, as a whole, were 37.7%, 28.65, and 28.2%, respectively. NIDCD is proud of its success rates.

NIDCD Fellowships R25 Programs: Successful Examples ..... Dr. Alberto Rivera-Rentas
Dr. Lauren Calandruccio
Dr. Rochelle Newman
Dr. Jay Piccirillo
Dr. John Oghalai

Dr. Rivera-Rentas, the Research Training Officer for Institutional Research Training Programs and Mentored Career Development “K” Programs, explained that NIDCD already had an R25 program, but this is an expanded R25 program to include clinical scientists in research. The result was the creation of new R25 programs: PAR-21-185: Mentoring Networks to Enhance Diversity in NIDCD’s Extramural Research; PAR-21-186: Enhancing NIDCD’s Extramural Workforce Diversity through Research Experiences; and PAR-24-166: Promoting Broad Participation in NIDCD’s Extramural Workforce through Research Education Experiences and/or Mentoring Networks (a combination of the first two programs).

Dr. Rivera-Rentas mentioned successful PAR-21-185 grantees. In 2022, Dr. Calandruccio received a PAR-21-185 award for IMPACT: Promoting Diversity and the Success of Underrepresented Minority Students in the Clinical and Research Workforce for Communication Sciences and Disorders for research at Case Western Reserve University and Hampton University. In 2024, Dr. Santos-Cortez, University of Colorado, Denver, received an award in response to PAR-21-185 for Development of a Diverse Workforce through Mentoring Networks Among Otitis Media Researchers.

Dr. Rivera-Rentas mentioned successful PAR-21-186 grantees. In 2022, Dr. Levi, New York University, received support for SHARE CSD: An undergraduate summer experience to increase diversity in the CSD research pipeline. In 2023, Dr. Newman, University of Maryland (UMD), College Park, received support for UMD-REACH (Research Equity and Access in Communication and Hearing), and Dr. Tilak Ratnanather, Johns Hopkins University, received support for Science, Technology, Engineering, Math, and Medicine (STEMM) opportunities for college students with Hearing loss to Engage in Auditory Research (STEMM-HEAR). In 2024, Dr. Joel Mainland, Monell Chemical Senses Center, received support for Monell Science Apprenticeship Program: Inspiring Biomedical Careers In Underrepresented Undergraduates.

Dr. Rivera-Rentas listed past recipients of PAR-24-127: R25 Awards: NIDCD's Mentored Research Education Pathway for Otolaryngology Residents and Medical Students. This award has been modified so that investigators can tailor the program to the needs of their trainees and institutions. Among the 2022 recipients were the following: Dr. Jennifer Long, University of California, Los Angeles; Dr. John Oghalai, University of Southern California; Dr. Rick Friedman, University of California, San Diego; Dr. Bradley Goldstein, Duke University; and Dr. Alan Cheng, Stanford University. Among the 2023 recipients were the following: Dr. Justin Turner, Vanderbilt University; Dr. Jay Piccirillo, Washington University; Dr. Xue Zhong Liu, University of Miami; and Dr. Gabriel Corfas, University of Michigan.

Dr. Lauren Calandruccio

Dr. Calandruccio, a professor in the Department of Psychological Sciences at Case Western Reserve University, presented on Innovative Mentoring Through Professional Advancement and Cultural Training (IMPACT), which she carries out with Dr. Jessica Sullivan, an assistant professor and chair of the Department of Communicative Sciences and Disorders at Hampton University. The program has three goals: increase the knowledge of the profession among students from underrepresented backgrounds; increase the students' sense of belonging, especially when they experience "othering" in graduate school; and increase the students' sense of self-efficacy (i.e., build students' confidence so that they see themselves in this professional space). The program uses a multiple-mentor model of mentorship, which requires creating a multi-member network for each student fellow. Each institution plays to its strengths: Case Western Reserve University is a research-intensive university, and Hampton University is one of the oldest historically Black colleges and universities (HBCUs) in the nation, as well as the first HBCU to have a clinical graduate program in speech language pathology. The program also benefits from institutional and corporate partnerships (with Boys Town National Research Hospital, LaCalle Group, and the American Auditory Society); the ability to see other virtual labs through a virtual tour; and an advisory board. These activities are meant to create a network for students and to improve the climate of diversity and inclusion at the students' institutions, which may encourage more candidates from underrepresented backgrounds to work there.

