#### NATIONAL DEAFNESS AND OTHER COMMUNICATION DISORDERS ADVISORY COUNCIL

#### May 17, 2019

#### National Institutes of Health Bethesda, MD

#### MINUTES

The National Deafness and Other Communication Disorders Advisory Council convened on May 17, 2019, at the Porter Neuroscience Center (Building 35), Conference Room 620, National Institutes of Health (NIH), Bethesda, MD. Dr. Judith A. Cooper, Acting Director, National Institute on Deafness and Other Communication Disorders (NIDCD), served as Chairperson. In accordance with Public Law 92-463, the meeting was:

Closed: May 17, 2019: 8:30 a.m. to 10:50 a.m. for review of individual grant applications and tours of the Intramural laboratories; and

Open: May 17, 2019: 11:05 a.m. to 2:00 p.m., for the review and discussion of program development needs and policy.

Council members in Attendance<sup>1</sup>:

Ms. Lisa Adams Dr. Sarah Blackstone Dr. John Carey Mr. Richard Einhorn Dr. Susan Ellis-Weismer Dr. Robert Hillman Dr. Sue Kinnamon Dr. M. Charles Liberman

Ms. Nanci Linke-Ellis Dr. Cynthia Morton

- Dr. Christoph Schreiner
- Dr. Neil Segil
- Dr. H. Steven Sims
- Dr. Donald Wilson
- Dr. Charlotte Yeh

Council members absent:

Dr. Judith Gierut Dr. Sandra Gordon-Salant Dr. Fan-Gang Zeng

Council ex-officio members in Attendance:

Dr. LaKeisha Henry Dr. Judy Schaffer for Dr. Lucille Beck

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:

Mr. Eddie Myrbeck Mr. Christopher Myers Dr. Amy Poremba Ms. Lisa Portnoy Dr. Bobby Ray Dr. Alberto Rivera-Rentas Dr. Elka Scordalakes Dr. Lana Shekim Dr. Kathy Shim Dr. Sheo Singh Ms. Nanette Stephenson Dr. Melissa Stick Dr. Susan Sullivan Ms. Kelli VanZee Dr. Bracie Watson Ms. Ginger Webb Mr. Timothy Wheeles Mr. Eric Williams Mr. Baldwin Wong Dr. Shiguang Yang

Other federal employees present during portions of the meeting:

Dr. Biao Tian, CSR Dr. Janita Turchi, CSR Dr. Andrea Kelly, CSR Dr. Alexei Kondratyev, CSR

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

Dr. Christopher Platt

- Ms. Kate Carr, Hearing Industries Association
- Ms. Lindsay Robinson, Hearing Industries Association
- Ms. Susan Pilch, American Academy of Audiology
- Ms. Donna Sorkin, American Cochlear Implant Society
- Ms. Deborah Outlaw, American Tinnitus Association

#### **CLOSED SESSION**

#### I. Call to Order and Opening Remarks ...... Dr. Judith A. Cooper

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

#### II. 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 conflict of appearance thereof 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 11:05 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 126 investigatorinitiated R01 grant applications; 107 applications had primary assignment to NIDCD, in the amount of \$39.9 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 14<sup>th</sup> percentile.

#### B. Special Programs Actions

- 1. NIH Mentored Research Scientist Development Award (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 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 five applications and support of two secondary applications.
- 5. Academic Research Enhancement Awards (AREA) (R15): The Council recommended support of four applications.
- 6. NIH Exploratory/Development Research Grant Award (R21): The Council recommended support of seven applications.
- 7. NIDCD Early Career Research (ECR) Award (R21): The Council recommended support of nine applications.
- 8. NIDCD Clinical Research Center Grant (P50): The Council recommended support of one application.

