

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

May 20, 2016

**National Institutes of Health
Bethesda, MD**

MINUTES

The National Deafness and Other Communication Disorders Advisory Council convened on May 20, 2016 in Building 31, Conference Room 6, National Institutes of Health (NIH), Bethesda, MD. Dr. James F. Battey, Jr., 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 20, 2016: 8:30 a.m. to 9:40 a.m. for review of individual grant applications; and
Open: May 20, 2016: 10:00 a.m. to 1:50 p.m., for the review and discussion of program development needs and policy.

Council members in Attendance:¹

Dr. Sarah Blackstone	Dr. Tommie Robinson
Dr. Diane Bless	Dr. Christoph Schreiner
Ms. Joan Kaye	Dr. Elba Serrano
Dr. Sue Kinnamon	Dr. Richard Smith
Dr. Jian-Dong Li	Dr. Helen Tager-Flusberg
Dr. M. Charles Liberman	Dr. Monte Westerfield
Dr. Joseph Perkell	Dr. Donald Wilson

Council members absent:

Dr. David Lee	Dr. Debara Tucci
Dr. David Myers	

Council ex-officio members in Attendance;

Ms. Christa Themann

The complete Council roster is found in Appendix 1.

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	Dr. Elyssa Monzack
Mr. Chris Carlsen	Mr. Christopher Myers
Ms. May Chiu	Mr. Edward Myrbeck
Dr. Laura Cole	Mr. Eric Nunn
Dr. Judith Cooper	Dr. Christopher Platt
Dr. Janet Cyr	Dr. Kausik Ray
Ms. Susan Dambrauskas	Dr. Alberto Rivera-Rentas
Mr. Hoai Doan	Mr. Mark Rotariu
Dr. Amy Donahue	Dr. Elka Scordalakes
Dr. Nancy Freeman	Dr. Lana Shekim
Ms. Maria Garcia	Dr. Katherine Shim
Dr. Stephen Hirschfeld	Dr. Sheo Singh
Mr. Howard Hoffman	Ms. Nanette Stephenson
Ms. LaTanya Holmes	Dr. Melissa Stick
Dr. Joanne Karimbakas	Dr. Susan Sullivan
Ms. Phalla Keng	Dr. Jean Tiong-Koehler
Dr. Eliane Lazar-Wesley	Ms. Kelli VanZee
Mr. Jixeon Lee	Dr. Bracie Watson
Dr. Chuan-Ming Li	Ms. Ginger Webb
Ms. Lonnie Lisle	Mr. Timothy Wheelles
Ms. Melissa McGowan	Mr. Baldwin Wong
Dr. Castilla McNamara	Dr. Shiguang Yang
Dr. Roger Miller	

Other federal employees present during portions of the meeting:

Dr. John Bishop, CSR
Dr. Paek Lee, CSR
Dr. Biao Tian, CSR
Dr. Judy Schafer, VA
Dr. Wind Cowles, CSR
Dr. Cristina Cassetti, NIAID
Dr. Kristen Casto, DOD
Dr. Rachel McArdle, VA

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

Ms. Jen McCulley IQ Solutions
Dr. Joshua Alexander, Purdue University
Dr. Francoise Brosseau, Purdue University

CLOSED SESSION

I. Call to Order and Opening RemarksDr. James F. Battey, Jr.

The meeting was called to order by Dr. Battey, 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 9:40 a.m.

III. Council Consideration of Pending Applications

A. Research Project Grant Awards

1. Consideration of Applications: On the Council's agenda was a total of 143 investigator-initiated R01 grant applications; 127 applications had primary assignment to NIDCD, in the amount of \$41.9 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 15th percentile.

B. Special Programs Actions

1. NIH Mentored Patient-Oriented Research Career Development Award (K23): The Council recommended support of two applications.
2. NIH Midcareer Investigator Award in Patient-Oriented Research (R24): The Council recommended support of one application.
3. NIH Pathway to Independence (PI) Award (K99): The Council recommended support of two applications.
4. NIH Small Grants (R03): The Council recommended support of twelve applications.
5. NIH Support for Conferences and Scientific Meetings (R13): The Council recommended support of three applications and partial support for one application with dual assignment.
6. NIH Academic Research Enhancement Awards (AREA) (R15): The Council recommended support of one application.
7. NIH Exploratory/Development Research Grant Award (R21): The Council recommended support of five applications.

