



Eunice Kennedy Shriver National Institute
of Child Health and Human Development

NATIONAL ADVISORY CHILD HEALTH
AND HUMAN DEVELOPMENT
COUNCIL

MEETING MINUTES

January 31, 2017

**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**

January 31, 2017¹

The National Advisory Child Health and Human Development (NACHHD) Council convened its 163rd meeting at 8:00 a.m., Tuesday, January 31, 2017, 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 12:15 p.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 1:30 p.m. until 4:00p.m.

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

Council members present:

Dr. Anne Case

Ms. Barbara Collura

Dr. Patricia Flynn

Dr. Melissa Gilliam

Dr. Gregory Kopf

Dr. Richard Krugman

Dr. Stephen Petrill (virtual)

Dr. Frederick Rivara

Ms. Leslie Rotenberg

Dr. George Saade

Dr. Timothy Shriver

Ms. Sheila Zimmet

Council members absent:

Dr. DeWayne Pursley

Department of Defense

Col. Teresa Brininger

National Advisory Board on Medical Rehabilitation Research Council Liaison

Dr. Richard Shields

Ex officio members present:

Dr. Patricia Dorn

Dr. Aaron Lopata

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.

Non-voting Council members present:

Dr. Michael Boninger

Dr. Atul Butte

Dr. Catherine Gordon

Dr. Clifford Tabin

Ms. Alyce Thomas

Others present:

Dr. Diana Bianchi, Director, NICHD

Dr. Catherine Spong, Deputy Director, NICHD

Dr. Della Hann, Director, Division of Extramural Research (DER) and Associate Director for Extramural Research, NICHD

Dr. Constantine Stratakis, Director, Division of Intramural Research (DIR), NICHD

Members of NICHD Staff

Members of NIH Staff

Invited Guests:

James Baumberger, American Academy of Pediatrics

Craig Fisher, American Psychological Association

Dawn Ireland, CHERUBS

Joseph Laakso, The Endocrine Society

I. CALL TO ORDER AND INTRODUCTORY REMARKS

Dr. Bianchi welcomed Council members, guests, and staff to the 163rd meeting of the National Advisory Council and announced that the meeting would be open to the public for the morning portion and would be broadcast on the NIH VideoCast Network.

A. Review of Confidentiality and Conflict of Interest

Dr. Hann reminded Council members that on the Council Member Website, all members are required to read, agree to, and sign the confidentiality and non-disclosure rules for special government employees before reviewing any NIH grant 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, that they are required to recuse themselves from the discussion and leave the room. Dr. Hann informed Council members to sign the Conflict of Interest Certification form prior to the closed session of the review of applications. Council members are not allowed to serve on the NIH Peer Review Panel while serving as a Council member. Per NIH policy, individuals may not serve on both the first and the second levels of peer review.

B. Council Minutes

Dr. Hann moved to approve the September 2016 *meeting minutes*. The *Minutes* were approved unanimously, as written.

C. Future Meeting Dates

Dr. Hann reviewed the future meeting dates:

June 8, 2017	(Thursday)
September 14, 2017	(Thursday)
January 18, 2018	(Thursday)
June 7-8, 2018	(Thursday-Friday)
September 26-27, 2018	(Wednesday-Thursday)

II. NEW DIRECTOR'S VISION FOR NICHD

Dr. Bianchi expressed how incredibly humbled she is to be at the helm of this great organization and that she has always been a passionate advocate for NICHD. Of her 43-funded project-years in the Research Portfolio Online Reporting Tools (RePORT) database, 41 were funded by NICHD. She served as both a participant and a moderator in the 2010 Vision Process and the Human Placenta Project (HPP) workshop and is a past NICHD Council Member.

Dr. Bianchi expressed the core values of the Institute: maintain a high level of excellence, promote transparency, take time to listen, learn, and think. She explained how NICHD is already excellent, but the Institute needs to maintain high standards in challenging times and even try to exceed them. Promoting transparency is another priority by communicating what priorities mean and being transparent in explaining how the information will be interpreted. Dr. Bianchi explained the need for time to listen, learn, and think, which includes asking for more information and taking the time to absorb and integrate all the information. This is her initial vision derived from preliminary observations and is only a suggested path forward. Dr. Bianchi requested feedback from Council Members.

