

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

January 24, 2014

**National Institutes of Health
Bethesda, MD**

MINUTES

The National Deafness and Other Communication Disorders Advisory Council convened on January 24, 2014 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: January 24, 2014: 8:30 a.m. to 9:45 a.m. for review of individual grant applications; and
Open: January 24, 2014: 10:05 a.m. to 1:45 p.m., for the review and discussion of program development needs and policy.

Council members in Attendance¹:

Dr. Lauren Bakaletz	Dr. Elba Serrano
Dr. Gerald Berke	Dr. Robert Shannon
Ms. Joan Kaye	Dr. Richard Smith
Ms. Tisha Kehn	Dr. Helen Tager-Flusberg
Dr. Paul Manis	Dr. Debara Tucci
Dr. Charlotte Mistretta	Dr. Monte Westerfield
Dr. James Schwob	Dr. Bevan Yueh

Council members absent:

Ms. Marcia Finisdore	Dr. Joseph Perzell
Dr. David Myers	Dr. Tommie Robinson

Ex-Officio Members Participating:
None

Ex-Officio Members Not Participating:

Dr. Lucille Beck	Dr. Michael E. Hoffer
Dr. Rick 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:

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

Other federal employees present during portions of the meeting:

Dr. Amy Adams, NINDS
Dr. John Bishop, CSR
Dr. Rene Etcheberrigaray, CSR
Dr. Alan Guttmacher, NICHD
Dr. Story Landis, NINDS
Dr. Paek Lee, CSR
Dr. Lynn Luethke, CSR
Dr. Christine Melchior, CSR
Dr. Weijia Ni, CSR
Dr. Biao Tian, CSR

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

Ms. Judy Harrison, A.G. Bell
Ms. June Martin, A.G. Bell
Ms. Susan Lott, ASHA
Ms. Maureen Corrigan, AAO-HNS
Ms. Catherine Murphy, Gallaudet University
Dr. Leslie Voshall, Rockefeller University
Ms. Margaret Rogers, AHSA

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 93 investigator-initiated research grant applications; 82 applications had primary assignment to NIDCD, in the amount of \$26.7 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 Institutional National Research Service Award (T32): The Council recommended support of the top seven applications.
2. NIH NRSA Short-Term Research Training (T35): The Council recommended support of one application.
3. NIH Mentored Research Scientist Development Award (K01): The Council recommended support of one application.
4. NIH Mentored Clinical Scientist Research Career Development Award (K08): The Council recommended support of one application.
5. NIH Research Career Enhancement Award for Established Investigators (K18): The Council recommended support of one application.
6. NIH Mentored Patient-Oriented Research Career Development Award (K23): The Council recommended support of one application.
7. NIH Pathway to Independence (PI) Award (K99): The Council recommended support of two applications.
8. NIH Small Grants (R03): The Council recommended support of twelve applications.
9. NIH Support for Conferences and Scientific Meetings (R13): The Council recommended

support of five applications.

10. NIH Academic Research Enhancement Awards (AREA) (R15): The Council recommended support of two applications.
11. NIH Exploratory/Development Research Grant Award (R21): The Council recommended support of five applications.
12. NIDCD Research Core Centers (P30): The Council recommended support of one application.
13. NIH Small Business Innovation Research Awards (SBIR): The Council recommended support of top five Phase I (R43) applications.
14. RFA-DC-12-004 Improving Access to Hearing Healthcare (SBIR) [R43/R44]: The Council recommended support of one Phase II (R44) application.
15. RFA-DC-13-002 Innovative and Novel Approaches Toward Inner Ear Regenerative Therapies by Early Stage Investigators (R01): The Council recommended support of three applications.
16. RFA-CA-13-008 Person-Centered Outcomes Research Resource (U2C): The Council recommended co-fund 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.

Consideration of Minutes of the Meeting of September 12, 2013

Dr. Battey called the members' attention to the minutes of the September 12, 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 Friday, May 16, 2014, in Building 31, Conference Room 6 on the NIH campus, Bethesda, Maryland. Several members expressed difficulty in attending the May 16th meeting so the staff at NIDCD is exploring options for a different meeting date.