Dr. Calandruccio and Dr. Sullivan serve as the academic mentors for student-fellows, and the research mentors come from Boys Town National Research Hospital. There are 11 affinity mentors with backgrounds similar to the students. There are also seven writing coaches.

Dr. Calandruccio said that in the past academic year, there were 21 student-fellows in the program. Each undergraduate student experiences 150 hours of professional development per academic year, and each graduate student has 50 hours. This curriculum is built into Canvas, an online course platform. Dr. Calandruccio plans to share this model via Canvas with other institutions, so that it can be replicated. Although meeting with mentors is required, students may select other aspects of professional development (e.g., writing development) to meet the time requirements. There are also special events such as a cultural empathy book club. The program is run according to scientific best practices such as filling out a plan of future goals and how to achieve them.

Dr. Calandruccio said that during the past academic year, there was an expansion of mentoring networks, three successful graduate school admissions, eight scholarships awarded, two people attended the Ohio Speech-Language-Hearing Association Workshop, six summer research experiences, a visit to Case Western Reserve University by Hampton University students, and attendance at national conventions. Collectively, the students completed more than 2,000 experience hours.

Discussion

Dr. Gottfried applauded Dr. Calandruccio for this program. Dr. Gottfried indicated that he has a postbaccalaureate student at the University of Pennsylvania on a similar career trajectory, and he commented that the program outlined by Dr. Calandruccio offers a template for how this should be done. Dr. Calandruccio said she hopes that all the relevant documentation for this program can be transferred to other institutions. Dr. Tucci asked whether there is information about this program on a website that could be linked. Dr. Calandruccio said that such a page is not currently available, but the program communicates nationally through its Instagram page, which highlights what the students are doing. They plan to develop a website.

Dr. Rochelle Newman
Dr. Newman presented on the UMD-REACH. Her co–principal investigator (PI) is Matthew Goupell. Their program is designed to increase the number and diversity of undergraduates going into research. Underrepresented undergraduates will conduct research in a one-year program. This paid, hands-on experience will give students the opportunity to learn about research; the paid aspect will help eliminate a potential financial barrier. There are mentoring opportunities to increase academic success and the potential for a research career. There are also professional development opportunities. The program has three main parts: laboratory-based experience, individualized mentoring, and education in professional development/responsible conduct of research. The students learn what a research career is like and how to succeed in a laboratory setting; they work with multiple mentors—research and career—who can help them pursue graduate training. The research mentors are the faculty and graduate students in the laboratories where they work. The career mentors have both clinical and research experiences and can provide feedback on both career trajectories; the career mentors are also from underrepresented backgrounds. The program is built around skills, such as how to read and evaluate scientific literature, how to present data in publications and presentations, and how to apply for graduate education.

Dr. Newman said that the program is recruiting students who are already studying communication sciences and disorders, as well as those in adjacent fields (e.g., biology, computer science, electrical engineering). Two cohorts of students have been recruited so far, of which about half are communication science and disorders students and half are from adjacent fields. Most have had no prior research experience. Most of the students are female (18 out of 22); 60% are African American, 14% are Latino, and 5% are American Indian/First Nation. About a third are from disadvantaged backgrounds, about a third are first-generation college students, and about 15% have a disability.

Dr. Newman discussed the lessons learned, which involved the realization that the cohort had to be admitted yearly rather than in a staggered fashion. It also made more sense to have the summer period be the time of initial exposure rather than the capstone because it takes time for students to get oriented to research. The program required more effort than originally planned, and activities were mostly unreimbursed. The program also realized that planning had to be flexible to accommodate the students.

Discussion

Dr. Chaudhari asked about the decision to spend all the funds on the students rather than the PIs as PIs spend a lot of time helping students without research and professional training. Dr. Newman said that 22 faculty have committed to this program, most of whom have grants to keep their research going. However, this means that the faculty are, in effect, funding the research of these students. Similarly, the time spent mentoring is “mostly” being donated (the career ambassadors are being reimbursed, but other mentoring activity is not). Dr. Newman acknowledged that the program had underestimated how much time would be involved. Dr. Rivera-Rentas said that the NIH policy is not to pay mentors so that most of the resources can go to the students and Dr. Newman said that they took this policy to heart when they designed the program. Dr. Newman said that the faculty involved are committed to this type of work and want to see the students succeed. Dr. Tucci asked whether Dr. Newman’s institution values these mentoring activities, so that they would count towards promotion. Dr. Newman said that her college and university do consider these activities important for promotion and that this type of activity was highly valued at her college. However, there is variability among the university, colleges, and departments on this issue.