Dr. Bianchi acknowledged that the country is undergoing a time of transition and mentioned that she was sworn in by Dr. Francis Collins on Election Day. She stated that she went to the whitehouse.gov website and realized that there is no mention of health care in the list of important issues (as of that day). In the recent past, on the greatagain.gov website, there was a mention of advancing research and development in healthcare. However, that was the only mention of research.

Dr. Bianchi acknowledged Dr. Alan Guttmacher's time and achievements while at NICHD from December 2009 to September 2015. She summarized Dr. Guttmacher's achievements, including: the conception and completion of the NICHD Vision Process: the reorganization of NICHD that led to the formation of the Division of Extramural Research (DER), formerly housed within the Deputy Director's Office; the creation of the Pediatric Trauma and Critical Illness Branch (PTCIB) and the Gynecologic Health and Diseases Branch (DHDB); the reorganization of the Office of the Director (OD) that entailed splitting off the Office of Communication (OC) from the Office of Science Policy, Analysis and Communication, renaming it the Office of Science Policy Reporting and Analysis (OSPRA); creating the Human Placenta Project, and the PregSource™ Data App. After the closure of the National Children's Study (NCS), programs like ECHO and the IDeA States Pediatric Network were developed to fulfill the mission of the NCS.

Dr. Bianchi thanked Dr. Catherine Spong for her service as the Acting Director from October 2015 to November 2016 and for her many achievements. Dr. Spong developed a coordinated

effort to begin to understand how Zika virus affects pregnancy, which first became an issue during her tenure as Acting Director. She improved the funding payline, oversaw the relocation of staff to 6710B Rockledge Drive, worked with Dr. Della Hann to establish extramural branch priorities, and worked with Dr. Alison Cernich to complete the NIH Medical Rehabilitation Plan. Dr. Spong also finalized the restructuring of the Office of the Director and the Review of the Office of Health Equity (OHE).

Dr. Bianchi discussed the vision she has for NICHD and the need to define what is the brand, or focus, of NICHD. Once the focus is determined, the message needs to be communicated. There is a need to listen to the voice of the patient. The Institute needs to integrate obstetrics and pediatrics and take the long view with developmental origins of health and disease. There is a need to advocate for personalized medicine in pediatrics, obstetrics, and rehabilitative medicine.

For example, when the Personalized Medicine Initiative was first described, there was no mention of children. However, fortunately now that will change.

NICHD needs to build bridges between other Institutes, especially NICHD and National Human Genome Research Institute. The importance of data science and sharing to leverage investments needs to be stressed. Dr. Bianchi expressed the need to analyze and identify trainees who are most likely to succeed. Access to clinical trials for pediatric and obstetric patients both extramurally and intramurally needs to be increased. Innovation needs to be catalyzed. Dr. Bianchi emphasized the “A” for “Advice” in the Advisory Committee, as she wants to call on Council Members even more to weigh in on certain issues.

Dr. Bianchi reviewed the NICHD budget. The budget for Fiscal Year (FY) 16 was \$1.338 billion. NICHD is not the biggest Institute, but falls in with the top half of Institutes at NIH. The majority of the money goes to extramural, at \$1.04 billion. Intramural totaled \$124 million. The total Research Management Systems (administrative) costs were \$24 million. Taps, a tax that all institutes pay for trans-NIH expenses, totaled \$127 million. Dr. Bianchi discussed the extramural budget for FY16. Each year over half of the extramural budget goes to continuing grants. Only about 18% of the budget goes to competing new research grants (mainly R01s), and that is why the payline is low. NICHD is different from some of the other Institutes and Centers, as a large percentage of the budget funds networks and centers. Dr. Bianchi explained that there is not a big pool for new grants because NICHD is locked into funding a significant number of continuing grants. The training budget usually stays around 6-7%. Interestingly, NICHD only funds 18% of child health research at NIH.

Dr. Bianchi discussed how the name of the Institute, while mandated in legislation, does not mention critical features of the portfolio. Pregnancy and women’s health does not appear in the name. Even though NICHD is responsible for medical rehabilitation for children and adults, it also does not appear in the name of the Institute. The name of the Institute should reflect what it actually does. The Institute’s tag line and mission statement also could be reviewed from this perspective.

