Eunice Kennedy Shriver National Institute of Child Health and Human Development

NATIONAL ADVISORY CHILD HEALTH AND HUMAN DEVELOPMENT COUNCIL

MEETING MINUTES

June 7, 2018

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE

***EUNICE KENNEDY SHRIVER* NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT**

NATIONAL ADVISORY CHILD HEALTH AND HUMAN DEVELOPMENT COUNCIL SUMMARY MINUTES

June 7, 2018[1]

The National Advisory Child Health and Human Development (NACHHD) Council convened its 167th meeting at 8:00 a.m., Thursday, June 7, 2018, in Building 31, Conference Room 6, of the National Institutes of Health (NIH) in Bethesda, Maryland. The meeting was open to the public from 8:00 a.m. to 11:30 a.m. As provided in Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., and Section 10(d) of Public Law 92-463, for the review, discussion, and evaluation of grant applications and related information, the meeting was closed to the public from 12:30 p.m. until 4:30 p.m.

Diana W. Bianchi, M.D., Director, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), presided.

Council members present:
Diana W. Bianchi, M.D. (Chair)
Michael Boninger, M.D.
Anne C. Case, Ph.D., M.P.A.
Barbara L. Collura
Catherine Gordon, M.D., M.Sc.
Richard D. Krugman, M.D.
DeWayne M. Pursley, M.D., M.P.H.
Frederick P. Rivara, M.D., M.P.H.
Lesli Rotenberg (remote)
Clifford Tabin, Ph.D. (remote)
Alyce Thomas, R.D.

Council members absent:
Melissa L. Gilliam, M.D., M.P.H.
Timothy P. Shriver, Ph.D.

Department of Defense
Col. Teresa L. Brininger, Ph.D. (remote)

National Advisory Board on Medical Rehabilitation Research Council Liaison
Kenneth Ottenbacher, Ph.D., OTR

Ex officio members present:
Patricia Dorn, Ph.D.
Aaron M. Lopata, M.D., M.P.P.

Observers (pending members) present:
Susan Bookheimer, Ph.D.
Atul J. Butte, M.D., Ph.D.
Stephen A. Foley, M.D.
Annette Sohn, M.D.

Ad hoc reviewer
Martin M. Matzuk, M.D., Ph.D. (remote)

[1] Members absent themselves from the meeting when the Council discusses applications from their own institutions or when a conflict of interest might occur. The procedure applies only to individual applications discussed, not to *en bloc* actions.

Others present:
Della M. Hann, Ph.D., Director, Division of Extramural Research and Associate Director for Extramural Research, NICHD
Constantine Stratakis, M.D., D.Sc., Director, Division of Intramural Research, NICHD
Members of NICHD Staff
Members of NIH Staff

I. CALL TO ORDER AND INTRODUCTORY REMARKS

Dr. Bianchi began the meeting at 8:00 a.m. The meeting was videocast live.

A. Review of Confidentiality and Conflict of Interest

Dr. Della Hann reminded Council members that all members were required to read and sign the confidentiality and nondisclosure rules for special government employees on the Council member website before evaluating any NIH grant applications. Council members also received a conflict-of-interest certification form, which they were required to sign before the closed session of the review of applications. Dr. Hann also reminded Council members that if there is a specific discussion involving any organizations or universities for which they are in conflict, in addition to those listed on the Council Action document, those members are required to recuse themselves from the discussion and leave the room. Council members are not allowed to serve on the NIH peer review panel while serving as Council members. It is NIH policy that individuals may not serve on both the first and second levels of peer review.

B. Council Minutes

Dr. Hann moved to approve the January 2018 meeting minutes. The minutes were approved unanimously.

C. Future Meeting Dates

Dr. Hann reviewed the future meeting dates:

September 13–14, 2018
January 24–25, 2019
June 11, 2019
September 19, 2019

II. NICHD DIRECTOR'S REPORT AND DISCUSSION

Dr. Bianchi provided the Director's report.

