MINUTES

The National Deafness and Other Communication Disorders Advisory Council (NDCDAC) convened on January 31, 2020 at 6001 Executive Blvd., Room CD at the National Institutes of Health (NIH) in Bethesda, MD. Dr. Debara L. Tucci, Director, National Institute on Deafness and Other Communication Disorders (NIDCD), served as Acting Chairperson. In accordance with Public Law 92-463, the meeting was:

Closed: January 31, 2020: 8:30 a.m. to 10:05 a.m. for review of individual grant applications; and

Open: January 31, 2020: 10:05 a.m. to 1:45 p.m., for the review and discussion of program development needs and policy.

Council members in attendance:

Ms. Lisa Adams Ms. Nanci Linke-Ellis
Dr. John Carey Dr. Cynthia Morton
Dr. Ruth Anne Eatock Dr. Dan Sanes
Mr. Richard Einhorn Dr. H. Steven Sims
Dr. Lisa Goffman Dr. Ben Strowbridge
Dr. Sandra Gordon-Salant Dr. Charlotte Yeh
Dr. Robert Hillman Dr. Fan-Gang Zeng
Ms. Barbara Kelley

Council Members Absent:
Dr. Susan Ellis-Weismer

Ad-Hoc Council Members in attendance:

Dr. Sue Kinnamon
Dr. Andrew Groves

Council ex-officio members in attendance:

Ms. Christa Themann
Dr. Lakeisha Henry
Dr. Judy Schafer

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1 For 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  Ms. Phalla Messina
Mr. Thomas Berry  Dr. Roger Miller
Ms. Cara Brennan  Ms. Kristen Mullsteff
Mr. James Burton  Mr. Eddie Myrbeck
Dr. Wade Chien  Mr. Christopher Myers
Dr. Laura Cole  Dr. Amy Poremba
Dr. Judith Cooper  Ms. Lisa Portnoy
Dr. Janet Cyr  Dr. Alberto Rivera-Rentas
Ms. Susan Dambrauskas  Dr. Elka Scordalakes
Mr. Hoai Doan  Dr. Lana Shekim
Dr. Nancy Freeman  Dr. Kathy Shim
Ms. Maria Garcia  Dr. Sheo Singh
Dr. Michael Hoa  Dr. Melissa Stick
Mr. Howard Hoffman  Dr. Susan Sullivan
Dr. Craig Jordan  Ms. Nanette Stephenson
Ms. Joanne Karimbakas  Dr. Debara Tucci
Dr. Kelly King  Dr. Bracie Watson
Dr. Chuan-Ming Li  Ms. Ginger Webb
Ms. Lonnie Lisle  Dr. Eliane Lazar-Wesley
Dr. Trinh Ly  Mr. Eric Williams
Ms. Nakia Makonnen  Mr. Baldwin Wong
Ms. Laura Manella  Dr. Shiguang Yang
Dr. Castilla McNamara

Other federal employees present during portions of the meeting:

Dr. Biao Tian, CSR
Dr. Janita Turchi, CSR
Dr. Alexei Kondratyev, CSR
Dr. Andrea Kelley, CSR
Dr. John Bishop, CSR
Ms. Essence Motley, OD
Dr. Noni Byrnes, CSR

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

Ms. Bridget Dobyen, Hearing Industries Association
Mr. Erik Lazdins, American Speech-Language-Hearing Association
Ms. Susan Lott, American Speech-Language-Hearing Association
Mr. Jerry White, American Speech-Language-Hearing Association
CLOSED SESSION

Call to Order and Opening Remarks ................................................................. Dr. Debara L. Tucci

The meeting was called to order by Dr. Tucci, Director, NIDCD, who expressed appreciation to the entire Council for their service and advice.

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 any conflict of interest and even any appearance of a conflict 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.

