

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

May 31, 2013

**National Institutes of Health
Bethesda, MD**

MINUTES

The National Deafness and Other Communication Disorders Advisory Council convened on May 31, 2013 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 31, 2013: 8:30 a.m. to 9:40 a.m. for review of individual grant applications; and

Open: May 31, 2013: 10:00 a.m. to 1:30 p.m., for the review and discussion of program development needs and policy.

Council members in Attendance¹:

Dr. Lauren Bakaletz	Dr. Charlotte Mistretta
Ms. Brenda Battat	Dr. John Niparko
Dr. Gerald Berke	Dr. Joseph Perrell
Dr. William Brownell	Dr. Tommie Robinson
Mr. Richard Ellenson	Dr. James Schwob
Dr. Karen Friderici	Dr. Robert Shannon
Ms. Tisha Kehn	Dr. Helen Tager-Flusberg
Dr. Paul Manis	Dr. Bevan Yueh

Council members absent:

Ms. Joan Kaye

Ex-Officio Members Participating:

Dr. Rickie Davis

Ex-Officio Members Not Participating:

Dr. Lucille Beck

Dr. Michael E. Hoffer

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	Dr. Christine Livingston
Mr. Chris Carlsen	Dr. Castilla McNamara
Dr. Laura Cole	Dr. Roger Miller
Dr. Judith Cooper	Mr. Robert Miranda-Acevedo
Dr. Janet Cyr	Mr. Christopher Myers
Ms. Sherry Dabney	Mr. Edward Myrbeck
Ms. Susan Dambrauskas	Mr. Eric Nunn
Ms. Laura Damiano	Mr. Luis Ochoa
Ms. Lesley DeRenzo	Dr. Christopher Platt
Mr. Hoai Doan	Ms. Lisa Portnoy
Dr. Amy Donahue	Dr. Kausik Ray
Dr. Nancy Freeman	Dr. Lana Shekim
Ms. Maria Garcia	Dr. Sheo Singh
Dr. Andrew Griffith	Dr. Daniel Sklare
Mr. Howard Hoffman	Ms. Nanette Stephenson
Ms. Debbie Holmes	Dr. Susan Sullivan
Dr. Gordon Hughes	Dr. Jean Tiong-Koehler
Mr. Vivek Kamath	Dr. Bracie Watson
Ms. Bella Kazantseva	Ms. Ginger Webb
Ms. Phalla Keng	Mr. Timothy Wheelles
Dr. Andrea Kelley	Mr. Baldwin Wong
Ms. Robin Latham	Mr. Chad Wysong
Ms. Mimi Lee	Dr. Shiguang Yang
Dr. Chuan-Ming Li	

Other federal employees present during portions of the meeting:

Dr. Yvonne Bennett, CSR
Dr. John Bishop, CSR
Dr. Rene Etcheberrigaray, CSR
Dr. Seymour Garte, CSR
Dr. Paek Lee, CSR
Dr. Lynn Luethke, CSR
Dr. Christine Melchior, CSR
Dr. Dana Plude, CSR
Dr. Weijia Ni, CSR
Dr. Biao Tian, CSR
Mr. David Baquis, Access Board

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

Mr. Andy Bopp, Hearing Industries Association
Ms. Susan Lotte, American Speech-Language-Hearing Association
Ms. Deborah Outlaw, American Tinnitus Association
Mr. Neil Snyder, American Speech-Language-Hearing Association
Ms. Kate Thomas, American Academy of Audiology

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 10:30 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 102 investigator-initiated research grant applications; 90 applications had primary assignment to NIDCD, in the amount of \$28.3 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 Research Scientist Development Award (K01): The Council recommended support of one application.
2. NIH Pathway to Independence (PI) Award (K99): The Council recommended support of four applications.
3. NIH Small Grants (R03): The Council recommended support of eight applications.
4. NIH Support for Conferences and Scientific Meetings (R13): The Council recommended support of three applications and partial support of two applications with dual assignment.
5. NIH Support for Conference Cooperative Agreements (U13): The Council recommended support of one application and partial support of one application with a 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 eight applications.
8. NIDCD Research Core Center Grants (P30): The Council recommended support of one application.

