

NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS

ADVISORY COUNCIL

May 29, 2020

National Institutes of Health

Bethesda, Maryland

MINUTES

The National Deafness and Other Communication Disorders Advisory Council (NDCDAC) convened on May 29, 2020 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 Acting Chairperson. In accordance with Public Law 92-463, the meeting was:

Closed: May 29, 2020: 9:00 a.m. to 10:30 a.m. for review of individual grant applications; and

Open: May 29, 2020: 10:30 a.m. to 12:55 p.m., for the review and discussion of program development needs and policy.

Council members in attendance¹:

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

Council Members Absent:

None

Ad-Hoc Council Members in attendance:

Dr. Sue Kinnamon
Dr. Andrew Groves

Council ex-officio members in attendance:

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

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

NIDCD employees present during portions of the meeting:

Dr. Kathy Bainbridge	Mr. Christopher Myers
Mr. James Burton	Mr. Eric Nunn
Dr. Laura Cole	Dr. Amy Poremba
Dr. Judith Cooper	Ms. Lisa Portnoy
Dr. Janet Cyr	Dr. Kausik Ray
Ms. Susan Dambraskas	Dr. Alberto Rivera-Rentas
Mr. Hoai Doan	Dr. Elka Scordalakes
Ms. Emma Eggerman	Dr. Lana Shekim
Dr. Nancy Freeman	Dr. Kathy Shim
Ms. Maria Garcia	Dr. Sheo Singh
Mr. Howard Hoffman	Dr. Melissa Stick
Dr. Craig Jordan	Dr. Susan Sullivan
Ms. Joanne Karimbakas	Ms. Nanette Stephenson
Dr. Kelly King	Dr. Debara Tucci
Ms. Mimi Lee	Dr. Bracie Watson
Dr. Chuan-Ming Li	Mr. Mitchell Wainberg
Dr. Trinh Ly	Ms. Ginger Webb
Dr. Castilla McNamara	Mr. Eric Williams
Dr. Roger Miller	Mr. Baldwin Wong
Mr. Eddie Myrbeck	Dr. Shiguang Yang

Other federal employees present during portions of the meeting:

Dr. Biao Tian, CSR
Dr. Alexei Kondratyev, CSR
Dr. Andrea Kelley, CSR
Dr. John Bishop, CSR
Dr. Maribeth Champoux, CSR

CLOSED SESSION

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. Craig A. Jordan

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 and would be open to the public at approximately 10:30 a.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 113 investigator-initiated R01 grant applications; 96 applications had primary assignment to NIDCD, in the amount of \$36.5 million first-year direct costs. It is anticipated that, of the applications competing at this Council, NIDCD will be able to award grants to R01 applications scoring up through the 13th percentile.

Special Program Actions

1. NIH Mentored Scientist Research Career Development Award (K01): The Council recommended support of one application.
2. NIH Mentored Patient-Oriented Research Career Development Award (K23): The Council recommended support of one application.
3. NIH Pathway to Independence Award (K99): The Council recommended support of two applications.
4. NIH Support for Conferences and Scientific Meetings (R13): The Council recommended support of six applications.
5. NIH Research Enhancement Award (R15): The Council recommended support of two applications.
6. NIH Exploratory/Development Research Grant Award (R21): The Council recommended support of nine applications.
7. NIDCD Early Career Research (ECR) Award (R21): The Council recommended support of ten applications.
8. NIH Small Business Innovation Research Awards (SBIR): The Council recommended support for three Phase I (R43) applications.

9. NIH Small Business Innovation Research Awards (SBIR): The Council recommended support of three Phase II (R44) applications.
10. NIH/NSF Collaborative Research in Computational Neuroscience (CRCNS) (R01): The Council recommended support of two applications.
11. Limited Competition: Consortium on Biomarker and Outcome Measures of Social Impairment for Use in Clinical Trials in Autism Spectrum Disorders (U01 Clinical Trial Not Allowed): The Council recommended co-fund support of one application.
12. NIH Common Fund Pilot Projects Investigating Understudied G Protein-Coupled Receptors, Ion Channels and Protein Kinases (R03 Clinical Trial Not Allowed): The Council recommended co-fund support of one application.