Budget Update

Congress passed the budget on March 23, 2018, funding the government through September 30, the end of the fiscal year (FY). NIH received $37 billion for FY 2018, an increase of $3 billion over FY 2017. NICHD received an increase of $75 million.

NICHD also received additional funding for its role in two trans-NIH projects. The first is the Helping to End Addiction Long-term (HEAL) Initiative, an effort to quickly develop scientific solutions to the opioid crisis. As part of the HEAL Initiative, NICHD will receive $30 million for

the Advancing Clinical Trials in Neonatal Opioid Withdrawal Syndrome (ACT NOW): Act Two program.

ACT NOW: Act Two grew out of the ACT NOW: Act One partnership, a research program to evaluate treatment options for newborns with opioid withdrawal syndrome. ACT NOW: Act One took place at 20 clinical sites with the goals of assessing the prevalence of opioid withdrawal in neonates, understanding approaches to treatment, and developing a common protocol for future studies.

ACT NOW is a collaboration between NICHD's Neonatal Research Network (NRN) and the Institutional Development Award States Pediatric Clinical Trials Network. The short-term goals of ACT Now: Act Two are to:

- Develop a simplified scoring tool to rate neonatal opioid withdrawal,
- Determine best practices for clinical care,
- Use randomized trials to determine the effectiveness of medications to treat withdrawal, and
- Use randomized trials to determine the effectiveness of pharmacologic versus nonpharmacologic strategies.

The long-term goals of ACT NOW: Act Two are to:

- Rapidly evaluate new pharmacologic treatments as they are developed and
- Work with NIH Institutes and Centers (ICs) to determine how prenatal and neonatal pharmacologic treatments will affect the neonatal brain in the long term.

The second trans-NIH project for which NICHD will receive funding is an initiative to improve the health and neurodevelopment of individuals with Down syndrome and typical individuals who are at risk for Alzheimer's disease, cancer, cardiovascular disease, immune system dysregulation, and autism. The National Institute on Aging and the National Cancer Institute are also involved in the initiative. NIH funding for Down syndrome research is expected to increase by about 65 percent over the next two fiscal years.

NICHD Vision

NICHD has begun its strategic planning process. The plan will not include NICHD components that already have their own strategic plans, such as the National Center for Medical Rehabilitation Research. NICHD will integrate existing strategic plans into the overall NICHD plan. The preplanning, including the collection and analysis of data, began in January. NICHD will develop objectives by October, the draft plan by December, and the final plan by March 2019.

The strategic plan will include the identification of scientific priorities and a plan to align resources with priorities. The process will be evidence-based, transparent, and community-centric. The planning group will include about 80 people, one-third from within NIH and two-thirds from outside. NICHD was set to send out invitations to potential participants by mid-June. A two-day planning meeting will be held in October. NICHD will post updates on the process on its website.

Trans-NIH Pediatric Research Consortium (N-PeRC) Funding

In FY 2017, NIH pediatric research funding totaled $4.18 billion. Although NICHD expends the most money on pediatric research, the Institute accounts for only 18 percent of the spending within NIH. Every IC funds some aspect of child health research. NIH is forming N-PeRC to harmonize efforts in child health research across the ICs; identify gaps and opportunities for collaboration; enhance communication among NIH, advocacy groups, and Capitol Hill; establish an outreach effort to encourage senior pediatric researchers to serve on review panels; and ensure trans-NIH support to grow the pediatric workforce.

Inclusion

NICHD has been working on inclusion efforts. Drs. Bianchi and Spong, published a Viewpoint article in *JAMA*, "Improving Public Health Requires Inclusion of Underrepresented Populations in Research," to stress the importance of including all segments of the population in clinical research. Inclusion is necessary to realize the promise of personalized medicine.

Inclusion efforts include the formation of N-PeRC, which was scheduled to hold its first meeting on June 12. In addition, children and people with physical and intellectual disabilities will be included in the *All of Us* Research Program.

