MINUTES

The National Deafness and Other Communication Disorders Advisory Council convened on May 9, 2014 in Building 31, Conference Room 10, 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 9, 2014: 8:30 a.m. to 9:40 a.m. for review of individual grant applications; and
Open: May 9, 2014: 10:00 a.m. to 1:55 p.m., for the review and discussion of program development needs and policy.

Council members in Attendance:

Dr. Gerald Berke  Dr. James Schwob
Ms. Joan Kaye    Dr. Robert Shannon
Ms. Tisha Kehn   Dr. Helen Tager-Flusberg
Dr. Paul Manis   Dr. Debara Tucci
Dr. Charlotte Mistretta  Dr. Monte Westerfield
Dr. David Myers   Dr. Bevan Yueh
Dr. Tommie Robinson

Council members absent:

Dr. Lauren Bakaletz  Dr. Joseph Perkell
Dr. Elba Serrano        Dr. Richard Smith

Ex-Officio Members Participating:
Dr. Rickie Davis

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:

<table>
<thead>
<tr>
<th>Name</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Dr. Kathy Bainbridge</td>
<td>Mr. Christopher Myers</td>
</tr>
<tr>
<td>Dr. Laura Cole</td>
<td>Mr. Edward Myrbeck</td>
</tr>
<tr>
<td>Dr. Judith Cooper</td>
<td>Mr. Eric Nunn</td>
</tr>
<tr>
<td>Dr. Janet Cyr</td>
<td>Mr. Luis Ochoa</td>
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<tr>
<td>Ms. Susan Dambrauskas</td>
<td>Dr. Christopher Platt</td>
</tr>
<tr>
<td>Ms. Laura Damiano</td>
<td>Ms. Lisa Portnoy</td>
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<tr>
<td>Mr. Hoai Doan</td>
<td>Dr. Kausik Ray</td>
</tr>
<tr>
<td>Dr. Amy Donahue</td>
<td>Mr. Mark Rotariu</td>
</tr>
<tr>
<td>Dr. Nancy Freeman</td>
<td>Dr. Lana Shekim</td>
</tr>
<tr>
<td>Ms. Maria Garcia</td>
<td>Dr. Sheo Singh</td>
</tr>
<tr>
<td>Dr. Andrew Griffith</td>
<td>Ms. Nanette Stephenson</td>
</tr>
<tr>
<td>Mr. Howard Hoffman</td>
<td>Dr. Melissa Stick</td>
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<tr>
<td>Ms. Debbie Holmes</td>
<td>Dr. Susan Sullivan</td>
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<tr>
<td>Dr. Gordon Hughes</td>
<td>Dr. Jean Tiong-Koehler</td>
</tr>
<tr>
<td>Ms. Lynnette Jeffers</td>
<td>Dr. Bracie Watson</td>
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<tr>
<td>Dr. Lisa Kennedy</td>
<td>Ms. Ginger Webb</td>
</tr>
<tr>
<td>Dr. Eliane Lazar-Wesley</td>
<td>Mr. Timothy Wheeles</td>
</tr>
<tr>
<td>Dr. Chuan-Ming Li</td>
<td>Mr. Baldwin Wong</td>
</tr>
<tr>
<td>Dr. Castilla McNamara</td>
<td>Mr. Chad Wysong</td>
</tr>
<tr>
<td>Dr. Roger Miller</td>
<td>Dr. Shiguang Yang</td>
</tr>
<tr>
<td>Mr. Robert Miranda-Acevedo</td>
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</tbody>
</table>

Other federal employees present during portions of the meeting:

- Dr. Cate Bennett, CSR
- Dr. John Bishop, CSR
- Dr. Rene Etcheberrigaray, CSR
- Dr. Lynn Luethke, CSR
- Dr. Christine Melchior, CSR
- Dr. Dana Plude, CSR
- Dr. Biao Tian, CSR

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

- Mr. David Grogan, IHS
- Ms. Joan Martin, A.G. Bell
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 10:20 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 92 investigator-initiated R01 grant applications; 82 applications had primary assignment to NIDCD, in the amount of $27.4 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 16th percentile.

B. Special Programs Actions

1. NIH Mentored Clinical Scientist Research Career Development Award (K08): The Council recommended support of one application.

2. NIH Research Career Enhancement Award for Established Investigators (K18): The Council recommended support of one application.