[Executive Secretary Note:

Following the January 24th meeting it was determined that the May 2014 meeting of the NIDCD Advisory Council will be held on May 9 in Building 31C 6th floor Room 10.]

V. Report of the Director, NIDCD Dr. Battey

Agenda Update

It is true that across NIH, Council meetings have become shortened, with more focused agendas. Agenda items such as my budget presentation or any of the staff presentations you will hear later

today often instill comments or questions from members of Council. To allow for discussion of issues that arise during the day of Council, we will plan in the future to leave some time at the end of the meeting for anything you might like to talk about. In addition, when you have any topics you would like to see on the agenda, please feel free to let us know. I and all the NIDCD staff truly want to encourage your inquiry and advice to the Institute.

Budget Update

Dr. Battey began his presentation by displaying the FY 2013 Obligations versus the FY 2014 Omnibus Budget Level. He pointed out that while the overall Omnibus Budget level has been approved, the detailed Mechanism breakdown numbers coming to the NIH have not been finalized. As a consequence, the right hand column of the first page is blank, without the breakdown by Mechanism that is usually provided to Council. As presented at the last Council, NIDCD has adopted a conservative fiscal plan for FY 2014 based on the assumption of a 2.5% reduction from the FY 2013 level. Without the detailed Mechanism figures being available for the FY 2014 Omnibus Appropriation, the Funds Available table largely reflects an updated version of the table from the September Council meeting. Once other components of the NIDCD budget are considered there would be \$268.9 million available for research project grants. From this total, \$10.5 million is reserved for Small Business Research grants, \$750 thousand for administrative supplements, \$203.1 million for commitments to noncompeting grants, \$1.3 million for commitments carried over from FY2013, and \$13.5 million for program requirements. An additional estimated \$1.2 million is available from end of year FY 2013 funds. Of the remaining \$40.8 million, twenty percent (\$8.1 million) is designated for High Program Priority (HPP). Consequently, there is \$32.7 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 \$8.1 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

Endorsement of Council Operating Procedures

Dr. Jordan called Council's attention to a copy of the Council Operating Procedures which had been provided to members prior to the meeting. The Council Operating Procedures state those actions which Council empowers staff to take without specific prior Council approval. It is the NIDCD's practice to review the Council Operating Procedures annually at the January meeting of Council. He pointed out that there were no changes to the document this year. Dr. Jordan reviewed the document and it was endorsed unanimously for the current year; a copy is included in these minutes as Appendix 3.

Budget Notes

Next Dr. Jordan highlighted two important points from the Notice "NIH Operates Under a Continuing Resolution" NOT-OD-14-043 which was released on January 16, 2014. First, non-competing awards are to be issued at a reduced level of ~90%. The Notice also mentioned Executive Order 13655 which increased the Executive Level II salaries by 1% to \$181,500. The Executive Level II cap is also applied to investigator salaries on research grants and so that salary cap was increased as well. He continued with information from the FY 2014 Omnibus Spending bill signed by President Obama on January 17, 2014 highlighting the fact that there will be about a \$1 Billion increase for NIH which is still less than FY 2012, and extended the 1% pay increase to the Wage Grade employees. The appropriation language indicates that there will be increased reporting requirements but there are many details to be finalized and negotiated.

Rock Talk

Introducing Dr. Sally Rockey as NIH’s Deputy Director for Extramural Research, Dr. Jordan highlighted her blog entitled ‘RockTalk’ where she helps connect the public with the NIH perspective. He highlighted the January 10, 2014 edition where Dr. Rockey presented current trends for research project grants (RPGs) contrasting the differences between 2012 and 2013. Of particular note application success rates declined in 2013 to a historic low. The data used in Dr. Rockey’s presentation came from a resource available to the public, the NIH Data Book. Most of the numbers seen throughout the Data Book went down because of the reduction of NIH’s FY 2013 budget. That significant reduction was due in large part to sequestration which lowered NIH appropriations by more than 5% or \$1.55 billion below the previous fiscal year. The table from RockTalk included 14 comparisons between 2012 and 2013; in each case (success rates, award numbers, application numbers, average award size) the 2013 showed a decrease from the 2012 level. NIH also saw a small decline in incoming applications, the first since before the Recovery Act (ARRA) of 2009 which bolstered NIH application submissions for a number of years even after ARRA funding ended.