8. NIH Small Business Technology Transfer Awards (STTR): The Council recommended support of one Phase I (R41) application.
9. NIH Small Business Innovation Research Awards (SBIR): The Council recommended support for one Phase I (R43) application.
10. NIH Small Business Innovation Research Awards (SBIR): The Council recommended support for four Phase II (R44) applications.
11. Open Design Tools for Speech Signal Processing (R01): The Council recommended support for three applications.
12. Open Design Tools for Speech Signal Processing (R43/R44): The Council recommended support for three applications.

OPEN SESSION

IV. Opening Remarks.....Dr. Battey

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

Recognition of New Members

- **Dr. Christoph Schreiner** is Professor and Vice Chairman in the Department of Otolaryngology-Head and Neck Surgery (OHNS) at the University of California, San Francisco. He received his doctoral degree in physics. He received his medical degree from Georgia-Augusta-Universität and the Max-Planck-Institute for Biophysical Chemistry, Göttingen, Germany. Dr. Schreiner's research focuses on understanding of the functional organization of central auditory stations of the mammalian brain. He is mainly interested in the role of the auditory forebrain (medial geniculate body and auditory cortex) in the encoding of complex auditory signals – such as speech and communication signals – in normal and hearing-impaired models. By combining physiological, neuroanatomical, and computational approaches, Dr. Schreiner and his colleagues attempt to provide a better understanding of the cortical processing of complex sounds and its contribution to sound perception. He is a member of many professional organizations such as the Association for Research in Otolaryngology and the Society for Neuroscience. He has published over 140 reviewed articles, and he has also contributed to over 50 book chapters. Welcome Christoph.

One of the Council's Ex Officio members, Dr. Rick Davis, recently retired and Ms. Christa Themann was nominated by the Director of the Centers for Disease Control and Prevention (CDC) to fill that vacancy on our Council.

- **Ms. Christa Themann** received her master's degree in Audiology from the University of Cincinnati. She has a certification in clinical competence in Audiology and is pursuing a doctoral degree in Epidemiology. Ms. Themann is currently a Research Audiologist on the Hearing Loss Prevention Team of the Engineering and Physical Hazards Branch in the Division of Applied Research and Technology with the National Institute for Occupational Safety and Health (NIOSH) which is a part of the CDC. Her research interests include epidemiology of noise exposure and hearing loss, public health outreach programs for hearing loss prevention and utilization of social media and special

needs of workers with hearing loss and the definition of hearing critical jobs. Ms. Themann's professional activities include membership with organizations such as the American Speech-Language-Hearing Association and the National Hearing Conservation Association. She has received many awards from various organizations such as Bullard-Sherwood Award for Research to Practice (Technology Category) in 2013. Ms. Themann has an array of publications in several professional journals, some co-authored with NIDCD scientists.

Recognition of Retiring Members

Dr. Battey thanked the following retiring members for their service on the Advisory Council and presented them with certificates of appreciation. He also invited each one to provide parting remarks:

- Ms. Joan Kaye
- Dr. Joe Perkell
- Dr. Tommie Robinson
- Dr. Helen Tager-Flusberg

Consideration of Minutes of the Meeting of January 22, 2016

Dr. Battey called the members' attention to the minutes of the January 22, 2016 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 2018 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 9, 2016, in Building 31, Conference Room 6 on the NIH campus, Bethesda, Maryland.

V. Report of the Director, NIDCDDr. Battey

Budget Update

Dr. Battey began his presentation by pointing out that the FY 2016 Operating Budget for NIDCD reflects an approximate increase of \$17.5 million over the FY 2015 budget. With this budget increase NIDCD will fully fund 2016 Noncompeting Research Projects, unlike the reductions imposed in recent years. Competing Research Project grants (RPGs) continue to be a high priority for NIH and NIDCD and will receive ~70% of the overall increase. We estimate we will be able to award 33 more Competing RPG's than last year. Individual and institutional training stipends are being increase by 2%. With OMB guidance for next fiscal year, the NIH administration is requesting an increase of \$825 million, or about 2.5%. Those increased dollars are targeted for an increase to NCI of \$680 million to accelerate cancer research--the cancer "moonshot" initiative. Another \$145 million is targeted to the NIH OD for the BRAIN and Precision Medicine initiatives. The NIH budget request does not include any increases for the other IC's relative to FY 2016. Due to the relatively large increase in NIDCD's FY 2016 budget for Competing RPG's, noncompeting RPG costs go up by \$16 million in FY 2017. With a flat budget in FY 2017, the dollars available for competing RPG's would go down by ~\$16 million. As witnessed in the past, such a fluctuation in funding would result in a roller-coaster effect on our ability to fund competing RPG's.

