

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

September 9, 2016

**National Institutes of Health
Bethesda, MD**

MINUTES

The National Deafness and Other Communication Disorders Advisory Council convened on September 9, 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: September 9, 2016: 8:30 a.m. to 10:05 a.m. for review of individual grant applications; and

Open: September 9, 2016: 10:20 a.m. to 1:50 p.m., for the review and discussion of program development needs and policy.

Council members in Attendance¹:

Dr. Sarah Blackstone	Dr. Christoph Schreiner
Dr. Diane Bless	Dr. Richard Smith
Dr. Sue Kinnamon	Dr. Helen Tager-Flusberg
Dr. David Lee	Dr. Debara Tucci
Dr. Jian-Dong Li	Dr. Monte Westerfield
Dr. David Myers	Dr. Donald Wilson

Council members absent:

Dr. Charlie Liberman	Dr. Elba Serrano
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Council ex-officio members in Attendance;

Ms. Christa Themann	Dr. Judy Schaffer
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Council Ad-Hoc members in Attendance:

Dr. Judith Gierut	Dr. Susan Ellis-Weismer
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The complete Council roster is found in Appendix 1.

¹For 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. Eric Nunn
Mr. Jim Burton	Dr. Christopher Platt
Dr. Laura Cole	Dr. Amy Poremba
Dr. Judith Cooper	Dr. Kausik Ray
Dr. Janet Cyr	Dr. Alberto Rivera-Rentas
Ms. Susan Dambrauskas	Mr. Mark Rotariu
Mr. Hoai Doan	Dr. Elka Scordalakes
Dr. Amy Donahue	Dr. Lana Shekim
Dr. Nancy Freeman	Dr. Katherine Shim
Ms. Maria Garcia	Dr. Sheo Singh
Mr. Howard Hoffman	Ms. Nanette Stephenson
Ms. Nichelle Johnson	Dr. Melissa Stick
Ms. Phalla Keng	Dr. Susan Sullivan
Dr. Eliane Lazar-Wesley	Dr. Jean Tiong-Koehler
Dr. Chuan-Ming Li	Ms. Kelli VanZee
Ms. Lonnie Lisle	Dr. Bracie Watson
Dr. Castilla McNamara	Ms. Ginger Webb
Dr. Roger Miller	Mr. Timothy Wheelles
Dr. Elyssa Monzack	Mr. Baldwin Wong
Mr. Christopher Myers	Mr. Chad Wysong
Mr. Edward Myrbeck	Dr. Shiguang Yang

Other federal employees present during portions of the meeting:

Dr. Biao Tian, CSR
Dr. Maribeth Champoux, CSR
Dr. Wind Cowles, CSR

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

Ms. Jen McCulley, IQ Solutions
Mr. Andrew Bopp, HIA
Ms. Susan Lott, ASHA

CLOSED SESSION

I. Call to Order and Opening Remarks Dr. 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 10:00 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 112 investigator-initiated R01 grant applications; 94 applications had primary assignment to NIDCD, in the amount of \$32.5 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.

B. Special Programs Actions

1. NIH Mentored Patient-Oriented Research Career Development Award (K23): The Council recommended support of one application.
2. NIH Support for Conferences and Scientific Meetings (R13): The Council recommended support of two applications and partial support for two applications with dual assignment.
3. NIH Academic Research Enhancement Awards (AREA) (R15): The Council recommended support of one application.
4. NIH Exploratory/Development Research Grant Award (R21): The Council recommended support of six applications.
5. NIDCD Early Career Research (ECR) Award (R21): The Council recommended support of seven applications.
6. NIH Small Business Innovation Research Awards (SBIR): The Council recommended support for one Phase I (R43) application.
7. NIH Small Business Innovation Research Awards (SBIR): The Council recommended

support for one Phase II (R44) application.

8. NIDCD National Human Ear Tissue Laboratory Resource for Hearing and Balance Research (U24): The Council recommended support for one application.