Council Consideration of Pending Applications ......................... Dr. Judith Cooper and Staff

Research Project Grant Awards

Consideration of Applications: On the Council’s agenda was a total of 112 investigator-initiated R01 grant applications; 107 applications had primary assignment to NIDCD, in the amount of $39.7 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 13th percentile.

Special Program Actions

1. Ruth L. Kirschstein National Research Service Award (NRSA) Institutional National Research Training Service Award (T32): The Council recommended support of seven applications.
2. NIH Mentored Clinical Scientist Research Career Development Award (K08): The Council recommended support of one application.
3. NIDCD Research Career Enhancement Award (K18): The Council recommended support of one application.
4. NIH Mentored Patient-Oriented Research Career Development Award (K23): The Council recommended support of three applications.
5. NIH Pathway to Independence Award (K99): The Council recommended support of three applications.
6. NIH Support for Conferences and Scientific Meetings (R13): The Council recommended support of eight applications.
7. NIH Research Enhancement Award (R15): The Council recommended support of one application.
8. NIH Exploratory/Development Research Grant Award (R21): The Council recommended support of six applications.

10. NIH Small Business Technology Transfer (STTR) Grant (R42): The Council recommended support for one application.

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

12. NIH Small Business Innovation Research Awards (SBIR): The Council recommended support of seven Phase II (R44) applications.


**OPEN SESSION**

**Opening Remarks ....................................................................................................................Dr. Tucci**

Dr. Tucci welcomed additional staff and visitors to the open session of the meeting. She updated the council about four NIDCD meetings that will be happening in the coming months, including a Blue Ribbon Panel Review of the Intramural Program, a Human Temporal Bone Histopathology/Imaging Advisory Group, an Otitis media Working Group, and a Cochlear Implant Electrode Design Advisory Group – Lawrence Livermore National Lab collaboration. Each of the meetings will have a representative from the advisory council and will involve NIDCD staff. Dr. Tucci then shared highlights from the recent Association for Research in Otolaryngology (ARO) meeting she attended in San Jose. NIDCD staff presented three workshops to attendees covering the different research grant and training programs offered by NIDCD. Dr. Tucci also organized two Focus Group session to gather input related to the training of surgeon-scientists. She was also invited by the ARO to present an NIDCD Town Hall session where she met with the ARO membership and communicated many of the same updates being presented here to Council.

Dr. Tucci closed out her presentation by highlighting several NIH priorities, including the focused support of Early Stage Investigators (ESI) that has been a priority for several years. That priority is reflected by the NIH target of supporting at least 1100 ESIs each year, special handling during peer review, and providing special consideration at the council level. NIH is also in the process of developing a new R01 program, the Katz Award, dedicated to ESIs pursuing a new research direction. NIH is continuing efforts to change the culture and end sexual harassment. Most recently, the Advisory Council to the NIH Director presented the NIH with a series of recommendations in the areas of transparency and accountability in reporting of professional misconduct; establishing mechanisms for restorative justice; and creation of system-wide change to ensure safe, diverse, and inclusive research and training environments. One proposed approach is to elevate sexual harassment (and other inappropriate behaviors) to the same level of oversight as research misconduct. Dr. Tucci shared a new email address for concerns related to NIH-funded research GranteeHarrassment@od.nih.gov which will enable the NIH to take action if there are concerns that sexual harassment is affecting NIH-funded research.

**Consideration of Minutes of the Meeting of September 13, 2019**

Dr. Tucci called the members’ attention to the minutes of the September 13, 2019 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 2021 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 29, 2020.