The Task Force on Research Specific to Pregnant Women and Lactating Women (PRGLAC) has been working on including pregnant women and lactating women in research. NIH now has Research, Condition, and Disease Categorization codes to track research related to pregnancy and lactation, and a new crowdsourcing application, PregSource®, is now active.

In addition, a working group will examine the benefits and the risks of having healthy pregnant women participate in research protocols at the NIH Clinical Center. Pregnant women are currently excluded from research at the Clinical Center because of concern that a pregnant woman may go into labor at the hospital, which does not have obstetrical facilities.

PRGLAC

PRGLAC has issued 15 recommendations, which are now online, and is preparing its final report. Among the Task Force recommendations are to:

- Change the culture that has limited scientific knowledge of therapeutic product safety, effectiveness, and dosing for pregnant and lactating women by including pregnant women and lactating women in clinical research;
- Expand the workforce of clinicians and researchers with expertise in obstetric and lactation pharmacology and therapeutics; and
- Increase research on the safety and efficacy of therapeutic products used by pregnant women and lactating women.

Staff Updates

- Rosalind King, Ph.D., was named the Associate Director for Prevention.
- Scientific Director Dr. Constantine Stratakis is undergoing a performance review. This is a routine evaluation that all scientific directors undergo every 5 years. Council member Dr. Catherine Gordon will present the results at the September Council meeting.

- Dr. Spong, NICHD Deputy Director, has accepted a position at the University of Texas Southwestern Medical Center in Dallas as Chief of Maternal-Fetal Medicine and Vice Chair of the Department of Obstetrics and Gynecology.

Council Discussion

Dr. Anne Case said that she was surprised that the Clinical Center excludes pregnant women from studies for fear that they could go into labor while at the hospital. She would have thought that the concern would be about a study's risk to the fetus. Dr. Bianchi said that the Clinical Center was concerned about mothers going into labor on site where there are no obstetrical facilities. However, the Clinical Center has many resources that would benefit pregnant women. For example, the Clinical Center has metabolomic facilities that could help researchers better understand the metabolic changes that women undergo during pregnancy.

Dr. Richard Krugman said that the Global Down Syndrome Foundation was established 10 years ago with an aim to increase funding. It is interesting to see the impact that the foundation's efforts are having now.

III. INTRODUCTION OF NEW MEMBERS

Dr. Susan Bookheimer is the Joaquin Fuster Chair of Cognitive Neuroscience at the University of California, Los Angeles David Geffen School of Medicine. Her research focuses on autism.

Dr. Stephen Foley is with Prowers Medical Center in Lamar, Colorado. He is an obstetrician/gynecologist who works in a rural area that has been hard hit by the opioid crisis.

Dr. Annette Sohn is the Director of Therapeutics Research, Education, and AIDS Training in (TREAT) Asia and the Vice President of Global Initiatives for TREAT Asia/amfAR, The Foundation for AIDS Research, in Bangkok, Thailand.

Dr. Kenneth Ottenbacher is a Professor and Director of the Division of Rehabilitation Sciences at the University of Texas Medical Branch in Galveston, Texas. His research includes investigation of the role of rehabilitation practitioners in post-acute care.

IV. DIVISION OF EXTRAMURAL RESEARCH REPORT

Dr. Hann presented an analysis of the impact that large NICHD-funded programs have had on the field and on practice guidelines. She also provided staff updates.

Impact Analysis of Large Programs

NICHD has developed a battery of metrics to quantify the impact of large programs that it funds. The analysis began in 2017 to inform the NICHD strategic plan and to respond to Congress' request to show what public research dollars have accomplished.

Using these metrics, the NICHD staff analyzed the Maternal-Fetal Medicine Units (MFMU) Network, the Learning Disabilities Research Centers (LDRCs) and Learning Disabilities Innovation Hubs, the Pediatric HIV/AIDS Cohort Study (PHACS), the National Centers for Translational Research in Reproduction and Infertility (NCTRI), and the Population Dynamics Centers Research Infrastructure (PopCCIP).