OPEN SESSION

Opening RemarksDr. Tucci

Dr. Tucci welcomed additional staff and visitors to the open session of the meeting which was available to the public from the NIH Videocast website. (<https://videocast.nih.gov/watch=37452>)

Dr. Tucci updated the council about some COVID-related flexibilities that are available for review on the NIH Grants website. The NIH and NIDCD is trying very hard through this time to give maximal flexibility to our investigators and our scientific community. Many initiatives are going on trans-NIH and NIDCD is participating in those initiatives as appropriate. Many of the initiatives have to do with developing treatments and vaccines for COVID. NIDCD has an interest in better understanding the issues around loss of taste and smell as a possible early indicator of the viral infection. NIDCD has published an initiative to capitalize on this recent finding.

Dr. Tucci thanked the following retiring members for their service on the Advisory Council and promised a certificate of appreciation by mail after the meeting. Each member was provided an opportunity to share with the Council their perspective on council service.

- Ms. Lisa Adams
- Dr. Susan Ellis-Weismer
- Dr. Lisa Goffman
- Dr. Sue Kinnamon
- Dr. H. Steven Sims

Consideration of Minutes of the Meeting of January 31, 2020

Dr. Tucci called the members' attention to the minutes of the January 31, 2020 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 2022 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, September 11, 2020.

[Executive Secretary Note: The September council meeting will be virtual and held in the afternoons of Thursday, September 10, 2020 from 12:00 p.m. until 4:00 p.m., and Friday September 11, 2020 from 10:00 a.m. until 2:00 p.m. EST.]

NIDCD Budget Report

NIDCD's Budget Officer, Mr. Eric Williams, presented information on the current and previous fiscal year budgets. He shared the NIDCD's 2020 Budget Operating Plan as compared against the FY 2019 final allocation. The FY2020 budget benefits from a \$18 M increase. That increase is largely applied to the out-year commitments of the grants awarded in prior years. The Administrative Supplements line has been increased to \$3 M which will allow support of anticipated supplemental requests related to the COVID-19 pandemic. He indicated that NIDCD will likely recoup some funds that would have been spent on travel and contracting efforts that will be scaled back due to the pandemic.

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

Report of the Division of Scientific Programs

Dr. Cooper presented concepts that represent the early planning stages for what might become initiatives (such as requests for applications or notices of special interest) or other activities (such as workshops or working groups). Concepts requiring clearance also may include scientific topics that NIDCD intends to continue using as vehicles for receipt of applications. Concepts are discussed with the NIDCD Advisory Council and through other public venues. The concepts presented at this meeting included:

Re-Issuances

- NIDCD Research Dissertation Fellowship for Au.D. Audiologists
- NIDCD Mentored Career Development Award for Post doctorate Au.D./Ph.D. Audiologists
- NIDCD Research Career Enhancement Award for Established Investigators
- NIDCD Cooperative Agreement for Clinical Trials in Communication Disorders NIDCD Clinical Trials in Communication Disorders

New Concept

- Research Training for Residency in Otolaryngology

Members unanimously approved the proposed concepts. Council approval of a concept does not guarantee that it will become an initiative. That decision would be based on scientific and programmatic priorities and the availability of funds.

From Sugar to Sweet: Transduction and Transmission of Taste

Dr. Tucci welcomed Dr. Sue Kinnamon to discuss her research on taste receptors. Dr. Kinnamon is Professor and Vice Chair of Research in the Department of Otolaryngology—Head & Neck Surgery at the Anschutz Medical Campus of the University of Colorado in Aurora. Research in her laboratory focuses on the mechanisms used by taste receptor cells to detect and transduce sweet, salty, sour, bitter and umami tastes, and how these qualities are transmitted to the nervous system. She uses a variety of approaches including

electrophysiology, calcium imaging, immunocytochemistry and molecular biology on various lines of transgenic mice.