VII. Brain Research through Advancing Innovative Neurotechnologies (BRAIN)Dr. Story Landis

Dr. Story Landis is the Director of the National Institute for Neurological Disorders and Stroke (NINDS) and she has garnered many awards for her scientific achievements including election as a fellow of the Institute of Medicine. As the Director of NINDS, Dr. Landis oversees an annual budget of \$1.6 billion that supports neuroscience research across the country. Dr. Landis co-chairs the NIH Blueprint for Neuroscience Research, and also serves as chair of the NIH Stem Cell Task Force. Dr. Landis accepted our invitation to discuss the BRAIN initiative which is part of a new Presidential focus aimed at revolutionizing our understanding of the human brain.

The **Brain Research through Advancing Innovative Neurotechnologies (BRAIN)** Initiative is part of a new Presidential focus aimed at revolutionizing our understanding of the human brain. By accelerating the development and application of innovative technologies, researchers will be able to produce a revolutionary new dynamic picture of the brain that, for the first time, shows how individual cells and complex neural circuits interact in both time and space. Long desired by researchers seeking new ways to treat, cure, and even prevent brain disorders, this picture will fill major gaps in our current knowledge and provide unprecedented opportunities for exploring exactly how the brain enables the human body to record, process, utilize, store, and retrieve vast quantities of information, all at the speed of thought.

Dr. Landis provided an overview of the NIH response to this Presidential initiative including the formation of the NIH BRAIN Working Group, the extensive process used by the Working Group to hold multiple workshops/meetings during the Spring/Summer of 2013, solicit feedback from the Society for Neuroscience, and develop recommendations. The Working Group reported back to the Advisory Committee to the Director (ACD) and through this process developed Principles and High Priority Research areas. The NIH is utilizing the existing NIH Blueprint structure to facilitate the BRAIN initiative and recently published six RFAs with applications due in March (<http://www.nih.gov/science/brain>). Dr. Landis presented information about the FY 2014 funding of the BRAIN initiative, pointing out that \$22.43 million is new money from the FY 2014 appropriations bill with a total NIH investment of \$40.7M. She closed her presentation by highlighting plans from other agencies that are contributing to the BRAIN initiative and potential ‘next steps’.

VIII. “The National Center for Medical RehabilitationDr. Alan Guttmacher Research: Future Directions”

As the Director of the Eunice Kennedy Shriver National Institute on Child Health and Human Development (NICHD), Dr. Guttmacher oversees an annual budget of \$1.3 billion for research in

pediatric health and development, maternal health, reproductive health, intellectual and developmental disabilities, and rehabilitation medicine, among other areas. The National Center for Medical Rehabilitation Research (NCMRR) falls under his purview at NICHD and today he shared his vision for the future of the NCMRR.

Dr. Guttmacher started his presentation by reviewing the NCMRR purpose. “The general purpose of the Center is the conduct and support of research and research training (including research on the development of orthotic and prosthetic devices), the dissemination of health information, and other programs with respect to the rehabilitation of individuals with physical disabilities resulting from diseases or disorders of the neurological, musculoskeletal, cardiovascular, pulmonary, or any other physiological system.” Through basic, translational, and clinical research, the NCMRR aims to foster development of scientific knowledge needed to enhance the health, productivity, independence, and quality-of-life of people with physical disabilities.