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

Next, Dr. Battey 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. Battey

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

Recognition of Ad-Hoc Members

The NDCD Advisory Council slate for new members has been delayed. In order to supplement the expertise of the Council following the 2016 member retirements additional scientific expertise was required. Two members of our research community graciously agreed to serve as Ad Hoc Consultants and to review summary statements and other materials in order to advise the Council members and the Director, NIDCD during the meeting. I'd like to briefly introduce these consultants:

Dr. Judith A. Gierut Ph.D. is Professor Emerita at the Department of Speech and Hearing Sciences and Program in Cognitive Science at Indiana University and is an expert in the field of Speech and Language Sciences with an emphasis in language acquisition and phonology. She is very qualified to present/review research in this field, and answer and questions at the government sponsored meeting convened to discuss the Advisory Council business.

Dr. Susan Ellis Weismer Ph.D. is the Oros Bascom Professor of Communication Sciences & Disorders at the University of Wisconsin-Madison and is an expert in the field of Speech and Language Sciences with an emphasis on early language development and autism. She is very qualified to present/review research in this field, and answer any questions at the government sponsored meeting convened to discuss the Advisory Council business.

My thanks to you both for assisting us with this important work.

Dr. Battey thanked Dr. Helen Tager-Flusberg for extending her service on the Advisory Council also in an effort to assist with the work.

Consideration of Minutes of the Meeting of May 20, 2016

Dr. Battey called the members' attention to the minutes of the May 20, 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, January 27, 2017, in Building 31, Conference Room 6 on the NIH campus, Bethesda, Maryland.

VI. Report of the Director, Division of Intramural Research Dr. Griffith

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 2016 report.

Board of Scientific Counselors

Dr. Griffith updated the Council on the membership of the Board of Scientific Counselors. Dr. Andrew Groves from the Baylor College of Medicine is the Chair of the committee; the committee currently has 8 members and on average 20% of the membership is replaced annually.

Personnel

The intramural program is currently composed of 10 tenured investigators and two tenure-track investigators along with a large contingent of supporting scientists. There are also four individuals in the Surgeon-Scientist Career Development program.

Highlights

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.

The third EARssentials course was held in July, 2016 at the Porter Neuroscience Research Center with the main 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 2016, attendees included trainees from eight extramural research organizations.

VII. Report of the Director, NIDCD Dr. Battey

Budget Update

Dr. Battey began his presentation by pointing out that HHS Secretary Burwell recently exercised her transfer authority to provide NIAID with additional funds to combat Zika virus. A total of \$34.2 million was transferred from other NIH institutes, including \$585 thousand from NIDCD.

At this time the House and Senate Appropriations Committees have reported-out bills which would provide significant increases over the President’s request – this is the good news. The other news is that the government will likely begin the next fiscal year under a continuing resolution (CR). We remain hopeful that eventually the Congress will enact a budget that includes and increase for NIH and NIDCD. There is much uncertainty about when our annual budget will be determined. The biggest budgetary challenge for FY 2017 for NIDCD is the large increase in noncompeting Research Project Grant (RPG) costs, driven by increased FY 2016 funding for competing RPGs. Consequently, NIDCD is following a conservative path, that allows funding of R01 applications up through the 13th percentile for this Council.

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

VIII. Report of the Director, Division of Scientific Programs Dr. Judith Cooper

Dr. Cooper introduced Dr. Christopher Platt who has served the NIDCD in the hearing and balance area since 2003. He will be retiring at the end of December so his presentation today will represent his swan song to the Council. Christopher has been an invaluable colleague to us in the institute, and an equally invaluable resource to the hearing and balance/vestibular research community. In addition, he has served NIDCD and the broader NIH community on such things as the trans-NIH BRAIN program and advising/handling all things related to the AREA grant program. Christopher has dedicated over 30 years of service to the Federal government, including 19 years as Program Director, Sensory Systems; Biological Sciences Directorate at the National Science Foundation. He has been a remarkable colleague and friend. His light-hearted nature and his exceptionally keen intellect made us all better people. As a tribute to his career, service, and achievements, we today will honor him with the NIDCD Award of Excellence. We consider this a prestigious award for NIDCD staff members who have made significant contributions to the NIDCD mission. The award recognizes Christopher’s “sustained support of the NIDCD mission”.