9. NIDCD Clinical Research Center Grants (P50): The Council recommended support of one application.
10. NIH Small Business Technology Transfer Awards (STTR): The Council recommended support of one Phase I (R41) application via email balloting in advance of the May 31st Council meeting.
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 one Phase II (R44) application.
13. PAR-13-806 NSF-NIH Collaborative Research in Computational Neuroscience (CRCNS) Program (R01): The Council recommended support for two applications.
14. PA-10-039 Dissemination and Implementation Research in Health (R03): The Council recommended support of one application.

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:

- Ms. Brenda Battat
- Dr. William Brownell
- Dr. Karen Friderici
- Mr. Richard Ellenson
- Dr. John Niparko

Consideration of Minutes of the Meeting of January 25, 2013

Dr. Battey called the members' attention to the minutes of the January 25, 2013 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 2015 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 Thursday, September 12, 2013, 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 pointing out that the potential NIDCD budget for fiscal year (FY) 2014 is quite uncertain. For FY 2014, the President's Budget, the House Budget Resolution, and the Senate Budget Resolution all differ markedly from each other. He went on to explain that the President's Budget is based on a much higher FY 2013 level (\$418.328 million) than what NIDCD actually received due to Sequestration. The House and Senate have passed budget resolutions setting high-level spending targets for FY 2014, but they are very different; reflecting different priorities. If no legislation is enacted, then the existing FY 2014 Sequestration targets could result in a further reduction of about 1.7% versus the FY 2013 Operating Budget. This translates to a further cut of about \$6.7 million for NIDCD. Predicting budgetary outcomes has become extraordinarily difficult, as demonstrated by the FY 2013 process. NIDCD will model the best we can for September Council. In recognition of this high level of uncertainty, NIDCD is adopting a conservative fiscal plan for FY 2014.

Dr. Battey then provided details about the FY 2013 NIDCD budget plan by sharing the recently released FY 2013 Operating Budget and comparing it to the FY 2012 Final Allocation. The FY 2013 operating budget for NIDCD is \$392 million, a reduction of ~\$23.6 million (5.7%) from FY 2012. Dr. Battey detailed how these funds are allocated within NIDCD. Once other components of the NIDCD budget are considered there would be \$280.8 million available for research project grants. From this total, \$10.2 million is reserved for Small Business Research grants, \$850 thousand for administrative supplements, \$212.9 million for commitments to noncompeting grants, \$650 thousand for carryover commitments from last year, and \$12.4 million for program requirements. An additional \$3.1 million was applied from end of year FY 2012 funds. Twenty percent of the remaining \$46.9 million is designated for High Program Priority (HPP). Consequently, there is \$37.5 million available for the initial pay line across the year's three Council meetings. This should allow funding of applications up through the 15th percentile. The \$9.4 million for HPP applications will be available to support additional applications.

[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 Programs Dr. Judith Cooper

Dr. Cooper introduced Drs. Christopher Platt, Janet Cyr, and Nancy Freeman NIDCD program directors. Drs. Platt, Cyr and Freeman presented information on "Trans-NIH Initiatives: OppNet, Neuroscience Blueprint, and Common Fund." All are NIH-wide programs receiving some funding from the NIH Office of the Director.

Dr. Platt outlined how the NIH Office of Behavioral and Social Sciences Research (OBSSR) formed OppNet in 2009, for opportunities to network between biology and the basic behavioral and social sciences. This initiative is co-managed and co-funded by all NIH Institutes, Centers and Offices (ICOs) that handle extramural research, totaling \$10-20M/year. OppNet fosters work on basic social processes and mechanisms of behavior relevant to public health, prevention and treatment, and the missions of individual NIH ICOs, by adding investments that complement the NIH extramural biomedical research portfolio. One large investment of OppNet was in the new NIH Toolbox for the Neuroscience Blueprint, to develop instruments for assessing neurological and behavioral function for nationwide studies, including sensory tests for hearing, balance, smell and taste, which added particular value for NIDCD.