In response to concerns from the rehabilitation research community, the NICHD director in conjunction with the NIH director empanelled a Blue Ribbon Panel (BRP) in 2011 to assess the state of rehabilitation research across the NIH, identify scientific opportunities, and recommend what NCMRR and NIH could do to better catalyze and support rehabilitation research. The BRP developed a number of recommendations in the areas of NCMRR’s structure, role, collaborations, etc. In response to the BRP guidance, NCMRR is undergoing a ‘redesign’ with the goals being to increase the quality of rehabilitation research supported by the center and more broadly throughout NIH, further improving the research training and career development in rehabilitation research and better coordinate NIH rehabilitation research activities and as possible interagency rehabilitation research. The plan for NCMRR is to focus somewhat more on strategic planning, coordinator, catalyzing, and less on grants administration. The Medical Rehabilitation Coordinating Committee will be reinvigorated (NDCMRR, NICHD, NIA, NIAMS, NHLBI, NINDS, and others) will work hard to that end. Under a new funding model, NCMRR would support new research projects primarily through a co-funding approach with other ICs. Direct funding and co-funding will be used to support other efforts like research infrastructure, training and career development, conferences, and STTR/SBIR applications. The Council was invited to comment on their thoughts on the future of rehabilitation research.

**IX. Human sweat and insect repellents: the molecularDr. Leslie Vosshall
biology of mosquito olfaction**

Dr. Vosshall is a Howard Hughes Medical Institute Investigator and the Robin Chemers Neustein Professor in the Laboratory of Neurogenetics and Behavior at The Rockefeller University agreed to present her research to the Council. One aim of her research is to understand the genetic basis of behavior, with particular emphasis on how organisms perceive and respond to external sensory stimuli and how these responses are modulated by the internal physiological state of the animal.

Female mosquitoes require a blood meal to complete egg development. In carrying out this innate behavior, mosquitoes spread dangerous infectious diseases such as malaria, dengue fever, and yellow fever. Humans attract mosquitoes via multiple sensory cues including emitted body odor, heat, and carbon dioxide in the breath. The mosquito perceives differences in these cues, both between and within species, to determine which animal or human to target for blood-feeding. My group is interested in the molecular neurobiology of mosquito host-seeking behavior. We have developed a technique for targeted mutagenesis in the yellow fever and dengue vector mosquito, *Aedes aegypti*, using zinc-finger nucleases (ZFNs). We have recently generated the first targeted null mutations in *Aedes aegypti* mosquitoes using ZFNs, specifically in the critical olfactory co-receptor *orco* and in *Gr3*, an essential subunit for carbon dioxide chemoreception. These mutant strains will allow us to understand how sensory cues are integrated by the female mosquito to lead to host-seeking behavior. Recent advances from my group in analyzing the molecular biology of host-seeking behavior will be discussed.

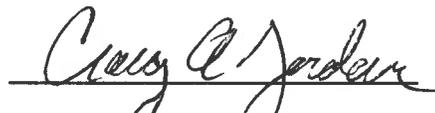
X. Adjournment

The meeting was adjourned at 1:45 p.m. on January 24, 2014.

XI. Certification of Minutes

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

2-27-14



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

2-26-2014



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

² These minutes will be approved formally by the Council at the next meeting on May 9, 2014, and corrections or notations will be stated in the minutes of that meeting.

APPENDICES

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NIDCD Director's Budget

James F. Battey, Jr., M.D., Ph.D.
NIDCD Advisory Council Meeting
January 24, 2014

National Institute on Deafness and Other Communication Disorders

January 2014 Council Budget Mechanism (Dollars in thousands)

<i>Budget Mechanism</i>	FY 2013		FY 2014	
	<i>Number</i>	<i>Amount</i>	<i>Number</i>	<i>Amount</i>
Research Projects				
Noncompeting	623	\$213,472		
Admin. Supplements	26	728		
Competing	162	57,262		
Subtotal	785	271,462		
SBIR/STTR	24	10,103		
Subtotal, RPG's	809	281,565		
Research Centers	19	16,043		
Other Research	61	10,588		
Total Research Grants	889	308,196		
Individual Training	113	4,514		
Institutional Training	172	7,936		
R & D Contracts	30	15,760		
Intramural Research		36,492		
Research Mgmt. & Support		19,642		
TOTAL		\$392,540		\$404,049