**The 2022-2026 NIDCD Strategic Plan.......................................................... Mr. Baldwin Wong**

**Proposed Timeline and Portfolio Analysis ...................................................... Dr. Laura Cole**

The National Institute on Deafness and Other Communication Disorders (NIDCD) is developing a new strategic plan for 2022–2026. The NIDCD Strategic Plan (the plan) helps identify the most promising cross-cutting research areas within the NIDCD’s mission. In addition, the plan presents a series of goals and objectives that serve as the NIDCD’s guide in prioritizing its research investment. The NIDCD Science Policy and Planning Branch (SPPB) is currently laying the foundation for the new plan by analyzing the NIDCD grant portfolio relative to the objectives laid out in the current strategic plan codes contained in the current plan (2017 – 2021 version) and working with the NIDCD Epidemiology and Statistics Program to collect public health burden data and then to compare the health burden data. The health burden data will be obtained from the CDC’s National Center for Health Statistics, national health surveys (e.g., Healthy People 2020/30), and review of the scientific literature. SPPB will then compare the health burden data against the current portfolio to identify gaps in the portfolio and can be used to identify opportunities for the next five years.

Stakeholder input will be solicited by publishing a Request for Information (RFI, February 2020) and hosting an Idea-Generating Meeting (Fall 2020). From these ideas, NIDCD will develop a draft Strategic Plan, and publish a second RFI to solicit comments on the draft plan (winter 2021). The first RFI is published and interested members of the public can enter responses to the RFI via the NIDCD’s public website. For the RFI, NIDCD we welcome feedback on the following questions:

1. What are the most significant scientific discoveries in hearing and balance, taste and smell, and voice, speech, and language that have occurred in the past five years?
2. What are the unmet needs in current research and training that may impact hearing and balance, taste and smell, and voice, speech, and language?
3. Describe the opportunities in hearing and balance, taste and smell, and voice, speech, and language that may be realized in the next five years.
4. What are the greatest challenges or barriers to progress in hearing and balance, taste and smell, and voice, speech, and language?
5. What is the greatest public health need of individuals with disorders of hearing and balance, taste and smell, or voice, speech, and language that may be helped with additional research?

[Executive Secretary Note: The RFI can be accessed at: https://grants.nih.gov/grants/guide/notice-files/NOT-DC-20-001.html Responses can also be submitted via the NIDCD website through March 31, 2020: https://www.nidcd.nih.gov]
NIDCD’s Budget Officer, Mr. Eric Williams, presented detailed information on the fiscal year 2019 (FY2019) budget including a breakdown based on scientific mission areas. Using the FY2019 Operating Plan, he detailed the dollars invested during 2019 in the various grant programs, training programs, and other institutional commitments. Where applicable, the table also provided numbers of grant awards and revealed the great care in closing out the FY budget, reserving $8 thousand dollars for to be identified FY2019 needs. The table depicting Spending by Mission Area showed that 54% of expenditures supported the hearing mission area while the remaining 46% was shared across the other 6 mission areas. Mr. Williams emphasized that the mission area breakdown has fluctuated very little over time and that the main driver of that distribution has been the number of applications submitted by the research community. In his final slide, he summarized the growth in the NIDCD budget over the past three years and shared the calculation that determined the dollars available to award R01/U01 grants at this council meeting.

Dissecting the Role of the Stria Vascularis in Hearing Loss and Hearing Fluctuation

Dr. Michael Hoa is an investigator in the Otolaryngology Surgeon-Scientist Program at the NIDCD. Research in his laboratory focuses on mechanisms related to the generation of the endocochlear potential by the stria vascularis and mechanisms underlying hearing fluctuation. Studying the stria vascularis as an entry point into understanding ionic homeostasis in the inner ear with a combination of single-cell/single-nucleus transcriptional profiling, molecular biology and electrophysiology, his lab aims to dissect mechanisms behind diseases such as hearing fluctuation which have few effective treatments currently. His work utilizing single-cell and single-nucleus RNA-sequencing in the unperturbed adult mouse stria vascularis represents the beginnings of these efforts.

