# NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS ADVISORY COUNCIL

## September 13, 2019

# National Institutes of Health Bethesda, MD

## **MINUTES**

The National Deafness and Other Communication Disorders Advisory Council convened on September 13, 2019 at 6001 Executive Blvd., Room C/D at the National Institutes of Health (NIH), Bethesda, MD. Dr. Debara L. Tucci, Director, National Institute on Deafness and Other Communication Disorders (NIDCD), served as Acting Chairperson. In accordance with Public Law 92-463, the meeting was:

Closed: September 13, 2019: 8:30 a.m. to 11:05 a.m. for review of individual grant applications and Board of Scientific Counselors update; and

Open: September 13, 2019: 11:05 a.m. to 1:45 p.m., for the review and discussion of program development needs and policy.

## Council members in Attendance1:

Ms. Lisa Adams Dr. Sue Kinnamon Dr. John Carev Ms. Nanci Linke-Ellis Dr. Ruth Anne Eatock Dr. Cynthia Morton Mr. Richard Einhorn Dr. Dan Sanes Dr. Susan Ellis-Weismer Dr. Neil Seail Dr. H. Steven Sims Dr. Lisa Goffman Dr. Sandra Gordon-Salant Dr. Ben Strowbridge Dr. Robert Hillman Dr. Charlotte Yeh Ms. Barbara Kelley Dr. Fan-Gang Zeng

### Council members absent:

None

Council ex-officio members in Attendance:

Ms. Christa Themann Dr. LaKeisha Henry Dr. Judy Schafer

The complete Council roster is found in Appendix 1.

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

## NIDCD employees present during portions of the meeting:

Dr. Kathy Bainbridge Mr. James Burton Dr. Laura Cole Dr. Judith Cooper

Ms. Susan Dambrauskas

Mr. Hoai Doan Dr. Nancy Freeman Ms. Maria Garcia Dr. Andrew Griffith Ms. LaTanya Holmes Dr. Craig Jordan Dr. Kelly King Ms. Tanjier Belton Dr. Chuan-Ming Li Ms. Lonnie Lisle Dr. Trinh Ly Mr. Vivek Kamath Ms. Joanne Karimbakas Ms. Laura Mannella

Dr. Castilla McNamara

Ms. Phalla Messina

Dr. Roger Miller Ms. Kristen Mullsteff Mr. Eddie Myrbeck Mr. Christopher Myers

Mr. Eric Nunn

Dr. Amv Poremba Dr. Alberto Rivera-Rentas Dr. Elka Scordalakes Dr. Lana Shekim Dr. Kathy Shim Dr. Melissa Stick Dr. Susan Sullivan Ms. Kelli Van Zee Dr. Bracie Watson Ms. Ginger Webb Mr. Timothy Wheeles Mr. Eric Williams Mr. Baldwin Wong Dr. Carter Van Waes

Dr. Shiguang Yang

Other federal employees present during portions of the meeting:

Dr. Biao Tian, CSR

Dr. Janita Turchi, CSR

Dr. Alexei Kondratyev, CSR

Dr. Andrea Kelly, CSR

Members of the public present during open portions of the meeting:

Dr. Christopher Platt

Ms. Alissa Parady, International Hearing Society

Ms. Joy Onozuka, American Tinnitus Association

Ms. Kitty Werner, American Academy of Audiology

Ms. Jen McCulley, IQ Solutions

Ms. Lisa Chutiian, AG Bell

Ms. Torryn Brazell, American Tinnitus Association

## **CLOSED SESSION**

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

## Procedural Matters

Dr. Jordan 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. Jordan announced that the Council meeting would be closed for consideration of grant applications during the morning session, but would be open to the public at approximately 11:00 a.m.

## III. Council Consideration of Pending Applications

## A. Research Project Grant Awards

Consideration of Applications: On the Council's agenda was a total of 115 investigator-initiated R01 grant applications; 101 applications had primary assignment to NIDCD, in the amount of \$37.3 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 13<sup>th</sup> percentile.