Dr. Jay Piccirillo
Dr. Piccirillo made a presentation on his R25, which has been funded since 1985. The goals of his program are to take medical students and otolaryngology residents and expose them to the tools of research. He explained the types of students recruited to participate, their activities, and the outcomes (e.g., presentations and publications, career in academic medicine). Like the other programs presented at the meeting, an individual development plan (IDP) is developed to help trainees identify annual progress, professional development needs, and career objectives. These plans are discussed in meetings with mentors and program directors. The program is based on three core pillars: mentored research training, customized coursework that reflects the trainee’s IDP, and career development opportunities. There is a mentor team

consisting of a primary mentor and a secondary mentor from a different discipline. One of the R25 program directors, and a junior faculty member on the physician-scientist track to serve as a near-peer mentor for resident investigators. For flexibility within this structure, numerous digital and in-person courses are available. Also, there are multiple career development activities throughout the year. The highlight of the year is the research day and lectureship. The trainees in St. Louis can engage in innovation and entrepreneurship relating to commercialization, translational discoveries, and implementation science.

Dr. Piccirillo explained the timeline for an R25 resident, which involves two years of clinical rotation, followed by two years of research, then a return to clinical work for three years (though many put the finishing touches on their research during an 11-week period in Year 5). He said that the transition from the T32 funding mechanism to the R25 has pros and cons. Some trainees appreciate the 20% of time spent on clinical matters because it maintains and refines their clinical skills, but others do not like the loss of time for research experience. He also discussed the challenges about covering the salary, benefits, and malpractice for individuals on the R25; the learning experience of clinical-track residents is affected when assigned to clinical rotations with R25 research residents; and surgical cases and procedures performed during R25 training are not recognized by the Accreditation Council for Graduate Medical Education (ACGME) for surgical case logs.

Discussion

Dr. Thibeault asked for clarification on the outcomes for medical students in the program. Dr. Piccirillo said that most (but not all) of these students get into otolaryngology residency programs if they want. Dr. Tucci asked about the students who were not from Washington University, and Dr. Piccirillo confirmed that the program recruits from outside of that school. He also clarified that the medical student rotations are nine months.

Dr. John Oghalai
Dr. Oghalai presented on the Clinician-Scientist Training Program (CSTP) for Residents and Medical Students at the University of Southern California. He said that it is a completely new program. The goals of the program are to learn the scientific method and experimental techniques, build a record of high-impact publications, develop close mentoring relationships, see research as part of the career of an academic surgeon, and sustain excellence in both clinical care and research. It is designed for individuals who will eventually get NIH funding on research to improve human health. Dr. Oghalai explained the holistic process of selecting candidates, which involves their scholarly records, an interest in research for a career, their fit with the research of the faculty, leadership and professional/interpersonal skills, whether they come from a disadvantaged background, and whether they come from groups underrepresented in medicine.

Dr. Oghalai said that the students do the research component before they do the five years of clinical training. This molds the students as researchers, but they still spend 20% of their time doing clinical research in the first two years; they also spend 25% of their time on research in their fourth clinical year. The hope is that the residents can develop their research in the first two years, finish their publications, and develop a draft of a K08 application. As faculty, they can use the K08 grant for preliminary data for R01 and then get R01 funding.

Dr. Oghalai said that medical students spend one year doing full-time research, usually between Years 2 and 3 or between Years 3 and 4. The program takes medical students from any institution, and there is outreach to medical schools with underrepresented populations.

Dr. Oghalai said that medical students want multiple publications to differentiate themselves, but this program emphasizes quality over quantity (i.e., one impactful study rather than multiple publications). He sees a benefit of this training grant allowing this type of focus. The program has the standard training activities that have already been discussed. The clinical experience is done one day a week rather than in a block in two-month rotations. This program has set up a CSTP seminar series, which is open to a wider audience and meets monthly. Dr. Oghalai explained how the CSTP dovetails with the Hearing and Communication Neuroscience Training Program. All faculty are R01 funded, except for one member. This ensures that trainees are well supervised. As in the other programs, there are multiple mentors. Dr. Oghalai showed

current students and briefly described their research. He said that the students have all been productive and that this program has increased collaboration between his department and faculty in affiliated departments. There is a good demographic mix among CSTP students and residents. Based on a yearly survey, the students appear to be happy.