3. NIH Mentored Patient-Oriented Research Career Development Award (K23): The Council recommended support of two applications.

4. NIH Mentored Quantitative Research Development Award (K25): The Council recommended support of one application.

5. NIH Pathway to Independence (PI) Award (K99): The Council recommended support of one application.

6. NIH Small Grants (R03): The Council recommended support of ten applications.

7. NIH Support for Conferences and Scientific Meetings (R13): The Council recommended support of one application and partial support of one application with dual assignment.

9. NIH Exploratory/Development Research Grant Award (R21): The Council recommended support of eight applications.

10. NIH Small Business Technology Transfer Awards (STTR): The Council recommended support of one Phase I (R41) application.

11. NIH Small Business Innovation Research Awards (SBIR): The Council recommended support for three Phase I (R43) applications.

12. NIH Small Business Innovation Research Awards (SBIR): The Council recommended support for one Phase II (R44) application.

13. RFA-DC-12-004 Improving Access to Hearing Healthcare (SBIR) [R43/R44]: The Council recommended support of one Phase I (R43) application and one Phase II (R44) application.

14. PAR-12-123 NIDCD Phase I/II/III Clinical Trials in Communication Disorders (U01): The Council recommended support of one application.

15. PAR-14-804 NSF-NIH Collaborative Research in Computational Neuroscience (CRCNS) Program (R01): The Council recommended support for three applications.


17. RFA-DC-14-002 NIDCD National Temporal Bone, Hearing Balance Pathology Resource Registry (U24): The Council recommended support of one application.

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. Lauren Bakaletz
- Dr. Gerald Berke
- Dr. Richard Smith
- Dr. Bevan Yueh

Consideration of Minutes of the Meeting of January 24, 2014

Dr. Battey called the members’ attention to the minutes of the January 24, 2014 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 2016 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 12, 2014, 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 FY 2014 Operating Budget for NIDCD reflects an approximate increase of 2.9% over the FY 2013 budget. While pleased to have received an increase this year, the reality is that we are still about $10.5 million below the FY 2012 appropriation level. Both the House and Senate have held hearings on the FY 2015 budget, but the potential NIDCD budget for FY 2015 remains uncertain.

NIDCD’s Operating Budget for FY 2014 is $403,035,000. Once other components of the NIDCD budget are considered there would be $284.5 million available for research project grants. From this total, $11 million is reserved for Small Business Research grants, $1.7 million for administrative supplements, $209.4 million for commitments to noncompeting grants, $1.3 million for commitments carried over from FY2013, and $13.7 million for program requirements. An additional estimated $1.2 million is available from end of year FY 2013 funds. Of the remaining $48.5 million, twenty percent ($9.7 million) is designated for High Program Priority (HPP). Consequently, there is $38.8 million available for the initial pay line across the year’s three Council meetings. This should allow funding of R01 applications up through the 16th percentile. The $9.7 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 Extramural Activities ............................. Dr. Jordan

Dr. Jordan began by summarizing two recent NIH Guide Notices. The first one highlighted a change to NIDCD’s K08 and K23 programs, allowing a ‘long distance’ Primary Mentor because the mentored relationship can be facilitated by electronic communications. This change to NIDCD’s practice was a direct result of advice provided by Council at the January meeting. The second Notice highlighted a change to NIH’s application submission policy. The new policy allows applicants to submit the same idea as a new application (A0) and NIH will not assess the similarity of the science in the new (A0) application versus the prior application. As always, NIH encourages applicants to refine and strengthen all application submissions.

Next he highlighted two staff changes welcoming Dr. Eliane Lazar-Wesley a new Scientific Review Officer and bidding a fond farewell to Ms. Sherry Dabney, Deputy Chief of the Grants Management Branch who is retiring after 38 years of government service.

Finally, Dr. Jordan introduced the NIH Big Data to Knowledge (BD2K) program which will enable biomedical scientists to capitalize more fully on emerging large, complex and diverse datasets, i.e., Big Data. BD2K aims to develop the new approaches, standards, methods, tools, software, and competencies that will enhance the use of biomedical Big Data by supporting research, implementation, and training in data science and other relevant fields. The goals are being approached through four major areas:

- Appropriate access to shareable biomedical data through technologies, approaches, and policies that enable and facilitate widespread data sharing, discoverability, management, curation, and meaningful re-use;
- Development of and access to appropriate algorithms, methods, software, and tools for all aspects of the use of Big Data, including data processing, storage, analysis, integration, and visualization;
• Appropriate protections for privacy and intellectual property;
• Development of a sufficient cadre of researchers skilled in the science of Big Data, in addition to elevating general competencies in data usage and analysis across the behavioral research workforce.