## **B.** Special Programs Actions

- 1. NIH Mentored Career Development Award Research and Training (K01): The Council recommended support of two applications.
- 2. NIH Mentored Patient-Oriented Research Career Development Award (K23): The Council recommended support of one application.
- 3. NIH Midcareer Investigator Award in Patient-Oriented Research (K24): The Council recommended support of one application.
- 4. NIH Pathway to Independence Award (K99): The Council recommended support of two applications.
- 5. NIH Support for Conferences and Scientific Meetings (R13): The Council recommended support of four primary applications.
- 6. NIH Exploratory/Development Research Grant Award (R21): The Council recommended support of five applications.
- 7. NIDCD Early Career Research (ECR) Award (R21): The Council recommended support of eleven applications

- 8. NIDCD Clinical Research Grant (P50): The Council recommended support of one application.
- 9. NIH Small Business Innovation Research Awards (SBIR): The Council recommended support for eight Phase I (R43) applications in an August email vote.
- 10. NIH Small Business Innovation Research Awards (SBIR): The Council recommended support of two Phase II (R44) applications in an August email vote.
- 11. Early Screening for Autism Spectrum Disorder (RFA-MH-19-120): The Council recommended co-fund support of one application.
- 12. Promoting Research on Music and Health: Fundamentals and Applications (RFA-NS-19-008): The Council recommended co-fund support of one R01 application in a September email vote.
- 13. Promoting Research on Music and Health: Fundamentals and Applications (RFA-NS-19-009): The Council recommended co-fund support of one R21 application in a September email vote.

## IV. Report of the Board of Scientific Counselors .......Dr. Andrew Griffith

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

Dr. Griffith presented Reports of the BSC regarding the review of several intramural laboratories. He then presented his responses to the reports and responded to questions from Council.

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

## **OPEN SESSION**

## V. Opening Remarks ......Dr. Tucci

Dr. Tucci welcomed additional staff and visitors to the open session of the meeting. Dr. Tucci shared brief remarks about her family and her history in the scientific community. She detailed her educational background and research interests before sharing her vision for the future at the NIDCD. Lastly, she thanked Drs. Judith Cooper and Andrew Griffith for their leadership to the institute during the last 15 months.

## Consideration of Minutes of the Meeting of May 17, 2019

Dr. Tucci called the members' attention to the minutes of the May 17, 2019 meeting of the Advisory Council. The minutes were approved as written.

## Confirmation of Dates for Future Council Meetings

Dates for the Council meetings through September 2021 have been established. A list of these meetings was distributed to the Council members and posted on the web site prior to this meeting. The next meeting of the Council is scheduled for Friday, January 31, 2020.