In this talk Dr. Kinnamon described experiments done in close collaboration with Dr. Thomas Finger's laboratory in which they identified ATP as a crucial transmitter linking taste cells to sensory nerve fibers. Type II taste cells, those that respond to bitter, sweet, or umami release ATP via a large pore ATP release channel to activate purinergic P2X receptors on the sensory nerve fibers. Knockout or pharmacological blockade of the P2X receptors blocks all taste qualities, including sour taste which is mediated by Type III taste cells. The role of ATP in sour taste is still not clear, since these cells release serotonin via synaptic vesicles to activate 5-HT₃ receptors on the afferent nerves. However, all taste nerve fibers, including those with 5-HT₃ receptors, also express purinergic P2X receptors, and full activation requires ATP as well as 5-HT. Pharmacological blockade of P2X₃ receptors is a treatment for chronic cough in humans, and loss of taste is a common complaint in patients receiving this treatment.

Dr. Kinnamon also gave a short update on the global efforts to understand the role of COVID-19 in causing taste and smell loss.

Council Discussion: Recovery of NIDCD Research from COVID-19 Impacts

Dr. Tucci invited the council members to discuss the impact of COVID-19-related work stoppages on the NIDCD research enterprise and the hurdles in restarting research activities. The common assumption is that all research/training activities ranging from basic to clinical and translational science have been effectively halted or greatly curtailed. The focus of the discussion was to identify the consequences of the extensive hold on research activity and to advise on the prioritization of "re-start" activities germane to the four topic areas listed below:

- Basic Science moderated by Dr. Ruth Anne Eatock
- Clinical/Translational Science moderated by Dr. Sandra Gordon-Salant
- Training, Career Development, Early Stage Investigators (ESI) moderated by Dr. John Carey
- Administrative/Operational Hurdles moderated by Dr. Robert Hillman

Members were appreciative of the flexibilities NIH has made available, such as the flexibility to reassign MD trainees to clinical service and supporting researcher salaries regardless of their level of productivity. Members reported numerous challenges at their home institution including significant loss of institutional financial support, lack of consistent guidance on safety practices, when/how to reopen laboratories, onerous policies that are not seemingly evidenced based, IRBs focus limited to COVID-19 related protocols, redirecting research efforts to training and clinical service, and how to provide training traditionally done in a hands-on manner. Members expressed concerns for the training of future researchers and mentioned the critical nature of access to cleaning supplies, PPE, full-functioning animal colonies, and a dependable stream of human subjects that may take an extended time to return to acceptable levels.

Members raised several questions and/or suggestions for NIDCD/NIH to consider when attempting to stabilize and help the recovery of research efforts. Those comments included considering ways to stabilize the research workforce, such as bridge funding; extending the time of eligibility for training grants, fellowships, and Career Development awards; change the culture of peer review to take into account pandemic ramifications. Some suggested that NIH might

consider modifying the eligibility and payback obligations associated with Loan Repayment programs and extending the flexibility to reassign MD trainees to clinical service.

They also wondered if NIH could provide additional flexibilities for research grant budgets to address the increased needs of research staff for daycare, transportation, and PPE.

Members stressed the importance that NIH communicate to Congress and other parts of the government about the long-term impacts of COVID-19. They indicated that NIH is seen as an authoritative and consistent source of advice that might be used to inform best practices for research institutions and/or facilitate forums for idea sharing through the community.

Dr. Tucci thanked the council and the moderators of each section, Drs. Eatock, Gordon-Salant, Carey and Hillman for their discussions and advice on COVID-19 impacts and research recovery.

Adjournment

The meeting was adjourned at 12:55 p.m. on May 29, 2020.

Certification of Minutes

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

7/22/2020

/Craig A. Jordan/

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

7/21/2020

/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
NDOD Advisory Council

² These minutes will be approved formally by the Council at the next meeting on September 11, 2020, and corrections or notations will be stated in the minutes of that meeting.