Dr. Bianchi stressed the importance of communicating the Institute’s mission and achievements to a variety of stakeholders. One of the biggest priorities is to update the NICHD website. Although the current website has a great deal of information, it is very text heavy. The new website is going to be designed to improve search functions, design/layout, navigation, management and maintenance, and to optimize for search engines. The new website will also

introduce new features that highlight NICHD's scientific contributions, including clinical trial data.

Dr. Bianchi acknowledged the importance of advocacy. The Friends of NICHD provide a valuable means of advocating NICHD's mission. Another type of advocacy is the voice of the patient. Although NICHD does include patient input in some studies, Dr. Bianchi believes the Institute needs to embrace the extremely valuable input of patient advocacy groups.

Dr. Bianchi touched on the idea of building bridges by integrating obstetric and pediatric research at NICHD. Obstetric and pediatric research is siloed at NICHD. As an example, she spoke about the Maternal Fetal Medicine Unit (MFMU) and the Neonatal Research Network (NRN) that are housed in the same extramural branch at NICHD. There are 12 sites enrolling participants in the MFMU and 15 sites enrolling babies in the NRN. Eight of these sites have both an MFMU and an NRN but they are administratively separate and have no formal mechanisms through which to share data. Consequently, it is difficult to obtain long-term outcome data on infants born to mothers in the MFMU, and maternal data on infants enrolled in the NRN. Dr. Bianchi expressed an interest in having the eight institutions with both an MFMU and an NRN on site to develop pilot protocols to begin to integrate data.

There is a need to increase synergies between basic science research and medical research. She used the NICHD Exchange and the All of Us Precision Medicine Initiative, led by Dr. Eric Dishman and Dr. Stephanie Devaney, as examples of how researchers are beginning to communicate. The Kids First, Newborn Sequencing in Genomic Medicine and Public Health (NSIGHT) program, Clinical Genome Resource (ClinGen), and the Undiagnosed Diseases Network UDN) were also listed as examples.

The importance of data science and shared resources was discussed. There is a need to leverage investments. NICHD's Data and Specimen Hub (DASH) resource was identified, and there are already many projects archived on that site. There is also a National Library of Medicine Task Force, led by Dr. Patti Brennan, which is evaluating what data should be archived, what needs to be done currently, what needs to be done in five years, and what needs to be archived indefinitely. Dr. Bianchi has volunteered to participate in this task force. Dr. Bianchi acknowledged Dr. Germaine Buck Louis, whose Division of Intramural Population Health Research is creating a number of shared resources. This includes a publicly accessible Fetal Growth Calculator, the result of a NICHD-funded study, which is not yet online.

Dr. Bianchi raised the question of how to wisely invest training dollars in people most likely to succeed. After analyzing the way NICHD invests its training dollars, the Training Review Task Force recommended that the Institute start shifting training dollars from institutional grants to individuals as the rate for successfully competing for NIH research grants is much better for those with individual training awards. Dr. Bianchi stressed that the total dollars that are being committed to research training, but rather we are changing the emphasis to more individual awards versus institutional awards. Dr. Bianchi also discussed the potential for a scientific version of, "Moneyball," and similar to the movie, determining a quantitative method to identify those who have the highest probability of succeeding in a research career.

Dr. Bianchi discussed the examination of clinical trials and clinical research at the Clinical Center and determining what core pediatric services and consultants are necessary for safe care in the intramural program. At the Clinical Center, there are no obstetrical research protocols or

research performed in children under the age of three. She is questioning whether this need to be changed and what resources will be needed.

Dr. Bianchi also discussed a need to support innovation. For example, there have been advances in non-invasive testing by industry and none of it has been funded by NICHD. Dr. Bianchi explained that since 2011, the number of non-invasive prenatal tests accelerated into the millions and resulted in a 70% reduction in amniocentesis and chorionic sampling, all of which were funded by industry and not NIH. Dr. Bianchi asserted the need to think of ways to partner with industry and the need to become more innovative.

Dr. Bianchi emphasized the need to leverage and utilize the collective expertise and wisdom of the NICHD Advisory Council. She asked the group about whether they should undergo a strategic planning process, which could include analyzing potential impact, and the probability of success and gaps in the portfolio. She asked what the funding priorities should be and stressed the difficult choices that may need to be made. She also asked the group how physician-scientists should be best trained and if there are strategic partnerships that could help fulfill the mission of the Institute.