NIDCD's Operating Budget for FY 2016 is \$422.9 million. Once other components of the NIDCD budget are considered there would be \$304.2 million available for research project grants. From this total, \$12.5 million is reserved for Small Business Research grants, \$2.5 million for administrative supplements, \$210.6 million for commitments to noncompeting grants, \$2.2 million for commitments carried over from FY2015, and \$18.9 million for program requirements. An additional estimated \$1.1 million was applied from end of year FY 2015 funds. Of the remaining \$58.6 million, twenty percent (\$11.7 million) is designated for High Program Priority (HPP). Consequently, there is \$46.9 million available for the initial R01 pay line across the year's three Council meetings. This should allow funding of R01 applications up through the 15th percentile. The \$11.7 million for HPP applications will be available to support additional applications throughout the year.

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

VI. Report of the Director, Division of Scientific ProgramsDr. Judith Cooper

Dr. Cooper introduced Mr. Howard Hoffman, the head of the Epidemiology and Statistics Program at NIDCD who provided an update on NIDCD's Collaborative Epidemiologic Research Studies. The Epidemiology and Statistics Program has a number of goals including the maintenance of selected data sets from population-based studies in the NIDCD mission areas and the sponsoring/collecting of new data sets, using Interagency Agreements (IAAs), research contracts, and research grants. Many of these efforts are cooperative in nature involving development of exams and interview content, data analysis, and presentation/publication of findings. In his presentation, Mr. Hoffman focused his talk specifically on multi-year efforts negotiated via IAAs with the National Center for Health Statistics (NCHS) and the Department of Education, National Center for Education Statistics (NCES). Specific studies during these collaborations have spanned many years to decades and have included the National Health Interview Survey (NHIS), National Health and Nutrition Examination Survey (NHANES), and the Early Childhood Longitudinal Study (ECLS).

We have learned much about hearing health such as national estimates for age-specific prevalence of hearing loss, tinnitus, frequency of hearing exams, use of hearing protection and use of hearing aids. These large studies allow the examination of co-morbidities with other illnesses/conditions and evaluation of risk factors. A number of examples were provided of data that has been obtained from these studies and the types of new data still to come. Through on-going collaborations over the years, additional focusses have been introduced to these studies, beyond just hearing-related measures to include voice, speech, language, balance, and even taste and smell. The taste and smell testing was incorporated into designated space in the NHANES mobile exam center that travels around the country. Mr. Hoffman closed by introducing other staff of the NIDCD's Epidemiology and Statistics Program.

VII. Report of the Director, Division of Extramural ActivitiesDr. Jordan

Dr. Jordan introduced Dr. Katherine Shim, Ph.D. who joined NIDCD's Scientific Review Branch as a Scientific Review Officer in October 2015. Next he provided a summary of Interim Actions handled by the Grants Management Branch over the past year; administrative actions performed on funded research grants in between council meetings.

Dr. Jordan summarized three changes ongoing at NIH including the addition of Rigor and Reproducibility elements into grant applications, that there are major changes to grant applications with new application packages (FORMS-D), totally restructured application guides,

and new biosketch instructions and format pages. Also, there is a Notice of Intent to Release Names of NIH-Funded Research Project Personnel (NOT-OD-16-088) which is in response to an Executive Order to make federal agencies information resources more accessible to the public. The information to be made public is limited to the name, degrees, role on the project and if applicable the foreign organization and country. This increased level of reporting will be effective for FY2016 awards.

Finally, Dr. Jordan presented data on multi-year trends of NIDCD R01 application numbers, success rates, and average costs. He highlighted how the trends changed over time when compared to fluctuations in the appropriation, inflation, and provided comparisons to overall NIH figures.

