

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

May 20, 2011

**National Institutes of Health
Bethesda, Maryland**

MINUTES

The National Deafness and Other Communication Disorders Advisory Council convened on May 20, 2011 in Building 31, Conference Room 6, National Institutes of Health (NIH), Bethesda, MD. Dr. James Battey, 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, 2011: 8:30 a.m. to 10:10 a.m. for review of individual grant applications; and

Open: May 20, 2011: 10:10 a.m. to 1:50 p.m., for the review and discussion of program development needs and policy.

Council members in attendance¹

Dr. Lauren Bakaletz
Ms. Brenda Battat
Dr. Gerald Berke
Dr. William Brownell
Dr. Karen Cruickshanks
Mr. Richard Ellenson
Dr. Karen Friderici
Dr. Charles Greer

Dr. Saumil Merchant
Dr. John Niparko
Dr. Randall Reed
Dr. Mabel Rice
Dr. Carolyn Stern
Dr. William Yost
Dr. Bevan Yueh

Council members absent:

Dr. Anne Smith

Ex-Officio Members Participating:

Dr. Lucille B. Beck was represented at the Open Session by Dr. Colleen Noe.

Ex-Officio Members Not Participating:

Dr. Rickie Davis

Dr. Michael E. Hoffer

The Council roster is found as Appendix 1.

Various members of the public, as well as NIDCD staff and other NIH staff, were in attendance during the open session of the Council meeting. A complete list of those present for all or part of the meeting is found in Appendix 2.

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.

CLOSED SESSION

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

The meeting was called to order by Dr. Battey, Director, NIDCD, who expressed appreciation to the entire Council for their service and advice. Dr. Anne Smith had scheduling conflicts which prevented her from attending this meeting.

II. Council ProceduresDr. Craig 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 interest, or the 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.

Dr. Jordan pointed out some changes for today's Council meeting, including the change from paper to electronic Council Workbooks and other logistical changes.

III. Council Consideration of Pending Applications

The Council gave special attention to applications involving issues related to protection of human subjects, animal welfare, biohazards and/or women/minority/children representation in study populations as identified by the initial review groups. The Council individually discussed applications being considered for High Program Priority, from New Investigators, and whenever additional discussion was required.

A. Research Project Grant Awards

1. Consideration of Applications: On the Council's agenda was a total of 117 investigator-initiated research grant applications; 97 applications had primary assignment to NIDCD, in the amount of \$31.6 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 17th percentile.

B. Special Programs Actions

1. NIH Mentored Clinical Scientist Development Award (K08): The Council recommended support of one application.
2. NIH Mentored Quantitative Research Career Development Award (K25): 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 eight applications.
5. NIH Support for Conferences and Scientific Meetings (R13): The Council recommended support of four applications and partial support of one application with dual assignment.
6. NIH Support for Conferences and Scientific Meetings (U13): The Council recommended support of one application.
7. NIH Academic Research Enhancement Award - AREA (R15): The Council recommended support of three applications.
8. NIH Exploratory/Development Research Grant Award (R21): The Council recommended support of seven applications.
9. NIH Research Core Center Grants (P30): The Council recommended support for two applications.
10. NIH Small Business Technology Transfer Grants (STTR): The Council recommended support for one Phase I (R41) application.
11. NIH Small Business Innovation Research Awards (SBIR): The Council recommended support for one Phase I (R43) application.
12. NIH Small Business Innovation Research Awards (SBIR): The Council recommended support for three Phase II (R44) applications and support for one application with dual assignment.
13. PAR-08-223 - Fogarty International Research Collaboration Behavioral and Social Sciences (FIRCA-BSS) Research Award (R03): The Council recommended support for one application.
14. PA-10-159 - Research on Autism and Autism Spectrum Disorders (R03): The Council recommended support for one application.
15. PAR-10-267 - NIMH Research Education Grants (R25): The Council recommended partial support for one application with dual assignment.
16. NOT-DC-11-001- NIDCD and NIMH Competitive Revision Applications for Targeted Research on Non-Verbal School-Aged Children with Autism: The Council recommended support for two R01 applications.
17. RFA-DC-10-002 - Accessible and Affordable Hearing Health Care (R21/R33): The Council recommended support for one application.
18. RFA-DC-11-002 - Identification of Immune Mediated Causes of Sensorineural Hearing Loss (R21/R33): The Council recommended support of two applications.
19. RFA-DC-11-003 – NIDCD Otopathology Research Collaboration Network (U24): The Council recommended support of three applications.
20. RFA-NS-11-806 – Collaborative Research in Computational Neuroscience (R01): The Council recommended support for one application.