The metrics included the following:

- Research products such as the number of publications, clinical trials, biologics, devices, patents, collaborations, resource sharing, training, and future funding that the program produced;
- Impact, including the scientific impact, the field saturation, and the impact on funding
- Practice, including impact that the program has had on medical practice and insurance guidelines; and
- Public engagement, including news stories that the program generates, its impact on policy, and the conferences that are held.

The analysis compared each large program to two primary reference groups. The programs were matched by content to other R01 studies and compared with NICHD Branch awards with similar program start dates.

An example of a product metric is the relative citation ratio (RCR), which shows the influence of an article compared with other NIH-funded papers in the same field. A paper that is cited an average number of times compared with other NIH-funded studies in the field receives an RCR of 1. If the paper is never cited, it receives an RCR of 0. The median RCR for PopCCIP and Branch were e similar, but PopCCIP also had one grant with a very high RCR.

Another example of a product metric is the number of awarded patents that are linked to the program. Twenty-four percent of NCTRI grants were associated with patents, compared with 4 percent of Branch grants and 2 percent of R01s.

Content analysis can address questions such as whether the program publications fill a niche. The content analysis for the LDRCs, for example, showed that they produced most of the learning disability publications related to reading comprehension, children, and dyslexia, filling a research gap that otherwise might remain unfilled.

An example of a practice impact involved citations for guidelines related to PHACS that showed that PHACS has nearly 7 percent of its publications cited in guidelines, compared with 2.7 percent for Branch publications and 1.7 percent for R01 publications. UpToDate showed that 38 percent of MFMU publications were cited in this clinical-practice tool, compared with 7.7 percent of Branch publications and 13.8 percent of R01 publications.

The next step is to analyze the impact of the Intellectual and Developmental Disabilities Research Centers, the Reproductive Medicine Network, the Neonatal Research Network, the Pelvic Floor Disorders Network, and the Collaborative Pediatric Critical Care Research Network.

Council Discussion

Dr. Michael Boninger asked whether the analysis controlled for the amount of funding and for the type of research such as translational or basic science. Dr. Hann said that the analysis did not control the amount of funding a project received. Bill Duval, Ph.D., said that the programs were matched with Branch programs and R01s based on content.

Staff Updates

Andrew Bremer has been appointed the Branch Chief of the Pediatric Growth and Nutrition Branch. He is an M.D, Ph.D. M.A.S, is triple board certified in internal medicine, pediatrics, and pediatric endocrinology, and has a Ph.D. in pharmacology.

Ted Williams retired on June 1. He was a team leader in the Grants Management Branch.

V. UPDATE FROM NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH)

Joshua Gordon, M.D., Ph.D., Director of NIMH, provided an update on the work of his Institute, the lead federal agency for research on mental disorders. Currently, NIMH supports more than 3,000 research grants and contracts at universities and other organizations throughout the United States and overseas. NIMH has approximately 600 scientists in its intramural research program. Its mission is to transform the understanding and treatment of mental illnesses through basic and clinical research.

In contrast with other diseases, disability due to mental illness starts earlier in life and lasts into late adulthood. Mental illness creates a tremendous burden on individuals, families, and society.

The NIMH strategic plan provides four high-level objectives:

- Define the mechanisms of complex behaviors;
- Chart mental illness trajectories to determine when, where, and how to intervene;
- Strive for prevention and cures; and
- Strengthen the public health impact of NIMH-supported research.

The NIMH strategic plan's priorities are to identify risk for disease, identify biomarkers, chart illness across development, and develop personalized interventions. Early pre-symptomatic phases in mental illness may provide the best opportunity to identify individuals at highest risk and allow intervention at the earliest time.