Dr. Cyr discussed how the NIH Blueprint for Neuroscience Research was begun in 2004 as a collaborative framework across 14 ICOs that contribute proportional funds totaling roughly \$35M/year for activities in the broad interdisciplinary field of neuroscience. Commonly called the

Neuroscience Blueprint, it develops initiatives using the combined expertise of many existing programs to identify cross-cutting areas of neuroscience research and scientific challenges too large for any single ICO. Blueprint funds support education, career development, training and short courses; animal models, brain atlases; tools for basic and clinical research; and Grand Challenge projects such as the Human Connectome, Biology of Chronic Pain, and the Blueprint Neurotherapeutics Network.

Dr. Freeman described the Blueprint Neurotherapeutics Network (BPN), designed to cross the large gap that currently hinders therapeutic development by carrying promising drugs or devices from a laboratory pilot stage to a successful clinical trial. The BPN program, a virtual pharma model, involves several milestones of feasibility over a few years, effectively narrowing the number of presumptive therapeutic candidates as possible candidates for potential final development by industry. One NIDCD project was highlighted in this program. In addition, Dr. Freeman also presented an overview of the NIH Common Fund's Protein Capture Reagents Program whose purpose is to generate renewable affinity reagents for human transcription factors and develop new technology to create affinity reagents for the human transcription factors. The NIDCD manages and oversees one component of this three-component common fund project.

VII. Presentation Dr. Christopher Austin

Dr. Battey introduced Dr. Christopher Austin, Director of the National Center for Advancing Translational Sciences (NCATS). Dr. Austin accepted our invitation to discuss his vision for NCATS in a presentation titled "The National Center for Advancing Translational Sciences: Status and Prospects."

Dr. Austin began with the observation that fundamental science is unprecedentedly advanced, but for a variety of reasons, people are unhealthier and funders of biomedical research enterprise (public and private) are impatiently waiting for change. He explained that the NCATS mission is to catalyze the generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions. NCATS was formed by bringing a number of existing NIH translational programs into one administrative home. This common home allows NCATS to better serve its catalytic role, catalyzing collaborations across the many NIH components; outside groups including Academia, Advocacy Groups, Non-Profits, FDA, Pharmaceuticals, and Biotechnology Groups; and, across the entire translational spectrum, T1 through T4. Dr. Austin provided an overview of the programs and initiatives being pursued within NCATS. One of the largest programs at NIH is the Clinical and Translational Science Awards (CTSAs). These 61 centers are located across the United States and form a national consortium of medical research institutions with goals of training the next generation of clinical and translational researchers, and accelerating the process of translating research results. He provided several examples of communication projects that have benefited from the CTSA network including development of the speech therapy device – SpeechVive™, new programming methods for cochlear implants, and the Thirty Million Words Project that addresses early language development delays.

Dr. Austin reviewed several projects in the areas of Rare Disease Research and Therapeutics and Re-engineering Translational Sciences. Several of the examples demonstrated the collaborative nature of NCATS programs, such as the CTSA Informatics Tools & Resources programs, the NIH Chemical Genomics Center with its obligatory collaboration model that currently involves over 200 collaborations worldwide, and the Pharmaceutical Collection, a resource for repurposing of clinically approved drugs. New NCATS initiatives are being developed in response to three goals: 1) Address significant bottlenecks in the process of translation, 2) Highly collaborative across NIH, other government agencies, and with the private sector, and 3) Quick to respond to needs of biomedical researchers. New initiatives include the Therapeutic Uses Pilot Program that involves

eight pharmaceutical company partners and 58 agents they have made available; the Therapeutics Discovery Pilot program that will announce awards in mid-June; the Tissue Chip for Drug Screening: Microsystems Initiative where DARPA and FDA help coordinate efforts to develop tissue chips that mimic human physiology to screen for safe, effective drugs; and the Tissue Chip Program to develop an in vitro platform that uses human tissues to represent ten human physiologic systems for evaluation of promising therapies. Dr. Austin closed by providing a number of additional NCATS contacts/resources and fielding a number of questions from Council members.