## Recognition of New Members

- Ruth Anne Eatock is Professor of the Department of Neurobiology and Dean of Faculty Affairs, Biological Sciences Division at the University of Chicago. She received her doctoral degree in Biology from California Institute of Technology. Her research focuses on sensory signaling by hair cells and neurons in the inner ear. Dr. Eatock has a long history of involvement in mentoring programs with organizations such as Society of Neuroscience, Association for Research in Otolaryngology, and Gordon Research Conferences. She also has experience in peer review including former Chair of the Hearing Research Study Section. Dr. Eatock is a member of several professional societies such as Society for Neuroscience, American Physiological Society and Association for Research in Otolaryngology. She is published widely and has served on many editorial boards such as the Journal of Neuroscience.
- Lisa Goffman is Professor and Nelle Johnston Chair in Early Childhood Communication Disorders, Behavioral and Brain Sciences at University of Texas at Dallas. She received her doctoral degree from Purdue University. Her research interests are in integration of language and action into new accounts of developmental language disorders, including specific language impairment, speech sound disorders, and autism. Dr. Goffman is a leading researcher in the area of language and motor interactions in typical and atypical language development. She has identified how deficits in language (words and grammar) and action (gestures and music) in children share common underlying principles of sequential learning. Dr. Goffman is a Fellow of the American Speech, Language and Hearing Association. She is a frequent presenter at scientific meetings, is widely published and has served on numerous peer review and editorial boards, including Associate Editor for Language and Speech.
- Barbara Kelley is Executive Director at the Hearing Loss Association of America. She has an extensive background in advocating for individuals with hearing loss. Her interests include managing programs, fundraising, advocacy, marketing/media relations, and community outreach. She has been an integral part of HLAA for the past 30 years. She has held various positions at the HLAA, including Deputy Executive Director and Director of Publications. Ms. Kelley serves on advisory boards including the Disability Advisory Committee as Co-chair for the Federal Communications Commission. She has published many articles on hearing loss and made many presentations.
- Dan Sanes is Professor of the Center for Neural Science, Department of Biology at New York University and Professor in the Department of Psychology. He is also Professor in the Neuroscience Institute at New York University Langone Medical Center. Dr. Sanes received his doctoral degree in Biology from Princeton University. His research interests include the development and plasticity of the auditory system. His lab studies the development and function of brain circuits that encode auditory cues, and the emergence of adult perceptual skills. Dr. Sanes is a leading researcher in the study of hearing loss during development. His studies have shown how early hearing loss affects brain development and how the developmental deficits, caused by deafness, might be reversed. He is a member of

professional organizations including the Association for Research in Otolaryngology, the Society for Neuroscience and, the Acoustical Society of America. Dr. Sanes is published widely and is a sought-after lecturer and presenter on auditory neuroscience and auditory processing.

• Ben Strowbridge is Professor of the Departments of Neurosciences and Physiology/Biophysics at Case Western Reserve University. He received his doctoral degree in Neuroscience from Yale University. His professional interests focus on understanding how small groups of neurons in the central nervous system function together. Dr. Strowbridge is involved in mentoring students and has received many honors and awards. He is a member of professional organizations including the Society for Neuroscience. Dr. Strowbridge is published widely and often an invited lecturer.

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NIH policy requires that the National Advisory Council for each institute review the activities of their respective intramural program once a year. Dr. Andrew Griffith, Scientific Director of NIDCD's Division of Intramural Research, presented the 2019 report.

The intramural program is currently composed of seven tenured investigators, two tenure-track investigators, and five surgeon scientists along with a large contingent of supporting scientists. Two tenured investigators, Drs. Richard Chadwick and Dennis Drayna retired in the summer of 2019.

Oversight for the Intramural program is managed by the Board of Scientific Counselors. Dr. Paul Manis recently took over the Chair position. The current eight members of the BSC is composed of prominent researchers including several past Advisory Council members.

Dr. Griffith provided information about the NIDCD's Otolaryngology Surgeon-Scientist Program that is geared toward an integration of clinical and basic research opportunities in a mentored environment. The goal is to provide early career faculty development through graduated independence and resources. In addition, the intramural program provides a culture of scholarly inquiry and scientific rigor in conjunction with opportunities to maintain their important surgical skills. He also noted the strategic relationships for NIDCD with three local hospitals including the Walter Reed National Military Medical Center (WRNMMC), Suburban Hospital and Georgetown University where these surgeon-scientists can not only build their skills as researchers, but also as surgeons in the field of otolaryngology. The WRNMMC includes an otolaryngology residency program that also contributes residents into this strategic relationship. Dr. Nyall London is the newest member to join this surgeon/scientist program and brings his experience with olfactory neuroblastomas, tumor immunity, and genetic mutations.

The fifth EARssentials course was held in July 2019 at the Porter Neuroscience Research Center with the focus being, "Concepts and Techniques of Contemporary Hearing Research." The primary target audience was new NIDCD intramural trainees; however, the course was offered free of charge and was open to any interested individual, even scientists from outside the NIH. The week-long course included morning lectures and afternoon laboratory sessions. In 2019, several laboratory slots were reserved for extramural trainees and attendees included individuals from nine extramural research organizations and industry labs from across the country.