21. RFA-HD-10-018 – The role of Prenatal Alcohol Exposure in SIDS and Stillbirth (PASS Network) (U01): The Council recommended partial support to the PASS network.

C. Administrative Issues

Council was informed about, and approved, three administrative issues, regarding:

1. Partial support of a Research Conference from the prior January 2011 Council round,
2. Partial support of ongoing cooperative agreements with NIDCD AIDS dollars,
3. Administrative supplement to an SBIR application to acquire safety data in support of an Investigational Device Exemption (IDE) application to the FDA.

OPEN SESSION

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

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

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:

- *Dr. Karen Cruickshanks*
- *Dr. Charles Greer*
- *Dr. Randall Reed*
- *Dr. William Yost*

Consideration of Minutes of the Meeting of January 28, 2011

Dr. Battey called members' attention to the minutes of the January 28, 2011 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 2013 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 Council is scheduled for Friday, September 16, in Building 31, Conference Room 6 on the NIH campus, Bethesda, Maryland.

V. Report of the Director, NIDCD.....Dr. Battey

Budget Update

Dr. Battey began his presentation by stating that our FY2011 budget appropriation was recently approved; however, the comprehensive allocation details are still pending approval from the Department of Health and Human Services and the Office of Management and Budget. Dr. Battey presented NIDCD's estimated budget for the May Council meeting based on the estimate of \$299 million available for research project grants. From this total, \$9.8 million is reserved for Small Business Research grants, \$1 million for administrative supplements, \$222.6 million for

commitments to noncompeting grants, \$1.6 million for carryover commitments from prior Council meetings, \$13.9 million for program requirements, \$2.1 million for Neuroscience Blueprint, and the addition of \$2.4 million from FY2010 appropriation/ARRA funds. Twenty percent of the remaining \$50.7 million is designated for High Program Priority (HPP). Consequently, there is \$40.6 million available for the initial pay line across the year's three Council meetings. This should allow funding of applications through the 17th percentile. The \$10.1 million for HPP applications will be available to support additional applications. [Executive Secretary Note: An updated copy of the slides (includes mechanism details subsequently approved by HHS and OMB) Dr. Battey used for this budget presentation is included in Appendix 3.]

VI. Update on NIDCD Strategic Plan Rewrite Mr. Baldwin Wong and Drs. William Yost, Charles Greer, and Mabel Rice

Dr. Battey introduced Mr. Baldwin Wong, Chief of NIDCD's Science Policy and Planning Branch (SPPB). SPPB is coordinating the effort to develop a new FY 2012-2016 NIDCD Strategic Plan (Plan). Mr. Wong introduced the members of his staff who are working on the Plan rewrite: Dr. Laura Cole, Dr. Lisa Kennedy, Ms. Reaya Reuss, and Ms. Kate Saylor (a Presidential Management Fellow on detail at SPPB). Mr. Wong presented an overview on the Plan's rewrite and the purpose of the Plan. He announced that NIDCD convened three Working Groups (for Hearing/Balance, Chemical Senses, and Voice/Speech/Language) in March 2011 to discuss recent advances in their respective fields and to identify areas of emerging opportunities in communication sciences research that should be included in the Plan.

Mr. Wong then introduced the co-chairs/council liaisons for the Working Groups: Hearing/Balance - Dr. William Yost; Chemical Senses - Dr. Charles Greer; and Voice/Speech/Language: Dr. Mabel Rice. Each Working Group Council liaison provided a summary of their respective Working Group's efforts and the research priority areas that their group developed. After the co-chairs' presentation, several Council members suggested other areas to consider for the Plan. NIDCD will take these comments into consideration as it develops the next version of the Plan.

Mr. Wong described the next steps for the Plan. Over the summer, NIDCD staff and the Working Groups will develop the first draft of the Plan. Council members will have the opportunity to review the ensuing draft Plan, and it will be discussed at the September 16, 2011, NIDCD Advisory Council meeting.