VIII. Scientific Presentation.....Dr. Mary Pat Moeller

Dr. Battey introduced Dr. Mary Pat Moeller who is the Director of the Center for Childhood Deafness and the Infant Language Development Laboratory at the Boys Town National Research Hospital. Dr. Moeller agreed to present her research entitled, “Longitudinal outcomes of preschoolers with mild to severe hearing loss: the impact of inconsistent access to auditory-linguistic input.” She provided the following abstract and recognized co-author J. Bruce Tomblin, University of Iowa:

Early and consistent access to linguistic input is important if not essential for speech and language development in typically developing children. Our research suggests that permanent hearing loss places young children at risk for language delays to the extent that it restricts access to speech and language input. The historical literature documents extensive delays in speech, language, academic, and psychosocial development in children who are deaf or hard of hearing. However, researchers are now met with a new generation of children who are commonly identified in infancy and receive early interventions that include improved hearing technologies. Although the expectation is that these service innovations should prevent or minimize speech and language delays, the requisite studies documenting children’s outcomes are only recently emerging. With support from the NIDCD, our team systematically explored factors predicted to influence children’s access to linguistic input through a multi-site, longitudinal study of the outcomes of more than 300 children with mild to severe hearing loss (Outcomes of Children with Hearing Loss, OCHL). Our research team concluded that the language learning system is vulnerable when there are constraints in the availability of auditory-linguistic cues. We also found that gain in audibility provided by hearing aids reduces this vulnerability. This presentation will describe longitudinal results from the OCHL study, with emphasis on three major factors found to influence children’s auditory-linguistic access and longitudinal outcomes: 1) audibility of speech sounds with hearing aids, 2) consistency and duration of hearing aid use, and 3) characteristics of caregivers’ language input. Risk and protective factors that influence the outcomes of early- and later-identified children who are hard of hearing will also be described. Throughout the discussion, we will consider ways in which research with this group of children can inform more general theories of child language acquisition.

(This work was supported by NIH-NIDCD R01DC009560.)

**IX. Progress on the NIDCD Strategic Plan Mr. Baldwin Wong
Update Dr. Charles Liberman**

The NIDCD's strategic plan is in the process of being updated by the NIDCD Strategic Plan Working Group and a number of working group meetings have been held since the effort was initiated last January. The working groups have been focused on identifying Scientific Advances from the last five years and proposing new Research Objective for the next five years. Dr. Liberman highlighted specific examples of new research objectives from across NIDCD's seven mission areas: hearing, balance, taste, smell, voice, speech, and language.

Progress has been made thanks in large measure to the efforts of the working group members, many of them in attendance today. Buck Wong provided a timeline to completion, including comment periods by the full Council, NIDCD staff, and later in the year, by members of the public. The goal is to have the 2016-2021 NIDCD Strategic Plan posted on the NIDCD website in January 2017. The next step is to provide a first draft to Council for consideration/comment by late June 2016.

**X. Enhancing Research Reproducibility Dr. Shai Silberberg
Perspectives and Initiatives**

Dr. Shai Silberberg presented his talk on “Enhancing Research Reproducibility: NIH/NINDS Perspectives and Initiatives” to the Council. He has been involved in trans-NIH efforts addressing this topic. One of the early efforts was when NINDS convened major stakeholders in 2012 to discuss how to improve the predictive value of preclinical research used as the premise to support clinical research.

The quality of research depends on the rigor with which researchers conduct studies and control for potential biases. Recent publications and meetings have focused on the observation that published research results are often not reproducible. Although there are many possible causes for this problem, unintentional bias, poor experimental design and inadequate reporting appear to be significant contributing factors. Evidence for this deduction will be presented, as well as actions taken by the US National Institutes of Health (NIH) and publishers to address the issues.

XI. Adjournment

The meeting was adjourned at 1:50 p.m. on May 20, 2016.

XII. Certification of Minutes

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

6/22/2016

/Craig A. Jordan/

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

6/22/2016

/James F. Battey, Jr./

James F. Battey, Jr., M.D., Ph.D.
Chairman
National Deafness and Other Communication
Disorders Advisory Council

Director
National Institute on Deafness and
Other Communication Disorders

Ginger Webb
Council Assistant
NDCD Advisory Council

NOTE: These minutes will be approved formally by the Council at the next meeting on September 9, 2016, and corrections or notations will be stated in the minutes of that meeting.