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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., Director
National Institute on Deafness and Other Communication Disorders
Bethesda, MD 20892

ADAMS, Lisa C., J.D. Founding Member and President Massachusetts Hearing Aids for Children Coalition Newton, MA 02458	2020	GORDON-SALANT, Sandra, Ph.D. Director, Doctoral Program in Clinical Audiology University of Maryland College Park, MD 20742	2021
CAREY, John Patrick, M.D. Professor, Department of Otolaryngology The Johns Hopkins University School of Medicine Baltimore, MD 21205	2021	HILLMAN, Robert E., Ph.D. Co-Director and Research Director Center for Laryngeal Surgery and Voice Rehabilitation at Massachusetts General Hospital and Professor of Surgery: Harvard Medical School Boston, MA 02114	2022
EATOCK, Ruth Anne, Ph.D. Professor of Neurobiology Dean of Faculty Affairs, Biological Sciences Division University of Chicago Chicago, IL 60637	2023	KELLEY, Barbara Executive Director Hearing Loss Association of America Bethesda, MD 20814	2023
EINHORN, Richard Consultant Einhorn Consulting, LLC New York, NY 10025	2022	LINKE ELLIS, Nanci Specialty Marketing Consultant for Hearing Loss and Vision Impaired Audiences Culver City, CA 90232	2020
ELLIS WEISMER, Susan, Ph.D. Oros-Bascom Professor Department of Communication Sciences and Disorders Waisman Center University of Wisconsin-Madison Madison, WI 53705	2020	MORTON, Cynthia C., Ph. D. William Lambert Richardson Professor of Obstetrics, Gynecology and Reproductive Biology and Professor of Pathology, Harvard Medical School Kenneth J. Ryan, M.D. Distinguished Chair in Obstetrics and Gynecology and Director of Cytogenetics, Brigham and Women's Hospital Chair in Auditory Genetics, University of Manchester Boston, MA 02115	2022
GOFFMAN, Lisa, Ph.D. Professor and Nelle Johnston Chair Callier Center for Communication Disorders School of Behavioral and Brain Sciences University of Texas at Dallas Dallas, TX 75235	2020	SANES, Dan H., Ph. D. Professor Center for Neural Science New York University New York, NY 10003	2023

SIMS, H. Steven, M.D. 2020
Associate Professor and Director
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YEH, Charlotte S., M.D. 2021
Chief Medical Officer
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ZENG, Fan-Gang, Ph.D. 2022
Professor, Otolaryngology School of Medicine
and Director, Center for Hearing Research
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STROWBRIDGE, Ben W., Ph.D. 2023
Professor of Neuroscience
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School of Medicine
Cleveland, OH 44106

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Ex Officio

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National Institute for Occupational Safety
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HENRY, LaKeisha R., M.D, FACS
Division Chief, Hearing Center for Excellence
Defense Health Agency
Assistant Professor of Surgery, USUHS
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Lackland, TX 78236

AZAR II, Alex M.
Secretary
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COLLINS, Francis S., Ph.D., M.D.
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Executive Secretary

JORDAN, Craig A., Ph.D.
Director, Division of Extramural Activities
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NIDCD Council Budget Report

Eric Williams, Budget Officer
NIDCD Advisory Council Meeting
May 29, 2020

**National Institute on Deafness and
Other Communication Disorders (NIDCD)
Comparing FY19 (Actual) and FY20 (Projected)
Operating Plans
(Dollars in thousands)**

<i>Budget Mechanism</i>	FY 2019		FY 2020	
	Final Allocation		Operating Plan*	
	<i>Number</i>	<i>Amount</i>	<i>Number</i>	<i>Amount</i>
Research Projects				
Noncompeting	614	\$249,191	620	\$267,600
Admin. Supplements	23	1,498	34	3,000
Competing	195	82,093	181	75,710
Subtotal	809	332,782	801	346,310
SBIR/STTR	38	14,639	39	15,178
Subtotal, RPG's	847	347,421	840	361,488
Research Centers	6	14,352	6	14,504
Other Research	74	10,748	73	10,735
Total Research Grants	927	372,521	919	386,727
Individual Training	123	5,860	140	6,975
Institutional Training	157	8,111	155	8,040
R & D Contracts	41	20,686	41	22,950
Intramural Research		42,558		42,500
Research Mgmt. & Support		23,251		23,500
TOTAL		\$472,987		\$490,692

*Projected