#### 

Dr. Carter Van Waes, Clinical Director at NIDCD, provided an overview of the NIDCD Intramural laboratory and clinical research, characterizing them as highly integrated and collaborative with connections in government, university and with biomedical industry partners. The NIDCD Otolaryngologist Surgeon Scientist program enhances career development of a next generation of clinical investigators and enables bench/bedside investigation of promising hypotheses and new interventions for prevention and therapy.

The protocols in the Intramural laboratory span the mission areas of the NIDCD. Dr. Van Waes highlighted ongoing efforts within three broad areas of research: Hearing and Balance, Voice and Speech, and Taste. Dr. Van Waes provided additional details on several of these efforts.

In the hearing and balance area he summarized work in the Section on Sensory Biology focused on the premise that statins (approved for high cholesterol treatment) may reduce cisplatin-induced hearing loss in humans. Studies have progressed from retrospective data analysis to prospective study in head and neck cancer patients. In the Molecular Biology and Genetics Section, studies have investigated a novel nonsyndromic hearing loss locus and identified a mutation in a gene called NLRP3. This gene regulates activation of interleukin 1 $\beta$  (IL-1 $\beta$ ), a potent pro-inflammatory cytokine and current studies are investigating the potential impact on syndromic family members and signs of systemic inflammation and hearing loss. The Inner Ear Gene Therapy Program is focused on developing a Whirlin gene therapy to the inner ear to enable stereocilia development in cochlea and vestibular hair cells. Experiments in animals have indicated that the gene therapy has improved hearing and reduced balance symptoms. Next directions will include study of families with autosomal dominant hearing loss and determining the feasibility of knocking out the mutant allele in human fibroblast cells.

In the voice and speech area he summarized work being done collaboratively by the Tumor Biology Section, Translational Tumor Immunology Program, and the Integrative Therapeutics Program with the goal of enhancing the immune response by therapeutic targeting of papillomas and cancers affecting human communication. Areas under investigation include cytotoxic therapies to enhance tumor antigen processed by antigen presenting cells, activation and expansion of endogenous or T cell receptor Engineered Antigen-specific T-lymphocytes, and how immune checkpoint and Inhibitors of apoptosis proteins (IAP) might enhance killing of tumor cells by Antigen-specific T-lymphocytes. He presented evidence that immune checkpoint inhibitor, Avelumab, reduces laryngeal papillomas and surgical interventions. He also described a newly opened dose escalation study for the inhibitor of IAP, Birinapant with radiation therapy in patients with recurrent head and neck cancer.

Dr. Van Waes closed by mentioning two other research projects that he would not be able to expand upon. The first involves human stuttering mutations that were engineered into mice and result in deficits in vocalization and the corpus callosum. The second is in the area of taste and is examining a novel African MRGXPR4 gene haplotype associated with menthol cigarette smoking.

#### 

NIDCD's Budget Officer, Mr. Eric Williams, presented information on three topics; current budget, success rates, and budget outlook. The current budget information consisted of a side-by-side comparison of NIDCD's fiscal year 2018 and 2019 mechanism tables. These tables provide a break-down of primary budget activities and their associated budgeted dollars and grant counts. The success rate information consisted of two charts comparing NIDCD's Research Project Grants (RPGs) and Fellowships (F's) success rates versus the NIH average from fiscal years 2010 through 2018. The tables included a likely projection for fiscal year 2019. The budget outlook information consisted of three proposed fiscal year 2019 budgets: the President's 2020 Budget Request of \$408,358, the House Mark-up for 2020 of \$497,590 and the Senate Mark-up which was still to be determined as of this meeting date.