Neurodevelopmental Perspective

Most common mental illnesses, such as anxiety disorders, mood disorders, and schizophrenia, begin during childhood and adolescence. Some risk factors can occur even before birth. For example, risk factors for schizophrenia include paternal age and maternal infection.

Brain imaging studies suggest that certain brain changes between 6 and 12 months of age may predict the development of autism spectrum disorder by age 2 years. Children with autism also spend less time looking at the mouth and eyes of their caregivers and peers. Early interventions may improve outcomes for children with autism. The Early Start Denver Model has resulted in gains in IQ, language, and adaptive behavior of children with autism spectrum disorder.

Early Identification and Intervention Across the Lifespan

Suicide Prevention

The Emergency Department Safety Assessment and Follow-up Evaluation (ED-SAFE) study carried out in adult emergency rooms found that a brief universal suicide screening followed by safety planning guidance for those identified as at-risk and periodic phone check-ins by a master's-level clinician over the following 4 months led to a 30 percent decrease in suicide

attempts over the 52 weeks of follow-up compared with standard emergency department care. Further, this intervention was found to be cost effective.

First-Episode Psychosis

Currently, on average, there is a 2-year gap between the first episode of psychosis and diagnosis. The NIMH Recovery After an Initial Schizophrenia Episode (RAISE) project demonstrated that a team-based, multi-component treatment program for first-episode psychosis produced superior clinical and functional improvements compared to typical care, especially among individuals with shorter duration of untreated psychosis. In addition, NIMH-supported scientists have uncovered altered brain development patterns in individuals who later develop psychosis. A better understanding of these patterns may help predict risk for developing psychosis, and, in turn, get at-risk individuals into treatment earlier.

Opportunities in the Era of Big Data

NIMH, together with 10 other NIH Institutes and Centers, supports the NIH Blueprint Human Connectome Project (HCP). The HCP aims to decipher the brain's complex wiring system and map the neural pathways that underlie typical human brain function. Building on the original HCP, the HCP Lifespan studies take a lifespan approach, examining the connectome in the age ranges of 0 to 5, 5 to 21, 22 to 35, and 36 to 100 years. These projects, as well as other large-scale efforts, including the NIH Adolescent Brain Cognitive Development (ABCD) study and the NIH All of Us Research Program, will improve our understanding of the many factors that influence brain development trajectories and outcomes, paving the way toward improved treatments and potential cures.

Council Discussion

Dr. Frederick Rivara said that suicide attempts involving firearms have a very high success rate. What can NIMH do to address the problem of suicide by firearm, given that federal law prevents funding of firearm research? Dr. J. Gordon said that NIMH has funded "means restriction" research. Gun rights advocates are supportive of this type of research, which involves gun safety. The U.S. Army is currently working with the National Rifle Association on a suicide prevention study for veterans who are at risk of suicide and who may own guns.

Dr. Rivara asked whether NIMH will issue requests for applications (RFAs) or program announcements (PAs) targeted at suicides involving firearms. Dr. J. Gordon said that there are no plans to do so but that NIMH could issue more RFAs involving means restriction. When Dr. Rivara asked why NIMH was not planning to issue an RFA or a PA involving firearm-related suicide, Dr. J. Gordon said that NIMH does not want to eliminate research on other means of suicide. Firearms are number one, but pills and strangulation are close behind.

Dr. Sohn asked about NIMH's plans for global mental health research, particularly in the area of adolescent depression and suicide. Dr. J. Gordon said that the NIMH focus in lower-income countries has been on capacity building and the delivery of mental health care through means that are appropriate for lower-resource settings. He did not know of any NIMH projects specifically focused on adolescent depression, but NIMH has projects that focus on maternal depression and has HIV/AIDS projects that focus on adolescents.

Ms. Alyce Thomas asked whether the link between nutrition *in utero* and schizophrenia involved a particular nutrient or malnutrition. Dr. J. Gordon said that he did not think that the studies

reached that level of specificity. The studies grew out of a famine in Northwestern Europe that led to increases in schizophrenia. Lack of folate has been tied to a variety of conditions within the central nervous system and it is conceivable that lack of folate may lead to psychiatric disorders.