VII. Report of the Division of Scientific ProgramsDr. Judith Cooper

Dr. Cooper turned the podium over to Dr. Janet Cyr, Division of Scientific Programs, NIDCD.

NIDCD's Individual NRSA Fellowship Program

Dr. Cyr provided an overview of NIDCD's Individual NRSA Fellowship Program including the F30 (integrated dual-degree predoctoral), F31 (predoctoral), and F32 (postdoctoral) fellowship mechanisms. Over the past 6 years, the success rate of NIDCD'S individual NRSA fellowships has been fairly stable and has ranged from 36-43%. This program is being utilized by all of NIDCD's scientific mission areas; the majority of the submitted applications are for predoctoral training. Data was presented which indicated that NIDCD's expedited fellowship submission/award program is appropriately utilized and that it continues to provide a valuable service to the extramural community and to the NIDCD research training enterprise. In addition, an analysis of the submission and acquisition of subsequent NIH grants by previous NIDCD F32 postdoctoral awardees (whose F32 fellowship terminated between FY1900-2005) demonstrated that the F32 postdoctoral award is an efficacious funding program for training future NIH-funded independent investigators.

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

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

NIH Working Group on the Future of the Biomedical Research Workforce

Dr. Jordan highlighted the April 27th NIH announcement that the NIH has established a working group on the future of the biomedical research workforce in the United States. Questions being entertained by this group include:

1. What is the right size of the workforce?
2. What are the appropriate types of positions that should be supported to allow people to have successful careers and to continue to advance biomedical and behavioral sciences?
3. What is the best way to support these positions?
4. What types of training should be provided?

In the announcement, NIH Director Francis S. Collins, MD indicated that, “The working group will help lay the foundation for ensuring that we have the biomedical workforce we will need to usher in the next generation of scientific discoveries.”

NIH Modular Research Grant Applications

Dr. Jordan reviewed with Council the history of NIH’s modular grant applications. The intent was to reinforce the grant-in-aid philosophy of supporting research as opposed to the contract mentality of “buying” research. In 1999 the goals were to:

- Focus the efforts of peer reviewers, principal investigators, institutional officials, and NIH staff on the science of the applications (rather than on the itemized budget)
- Reduce administrative burden for all stakeholders and simplify the grant administration process
- Accommodate principal investigators’ need for flexibility

Out of a total of 6,931 eligible applications, 6,403 (92.4%) modular grant applications were submitted for the first NIH-wide deadlines. Slightly less than half of R01 applications submitted (41%) requested \$175,000 or \$200,000 for the first year. The NIH’s Modular Research Grant Applications website currently contains NIH modular application data for FY 2000 – 2006. <http://grants.nih.gov/grants/funding/modular/modular.htm> Recently, the NIH Division of Information Services extended the data through FY 2010 and provided updated graphs.

The percentage of R01 awards going to modular applications has steadily decreased over time. The converse statement is that more and more R01 applications are requesting, and receiving >\$250K in Direct Costs. If one looks only at modular R01 applications, a higher percentage of those applications are requesting the maximum \$250K. Dr. Jordan showed figures that demonstrated the quick rise in direct costs to the \$250K modular cap and then the slow bleed-over into the more expensive non-modular category. In another graphic, he displayed NIDCD’s trend for modular R01 awards and how closely it follows the NIH trend. Data trends for all ICs reveal a consistent cost escalation across the scientific communities. Of the modular grant applications that receive awards in FY 2010, >80% requested \$250K. Dr. Jordan then shifted to NIDCD-specific application data, extended the data set to include available data for FY2011, and stratified into just three cost categories. This more dramatically demonstrated changing characteristics of R01s submitted to NIDCD. The category of expensive R01s (requesting >\$250K) jumped noticeably in 2006 and then again in 2010 when they became the predominate type of R01 submitted. This was in stark contrast to the less expensive R01s (<\$250K) that have dropped precipitously since FY2005.