Council Discussion

Dr. Gilman Grave asked what Dr. Bianchi remembered from support groups that are affected by prenatal screening. Dr. Bianchi clarified that the women themselves didn't have prenatal screening. They were the directors of the support groups that are affected by prenatal screening. Due to increased non-invasive screening, more women are being directed to these support groups. She noted there is an increase in people inquiring about screening for Jacobsen's syndrome, an extremely rare disorder that can now be screened for with a blood DNA test. The women who lead these support groups have few resources available for people who are inquiring about the screenings. The demand has greatly increased for information about these rare genetic conditions. It has given the support group heads a personal perspective of what it's like for a parent or individual who is faced with a disorder.

Dr. George Saade agreed with the strategy of digging deeper into the statistics and numbers and charts, rather than making decisions based only on numbers. Dr. Bianchi thanked Dr. Saade for the comment and stressed that the numbers were not presented in a way as to depict one as better than the other. Dr. Bianchi explained that it was important for them, as a community, to decide what their priorities are, what studies to place emphasis on, and where to spend their dollars.

Dr. Timothy Shriver asked what the, "straw man," was for the next name. Dr. Bianchi responded by saying she really didn't have one and added that the human development portion and the Shriver name were non-negotiable. Dr. Bianchi added that it would be great if the Institute's name could also include women and people with disabilities. She is open to all input. However, changing the name of the Institute would require an act of Congress. The discussion regarding the Institute's name was meant to stimulate thought.

III. INTRODUCTION OF NEW MEMBERS

Dr. Hann welcomed five new Council members and requested that they introduce themselves. New members presented brief overviews of their research and professional interests. All stated that they were looking forward to serving on the Council and future interactions with other Council members and NICHD staff.

- Dr. Michael Boninger, Professor and UPMC Endowed Vice Chair for Research, Department of Physical Medicine & Rehabilitation, University of Pittsburgh School of Medicine
- Dr. Catherine Gordon, Medical School Director, Division of Adolescent and Transition Medicine, Rauh Professor of Adolescent Medicine, Professor, Dept. of Pediatrics, University of Cincinnati College of Medicine
- Dr. Clifford Tabin, George Jacob and Jacqueline Hazel Leder Professor and Chairman, Department of Genetics, Harvard Medical School
- Ms. Alyce Thomas, R.D., Perinatal Nutrition Consultant, Department of Obstetrics and Gynecology, St. Joseph's Regional Medical Center
- COL Teresa Brininger, Ph.D., OTR/L, CHT Director, Clinical and Rehabilitative Medicine Research Program (CRM RP), US Army Medical Research and Materiel Command (MRMC)

IV. OFFICE OF THE DIRECTOR'S REPORT AND DISCUSSION

News from NIH

Dr. Catherine Spong announced several staff updates related to the NIH. Representative Dr. Tom Price was nominated as Secretary for the Department of Health and Human Services. Dr. Francis Collins was held over as the NIH Director by the new Trump Administration. Major General James Gilman will serve as the Inaugural CEO of the NIH Clinical Center. Dr. Phil Bourne, who is the Associate Director for Data Science resigned, but will continue through the end of April. His duties will be taken over by Dr. Patricia Brennan, the National Library of Medicine Director, while a search for his replacement is underway.

Dr. Spong also provided updates about several trans-NIH programs. The Precision Medicine Initiative was renamed to, "*All of Us*." The ECHO and the IDeA States Awards received \$157 million in FY16 and a meeting was held on November 9-10, 2017, with over 200 scientists in attendance. There are 35 awards covering 47 PIs and cohorts, and most of these cohorts began prenatally, covering many components of the United States. There are 17 clinical sites and a data coordinating center.

The Gabriella Miller Kids First Initiative focuses on the discovery of the genetic basis of childhood cancers and structural birth defects, predominantly through X01 mechanisms that allows the recipients to be selected to have their cohort sequenced and put into the Gabriella Miller Data Resource. For FY15, there were two childhood cancer cohorts and five structural birth cohorts selected. For FY 16, three childhood cancer cohorts and five structural birth cohorts were chosen. The cohorts are listed at <https://commonfund.nih.gov/kidsfirst>. The Kids First Pediatric Data Resource will harmonize and provide access to this well-curated clinical and genetic sequence data for the pediatric research community to facilitate identification of genetic pathways that underlie childhood cancer and structural birth defects.