The stria vascularis (SV) generates the endocochlear potential (EP) in the inner ear and is necessary for proper hair cell mechanotransduction and hearing. While channels belonging to SV cell types are known to play crucial roles in EP generation, relatively little is known about gene regulatory networks that underlie the ability of the SV to generate and maintain the EP. Single-cell RNA-sequencing approaches enable a more nuanced and detailed examination of the strial cell types which work together to generate the EP. Using single cell and single nucleus RNA-sequencing, we identify and validate known and rare cell populations in the SV. Furthermore, we establish a basis for understanding molecular mechanisms underlying SV function by identifying potential gene regulatory networks as well as druggable gene targets. This work establishes a basis for dissecting the genetic mechanisms underlying the role of the SV in hearing and will serve as a basis for designing therapeutic approaches to hearing loss related to SV dysfunction.

Development of Gene Therapy for Hearing Loss and Dizziness

Dr. Wade Chien is an investigator in the Otolaryngology Surgeon-Scientist Program at the NIDCD. Hearing loss and dizziness are common disorders affecting the world’s population today. Unfortunately, the current treatment options for these patients are limited. Gene therapy is a promising treatment modality that has the potential of reversing the disease process in the
inner ear. In this talk, I will discuss the application of inner ear gene therapy to a mouse model
of Usher syndrome, which is the most common cause of deafness-blindness. In addition, I will
also discuss our ongoing work on applying CRISPR genome editing as a form of inner ear gene
therapy in a mouse model of non-syndromic autosomal dominant hearing loss (DFNA).

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

Dr. Jordan reviewed with members the Council Operating Procedures document and highlighted
proposed changes to reflect council’s role in the Concept Clearance process and to provide
more latitude to staff when funds from other ICs are used for supplemental awards. Members
voted unanimously to accept the changes.

Dr. Jordan discussed several policies created or implemented recently at the NIH. In July 2019
the NIH published the Requirement for ORCID iDs for Individuals Supported by Research
Training, Fellowship, Research Education and Career Development Awards Beginning in FY
2020 (NOT-OD-19-109). NIH introduced the option for PD/PIs and other users to associate an
ORCID iD (Open Researcher and Contributor Identifiers) with their NIH eRA Commons
Personal Profile in 2017. Since that time, he noted that more than 30,000 eRA Commons
Profiles have been linked to ORCID iDs. Starting last October, ORCID iDs are required for
appointments to institutional training and career development awards. As of January 25, 2020,
ORCID iDs are required for individual fellowship and career development applications.

Based on the Notice published January 24, 2020, (NOT-OD-20-060) NIH is phasing-out
granting one-year continuous submission status to reviewers with recent substantial review
service, and it is moving back continuous submission deadlines. Prior policy had unintended
consequences, among them encouraging excessive review service and thus allowing
disproportionate influence by some. NIH believes that diverse advisory groups with a range of
familiar and fresh voices best identify high impact research. Limiting over-utilization of the same
reviewers on advisory groups is one step NIH is taking to address this goal.

Finally, Dr. Jordan highlighted the work of the NIDCD Scientific Review Branch (SRB). He
described the numbers of scientists who are recruited by the staff of SRB to performed peer
review on behalf of the NIDCD, the variety of the types of applications reviewed by SRB and the
number of review meetings held each year. He contrasted the SRB-specific data with similar
data from the trans-NIH reports available in the NIH Data Book
(https://report.nih.gov/nihdatabook/).

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

Dr. Cooper introduced Dr. Amy Poremba, Program Director for Central Pathways of Auditory
and Vestibular Processing, who presented a brief summary of the workshop entitled “Visualizing
the Human Inner Ear,” held in November 2019.

Workshop participants in the auditory and vestibular fields discussed working on specimens or
imaging, the current state of temporal bone research, advancements, and limitations of temporal
bone exploration with samples and specimens from the inner ear of both living and post-mortem
tissue in humans. The long-term goal is to image living human inner ear tissue at high resolution
across both structural and functional levels. The workshop participants identified gap areas in
knowledge, and/or how technology development may progress. Human temporal bone
specimens, from a variety of normal and disease state subjects, are particularly difficult to
retrieve and prepare for study post-mortem, as are smaller samples from pre-mortem humans.
Due to encasement with thick bone of the inner ear it is extremely hard to visualize in living humans. Images of structure and functioning in the living inner ear would benefit a broad spectrum of experimental projects and the overall knowledge base, including clinical and translational for the NIDCD mission to help prevent, detect, diagnose, and treat deafness, balance, and other communication disorders.