IX. Scientific Presentation..... Dr. Steven Rauch

Dr. Battey introduced Dr. Steven Rauch, Professor, Otolaryngology, Harvard Medical School, Mass Eye and Ear Infirmary. Dr. Rauch accepted our invitation to discuss his research in a presentation entitled “*Sudden Deafness – A Multicenter Treatment Trial.*”

Clinical trials and outcomes research are critical steps in the path from basic science investigation to improved health. Despite the fact that such studies are desperately needed, few have been done in our field. One explanation for the shortfall in clinical research may be the logistical problems encountered in trying to study diseases that are low incidence and/or low prevalence, a common situation in Otolaryngology. Another explanation may be the short supply of clinical investigators in Otolaryngology with expertise and experience in the field of clinical trials and outcomes research. Another may be the very limited epidemiologic research done to date that would lay the groundwork for clinical trials. Still another may be the fact that clinical trials are very expensive compared to typical basic science projects. In an effort to maintain support for the basic scientists in our field, few resources are allocated for clinical trials. This two-part presentation will first present results of our recently completed clinical effectiveness study comparing oral to intratympanic steroid treatment of idiopathic sudden sensorineural hearing loss. Then experiences drawn from this study will be used to illustrate some of the methodological, infrastructural, societal, and financial factors that are relevant to the conduct of clinical trials and outcomes research.

X. Adjournment: The meeting was adjourned at 1:50 p.m. on May 20, 2011.

XI. Certification of Minutes

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

6-10-2011

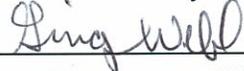

Craig A. Jordan, Ph.D.
Executive Secretary
National Deafness and Other Communication
Disorders Advisory Council

6-6-2011


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 formally considered by the NDCD Advisory Council at its next meeting; corrections or notations will be incorporated in the minutes of that meeting.

APPENDICES

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SMITH, Anne, Ph.D. 2012
Distinguished Professor
Department of Speech, Language
and Hearing Sciences
Purdue University
College of Liberal Arts
West Lafayette, IN

STERN, Carolyn R, M.D. 2012
Partner
DeafDOC.Org
Rochester, NY

YOST, William A., Ph.D. 2011
Chair of Speech and Hearing Science
Department of Speech and Hearing Science
Arizona State University
Tempe, AZ

YUEH, Bevan, M.D., MPH 2014
Professor and Chair
Department of Otolaryngology- Head &
Neck Surgery
University of Minnesota
Minneapolis, MN

EX-OFFICIO MEMBERS:

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

DAVIS, Rickie, Ph.D.
Team Leader
Hearing Loss Prevention Team
National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention
Cincinnati, OH

HOFFER, Michael E., M.D.
Co-Director
Department of Defense Spatial Orientation Center
Department of Otolaryngology
Naval Medical Center
San Diego, CA

SEBELIUS, Kathleen
Secretary
Department of Health and
Human Services
Hubert H. Humphrey Building
Washington, DC

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

EXECUTIVE SECRETARY:

JORDAN, Craig A., Ph.D.
Director
Division of Extramural Activities, NIDCD
Bethesda, MD

Rev. 5/2011

Appendix 2
ATTENDANCE LIST

Other than Council members, attendees at the May 20, 2011 Council meeting included:

NIDCD Staff:

Office of Administration

Wysong, Chad, Executive Officer (Acting)
Kerr, Dave, Consultant
Pierre, Natasha I. Intern

Financial Management Branch

Rotariu, Mark, Budget Officer
Lee, Mimi, Budget Officer
Rosado, Chris, Budget Analyst

Science Policy and Planning Branch

Wong, Baldwin, Chief
Cole, Laura, Ph.D., Science Policy Analyst
Reuss, Reaya, Health Science Policy Analyst
Kennedy, Lisa, Ph.D., Science Policy Analyst
Kate Saylor, Presidential Management Fellow

Office of Health Communication and Public Liaison

Blessing, Patricia, Chief
Latham, Robin, Science Writer

Information Systems Management Branch

Jones, Jackie, Chief Information Officer
Schecter, Steve, IT Specialist
Burgin, Tom, IT Specialist

Division of Extramural Activities

Jordan, Craig A., Ph.D., Director
Stephenson, Nanette, Committee Management Specialist
Webb, Ginger, M.S. Program Analyst/Council Assistant

Grants Management Branch

Myers, Christopher, Chief
Dabney, Sherry, Grants Management Officer
Doan, Hoai, Grants Management Specialist
Garcia, Maria, Grants Management Specialist
McNamara, Castilla, Ph.D., M.P.A., Grants Management Specialist