Dr. Spong gave an update on the NIH Clinical Center. The newly formed Clinical Center Research Hospital Board held its third meeting in January 13, 2017. The Board is reviewing information related to adverse event reporting and timely reporting of those events. Another topic discussed by the Board was the decrease in the Clinical Center census over time. This is a concern for the Board and the Institute directors. Dr. Steve Katz, director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), chairs a working group

developing strategies to present to the Board to address the census and to strengthen the Clinical Center's role as a local, regional, and national research resource. Strategies will also address facilities and capacity, increasing the opportunity for operating room (OR) time, the cost issues for off-label medications, dedicated clinical support to ACT's, and enhancing the responsibility for the IC director.

Dr. Spong discussed the Common Rule, a federal policy for the production of human subjects that governs the ethics of biomedical and behavioral research involving human subjects in the United States. The Office of Human Research Protections published revised regulations on January 19, 2017. Regulations affecting NICHD include, single IRBs for multi-institutional research studies, more detailed consent forms to provide potential participants in research a better understanding of a project's scope. Dr. Spong also pointed out that it's unclear whether the new Executive Order on Regulations will complicate this Common Rule because of the many different deadlines in that implementation process.

News from NICHD

Dr. Spong began with staff updates. Dr. Charisse Lamar, PhD, MPH, RRT was named the OHE Director. Dr. Lamar previously directed the Reproductive Neuroendocrinology, the Fertility Preservation Programs, and the Reproductive Scientist Development Program within the Fertility and Infertility Branch at NICHD. Dr. G. Stephane Philogene was named Director of the Office of Science Policy, Reporting, and Program Analysis (OSPRA). Dr. Philogene was formerly the Deputy Director in the Office of Behavioral and Social Sciences Research, (OBSSR).

Dr. Spong announced two Presidential Early Career Awards for Scientists and Engineers (PECASE) awardees who are connected to NICHD. This is the highest honor, bestowed by the United States Government on science and engineering professionals in the early stages of their independent research careers. The first awardee is Dr. Adriana Lleras-Muney, from the University of California, Los Angeles; she is a grantee from NICHD's Population Dynamics Branch. Her research focuses on relationships between socio-economic status and health, with a particular focus on education and income. The second awardee Dr. Shayne Piasta, from The Ohio State University, was awarded the PECASE through the Department of Education; she was mentored under the Florida State Learning Disabilities Research Center in the Child Development and Behavior Branch.

Dr. Spong gave an update on the Zika virus, which remains a public health emergency affecting many families around the world. The rapid funding announcement that allowed continuous submission for rapid review and funding ended on January 13, 2017. Zika-related R21 applications will be accepted under a program announcement that uses standard due dates and timeframes for review. Research on Zika virus remains a high priority for NICHD.

The Zika in Pregnancy (ZIP) study, enrolling internationally, reached 1,000 participants. Dr. Spong explained how large of an effort and how difficult it was to get this study up and going. Dr. Spong thanked everyone involved for their efforts. NICHD will take a first look at the study data when 20% of patients are delivered, which will hopefully take place at end of 2017 or the beginning of 2018.

Dr. Spong reminded Council of the workshop focused on the children who were impacted by ZIKA virus held on September 22-23, 2016 in Bethesda, Maryland. The goal of the workshop was to define the evidence to understand how prenatal ZIKA virus infection affects child development and to identify strategies for evaluation, management, and treatment, and to outline

future research needs. The workshop is available to view on NIH's VideoCast website. An executive summary was drafted and submitted for publication. Dr. Spong explained that this was another team effort by NICHD staff, and she thanked all the staff who helped with the workshop and paper.