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

## IX. NIDCD's Program on Accessible and Affordable ............... Drs. Laura Cole & Kelly King Hearing Health Care: 10 Years Later

Drs. Laura Cole and Kelly King provided an overview of the NIDCD's efforts over the last 10 years to advance the science of accessible and affordable hearing health care for adults. Hearing loss was defined as a public health issue and, as the lead federal agency promoting the Nation's hearing healthcare, the NIDCD has the responsibility to address it. Beginning in 2009 with an NIDCD-sponsored workshop, the Institute developed a broad research agenda that has, to date, been supported by 12 funding opportunity announcements (FOAs) targeting science in this area, including three that remain active. Forty grants that were responsive to this call have been awarded over a 10-year span and the Institute tracks and highlights these awards on the NIDCD website. NIDCD's involvement with and support of activities with the National Academies of Sciences, Engineering, and Medicine (NASEM) include sponsorship of a workshop on hearing loss and healthy aging in 2014 and a landmark consensus study on access and affordability of hearing healthcare for adults that was published in 2016. The Institute continues to collaborate with NASEM and other federal stakeholders to advance the recommendations that resulted from the 2016 consensus study. Dr. Cole provided a snapshot of the institute's portfolio in this area and feedback from a recent Office of Management and Budget-approved survey to grantees that noted, among other findings, that FOAs published in this area encouraged the research community to take their research in this direction. Dr. King concluded by highlighting some of the regulatory changes in recent years and legislative action that will result in a first-of-its-kind category of over-the-counter hearing aid. NIDCD-funded science was used to inform the legislative process. Continued collaborations with other federal partners including the Federal Trade Commission and the Food and Drug Administration were highlighted.

## 

Dr. Cooper introduced Drs. Lana Shekim and Kelly King who presented the ongoing efforts at NIH and NIDCD to engage with the World Health Organization (WHO).

Context was provided highlighting how NIH leadership has prioritized participation in global health for many years. Dr. Shekim described NIH's active role in supporting and conducting research and research training in medical rehabilitation through the National Center for

Medical Rehabilitation Research (NCMRR) and how NCMRR has participated with WHO and global rehabilitation stakeholders. Dr. King provided background and an update on WHO's efforts to develop the first ever World Report on Hearing that will launch in May 2020 in conjunction with the World Health Assembly. NIDCD supports WHO in their efforts to develop the World Report, which will emphasize to policy makers and global stakeholders that hearing care should be a public health priority.

#### 

Dr. Jordan provided a virtual tour of the NIH Research Portfolio Online Reporting Tools (RePORT), a tool that consolidates all information about NIH-supported extramural organizations. RePORT provides public access to reports, data and analysis of NIH research activities, including information on NIH expenditures and the results of NIH supported research. (https://report.nih.gov/)

Dr. Jordan pointed out the Matchmaker tool used to find program officials or similar projects and demonstrated a query using the term "genetics of hearing and deafness" searching for similar projects. This tool may be useful for identifying related areas of research, where such projects are peer reviewed and which NIH Program Officers manage related portfolios of awards.

He outlined multiple ways to access grant award data including how to use the Query screen to find R01 projects limiting them by state, funding component, and other parameters. Next he demonstrated new ways to visualize information and drill down into topic areas using the "Circle Visualization" tool.

Finally, Dr. Jordan highlighted Frequently Requested Reports where there are pull-down menus that can be used to access a wide array of preexisting reports. Filters on the query screen can be utilized to target and retrieve only those reports of interest. He utilized the features to pull down reports of application success rates across a wide array of grant mechanisms and institutes. He then used that data to compare success rates across mechanisms and rates at NIDCD versus NIH average rates.

## XII. Closing Comments

None.

## XIII. Adjournment

The meeting was adjourned at 1:30 p.m. on September 13, 2019.

## XIV. Certification of Minutes

We certify that, to the best of our knowledge, the foregoing minutes and attachments are accurate and correct<sup>2</sup>.