We will miss Christopher very much and please join me in thanking him for his years of service and wishing him all the best in this next phase of his life.

Dr. Platt’s talk is entitled: ‘Improving Balance for 25 Years: The Balance/Vestibular Program at NIDCD, 1992-2015.’

Information about posture and balance comes from the vestibular organs, named for their location just outside the cochlea of the inner ear. Vestibular sensorimotor behavior is mostly reflexive without a lot of conscious perception involved, but it is critical for 3-dimensionally stabilizing functions of visual gaze (vestibulo-ocular reflex or VOR), posture, locomotion and navigation. While usually considered a ‘slow’ system, its short-latency reflexive circuits provide valuable speed to avoid a sudden fall if you trip or slip, and for compensatory eye movements and blood-pressure changes needed with postural motions that are faster than visual or cardiovascular responses alone can handle. Malfunction can result in incapacity (visual

oscillopsia, dizziness, nausea) or injury from falls. The semicircular canal organs detect rotational motions using fluid inertia, and the otolithic organ pouches detect gravity and linear motions using an inertial mass of calcium crystals (otoconia); these motions stimulate mechanosensory hair cells. Neural signals are carried to the brain by branches of cranial nerve VIII, the auditory/vestibular nerve, and vestibular influences are extremely widespread down the spinal cord and up into the cerebellum and cerebral cortex.

Funding for balance/vestibular research has consistently represented about 5-7% of the NIDCD extramural research budget; changes up and down in yearly applications, award rates and success rates show rather close tracking with the NIDCD and NIH data trends for the same 25-year period. Over 450 awards have been made to over 100 institutions (including SBIR companies) in this period, with 13 institutions getting 10 or more awards. Advances have included development of successful treatments for disorders including benign paroxysmal positional vertigo (BPPV, producing a sudden spinning sensation) and semicircular canal dehiscence (SCD, a developmental anomaly of skull bone inadequately shielding the lateral semicircular canal from sound, touch and temperature), and development of new techniques for vestibular tests in human subjects. Currently, early stages are being tested of an electronic vestibular prosthetic implant, analogous to the widely successful cochlear implant, to provide an artificial electrical stimulus to the vestibular nerve or brainstem to replace peripheral loss of function. The vestibular sense has been called a '6th sense' not well studied in comparison to sight, hearing, touch, smell and taste, and it is so critical to overall health that it is an important specific mission area for NIDCD.

IX. Report of the Director, Division of Extramural Activities Dr. Jordan

Dr. Jordan apprised the group that the NIDCD Strategic Plan 2017-2021 draft document is available for comment through September 30, 2016. Interested individuals or organizations can access the document and the comment website by visiting the NIDCD Homepage or via the NIH Guide Notice [NOT-DC-16-006](#). He also highlighted several recent NIH Guide Notices about changing NIH practices including:

- [NOT-OD-16-164](#): Revised: Projected FY 2017 Stipend Levels for Postdoctoral Trainees and Fellows on Ruth L. Kirschstein National Research Service Awards. The Notice provides updated information about the implementation of projected stipend levels for postdoctoral trainees and fellows supported by Kirschstein-NRSA awards in Fiscal Year (FY) 2017.
- [NOT-OD-16-129](#): New Policy Eliminates Most Appendix Material for NIH/AHRQ/NIOSH Applications Submitted for Due Dates On or After January 25, 2017. The Notice clarifies the status of appendix materials in peer review and details the new policy.
- [NOT-OD-16-130](#): Changes to the NIH/AHRQ/NIOSH Policy on Post-Submission Materials for Applications Submitted for Due Dates On or After January 25, 2017. This Notice simplifies and consolidates current NIH and AHRQ policy concerning post-submission materials, and extends this policy to NIOSH.