Dr. Spong gave an update on PregSource™, which is a crowd-sourced, interactive mobile app that will help detail natural history and variations of human pregnancy, provide accurate info about pregnancy from trusted sources, and will let pregnant women know about opportunities to participate in targeted research. NICHD is working with 20 partner organizations. Pregnant women will be able to get trusted information, and it will also allow NIH to provide women who are interested in research the opportunity to know what studies or trials they might be eligible for. Beta testing is ongoing. The 4th Human Placenta Project (HPP) Meeting will be July 24-25, 2017 at the NIH main campus. There will be HPP grantee presentations, as well as technology and basic science talks. There will also be technology demonstrations and a poster session. Dr. Spong explained how the project is at a mature enough state to have results from some of the grants that have been funded.

Legislative and Budget Update

Dr. Spong presented the budget update. NIH is on a continuing resolution through April 28, 2017.

The 21st Century Cures Act passed the House 392-26. In this act, there is \$4.8 billion of additional NIH funding for over 10 years. This funding is targeted to PMI, Cancer Moonshot, and the Brain Initiative. There is \$1 billion in additional funding to states to supplement opioid abuse prevention and treatment. She pointed out that NICHD, as an Institute, did not receive additional funds from the 21st Century Cures Act. In the Cures Act, there are some provisions that are relevant to NICHD. Sec. 2040 focuses on improving medical rehabilitation research at NIH. This requires the NCMRR Director, when developing the current research plan, to identify existing resources available to support rehabilitation research and to include objectives, benchmarks, and guiding principles for rehabilitation research and develop an annual report for the Coordinating Committee and Advisory Board. It also requires the Coordinating Committee to host a scientific conference or workshop no less than every five years. Sec. 2041 establishes a task force on research specific to pregnant women and lactating women to provide advice and guidance to the HHS Secretary with the goal of addressing gaps in knowledge and research regarding safe and effective therapies for pregnant and lactating women. Sec. 2071 pertains to the National Pediatric Research Network. The establishment of a national network was authorized by Congress in 2013. NIH implemented the law with the creation of the IDeA States Pediatric Clinical Trials Network, which was funded in late FY 2016.

Dr. Spong explained how the IDeA States Network, which is part of the larger ECHO program run by the NIH Director's office, will help children in rural and underserved areas of the country participate in cutting edge pediatric clinical trials. Sec. 2072, the Global Pediatric Clinical Study Network Sense of Congress, is a provision that is not a mandate, but an encouragement, that NIH and FDA should work with non-United States entities to help establish a global pediatric clinical study network.

Dr. Spong highlighted a few meetings that staff participated in highlighting NICHD's work. Dr. Bianchi met with members of the rehabilitation community at a Capitol Hill briefing. Dr. Alison Cernich gave a keynote speech highlighting the need for medical rehabilitation research and

promoting the release of NIH's new rehabilitation research plan. Representatives Gregg Harper (R-MS) and Jim Langevin (D-RI) provided some opening remarks.

Dr. Bianchi, along with Ms. Lisa Kaeser, Dr. Stuart Moss, and Ms. Christie Rogers, met with the Friends of NICHD. Representatives of about 20 organizations were there, and Dr. Bianchi gave brief remarks about her first impressions of NICHD. Dr. Bianchi also attended a Kennedy Forum Event on Capitol Hill. Former United States Representative, Patrick Kennedy, was raising awareness to help address mental health and addiction. This topic is important to NICHD because of the increased rates of opioid use in pregnancy and neonatal abstinence syndrome, which are both major public health issues.

Council Discussion

Dr. Anne Case asked about the \$1 billion that was set aside for opioid reduction and how none of it came to NICHD. Dr. Case thought it might be in NICHD's wheel house. Dr. Spong responded stating that the 21st Century Cures Act had specific provisions, and that the funding went specifically to the states and not NIH or NICHD.

V. DIVISION OF EXTRAMURAL RESEARCH REPORT

Report of the Director, Division of Extramural Research (DER)

Staff Updates and Awards

Dr. Hann presented the DER updates. She introduced new staff members and announced staff members who transitioned to other positions.

Understanding NICHD Awards

Dr. Hann presented data on the success rate of NICHD from 1995 through 2015. She showed that there has been an increase in the number of applications during this time, however, the number of awards has not kept pace due to limited funds available, and therefore the success rate has steadily fallen. She added that the number of applications continued to increase over time by almost 200%.

Dr. Hann presented additional data that showed the individuals who were supported by F, K, and T's from 1995 to 2014. NICHD has supported an increase in the number of people trained in research and this increase continued well beyond the NIH doubling.