Ms. Barbara Collura asked whether NIMH would consider doing studies on adolescent depression and adolescents' use of social media, smartphones, and other technology. Dr. J. Gordon said that the Adolescent Brain Cognitive Development Study is collecting social media data and that NIMH is involved in a study with several ICs that is looking at social media use in adolescence. NIMH has not done such a study in partnership with the private sector, but the Foundation for the National Institutes of Health, which supports public-private partnerships, would likely be interested in partnerships with industry.

Dr. Case asked to what extent NIMH is considering socioeconomic status as a driver of suicide risk. She also asked how opioid addiction and alcoholism are connected to suicide. Dr. J. Gordon said that he is not aware of any hard data linking increased opiate overdoses or alcohol poisoning to increased rates of suicide. In general, NIMH looks for novel areas of research that provide ways to address mental health problems. In the case of socioeconomic disparities in suicide, NIMH would want to determine whether there are addressable risk factors within the socioeconomic disparities.

Dr. Susan Bookheimer said that various mental illnesses share the same risk factors. She asked whether this would be an area of NIMH inquiry. Dr. J. Gordon said that NIMH is trying to do more work that cuts across diagnoses, such as in the case of autism and schizophrenia.

VI. INNOVATIVE MODELS FOR PREVENTING SCHOOL READINESS DISPARITIES IN PEDIATRIC PRIMARY CARE

Alan L. Mendelsohn, M.D., of the New York University School of Medicine has focused his research on poverty-related disparities in early child development and school readiness. Poverty-related disparities that begin in early childhood affect educational, economic, and health outcomes throughout life. There is a need for primary prevention in early childhood, before problems appear.

About 52 percent of children in poverty are not ready for school, 41 percent of low-income children are not ready, and 25 percent of children who are not poor are not ready. These early gaps in achievement by income level widen over time.

Parent-child interactions account for about half of the disparity level. These interactions have been characterized as the "word gap", based on differences in both quantity of language exposure and in exposure to high quality language more broadly. Facilitating parent-child interactions such as reading can be an important way to narrow this gap.

Pediatric primary care represents a universal platform for promoting parenting and school readiness that can reach more than 90 percent of children at relatively low cost. Reach Out and Read is a program that uses volunteers and staff in the pediatrician's office who model reading activities in the waiting room and provide guidance about reading to parents. Pediatricians inform parents about the importance of reading and distribute free children's books.

Studies have found that the program affects children's vocabularies, is reaching more than 25 percent of low-income children, and costs only $25 per child per year.

Dr. Mendelsohn discussed the development of the Video Interaction Project (VIP). In VIP, a program interventionist videotapes sessions of a parent reading or playing with the child and uses the videotape to provide one-on-one coaching. The goal of VIP is to empower parents to take an active and planned role in supporting their children's development and school readiness. The program, which is for parents of children from birth to 5 years old, provides toys and books to the children and costs about $200 per year per child. Parents also receive a guide with suggested activities.

A study of VIP's effectiveness found that it increased parent-child interactions, enhanced psychosocial functioning, and reduced physical punishment. The program reduced maternal depressive symptoms and parenting stress and improved child development to some degree in language and cognition, and strongly and robustly in social-emotional development, including a reduction in hyperactive behavior. The reduction in hyperactive behavior was greater for children who were in the program through age 5 than for children who were in the program until age 3. In addition, the positive effects persisted 18 months after parents and children completed the program.

The investigators are currently working to scale up the program. They have developed a training manual and a training course for the interventionists, have implemented in additional sites in New York City through a City Council initiative called City's First Readers and have begun a pilot implementation in Flint, Michigan. The program is also being integrated with home visiting through Family Check Up in a tiered model called Smart Beginnings in Pittsburgh and New York City. Preliminary results indicate improvements in parenting skills and in child behavior. VIP and Reach Out and Read have together informed development of a reading support program in in Brazil; a recent publication documented impacts in Brazil on parenting and child development.