Overall, the focus of the BD2K initiative is the development of innovative and transforming approaches as well as tools for making Big Data and data science a more prominent component of biomedical research.

Dr. Jordan provided information about the organizational structure and leadership recently developed to lead the BD2K at the trans-NIH level, summarized the FY 2014 budget for BD2K ($25M), and described the breadth of Funding Opportunity Announcements (FOAs) currently being used to solicit new grant applications. He recognized Dr. Roger Miller as NIDCD’s programmatic liaison to the BD2K effort and provided the url for the NIH website where members could obtain additional information about BD2K (http://bd2k.nih.gov).

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

Dr. Cooper introduced Dr. Nancy Freeman one of NIDCD’s program directors. Dr. Freeman provided a current and historical overview of the NIDCD R21 program. The Exploratory/Developmental Research Grant Award (R21) mechanism is intended to encourage exploratory/developmental research by providing support for the early and conceptual stages of project development. NIDCD’s R21 program has a $4M set aside and receives the second largest number of research “R” mechanism applications next to the R01. The presentation included current and historical analysis of success rates and trends.

VIII. Presentation ......................................................................................................................... Dr. Eric Green

Dr. Battey introduced Dr. Eric Green, Director of the National Human Genome Research Institute (NHGRI). Dr. Green accepted our invitation to discuss his vision for NHGRI in a presentation titled “The Human Genomics Landscape: Bringing Genomic Medicine into Focus.”

The Human Genome Project’s generation of a reference human genome sequence was a landmark scientific achievement of historic significance. It also signified a critical transition for the field of genomics, as the new foundation of genomic knowledge started to be used in powerful ways by researchers and clinicians to tackle increasingly complex problems in biomedicine. To exploit the opportunities provided by the human genome sequence and to ensure the productive growth of genomics as one of the most vital biomedical disciplines of the 21st century, the National Human Genome Research Institute (NHGRI) is pursuing a broad vision for genomics research beyond the Human Genome Project. This vision includes using genomic data, technologies, and insights to acquire a deeper understanding of genome function and biology as well as to uncover the genetic basis of human disease. Some of the most profound advances are being catalyzed by revolutionary new DNA sequencing technologies; these methods are producing prodigious amounts of DNA sequence data as part of studies aiming to elucidate the complexities of genome function and to unravel the genetic basis of rare and complex diseases. Together, these developments are ushering in the era of genomic medicine.

Dr. Green closed by providing a number of additional NHGRI contacts/resources and fielding a number of questions from Council members and staff.

IX. Presentation “Exploring Language Variability in Autism.............Dr. Helen Tager-Flusberg

Dr. Battey introduced Dr. Helen Tager-Flusberg to speak about her research in Autism. Dr Tager-Flusberg is Professor at the Department of Anatomy and Neurobiology and Professor at the
Department of Pediatrics at Boston University. She is a member of several professional organizations including, Past-President of the International Society for Autism Research. Helen accepted our invitation to discuss her efforts in a presentation entitled “Exploring Language Variability in Autism.”

There is enormous variability in language abilities in autism. Across the spectrum children and adults with autism have significant impairments in communication, including the use of language in social contexts, but their language varies from being completely absent to the acquisition of intact language skills. The central question that is addressed by our current research programs is what accounts for this enormous variability in language. In this talk I will present some of our recent research on this issue including: developmental pathways to spoken language in autism; language development in deaf children with autism; neural bases of speech and language in autism; addressing the challenges of the minimally verbal child. Implications of our research on language variability in autism for understanding the foundations of human language will be discussed.