- 9. NIH Small Business Technology Transfer (STTR) Phase II (R42): The Council recommended support of one application.
- 10. NIH Small Business Innovation Research Awards (SBIR): The Council recommended support of five Phase I (R43) applications.
- 11. NIH Small Business Innovation Research Awards (SBIR): The Council recommended support of two Phase II (R44) applications.
- 12. NIDCD Hearing Healthcare for Adults: Improving Access and Affordability (R21/R33 Clinical Trials Optional): The Council recommended support of one application.
- Limited Competition: NIDCD National Temporal Bone, Hearing & Balance Pathology Resource Registry (U24 Clinical Trial Not Allowed): The Council recommended support of one application.
- 14. Collaborative Research in Computational Neuroscience (CRCNS) (R01): The Council recommended support of two applications.

#### IV. Tour of Intramural Labs in Porter Neuroscience Center ......Dr. Griffith & Staff

The John Edward Porter Neuroscience Center (PNC) is one of the newest research buildings on the NIH campus, and its opening in 2014 allowed NIDCD's intramural researchers to move their laboratories onto the NIH campus. Council previously toured the PNC in September 2018 and asked that if possible, we do it again. We wanted to take advantage of today's meeting location to provide another tour and allow a few different NIDCD investigators the opportunity to highlight their research efforts.

#### **OPEN SESSION**

#### V. Opening Remarks ..... Dr. Cooper

Dr. Cooper welcomed additional staff and visitors to the open session of the meeting.

#### Recognition of New Member

Our newest member from the Department of Defense, Dr. LaKeisha Henry, is an otolaryngologist and a Colonel in the United States Air Force. Dr. Henry leads the Center for Hearing Excellence for the Department of Defense as it executes the Congressionally-directed mission to optimize operational effectiveness, heighten medical readiness and enhance quality of life for Service members and Veterans through collaborative leadership and advocacy for hearing and balanced health initiatives.

#### Recognition of Retiring Members

Dr. Cooper thanked the following retiring members for their service on the Advisory Council and presented them with certificates of appreciation:

- Dr. Sarah Blackstone
- Dr. Judith Gierut (absent)
- Dr. Sue Kinnamon
- Dr. M. Charles Liberman
- Dr. Christoph Schreiner
- Dr. Donald Wilson

#### Consideration of Minutes of the Meeting of January 25, 2019

Dr. Cooper called the members' attention to the minutes of the January 25, 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, September 13, 2019.

#### VI. Report on the NIDCD Budget ...... Mr. Eric Williams

NIDCD's Budget Officer, Mr. Eric Williams, presented information on the current and previous fiscal year budgets. He shared the NIDCD's 2019 Budget Operating Plan as compared against the FY2018 final expenditures. The FY2019 budget benefits from a \$15.5M increase.

Next, Mr. Williams shared the FY 2020 Budget Outlook, at this early and incomplete time. Both the House and Senate budget subcommittees had meetings this spring, but only the House has released their FY 2020 budget Mark-up. The House Mark-up is almost \$90M more than the President's proposed budget. The Senate had not issued their Mark-up for FY 2020.

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

#### VII. NIH Addresses Sexual Harassment in ...... Dr. Michael Lauer Biomedical Science

Dr. Michael Lauer is the Deputy Director for Extramural Research at the National Institutes of Health (NIH). He serves as the principal scientific leader and advisor to the Director of the NIH on all matters relating to the substance, quality and effectiveness of the NIH extramural research program and administration. Today, Dr. Lauer updated the Council in a talk entitled, "NIH Addresses Sexual Harassment in Biomedical Science."

Dr. Lauer reviewed the expectations for working environments and civil rights protections that accompany extramural grant awards. He also discussed related expectations that funded institutions must meet as part of their stewardship of NIH grants. Data was shared demonstrating the gender distribution in academic job categories and NIH grant applications/awards. He shared the aim to reach gender equity and to increase NIH's role in addressing sexual harassment concerns.

In February, as part of a <u>statement from NIH leadership</u> on addressing sexual harassment in science, we encouraged the community to notify us about specific concerns by sending an email to <u>GranteeHarassment@od.nih.gov</u>. We received dozens of notifications through this channel and are taking each one seriously. We are working with the supported institutions to address these concerns and to assure that NIH-funded activities are conducted in a safe and harassment-free work environment. He reported that a number of institutions have instituted queries and numerous actions have been taken by those institutions.