Discussion

Dr. Lalwani said he thought that the issue of the timing for the research experience was very important. Most medical students take one or two gap years before going to medical school. Some specialties expect their students to produce 20 papers, and many students do a research year to help accomplish this. All this training is raising the age of R01 applicants. Dr. Lalwani liked the idea of a K pathway as part of a student's fellowship. He thought that research training should occur closer to the time that the student seeks a job. Dr. Lalwani said he does not know the right answer, but he thinks there has been a huge transition when it comes to the optimal timing for training. He looks forward to seeing how Dr. Oghalai's model will work, with a successful K08 transition. Dr. Lalwani said that creating the pipeline but not making people so old that they lose interest is a challenge for Dr. Tucci and NIDCD. Dr. Oghalai agreed, saying that students will need to stay engaged with the laboratory during their additional five years of clinical training or the model will not work. Dr. Tucci expressed that she thought that the continued engagement with research through the rest of the residency is really important.

Dr. Tucci said that there are funds in this award to pay a technician, and she asked Dr. Oghalai whether these funds were used to keep students in the lab. Dr. Oghalai said that they were used and that he had institutional support as well.

Dr. Tucci thanked all the presenters and said she looked forward to seeing how these programs develop in the future.

New Council Member Presentation .....Dr. Dan Merfeld

Dr. Merfeld described himself as a vestibular scientist. The vestibular system consists of organs in the inner ear next to the cochlea. He said that his early research had looked at how the brain deciphers what direction is down and when we are moving translationally. The brain couples information from the vestibular system with information from other senses to resolve this ambiguity. The vestibular model does four things for us: It helps ensure that blood reaches the brain; the vestibulo-ocular reflex helps us see while we are moving to create a stable vision of the external world when we move our heads (this reflex led to an attempt to create a vestibular implant, analogous to the cochlear implant); it helps our balance (e.g., it enables us to close our eyes and stand on one leg); and it helps with spatial orientation (e.g., how a person perceives rotational and translational motion). Understanding the vestibular system is important for public health because approximately 40% of the population will confront problems in the vestibular system (e.g., balance issues) at some point, and about 30% of those who go to a clinic with these problems are not diagnosed based on the best measurement and science. Dr. Merfeld's research has focused on bringing these tools into the clinic so that patients can be better diagnosed, but he thinks that more research is still needed. He noted that only four vestibular balance grants in this section were higher than the payline; this is not enough research to sustain a community.

Dr. Merfeld said that all vertebrates have vestibular systems, which means that it is fundamental. Humans, jellyfish, and even plants need to sense gravity in order to survive. For humans, falls are the leading cause of accidental death in older adult where each year, 1 in 4 older adults fall. The medical cost from falls is more than $50 billion a year.

Dr. Merfeld said, "Vestibular is to balance as hearing is to speech." What a person hears affects what they say in response. In the longer term, hearing guides learning. Analogously, the vestibular system contributes to reflexive responses for balance, as well as to learning about balance over time. To show schematically how the vestibular system contributes to balance, Dr. Merfeld showed a schematic in which the signal was clear (no "noise") and a schematic in which the signal was not clear (high "noise"). With a clear signal, a

person will stay balanced; with an unclear signal, there is a higher likelihood of a fall because individuals sway more.

Dr. Merfeld is now working on an R01 funded through a joint call from the National Institute on Aging (NIA) and NIDCD. His research is examining how the vestibular system contributes to balance and how balance contributes to falls. Specifically, Dr. Merfeld's team is measuring noise level and postural sway, with the hypothesis that higher vestibular noise contributes to higher sway. In a preliminary study of 54 adults between the ages of 18 and 84, the amount of sway was measured and found to be moderately correlated. Dr. Merfeld and colleagues are now trying to collect data on 200 individuals and develop ways to improve vestibular threshold, which may improve balance.

Discussion

Dr. Lalwani asked whether the situation described by Dr. Merfeld was like auditory processing disorder, wherein the tests are normal, but people complain that they cannot hear well. Dr. Lalwani asked whether there could be a vestibular processing disorder with good inputs but bad processing. Dr. Merfeld agreed that the inputs are important, but he said that what the brain does with those inputs is important as well. He thought that what Dr. Lalwani suggested was probably the case, but more research needs to be done on this issue.