Dr. Jordan told the members that NIH is continuing to examine and develop initiatives to strengthen the clinical trial portfolio across NIH. Visible activities in the past year included public comment periods on drafts of 'Clinical Trials Registration and Results Submission' and 'Clinical Trial Protocol Template,' and the recently published policy on 'Single IRB in Multi-Site Studies.' Additional topics being considered by the NIH's Trans-NIH Clinical Trial Stewardship Reforms Task Force include; How Best to Solicit Clinical Trials, Good Clinical Practice Training, Guiding

Principles for Management and Oversight, and an electronic system to facilitate that management and oversight.

He closed out his presentation with several geographic displays of where NIDCD applications arise and where awards are located across the United States. As of September 1st, the NIDCD portfolio consisted of 1305 awards spread across 257 institutions, representing all but a few of the 50 states, and supporting greater than 1100 unique principal investigators.

**X. Scientific PresentationDr. Richard Smith
Hearing Loss, Precision Medicine and Deafness: Revolutionizing
The Care of Persons with Hearing Loss**

Dr. Richard Smith is Director of the Iowa Institute of Human Genetics and the Sterba Hearing Research Professor, Department of Otolaryngology- Head and Neck Surgery at the University of Iowa. Dr. Smith’s clinical and research interests include complement-mediated renal diseases and deafness. In the area of deafness, his laboratory focuses on both syndromic and non-syndromic types of deafness. Ongoing research involves gene discovery, functional studies and gene therapy experiments using RNA interference to rescue deafness in mouse models of hearing loss. Dr. Smith accepted our invitation to discuss his research in a presentation entitled “Hearing Loss, Precision Medicine and Deafness: Revolutionizing the Care of Persons with Hearing Loss.”

Targeted genomic enrichment with massively parallel sequencing (TGE+MPS) has revolutionized human genetics and promises to be the harbinger of personalized medicine. In the care of deaf and hard-of-hearing persons, this technology has made comprehensive genetic testing possible, thereby changing the clinical evaluation of these persons. Over the past decade, we have developed three complementary tools to facilitate TGE+MPS for deafness. The first tool, a TGE+MPS platform, allows us to sequence all exons of all genes implicated in non-syndromic hearing loss. The second tool, a bioinformatics platform, facilitates variant identification. The third tool, a machine-learning algorithm, analyzes audiograms to cross-correlate phenotypic and genotypic data. Using these tools in sequentially accrued patients, we can identify a genetic cause for hearing loss in ~40% of patients, validating the use of comprehensive genetic testing as the most cost-effective test in the diagnostic evaluation of hearing loss after an audiogram.

In the near future, genetic results will be the foundation upon which personalized therapies for hearing loss are offered. As an example, missense variants underlie 85% of autosomal dominant non-syndromic hearing loss (ADNSHL), suggesting that selective suppression of mutant ADNSHL alleles by RNA interference may prevent this type of deafness. We have validated this hypothesis using artificial micro-RNAs to rescue the progressive hearing loss in the Beethoven mutant mouse, a model of deafness at the DFNA36 locus, suggesting that new therapies for hearing loss will soon complement the use of hearing aids and cochlear implants.

**XI. Hearing Healthcare for Adults: Priorities for Dr. Dan Blazer
Improving Access and Affordability**

Dr. Dan Blazer is the JP Gibbons Professor of Psychiatry Emeritus at Duke University Medical Center and recently served as Chair of the Committee on Accessible and Affordable Hearing Health Care for Adults. He accepted our invitation to discuss that effort and the resulting

Committee Report: “Hearing Health Care for Adults: Priorities for Improving Access and Affordability” with the Council.