As part of our continued efforts, NIH is developing a new webform that will allow anybody in the biomedical research community to share information related to a potential case of sexual harassment directly and, if desired, anonymously, to NIH. The establishment of this webform, in tandem with other actions, is taken as part of our continuing commitment to address the underlying culture that enables sexual harassment to take place. For additional information and resources, please see NIH's Anti-Sexual Harassment website.

We appreciate hearing from all those affected by this issue. NIH can and will follow up on all concerns related to NIH-funded research submitted through this resource. We also strongly encourage individuals to report allegations of sexual harassment or assault to the appropriate authorities, which may include local police department and/or organization/institution equal employment opportunity or human resources offices.

#### VIII. Report of the Division of Scientific Programs...... Dr. Cooper

Dr. Cooper introduced Dr. Amy Poremba to update the Council regarding recent BRAIN Initiative programs.

The BRAIN Initiative® (BI) is a trans-NIH program, established in 2013, that will have provided roughly \$5 Billion dollars in neuroscience funding over 10 years. BRAIN is an acronym for Brain Research Through Advancing Innovative Technologies®. This talk encompasses some of the highlights of the past five years of funding outcomes generally, as well as those pertaining particularly to NIDCD mission areas, the structure of the BI administration, and highlights of research being performed by some NIDCD investigators who are also supported by the BI.

The BI has created an exciting increase in tools that are helping to accelerate discoveries and building a foundation we need to reduce the burden of brain disorders. This initiative has brought about a new culture, bridging neuroscientists, physicists, engineers, biologists, chemists, to name a few, and promotes team science. More than 700 investigators are now supported by the BI starting with 58 awards in 2014, to 205 in 2018. In the first year, just four BI grants awarded related in some way to our NIDCD mission areas, and last year in 2018 that number had grown to 27. In 2018, 27.8 million BI dollars out of 400 million, about 7% of the total BRAIN budget for that year supported NIDCD related research including creation of a fast speech decoder, tinnitus research, and 8th nerve stimulation studies. Overall, NIDCD mission goals are benefitting from BI funding, with room for growth in the upcoming next five years of funding.

#### IX. BRAIN Initiative: The Next Five Years.....Dr. Christoph Schreiner

Dr. Christoph Schreiner is Professor and Vice Chairman in the Department of Otolaryngology – Head and Neck Surgery at the University of California, San Francisco. You all know him as a fellow Council member. For much of his time on Council, Christoph has also represented us on the NIH's BRAIN Multi-Council Working Group. He is here to share how the BRAIN Initiative® will continue during the next 5 years.

Dr. Schreiner recapped the BRAIN Initiative® (BI) goals, accomplishments, and funding since it began in 2014 and linked that progress back to the "Brain 2025: A Scientific Vision" report from 2014. That report, BRAIN 2025, noted that the Initiative must adapt in response to the evolving scientific landscape. In light of rapid scientific progress, NIH formed a new ACD BRAIN Initiative Working Group 2.0 to help steer the second half of the initiative. That body was charged with reviewing progress, suggesting tune-ups based on evolving scientific landscape, identify new opportunities for research and technology, and to consider opportunities to train, empower and diversify the broader neuroscience research community. He then discussed the suggested short-term and long-term goals for BRAIN 2.0, with a focus on two areas, Discovering Diversity and Advancing Human Neuroscience.

Dr. Schreiner also shared information about the Neuroethics Guiding Principles being developed/discussed for the BRAIN Initiative, published in the Journal of Neuroscience, December 2018. The main questions being raised in this area are:

1. What is the potential impact of a model or neuroscientific account of disease on individuals, communities, and society?

- 2. What are the ethical standards of biological material and data collection and how do local standards compare to those of global collaborators?
- 3. What is the moral significance of neural systems that are under development in neuroscience research laboratories?
- 4. How could brain interventions impact or reduce autonomy?
- 5. In which contexts might a neuroscientific technology/innovation be used or deployed?

Both the Brain 2.0 directions and the Neuroethics Guiding Principles documents have been available for public comment and those comment periods are closing soon. Both reports will then be shared with the ACD members at their June meeting.