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

Dr. Cooper, the director of the Division of Scientific Programs (DSP) at NIDCD, explained that DSP program officers and medical officers engage with the extramural scientific community on research and research training. They also promote the NIDCD mission within trans-NIH initiatives and serve as subject matter experts. Dr. Cooper also introduced the two newest members of the Division: Dr. Mary Ejiwale, a data science program officer, and Dr. Samah Jafari, a medical officer—who will oversee clinical trials.

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

Dr. Wagenaar-Miller announced the retirement of two members of the Division of Extramural Activities (DEA): Dr. Shiguang Yang, a scientific review officer, and Mr. Chris Myers, the chief grants management officer. Dr. Wagenaar-Miller personally thanked them both for their contributions to NIH and NIDCD. She welcomed three new staff to DEA: Ms. Ciara Hanshaw, an extramural support assistant; Ms. Samantha Tempchin, the new Chief Grants Management Officer who has a master's degree in library science; and Dr. Martin Basch, a new Scientific Review Officer.

Dr. Wagenaar-Miller then provided updates about NIH policies and announcements. She summarized the FDA-NIH Request for Information on a new resource for terminology in clinical research. A task force has identified 37 terms that are used inconsistently in clinical research. The task force wants feedback on whether any of these terms should be removed or if new terms should be added. Dr. Wagenaar-Miller asked those at the meeting to review the resource that has been created and provide input by the deadline of June 24, 2024.

Dr. Wagenaar-Miller reported on the increases for National Research Service Award Stipends and Childcare Subsidies (NOT-OD-24-104). With this increase, NIH has now provided the largest year-over-year increase in recent history. Over the course of three to four years, the stipend will reach the recommended $70,000, depending on NIH appropriations.

Dr. Wagenaar-Miller said that there will be a number of grant application and review changes (NOT-OD-24-084). The changes are substantial and described in a 25-minute video: Plugging Into NIH: Conversations and Connections -Overview of Grant Application and Review Changes. Also, three webinars have been designed based on the changes: These occurred or will occur on April 17, 2024, June 5, 2024, and September 19, 2024.

Dr. Wagenaar-Miller said that NIH is simplifying the peer-review framework for fellowship applications (NOT-OD-24-107). The focus of the review will now be on the candidate, specifically the candidate's goals and preparedness; the research training plan; and the commitment to the candidate (with a focus on mentoring). Also, the application for fellowships will be restructured (e.g., grades are not required or allowed), and Dr. Wagenaar-Miller recommended reviewing these changes prior to submitting an application.

Dr. Wagenaar-Miller provided links to several useful resources: NIH Open Mike, CSR Review Matters, Fellowship Changes, and Simplified Peer Review Framework. She also provided the link to the NIDCD Peer Reviewer Interest Form to allow individuals to self-nominate for NIDCD peer review meetings.

Dr. Wagenaar-Miller thanked all the DEA staff.

Closing Comments.....Dr. Tucci

Dr. Tucci concluded the meeting by thanking everyone for their attendance and contributions and wished everyone safe travels home. The next meeting is scheduled for September. The meeting was adjourned at 4:21 p.m.

Certification of Minutes

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

Rebecca A. Miller -S
Digitally signed by Rebecca A. Miller -S
Date: 2024.10.01 13:44:38 -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: 2024.09.25 17:00:06 -04'00'

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

Brooke Sydnor
Council Assistant
NDCD Advisory Council

[2] These minutes will be approved formally by the Council at the next meeting, on September 12 and 13, 2024. Corrections or notations will be stated in the minutes of that meeting.