Dr. Cooper then presented four concepts that represent the early planning stages for what might become initiatives (such as requests for applications or notices of special interest) or other activities (such as workshops or working groups). Concepts are discussed with the NDCD Advisory Council and through other public venues. The concepts presented at this meeting:

- Encourage educational and training opportunities for early stage investigators
- Encourage new direction in research in Hearing, Balance and Vestibular science
- Encourage research in AIDS/HIV and its impact on communication disorders
- Encourage research in laryngeal dystonia and associated voice disorders

Council approval of a concept does not guarantee that it will become an initiative. That decision would be based on scientific and programmatic priorities and the availability of funds.

Center for Scientific Review Update

Dr. Noni Byrnes from the NIH Center for Scientific Review (CSR) began by stating that the mission of CSR is to ensure that NIH grant applications receive fair, independent, expert and timely reviews – free from inappropriate influences - so NIH can fund the most promising research. CSR staff consists of 247 Scientific Review Officers who manage over 200 chartered or recurring study sections comprised of over 18,000 reviewers. CSR holds over 1,450 annual review meetings and reviews over 75% of NIH’s 82,600 grant applications.

Dr. Byrnes discussed several priorities for CSR with the goal to ensure the high quality of peer review. She described peer review with three underlying principles: 1. Transparent, data driven decision-making, 2. Involvement/engagement of stakeholders, and 3. Open, multi-directional communication strategies. There is a new Office of Communications and Outreach within the CSR Office of the Director (OD) which intends to increase the engagement of the community, through planning activities that target specific audiences using blogs, webinars and social media.

CSR depends upon its Advisory Council and the efforts of Council Working Groups. Recent Working Groups have worked on Revamping the Early Career Reviewer Program, Development of a Review Integrity Training Module, and are in the process of reporting out on ideas from the external scientific community on how review criteria could be simplified. Dr. Byrnes provided information about several efforts undertaken to improve the peer review process. One is the CSR’s Anonymization Study that evaluated 1200 previously reviewed applications in both full and redacted forms. Analyses are being completed and CSR plans to publish the results and to provide the data publicly for further analysis. A current collaboration between CSR, NIGMS, and NIH’s Chief Officer for Scientific Workforce Diversity (COSWD) is to pilot bias training for scientific review officers, reviewers and program officers.

Many other efforts have recently been completed by CSR, including a redesign of their internet site, including an update of study section descriptions with overlap statements and shared interests across study sections and restructuring their process for orienting incoming study
Currently under development is a user-friendly platform to receive reviewer suggestions from scientific societies.

Finally, Dr. Byrnes shared that CSR is constantly evaluating performance of peer review and the surrounding processes. To that end, CSR recently developed a new systematic evaluation framework for CSR study sections called “ENQUIRE” which stands for Evaluating Panel Quality in Review. The process involves reviewing a cluster of study sections based on their scientific relatedness by an external blue-ribbon panel to address the question, “How well does the scientific scope of the study sections align with the current state of the science?” The panel may recommend multiple actions for restructuring study sections through change in scientific guidelines, merging of study sections or creation or elimination of study sections. The ENQUIRE process also includes review by a second panel comprised of leadership from NIH extramural programs and CSR, whose review is focused on review process and function as opposed to scientific scope. Finally, recommendations made for restructuring of study sections are considered by the CSR Advisory Council and NIH’s Extramural Advisory Working Group prior to any implementation by CSR leadership. Last year, 2019, was the first year for the ENQUIRE process and it will be continuous with about 20% of CSR study sections evaluated every year.