The policy implications of these findings are that there is a need for prevention activities for all families in poverty before problems arise and that integrating with other programs, such as home visiting programs, can create even larger impacts. Delivering programs through the pediatrician's office is a cost-effective way to provide nearly universal access. Enhancing positive parenting through pediatric primary care interventions such as Reach Out and Read and VIP can create a positive cascade across developmental domains, with potential implications for long-term educational achievement and health.

Council Discussion

Dr. Krugman asked how VIP could reach children who are in rural communities and do not have a pediatrician. Dr. Mendelsohn said that all types of providers, including family physicians and nurse practitioners can deliver the program.

Dr. DeWayne Pursley said that the highest-risk families may not be receiving any medical care. Are there other ways to reach these families outside of the medical office, such as through social media or barbershops? Dr. Mendelsohn said that it is important to find ways to reach those who are not receiving health care. The Special Supplemental Nutrition Program for Women, Infants, and Children might be one way. Social media can help improve awareness but does not provide a platform from which to conduct interventions.

VII. VOICE OF THE PARTICIPANT

Ms. Kiara Gonzalez described her experience as a participant in VIP. She learned that talking to her 1-week-old baby, Samaris, about the color and texture of a toy and reading to her were good educational experiences for Samaris. At each doctor's appointment, Samaris received a new toy or book, and Ms. Gonzalez received coaching to read, play, sing songs, and use imagination in play activities. Samaris, now 5 years old, is a candidate for her school's gifted and talented program. Ms. Gonzalez said that she also benefited from the VIP visits, because it was her chance to leave the house for a few hours and interact with the program staff person. Ms. Gonzalez is now using what she learned with her second child and has recommended the program to her friends and family members.

Council Discussion

Dr. Sohn asked what kinds of questions she gets from family and friends when she recommends the program. Ms. Gonzalez said that she gets questions about what to expect from the program and where to find it. She tells those who ask where the program is located and gives them the program's website and the staff person's email address.

VIII. UPDATE: SMALL BUSINESS INNOVATION RESEARCH (SBIR) AND SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) PROGRAMS AT NIH AND NICHD

J. P. Kim, J.D., M.B.A., M.P.P., M.Sc., M.A.L.S., of the NIH SBIR/STTR Program Office provided an overview of the SBIR and STTR programs. SBIR funds early-stage small businesses seeking to commercialize innovative biomedical technologies that can improve health. The STTR program is similar but requires that small businesses collaborate with a research institution in Phase I and II of development.

The SBIR and STTR provide grants of up to $150,000 for the Phase I feasibility study. Phase II provides up to a total of $1 million over 2 years. Both programs also have a "fast track" component that allows the grantee to avoid a gap in funding between Phases I and II. Phase IIB is a competing renewal award that can pay up to $1 million per year for up to 3 years. Phase III is for commercialization. NIH does not fund Phase III.

The programs are similar in that they serve small businesses, but they differ in their partnering and work allocation/percentage requirements and the principal investigator's employment. The NIH also has programs that provide entrepreneurial training for scientists, marketing and commercialization mentoring, and help facilitate opportunities for small business companies to present their NIH-funded technologies and network at conferences.

The combined budget for the two programs is about $1 billion, with most of it within SBIR. The success rate of grant applications is 16 percent for Phase I and 42 percent for Phase II.

Mr. Kim discussed an example of an SBIR product, a "smart" spoon that stabilizes and levels the handle to allow people with hand tremors or limited hand mobility to feed themselves. The spoon counters the shake of an individual's hand.

Louis Quatrano, Ph.D., of the National Center for Medical Rehabilitation Research (NCMRR) said that SBIR and STTR funding is set by statute as a percentage of the NIH budget. SBIR funding for FY 2017 was $34.9 million. STTR funding was $4.9 million.