Appendices

Appendix 1 - Roster

Appendix 2 - Budget

Appendix 3 – Attendance Closed Session

Appendix 4 – Attendance Open Session

Appendix 1

Roster
National Deafness and Other Communication Disorders Advisory Council
(Terms end on 5/31 of the designated year)
Chair
Debara L. Tucci M.D., Director
National Institute on Deafness and Other Communication Disorders
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BOUTON, Katherine 2026
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Ex Officio

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Department of Health and Human Services
Washington, DC 20201

BERTAGNOLLI, Monica M., M.D.
Director
National Institutes of Health Bethesda, MD 20892

Executive Secretary

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

Appendix 2

National Institute on Deafness and Other Communication Disorders (NIDCD)

FY 2023 Actuals vs FY 2024 Operating Plan
(Dollars in thousands)

Mechanism	FY 2023 Actual		FY 2024 Plan	
	Number	Amount	Number	Amount
Research Projects				
Noncompeting	576	$263,385	**577**	**$267,943**
Administrative Supplements	*(65)*	$6,081	*(46)*	$3,500
Competing	183	$87,738	**177**	**$84,470**
Subtotal, RPGs	759	$357,204	754	$355,913
SBIR/STTR	19	$16,401	19	$16,400
Research Project Grants	778	$373,605	773	$372,313
Research Centers				
Specialized/Comprehensive	7	$18,515	**6**	**$15,717**
Clinical Research	0	$0	0	$28
Biotechnology	0	$0	0	$0
Comparative Medicine	0	$0	0	$0
Res. Centers in Minority Inst.	0	$0	0	$0
Subtotal, Centers	7	$18,515	6	$15,745
Other Research				
Research Careers	67	$10,891	68	$11,064
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	44	$9,251	**49**	**$10,385**
Subtotal, Other Research	111	$20,142	117	$21,449
Total Research Grants	896	$412,262	896	$409,507
Training				
Individual	136	$6,655	**136**	**$6,990**
Institutional	143	$9,096	**143**	**$8,386**
Total, Training (FTTPs and Award)	279	$15,751	279	$15,376
Research & Develop. Contracts	44	$23,217	**45**	**$26,250**
SBIR/STTR (non-add)	*(0)*	*($216)*	*(0)*	*($0)*
Intramural Research	58	$56,359	**64**	**$56,500**
Res. Management & Support	76	$26,742	**76**	**$26,700**
		0		0
Total, Program Level		**$534,330**		**$534,333**

Appendix 3
NIH Staff Present Closed Session

Chris Adams
Aruna Behera (CSR)
Nadine Bikim
Laura Cole
Judith Cooper
Janet Cyr
Hoai Doan
Mary Ejiwale
Nancy Freeman
Maria Garcia
Ciera Hanshaw
Sara Hargrave (CSR)
Rochelle Hentges (CSR)
LaTanya Holmes
Samah Jafari
Andrea Kelly
Lisa Kennedy
Kelly King
Trinh Ly
Jeanne McCaffery (CSR)
Eddie Myrbeck
Stephanie Nagle
Emmens (CSR)
Sonia Nanescu
Amy Poremba
Kausik (Bobby) Ray
Alberto Rivera-Rentas
Cathy Rowe
Merav Sabri
Jaclyn Schurman
Elka Scordalakes
Rass Shayiq (CSR)
Nanette Stephenson
Melissa Stick
Holly Storkel
Susan Sullivan
Brooke Sydnor
Samantha Tempchin
Dawn Walker
Bracie Watson
Evan Wicker
Eric Williams
Shiguang Yang

Appendix 4
NIH Staff Present Open Session

Kathy Bainbridge
Nadine Bikim
Alec Callahan
David Cheng Melendez
Laura Cole
Judith Cooper
Lisa Cunningham
Janet Cyr
Hoai Doan
Mary Ejiwale
Nancy Freeman
Sheri Grabus
Ciera Hanshaw
Howard Hoffman
LaTanya Holmes
Samah Jafari
Tanji Johnson
Joanne Karimbakas
Andrea Kelly
Lisa Kennedy
Kelly King
Chuan-Ming Li
Trinh Ly
Sherly Michel
Roger Miller
Chris Myers
Hua Ou
Amy Poremba
Alberto Rivera-Rentas
Heidi Rosvold-Brenholtz
Cathy Rowe
Joni Rutter
Merav Sabri
Elka Scordalakes
Jaclyn Schurman
Katherine Shim
Wei Song
Shirley Simson
Nanette Stephenson
Melissa Stick
Holly Storkel
Susan Sullivan
Brooke Sydnor
Jean Verheyden
Dawn Walker
Bracie Watson
Evan Wicker
Eric Williams
Doris Wu
Shiguang Yang

Other NIH Staff:
ASL Interpreter Rivka
ASL Interpreter Kristina Riley
ASL Interpreter Katelyn Mathis