National Institute on Deafness and Other Communication Disorders

January 2014 Council Competing Research Project Grants (Dollars in thousands)

January Council Funds for FY 2014 Competing R01's Based on FY 2014 Estimate of \$382,766 thousand (-2.5%) (\$ in thousands)

Estimated Total RPG budget	\$268,892
Less estimated SBIR/STTR budget	-10,545
Less estimated Administrative Supplements budget	-750
Less estimated Noncompeting budget (assumes -3%)	-203,147
Less FY14 "Carryover" Commitments from prior Council meetings	-1,261
Less FY14 Program Requirements	-13,500
Plus FY13 funding for Sept 2013 applications	1,174

Total

\$40,863

20% HPP

80% Regular

For FY 2014	\$8,173	\$32,690
Per Council Round	\$2,724	\$10,897

NDCD Advisory Council Operating Procedures

(As endorsed by Council consideration on January 24, 2014)

All scored research/training grant applications are taken to the National Deafness and Other Communication Disorders Advisory Council (NDCDAC) for second level review prior to possible funding actions. Specific situations are raised for Council consideration during each meeting. This includes:

1. Applications nominated for High Program Priority consideration,
2. Applications exceeding \$500K (DC) that are recommended for support,
3. Applications from Foreign Institutions recommended for support,
4. Applications from PD/PIs with \$1M (DC) active research NIH awards (Special Council Review),
5. Letters of Appeal,
6. Applications with issues raised by initial peer review regarding Human Subjects protection/inclusion or Animal Welfare.

The Institute staff may take the following actions on active grants without Council review. All actions shall be documented and presented to the Council for its information at the first appropriate opportunity.

1. Approval of New Principal Investigator or Program Director

Give approval of a new principal investigator or program director to continue an active grant at the grantee institution.

2. Transfer of Award to a New Institution

Make research grant awards equal to the remaining committed support for continuing work under the same principal investigator when that principal investigator moves from one domestic institution to another. This provision will not be automatic, however. Staff may approve less than the remaining committed support and will in all cases carefully document the file with the rationale for the action.

3. Awards for Orderly Termination

Make appropriate awards for orderly termination of competing continuation applications which were not recommended for further consideration, or which received a score too low for payment; this procedure is to be used only in those rare cases where sudden termination of the grant would cause a serious loss of scientific material or impose a hardship to already

employed personnel. In such cases, (1) the grant usually should be for a period not to exceed twelve months; (2) careful review should be given to any unobligated balances and needs for salaries and consumable supplies; (3) usually no funds would be provided for additional equipment or travel; and (4) in the case of training grants, support would be provided for those trainees already in the program.

4. Awards for Interim Period Due to a Deferral

Make awards in an appropriate amount and for an appropriate interim period of time when a recommendation of deferral on a competing continuation application results in a loss of continuity of the active research or training program. Careful review should be given to the needs for personnel and consumable supplies; however, usually no funds would be provided for equipment or travel.

5. Supplemental Support to Existing Research and Training Awards

Provide additional support up to \$100,000 in direct costs per year to carry out the scientific, administrative and fiscal intent of the research or training award. The additional support may be necessary to: a) make NIH-wide diversity and re-entry supplement awards; b) provide administrative increases; c) cover unanticipated costs; or d) ensure effective operation of the recommended program. Increases greater than \$100,000 will be presented to the NDCD Advisory Council for approval before an award is made.

Institute staff may take the following actions without subsequent reporting to the Council.

1. Continuation of Grant in Temporary Absence of Principal Investigator or Program Director.

Give approval for continuation of grants in the temporary absence of the principal investigator or program director. Give approval for temporary/interim principal investigator or program director.

2. Extension of Project Period Dates

Take necessary action on extensions of project period end dates without additional funds.