VIII. Presentation “The Magic of Science: from AHA in a Lab.....Mr. Richard Ellenson To OMG in a Life”

Dr. Battey introduced Mr. Richard Ellenson, inventor, advocate, father who began his career in advertising, creating high profile work for clients like American Express, Remy Martin and HBO. He founded Blink Twice in 2004 which brought innovation to the world of assistive technology. Mr. Ellenson accepted our invitation to discuss his work in a presentation entitled “The Magic of Science: from AHA in a Lab to OMG in a Life.”

Scientific discovery is a thoughtful and highly disciplined process. But those advances often have the most impact when their implementation requires the least from the people who need them most.

The Tango – a Speech Generating Device that began with a Small Business Innovation Research (SBIR) grant from the NIDCD – not only helped thousands of non-verbal individuals to communicate more efficiently, but also helped change the way an entire field approached creation of Assistive Technology. At the heart of the innovation were four basic principles:

- for technology to be usable in a mass market, it must be intuitive for users
- communication is not about what people say, but about what others hear
- for technology to address a systemic problem, it must address issues throughout an ecosystem
- for a product dealing in a low incidence market to be effective, it must incorporate principles of universal design to maximize its reach

Although the Tango was based on insights from decades of research into speech impairment and the associated approaches to building language – including language intent, language structure and language learning – the device gained its reputation for simply being “cool” and having a great voice. And in doing so, added a mass market sensibility to a field that had been isolated and rarely discussed. This new position brought energy to the field that benefitted everyone.

As importantly, the device became known for the coverage it got in mainstream news media – from features on CBS World News Tonight to CNN Squawkbox to major local newspapers. And in a time of tightening budgets, fierce financial pressures, and many global problems which tend to overshadow critical needs for people who struggle with everyday living, it is more important than ever not only to share the specific scientific advances being made, but also the results of that work – the magic that is brought to so many.

IX. Adjournment

The meeting was adjourned at 1:30 p.m. on May 31, 2013.

X. Certification of Minutes

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

June 20, 2013

Craig A. Jordan

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

June 19, 2013

Jim Battey

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 September 12, 2013, 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

BAKALETZ, Lauren O., Ph.D. Professor Departments of Pediatrics and Otolaryngology College of Medicine Ohio State University Columbus, OH 43205	2014	KEHN, Tisha A. Executive Director Association for Chemoreception Sciences Minneapolis, MN 55406	2015
BATTAT, Brenda, M.S., MCSP Executive Director Hearing Loss Association of America (HLAA) Bethesda, MD 20814	2013	MANIS, Paul B., Ph.D. Thomas J. Dark Distinguished Research Professor Department of Otolaryngology/Head and Neck Surgery University of North Carolina Chapel Hill Chapel Hill, NC 27599	2015
BERKE, Gerald S., M.D. Chair, Department of Head and Neck Surgery Center for Health Sciences School of Medicine University of California at Los Angeles Los Angeles, CA 90095	2014	MISTRETTA, Charlotte M., Ph.D. William R. Mann Professor Department of Biologic and Materials Sciences Associate Dean for Research and Ph.D. Training School of Dentistry University of Michigan Ann Arbor, MI 48109	2015
BROWNELL, William, Ph.D. Jake and Nina Kamin Chair Bobby R. Alford Department of Otolaryngology – Head & Neck Surgery Baylor College of Medicine Houston, TX 77030	2013	NIPARKO, John K., M.D. Tiber/Alpert Professor and Chair Department of Otolaryngology Head and Neck Surgery Keck School of Medicine University of Southern California Los Angeles, CA 90033	2013
ELLENSON, Richard, M.B.A. President Ellenson Interaction New York, NY 10128	2013	PERKELL, Joseph S., Ph.D., D.M.D. Research Affiliate Research Laboratory of Electronics Massachusetts Institute of Technology Cambridge, MA 02446	2016
FRIDERICI, Karen H., Ph.D. Professor Department of Microbiology and Molecular Genetics Michigan State University East Lansing, MI 48824	2013	ROBINSON, Jr., Tommie L., Ph.D. Director, Scottish Rite Center for Childhood Language Disorders Children's Hearing and Speech Center Children's National Medical Center Washington, DC 20009	2016
KAYE, Joan Executive Director Sophie's Soundcheck New York, NY 10128	2016		