In examining the complex issues around hearing loss in adults and hearing health care the committee worked toward an integrated approach prioritizing the needs of individuals with hearing loss, emphasizing hearing as a public health concern with societal responsibilities and effects and a goal of improving outcomes and raising awareness of patients’ rights of access to hearing health care information and records. Hearing is vital to communication, health, function and quality of life. Individuals need to be alert to their hearing health, as hearing loss can range from mild to profound and tends to increase with age. Onset can be gradual and each individual’s hearing needs are unique. Hearing health care involves a wide range of services and technologies with ever-expanding and evolving options; however, many people do not have access to these options or can afford them. Hearing loss is a public health and societal concern, engagement and action are needed across the spectrum of relevant stakeholders, including individuals and families, professionals, nonprofit organizations industries, government and the health care community.

The committee recommended the following actions (all are important and are not prioritized):

- Improve population-based information on hearing loss and hearing health care.
- Develop and promote measures to assess and improve quality of hearing health care services.
- Remove FDA’s regulation for medical evaluation or waiver of that evaluation prior to hearing aid purchase.
- Empower consumers and patients in their use of hearing health care.
- Improve access to hearing health care for underserved and vulnerable populations.
- Promote hearing health care in wellness and medical visits for those with concerns about their hearing.
- Implement a new FDA device category for over-the-counter wearable hearing devices
- Improve the compatibility and interoperability of hearing technologies with communications systems and the transparency of hearing aid programming.
- Improve affordability of hearing health care by actions across federal, state, and private sectors.
- Evaluate and implement innovative models of hearing health care to improve access, quality, and affordability.
- Improve publicly available information on hearing health
- Promote individual, employer, private sector, and community-based actions to support and manage hearing health and effective communication.

More information about the report can be found at this location:

<http://nationalacademies.org/hmd/reports/2016/Hearing-Health-Care-for-Adults.aspx>

XII. Adjournment

The meeting was adjourned at 1:50 p.m. on September 9, 2016.

XIII. Certification of Minutes

We certify that, to the best of our knowledge, the foregoing minutes and attachments are accurate and correct².

10/17/2016

/Craig A. Jordan/

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

10/17/2016

/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

² These minutes will be approved formally by the Council at the next meeting on January 27, 2017, 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	MYERS, David G., Ph. D. Professor Hope College Department of Psychology Holland, MI 49422	2017
BLESS, Diane M., Ph.D. Professor Emeritus Departments of Communicative Disorders And Surgery University of Wisconsin – Madison School of Medicine Madison, WI 53792	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
KINNAMON, Sue C., Ph.D. Professor Department of Otolaryngology University of Colorado, Denver Aurora, CO 80045	2019	SERRANO, Elba E., Ph.D. Regents Professor Department of Biology New Mexico State University Las Cruces, NM 88003	2017
LEE, David J., Ph.D. Professor Department of Public Health Sciences University of Miami School of Medicine Miami, FL 33136	2018	SMITH, Richard J. H., M.D. Professor Department of Otolaryngology University of Iowa – Carver College of Medicine Iowa City, IA 52242	2018
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	TAGER-FLUSBERG, Helen, Ph.D. Professor Department of Psychological and Brain Sciences Boston University Boston, MA 02215	2016
LIBERMAN, M. Charles, Ph.D. Director, Eaton-Peabody Laboratory Department of Otolaryngology Harvard Medical School Boston, MA 02114	2019	TUCCI, Debara L., M.D. Professor Division of Otolaryngology Department of Surgery Duke University Medical Center Durham, NC 27710	2017

WESTERFIELD, Monte, Ph.D. 2017
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NIDCD Director's Budget

James F. Battey, Jr., M.D., Ph.D.
NIDCD Advisory Council Meeting
September 9, 2016

National Institute on Deafness and Other Communication Disorders

September 2016 Council

FY 2017 Budget Levels

FY 2016:

Operating Level \$422,350,505 *

FY 2017:

President's Budget Request \$422,936,000

House Appropriations Bill \$434,126,000 **

Senate Appropriations Bill \$441,778,000 **

* Reflects Secretary's transfer of \$585,495.

**As reported-out by the Full Appropriations Committee.