X. Adjournment

The meeting was adjourned at 1:55 p.m. on May 9, 2014.
XI. Certification of Minutes

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

June 6, 2014

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

June 5, 2014

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

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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.
<table>
<thead>
<tr>
<th>APPENDIX 1</th>
<th>NDCD Advisory Council Roster</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>APPENDIX 2</td>
<td>NIDCD Director’s Report Slides</td>
<td>12</td>
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</table>
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.  2014
Professor
Departments of Pediatrics and Otolaryngology
College of Medicine
Ohio State University
Columbus, OH  43205

BERKE, Gerald S., M.D.   2014
Professor and Chair
Department of Head and Neck Surgery
Center for Health Sciences
School of Medicine
University of California at Los Angeles
Los Angeles, CA  90095

KAYE, Joan     2016
Executive Director
Sophie's Soundcheck
New York, NY  10128

KEHN, Tisha A.    2015
Executive Director
Association for Chemoreception Sciences
Minneapolis, MN  55406

MANIS, Paul B., Ph.D.   2015
Thomas J. Dark Distinguished Research Professor
Department of Otolaryngology/Head and Neck Surgery
University of North Carolina Chapel Hill
Chapel Hill, NC  27599

MISTRETTA, Charlotte M., Ph.D.  2015
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

MYERS, David G., Ph. D.   2017
Professor
Hope College
Department of Psychology
Holland, MI  49422

PERKELL, Joseph S., Ph.D., D.M.D.  2016
Research Affiliate
Research Laboratory of Electronics
Massachusetts Institute of Technology
Cambridge, MA  02446

ROBINSON, Jr., Tommie L., Ph.D.   2016
Director, Scottish Rite Center for Childhood Language Disorders
Children's Hearing and Speech Center
Children's National Medical Center
Washington, DC 20009

SCHWOB, James E., Ph.D., M.D.  2015
Bates Professor, Department of Developmental, Molecular and Chemical Biology
Tufts University School of Medicine
Boston, MA  02111

SERRANO, Elba E., Ph.D.   2017
Regents Professor
Department of Biology
New Mexico State University
Las Cruces, NM  88003

SHANNON, Robert V., Ph.D.   2015
Professor of Research Otolaryngology, Biomedical Engineering, and Neuroscience
Keck School of Medicine
University of Southern California
Los Angeles, CA  90007
SMITH, Richard J. H., M.D.  2014
Professor
Department of Otolaryngology
University of Iowa – Carver College of Medicine
Iowa City, IA  52242

TAGER-FLUSBERG, Helen, Ph.D.  2016
Professor
Department of Psychological and Brain Sciences
Boston University
Boston, MA  02215

TUCCI, Debara L., M.D.   2017
Professor
Division of Otolaryngology
Duke University Medical Center
Durham, NC  27710

WESTERFIELD, Monte, Ph.D.  2017
Professor and Chair
Institute of Neuroscience
Department of Biology
University of Oregon
Eugene, OR  97403

YUEH, Bevan, M.D., M.P.H.   2014
Professor and Chair
Department of Otolaryngology
Head and Neck Surgery
University of Minnesota
Minneapolis, MN  55455

Ex Officio

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

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

SEBELIUS, Kathleen
Secretary
Department of Health and Human Services
Washington, DC  20201

Executive Secretary

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

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

HOFFER, Michael E., M.D.
Co-Director
Department of Defense Spatial Orientation Center
Department of Otolaryngology
Naval Medical Center
San Diego, CA  92134

San Diego, CA  9213
NIDCD Director’s Budget

James F. Battey, Jr., M.D., Ph.D.
NIDCD Advisory Council Meeting
May 9, 2014
<table>
<thead>
<tr>
<th>Budget Mechanism</th>
<th>FY 2013</th>
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<td>Number</td>
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<td>TOTAL</td>
<td>$392,540</td>
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May Council Funds for FY 2014 Competing R01's
Based on FY 2014 Operating Budget
($ in thousands)

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
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<tr>
<td>Total RPG budget</td>
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<tr>
<td>Less SBIR/STTR budget</td>
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<tr>
<td>Less Noncompeting budget (zero reduction)</td>
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<td>Less FY14 &quot;Carryover&quot; Commitments from prior Council meetings</td>
<td>-1,261</td>
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<td>Less FY14 Program Requirements</td>
<td>-13,750</td>
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<td>Plus FY13 funding for Sept 2013 applications</td>
<td>1,174</td>
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<td>$48,533</td>
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For FY 2014
- 20% HPP: $9,707
- 80% Regular: $38,826

Per Council Round
- $3,236
- $12,942