When considering the past BI accomplishments and the pending changes to the initiative, Dr. Schreiner closed his presentation by raising a few upcoming challenges for NIDCD to consider.

- 1. How to disseminate and support latest technological advances for its investigators?
- 2. How to encourage equitable collaborations between technique-focused and conceptfocused investigators?
- 3. How to balance the Institute's emphasis on innovative technologies with concept-driven approaches that have perhaps less innovative technologies?
- 4. How to encourage and even require a more unified approach to informatics infrastructure?

#### X. Report of the Director, Division of Extramural Activities ......Dr. Jordan

[Executive Secretary Note: Due to time constraints, Dr. Jordan's report was put on hold to be shared at a future meeting.]

#### XI. Adjournment

The meeting was adjourned at 2:00 p.m. on May 17, 2019.

#### XII. Certification of Minutes

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

Ginger Webb Program Analyst NDCD Advisory Council

<sup>2</sup> These minutes will be approved formally by the Council at the next meeting on September 13, 2019, and corrections or notations will be stated in the minutes of that meeting.

#### APPENDICES

APPENDIX 1	NDCD Advisory Council Roster	10
APPENDIX 2	NIDCD Budget Report Slides	12

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

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

Chairperson Judith A. Cooper, Ph.D. Acting 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	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	2022
BLACKSTONE, Sarah W., Ph.D. President and CEO	2019	Boston, MA 02114	
Augmentative Communication, Inc. Monterey, CA 93940		KINNAMON, Sue C., Ph.D. Professor	2019
CAREY, John Patrick, M.D. Professor, Department of Otolaryngology – Head and Neck Surgery	2021	Department of Otolaryngology University of Colorado, Denver Aurora, CO 80045	
The Johns Hopkins University School of Medicine Baltimore, MD 21205		LIBERMAN, M. Charles, Ph.D. Director, Eaton-Peabody Laboratory Department of Otology and Laryngology	2019
EINHORN, Richard Consultant	2022	Harvard Medical School Boston, MA 02114	
Einhorn Consulting, LLC New York, NY 10025		LINKE ELLIS, Nanci Specialty Marketing Consultant for Hearing Loss and Vision Impaired	2020
ELLIS WEISMER, Susan, Ph.D. Oros-Bascom Professor Department of Communication Sciences	2020	Audiences Culver City, CA 90232	
and Disorders University of Wisconsin-Madison Madison, WI 53705		MORTON, Cynthia C., Ph. D. William Lambert Richardson Professor of Obstetrics, Gynecology and Reproductive Biology and Professor of Pathology,	2022 e
GIERUT, Judith A., Ph.D. Professor Emerita Department of Speech and	2020	Harvard Medical School Kenneth J. Ryan, M.D. Distinguished Chair Obstetrics and Gynecology and Director	in
Hearing Sciences Program in Cognitive Sciences Indiana University Bloomington, IN 47405		of Cytogenetics, Brigham and Women's Hospital Chair in Auditory Genetics, University of Manchester Boston, MA, 02115	
GORDON-SALANT, Sandra, Ph.D. Director, Doctoral Program in Clinical	2021	Boston, MA 02115 SCHREINER, Christoph, M.D., Ph. D.	2019
Audiology		Professor and Vice Chairman	2013
University of Maryland College Park, MD 20742		Department of Otolaryngology – Head and Neck Surgery	
		Center for Integrative Neuroscience School of Medicine	
		University of California, San Francisco San Francisco, CA 94158	

SEGIL, Neil, Ph.D.	2021
Professor of Research	
Keck School of Medicine	
University of Southern California	
Los Angeles, CA 90033	

2020

SIMS, H. Steven, M.D. Associate Professor and Director Department of Otolaryngology-Head and Neck Surgery University of Illinois Medical Center Chicago, IL 60612

#### **Ex Officio**

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

HENRY, Kristen L., Ph.D. Audiology Consultant to the Surgeon General Director Audiology and Speech Center Walter Reed National Military Medical Center Bethesda, MD 20889