Council Discussion

Dr. Patricia Dorn asked how many Phase II projects make it to commercialization. Mr. Kim said that they do not have complete data on how many projects make it to market. The SBIR/STTR program tracks about 80 projects per year for up to 18 months after they leave the program, and the Small Business Administration (SBA) also tracks the progress of the past awardees. Dr. Quatrano said that the program needs to be better at tracking data such as how many products make it to market. However, it can be difficult to track results, because, for example, a company that receives a grant may be taken over by another company, or technology may be sold to another company. Mr. Kim said that tracking intellectual property can be very difficult. Dr. Dorn said that the data are needed to assess how well the program is doing at getting out products that will improve people's lives.

Ms. Collura asked whether the program hosts live seminars, webinars, or innovation fairs to interact with people who have a product idea but are unfamiliar with NIH and its funding mechanisms. Mr. Kim said that NIH holds an annual 3-day conference in different locations around the country to help people navigate NIH. NIH also participates in the SBA road tours to give presentations and introduce people to the programs.

Dr. Bianchi asked whether NICHD has its own reviewers to review SBIR/STTR grant applications or whether this is done through the Center for Scientific Review (CSR). Dr. Hann said that CSR handles most of the applications, because there is a limited number of experts who can do these reviews. The CSR panel meets quarterly, because the programs have an accelerated timeline for handling grant applications and renewals.

Ralph Nitkin, Ph.D., of NCMRR said that SBIR/STTR has helped investigators develop prototypes that could help people with disabilities. However, many investigators have no background in regulatory requirements or in determining a product's potential market. The program has helped grantees think about these issues in advance. Dr. Hann said that the programs are trying to educate people even earlier in the pipeline so that they can pass muster with the U.S. Food and Drug Administration and other agencies.

Dr. Sohn asked about the patents that grantees receive as a result of work on the program. She also asked whether there are public-private partnerships to identify RFA topics that would attract biotechnology companies. Mr. Kim said that the small business must either bring the patented technology to commercialization or transfer the patent to the funding agency. Dr. Quatrano said that NICHD has discussed the possibility of public-private partnerships and has done some outreach but that it has not yet been done in a systematic way.

IX. 2018 STATEMENT OF UNDERSTANDING

Dr. Hann noted that the draft statement of understanding between NICHD and the NACHHD was posted on the Council members' website. It provides a synopsis of the Council activities including membership and structure, second-level review of grant applications, and concept review. She called for a motion to approve the statement. The motion was moved and unanimously approved.

Dr. Bianchi thanked members of the public for attending the meeting in person or through the videocast. She adjourned the open session of the meeting at 11:20 a.m.

X. CLOSED SESSION

This portion of the meeting was closed to the public in accordance with the determination that it concerned matters exempt from mandatory disclosures under Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

XI. REVIEW OF APPLICATIONS

The session included a discussion of procedures and policies regarding voting and confidentiality of application materials, committee discussions, and recommendations. Members absented themselves from the meeting during discussion of and voting on applications from their own institutions or other applications in which there was a potential conflict of interest, real or apparent. Members were asked to sign a statement to this effect. The Council considered and approved 617 HD-primary applications requesting $205,636,097 in direct costs and $286,442,347 in total costs.

XII. ADJOURNMENT

There being no further business, the meeting adjourned at 4:30 p.m. on Thursday, June 7, 2018. The next meeting is scheduled for September 13–14, 2018.

I hereby certify that, to the best of my knowledge, the foregoing minutes and attachments are accurate and complete.[2]

/SIGNED/ 7/27/18

Diana W. Bianchi, M.D. Date
Chair, National Advisory Child Health and Human Development Council
Director, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

Eugene Hayunga, Ph.D.
Acting Committee Management Officer, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

Attachment: Council Roster

[2] These minutes will be formally considered by the Council at its next meeting, and any corrections or notations will be incorporated in the minutes of that meeting.