10/25/2019

/Craig A. Jordan/

Craig A. Jordan, Ph.D. Executive Secretary National Deafness and Other Communication Disorders Advisory Council

10/25/2019

/Debara L. Tucci/

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

Director
National Institute on Deafness and
Other Communication Disorders

Ginger Webb Council Assistant NDCD Advisory Council

<sup>2</sup> These minutes will be approved formally by the Council at the next meeting on January 31, 2020, and corrections or notations will be stated in the minutes of that meeting.

## **APPENDICES**

APPENDIX 1	NDCD Advisory Council Roster	. 12
APPENDIX 2	NIDCD Director's Report Slides	.14

### Roster

## **National Deafness and Other Communication Disorders Advisory Council**

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

Acting Chairperson

Debara L. Tucci, M.D., M.S., M.B.A., Director National Institute on Deafness and Other Communication Disorders Bethesda, MD 20892

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### **Ex Officio**

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## **Executive Secretary**

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COLLINS, Francis S., Ph.D., M.D. Director
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# NIDCD Council Budget Report

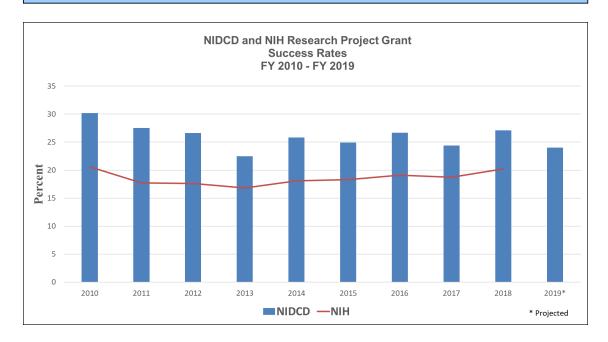
Eric Williams, Budget Officer NIDCD Advisory Council Meeting September 13, 2019

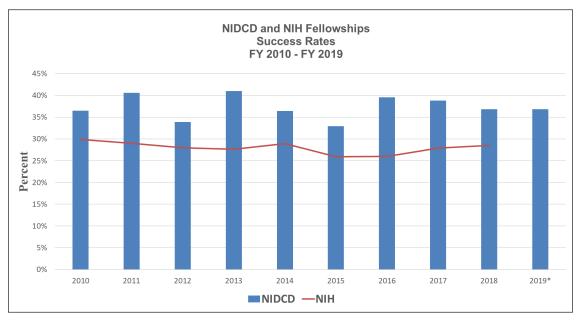
## **National Institute on Deafness and Other Communication Disorders (NIDCD)** Comparing FY 2018 and FY 2019 Operating Plans (Dollars in thousands)

	FY 2018			FY 2019	
5	Final All			ng Plan*	
Budget Mechanism	Number	Amount	Numbe	r Amount	
Research Projects	-			-	
Noncompeting	586	\$231,567	624	\$251,850	
Admin. Supplements	38	2,954	30	2,200	
Competing	228	93,186	195	81,278	
Subtotal	814	327,707	819	335,328	
SBIR/STTR	36	14,423	37	14,586	
Subtotal, RPG's	850	342,130	856	349,914	
Research Centers	5	11,652	5	11,978	
Other Research	72	10,210	77	10,958	
Total Research Grants	927	363,992	938	372,850	
Individual Training	130	5,894	132	6,248	
Institutional Training	165	8,306	169	8,133	
R & D Contracts	37	18,155	41	19,665	
Intramural Research		41,489		42,500	
Research Mgmt. & Support		21,040		23,600	
TOTAL	-	\$458,876		\$472,996	
				*Projected	

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

# Historical Success Rates FY 2010 - FY 2019





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

## **FY2020 Budget Outlook**

(Dollars in Thousands)

• FY 2018 Enacted: \$459,974

FY 2019 Enacted: \$474,404

• FY 2020 President's Budget: \$408,358

FY 2020 House Mark-up: \$497,590

FY 2020 Senate Mark-up: TBD