<p>SCHWOB, James E., Ph.D., M.D. Bates Professor and Chair of Anatomy and Cellular Biology Tufts University School of Medicine Boston, MA 02111</p>	<p>2015</p>	<p>TAGER-FLUSBERG, Helen, Ph.D. Professor Department of Psychology Boston University Boston, MA 02215</p>	<p>2016</p>
<p>SHANNON, Robert V., Ph.D. Director, Division of Communication and Auditory Neuroscience Head, Auditory Implant Research Laboratory House Research Institute Los Angeles, CA 90057</p>	<p>2015</p>	<p>YUEH, Bevan, M.D., M.P.H. Professor and Chair Department of Otolaryngology Head and Neck Surgery University of Minnesota Minneapolis, MN 55455</p>	<p>2014</p>

Ex Officio

<p>BECK, Lucille B., Ph.D. Director Audiology and Speech Pathology Service Department of Veterans Affairs Washington, DC 20422</p>	<p>COLLINS, Francis S., Ph.D., M.D. Director National Institutes of Health Bethesda, MD 20892</p>
<p>DAVIS, Rickie, Ph.D. Team Leader Hearing Loss Prevention Team Division of Applied Research and Technology National Institute for Occupational Safety And Health (NIOSH) Cincinnati, OH 45226</p>	<p>HOFFER, Michael E., M.D. Co-Director Department of Defense Spatial Orientation Center Department of Otolaryngology Naval Medical Center San Diego, CA 9213</p>
<p>SEBELIUS, Kathleen Secretary Department of Health and Human Services Washington, DC 20201</p>	

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 31, 2013

National Institute on Deafness and Other Communication Disorders

May 2013 Council Budget Mechanism (Dollars in thousands)

<i>Budget Mechanism</i>	FY 2012 Final Allocation		FY 2013 Operating Budget	
	<i>Number</i>	<i>Amount</i>	<i>Number</i>	<i>Amount</i>
Research Projects				
Noncompeting	632	\$225,201	623	\$212,925
Admin. Supplements	43	1,348	22	850
Competing	185	61,419	171	56,863
Subtotal	817	287,968	794	270,638
SBIR/STTR	29	10,454	28	10,200
Subtotal, RPG's	846	298,422	822	280,838
Research Centers	23	15,656	22	14,757
Other Research	54	9,068	60	10,345
Total Research Grants	923	323,146	904	305,940
Individual Training	110	4,515	119	4,875
Institutional Training	198	9,068	179	8,200
R & D Contracts	37	21,032	34	17,280
Intramural Research		38,000		36,500
Research Mgmt. & Support		20,121		19,450
TOTAL		\$415,880		\$392,245

National Institute on Deafness and Other Communication Disorders

May 2013 Council Competing Research Project Grants (Dollars in thousands)

May Council Funds for FY 2013 Competing R01's

Based on FY 2013 Operating Budget of \$392,245 thousand

(\$ in thousands)

Total RPG budget	\$280,838
Less SBIR/STTR budget	-10,200
Less Administrative Supplements budget	-850
Less Noncompeting budget	-212,925
Less FY13 "Carryover" Commitments from prior Council meetings	-650
Less FY13 Program Requirements	-12,450
Plus FY12 appropriated funds for R01's	3,106

Total

\$46,869

20% HPP

80% Regular

For FY 2013	\$9,374	\$37,495
Per Council Round	\$3,125	\$12,498