Scientific Review Branch

Stick, Melissa, Ph.D., M.P.H., Chief
Ray, Kausik, Ph.D., Scientific Review Officer

Livingston, Christine, Ph.D., Scientific Review Officer
Singh, Sheo, Ph.D., Scientific Review Officer
Sullivan, Susan, Ph.D., Scientific Review Officer
Yang, Shiguang A., Ph.D., Scientific Review Officer

Division of Scientific Programs

Cooper Judith, Ph.D., Director
Donahue, Amy, Ph.D., Deputy Director

Program Officers

Bainbridge, Kathy, Ph.D., Epidemiology
Cyr, Janet, Ph.D., Training/Hearing and Balance
Davis, Barry, Ph.D., Smell and Taste Program
Freeman, Nancy, Ph.D., Hearing and Balance
Hoffman, Howard, M.A., Epidemiology and Statistics
Hughes, Gordon, M.D., Clinical Trials
Miller, Roger, Ph.D., Neural Prosthesis
Platt, Christopher, Ph.D., Hearing and Balance
Shekim, Lana, Ph.D., Speech and Voice Program
Sklare, Daniel A., Ph.D., Training Officer/Hearing and Balance
Watson, Bracie, Ph.D., Hearing and Balance

Division of Extramural Administrative Support, OER, NIH

Holmes, Debbie, Extramural Support Specialist
Holmes, LaTanya, Extramural Support Assistant

Center for Scientific Review, NIH

Etcheberrigaray, Rene, Division Director, CSR
Melchior, Christine, Chief, Integrative Function & Cognitive Neuroscience IRG
Ni, Weijia, Ph.D., Scientific Review Officer
Tian, Biao, Ph.D., Scientific Review Officer
Luethke, Lynn, Ph.D., Scientific Review Officer
Bennett, Cate, Ph. D., Scientific Review Officer

Office of Director, NIH, and Others

Khachaturian, Henry, Extramural Program Policy, OD/OER
Parady, Alissa, Manager, International Hearing Society
Lott, Susan, Associate Director Research Education, ASHA
Outlaw, Deborah, ATA
Thomas, Kate, Government Relations Manager, AAA

Appendix 3

NIDCD Director's Report Slides

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

NIDCD Advisory Council Meeting

May 20, 2011

National Institute on Deafness and Other Communication Disorders

**May 2011 Council
Budget Mechanism
(Dollars in thousands)**

<i>Budget Mechanism</i>	FY 2010 Actual Obligations		FY 2011 Appropriation	
	<i>Number</i>	<i>Amount</i>	<i>Number</i>	<i>Amount</i>
Research Projects				
Noncompeting	621	\$219,223	651	\$222,608
Admin. Supplements	█ (21)	1,058	█ (20)	1,000
Competing	204	66,307	203	65,982
Subtotal	825	286,588	854	289,590
SBIR/STTR	35	9,967	33	9,765
Subtotal, RPG's	860	296,555	887	299,355
Research Centers	23	18,525	19	15,500
Other Research	60	7,849	59	6,700
Total Research Grants	943	322,929	965	321,555
Individual Training	128	4,847	131	5,000
Institutional Training	209	9,106	206	9,100
R & D Contracts	57	22,758	53	21,700
Intramural Research		38,408		38,000
Research Mgmt. & Support		19,953		19,800
TOTAL		\$418,001		\$415,155

National Institute on Deafness and Other Communication Disorders

**May 2011 Council
Competing Research Project Grants
(Dollars in thousands)**

May Council Funds for FY 2011 Competing R01's
Based on FY 2011 Appropriation
(\$ in thousands)

Estimated Total RPG budget	\$299,355	
Less estimated SBIR/STTR budget	-9,765	
Less estimated Administrative Supplements budget	-1,000	
Less estimated Noncompeting budget	-222,608	
Less FY11 "Carryover" Commitments from prior Council meetings	-1,600	
Less FY11 Program Requirements	-13,875	
Less FY 11 Neuroscience Blueprint RFA	-2,152	
Plus FY10 regular appropriation and ARRA funds	2,406	
	<hr/>	
<i>Total</i>	\$50,761	
	<u>20% HPP</u>	<u>80% Regular</u>
For FY 2011	\$10,152	\$40,609
Per Council Round	\$3,384	\$13,536