**Adjournment**

The meeting was adjourned at 1:45 p.m. on January 31, 2020.
Certification of Minutes

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

____3/30/2020_________________ /Craig A. Jordan/__
Craig A. Jordan, Ph.D.
Executive Secretary
National Deafness and Other Communication Disorders Advisory Council

____3/30/2020_________________ /Debara L. Tucci/__
Debara L. Tucci, M.D., M.S., M.B.A.
Acting Chair
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 29, 2020, and corrections or notations will be stated in the minutes of that meeting.
## APPENDICES

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<td>NIDCD Budget Officer Slides</td>
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<tr>
<td>Name</td>
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<td>ADAMS, Lisa C., J.D.</td>
<td>2020</td>
<td>Director, Doctoral Program in Clinical Audiology, University of Maryland, College Park, MD 20742</td>
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<tr>
<td>CAREY, John Patrick, M.D.</td>
<td>2021</td>
<td>Co-Director and Research Director, Center for Laryngeal Surgery and Voice Rehabilitation at Massachusetts General Hospital and Professor of Surgery, Harvard Medical School, Boston, MA 02114</td>
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<td>EATOCK, Ruth Anne, Ph.D.</td>
<td>2023</td>
<td>KELLEY, Barbara, Executive Director, Hearing Loss Association of America, Bethesda, MD 20814</td>
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<tr>
<td>KELLEY, Barbara</td>
<td>2023</td>
<td>Linke Ellis, Nanci, Specialty Marketing Consultant for Hearing Loss and Vision Impaired Audiences, Culver City, CA 90232</td>
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<td>MORTON, Cynthia C., Ph. D.</td>
<td>2022</td>
<td>Sanches, Dan H., Ph. D., Professor, Center for Neural Science, New York University, New York, NY 10003</td>
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SIMS, H. Steven, M.D.  2020
Associate Professor and Director
Department of Otolaryngology-
Head and Neck Surgery
University of Illinois Medical Center
Chicago, IL  60612-7333

STROWBRIDGE, Ben W., Ph.D.  2023
Professor of Neuroscience
Departments of Neuroscience and
Physiology/Biophysics
Case Western Reserve University
School of Medicine
Cleveland, OH  44106

Ad Hoc Members

GROVES, Andrew K., Ph.D.
Professor and Vivian L. Smith Endowed
Chair in Neuroscience
Baylor College of Medicine
Houston, TX  77030

KINNAMON, Sue C., Ph.D.
Professor
Department of Otolaryngology
University of Colorado, Denver
Aurora, CO  80045

EX Officio

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

HENRY, LaKeisha R., M.D, FACS
Division Chief, Hearing Center for Excellence
Defense Health Agency
Assistant Professor of Surgery, USUHS
Joint Base San Antonio-Lackland,
Lackland, TX  78236

THEMANN, Christa, M.S. CCC-A
Research Audiologist
Hearing Loss Prevention Team
Division of Applied Research and Technology
National Institute for Occupational Safety
And Health (NIOSH)
Cincinnati, OH  45226

Executive Secretary

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

Eric Williams, Budget Officer
NIDCD Advisory Council Meeting
January 31, 2020
# National Institute on Deafness and Other Communication Disorders (NIDCD)
## FY 2019 Operating Plan (Actual Allocations)
(Dollars in thousands)

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<tr>
<th>Budget Mechanism</th>
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<td>Research &amp; Develop. Contracts</td>
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National Institute on Deafness and Other Communication Disorders (NIDCD)
FY19 Spending by Mission Area

Includes intramural and extramural funding
National Institute on Deafness and Other Communication Disorders (NIDCD)

FY2020 Enacted Budget
(Dollars in Thousands)

- FY 2018 Enacted: $459,974
- FY 2019 Enacted: $474,404
- FY 2020 Enacted: $490,692

FY 2020 Competing R01/U01 Budget
Payline: $13,300 per Council
HPP: $3,325 per Council