#### **Executive Secretary**

JORDAN, Craig A., Ph.D. Director, Division of Extramural Activities National Institute on Deafness and Other Communication Disorders Bethesda, MD 20892 WILSON, Donald A., Ph. D. 2019 Senior Research Scientist and Deputy Director Emotional Brain Institute The Nathan S. Kline Institute for Psychiatric Research Professor New York University School of Medicine Orangeburg, NY 10962

YEH, Charlotte S., M.D. Chief Medical Officer AARP Services, Inc. Washington, DC 20049 2021

ZENG, Fan-Gang, Ph.D. 2022 Professor, Otolaryngology School of Medicine and Director, Center for Hearing Research University of California, Irvine Irvine, CA 92697

AZAR II, Alex M. Secretary Department of Health and Human Services Washington, DC 20201

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

COLLINS, Francis S., Ph.D., M.D. Director National Institutes of Health Bethesda, MD 20892

# NIDCD Council Budget Report

Eric Williams, Budget Officer NIDCD Advisory Council Meeting May 17, 2019

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

# FY2018 vs FY 2019 Operating Plan (Mechanism Table) (Dollars in Thousands)

						<b>FY 2018 Final</b> +/_	
MECHANISM	FY.	FY 2018 Final		Operating Plan		7- Planned	
	No.	Amount	No.	Amount	No.	Amount	
Research Projects:					×		
Noncompeting	586	\$231,567	624	S251,469	38	\$19,9 <b>0</b> 2	
Administrative Supplements	(38)	2,954	(30)	2,200	(-8)	-754	
Competing				1			
Renewal	49	24,278	41	20,364	-8	-3,914	
New	179	68,908	150	57,984	-29	-10,924	
Supplements	•	•	•	•	•	•	
Subtotal, Competing	228	\$93,186	191	\$78,348	-37	-S14,838	
Subtotal, RPGs	814	\$327,707	815	\$332,017	1	S4,310	
SBIR/SI'TR	36	14,423	37	14,915	1	492	
Research Project Grants	850	\$342,130	852	\$346 <sub>-</sub> 932	2	S4,802	
Research Centers:							
Specialized. <sup>®</sup> Comprehensive	5	S11,652	6	S14,471	1	S2,819	
Clin.cal Research	•	•	•	•	•	•	
Biotechnology	•	•	•	•	•		
Comparative Medicine	•	•	•		•		
Research Centers in Minority Institutions	•	•	•	•			
Research Centers	5	\$11,652	6	S14,471	1	\$2,819	
Other Research: Research Careers	42	S7 428	40	57.014		5498	
Cancer Education	43	\$7,430	49	\$7,91 <b>•</b>		S480	
	•		•		- -		
Cooperative Clin.cal Research			•		a l		
Biomedical Research Support	•		•		tă 👘		
Minority Biomedical Research Support		0.798	28	2,825		15	
•ther	29	2,780	28	2,825	-1	45	
Other Research Total Research Grants	72 927	\$10,210 \$363,992	77 935	\$10,735 \$372,138	5	\$525 \$8,146	
lotal Research Grans	927	3303,992	935	3372,138	8	38,140	
Ruth L Kirchstein Training Awards:	FTIPs		FTTPs		FIIPs		
Individual Awards	130	\$5,894	132	S6.133	2	\$239	
Institutional Awards	165	8,306	169	8,633	4	327	
Iotal Research Training	295	\$14,200	301	\$14,766	6	\$566	
Research & Develop Contracts	37	\$18,155	41	\$21.5 <b>0</b> 0	4	\$3.345	
(SBIRISTIR) (non-add)	(0)	(29)	(0)	(155)	(0)	(126)	
Intramural Research	60	41,489	67	42,500	7	1,011	
Res. Management & Support	69	21,057	73	23,500	4	2,443	
Res. Management & Support (SBIR Admin) (non- add)	(0)	(0)	(0)	(0)	(0)	(0)	
Construction		•					
Buildings and Facilities							
Total, NIDCD	129	S458,893	140	S474,404	11	\$15,511	

All items in italics and brackets are non-add entries.

### 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