APPENDICES

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Appendix 1

Roster

National Deafness and Other Communication Disorders Advisory Council

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

Chairperson

James F. Battey, Jr. M.D., Ph.D., Director

National Institute on Deafness and Other Communication Disorders

Bethesda, MD 20892

BLACKSTONE, Sarah W., Ph.D. President and CEO Augmentative Communication, Inc. Monterey, CA 93940	2019	LIBERMAN, M. Charles, Ph.D. Director, Eaton-Peabody Laboratory Department of Otology and Laryngology Harvard Medical School Boston, MA 02114	2019
BLESS, Diane M., Ph.D. Professor Emeritus Departments of Communicative Disorders and Surgery University of Wisconsin – Madison School of Medicine Madison, WI 53792	2018	MYERS, David G., Ph. D. Professor Hope College Department of Psychology Holland, MI 49422	2017
KAYE, Joan Executive Director Sophie's Soundcheck New York, NY 10128	2016	PERKELL, Joseph S., Ph.D., D.M.D. Research Affiliate Research Laboratory of Electronics Massachusetts Institute of Technology Cambridge, MA 02446	2016
KINNAMON, Sue C., Ph.D. Professor Department of Otolaryngology University of Colorado, Denver Aurora, CO 80045	2019	ROBINSON, Jr., Tommie L., Ph.D. Chief, Division of Hearing and Speech Children's Hearing and Speech Center Children's National Medical Center Washington, DC 20009	2016
LEE, David J., Ph.D. Professor Department of Public Health Sciences University of Miami School of Medicine Miami, FL 33136	2018	SCHREINER, Christoph, M.D., Ph. D. Professor and Vice Chairman Department of Otolaryngology – Head and Neck Surgery Center for Integrative Neuroscience School of Medicine University of California, San Francisco San Francisco, CA 94158	2019
LI, Jian-Dong, M.D., Ph.D. Georgia Research Alliance Eminent Scholar Director, Center for Inflammation, Immunity and Infection Professor, Department of Biology Georgia State University Atlanta, GA 30303	2018	SERRANO, Elba E., Ph.D. Regents Professor Department of Biology New Mexico State University Las Cruces, NM 88003	2017

SMITH, Richard J. H., M.D. 2018
Professor
Department of Otolaryngology
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TAGER-FLUSBERG, Helen, Ph.D. 2016
Professor
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TUCCI, Debara L., M.D. 2017
Professor
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WESTERFIELD, Monte, Ph.D. 2017
Professor and Chair
Institute of Neuroscience
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Senior Research Scientist and Deputy Director
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Ex Officio

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Executive Secretary

JORDAN, Craig A., Ph.D.
Director, Division of Extramural Activities
National Institute on Deafness and Other
Communication Disorders
Bethesda, MD 20892

NIDCD Director's Budget

James F. Battey, Jr., M.D., Ph.D.
NIDCD Advisory Council Meeting
May 20, 2016

National Institute on Deafness and Other Communication Disorders

May 2016 Council Budget Mechanism (Dollars in thousands)

<i>Budget Mechanism</i>	FY 2015 Final Allocation		FY 2016 Enacted	
	<i>Number</i>	<i>Amount</i>	<i>Number</i>	<i>Amount</i>
Research Projects				
Noncompeting	557	\$208,795	550	\$210,600
Admin. Supplements	26	1,375	45	2,500
Competing	180	65,220	213	78,596
Subtotal	737	275,390	763	291,696
SBIR/STTR	26	11,321	29	12,500
Subtotal, RPG's	763	286,711	792	304,196
Research Centers	18	17,039	15	16,760
Other Research	67	12,991	65	11,800
Total Research Grants	848	316,741	872	332,756
Individual Training	112	4,894	130	5,850
Institutional Training	160	7,633	153	7,400
R & D Contracts	30	19,102	30	18,750
Intramural Research		36,711		37,450
Research Mgmt. & Support		20,126		20,730
TOTAL		\$405,207		\$422,936

National Institute on Deafness and Other Communication Disorders

May 2016 Council Funds for Competing R01's (Dollars in thousands)

May 2016 Council Funds for FY 2016 Competing R01's
Based on FY 2016 Enacted Level - \$422.936 million
 (\$ in thousands)

Estimated Total RPG budget	\$304,196	
Less estimated SBIR/STTR budget	-12,500	
Less estimated Admin. Supplements budget	-2,500	
Less estimated Noncompeting budget	-210,600	
Less FY16 "Carryover" Commitments from prior Council meetings	-2,184	
Less FY16 Program Requirements	-18,907	
Plus FY15 funding for Sept 2015 applications	1,100	
	<hr/>	
<i>Total</i>	\$58,605	
	<pre> graph TD A["\$58,605"] --> B["20% HPP"] A --> C["80% Regular"] </pre>	
For FY 2016	\$11,721	\$46,884
Per Council Round	\$3,907	\$15,628