In another set of analyses, Dr. Hann showed the proportion of applicants on new and competing applications by their professional degree both for NIH and for NICHD. The largest number of applicants coming into the research pool from both NIH and NICHD have a Ph.D. She also pointed out that there has been a decline in the number of applicants who hold an M.D. The number of applicants who hold an M.D. / Ph.D. has been remarkably constant. The number of applicants who hold a degree other than an M.D. or Ph.D. has increased over time. In addition, Dr. Hann presented data on the proportion of new and competing awardees by degree. These data show very similar trends to what was seen in the applicant data.

Funding the Best Science

NICHD has undertaken a number of activities to improve the payline, many of which focus on clarifying the message about the types of research that NICHD is interested in supporting. The

branches developed up to seven priority topics for their branch using the Vision Document, strategic plans from across NIH, and a portfolio assessment. Information on the branch research priorities can be found on the NICHD website. These priorities will help to fund the best science by increasing the flexibility for discretionary funding and becoming more strategic about NICHD's investments. The priorities will also be used to evaluate the acceptance of large grants, as well as a review of NICHD's Funding Opportunity Announcements (FOAs), to determine whether there are any that are not well-aligned with NICHD's priorities.

Upcoming Changes to Clinical Trials

Dr. Hann reviewed how NICHD is planning to implement the many changes in policy regarding Clinical Trials. As background, Dr. Hann indicated that in 2016, the Government Accountability Office (GAO) released a report on how NIH is managing and conducting clinical trials. This report, and other similar reports, identified three main concerns: poor trial design (rigor and power), inconsistency in federal oversight and monitoring, and the inability to easily assess clinical trial information across NIH Institutes and Centers.

In May 2016, an article was published about NIH's overall vision on how to address the challenges that were posed by these various reports. This resulted in NIH looking at the entire life cycle of clinical trials and identifying a series of policy changes all along the clinical trial pathway. Effective October 2014, NIH issued a revised definition of a clinical trial. Effective September 27, 2017, a new policy will come into effect on the use of a single Institutional Review Board (IRB) for multi-site research. Effective September 27, 2017, requests for clinical trial funding will have to be submitted through FOAs, specific for clinical trials. A new NIH policy regarding the dissemination of NIH-funded clinical trial information also came into effect on January 18, 2017. The policy requires that all NIH-funded clinical trials be registered and reported in ClinicalTrials.gov. Lastly, a new policy will require that all NIH staff involved in the management or support of clinical trials will have to perform additional training and receive certification on Good Clinical Practice. This policy came into effect on January 1, 2017. In addition to these policy changes, NIH and FDA have also been working collaboratively on a protocol template for Phase 2 and 3 studies, and it is hoped that the template will be available soon.

Dr. Hann then reviewed the revised NIH definition of a clinical trial. She explained that this definition was developed to be purposefully broad to acknowledge the breadth of science and perspectives that can be taken in pursuing clinical trials across the entire portfolio of NIH. Determining what is and is not a clinical trial will have significant implications and changes for applicants and review during the application process, as well as for staff during the award monitoring phase.

Overview of the Public Council Archive Pages

Ms. Sandi Delcore provided a demo of the public Council Archive Pages and how to navigate the website. Slides presented at Council will become available on the public website once they have gone through 508 compliance.

Council Discussion

No discussion from Council members.

VI. DIVISION OF INTRAMURAL POPULATION HEALTH AND RESEARCH (DIPHR) REPORT

Who We Are

Dr. Germaine Buck Louis presented an overview of the NICHD Division of Intramural Population Health and Research (DIPHR). DIPHR's focus is on population health and its mission is to conduct research leading to the promotion of population health and well-being. She reviewed the organizational chart of NICHD and highlighted that DIPHR is one of two divisions of intramural research within NICHD. DIPHR employs approximately 30 scientific full time employees with an additional 40 fellows and trainees. It is comprised of the Office of the Director and three branches: Biostatistics and Bioinformatics; Epidemiology; and Health Behavior.

Dr. Buck Louis briefly reviewed the research expertise and types of work performed within DIPHR. The Epidemiology Branch performs reproductive, perinatal and pediatric research, as well as methodologic research for the scientific community. The Biostatistics and Bioinformatics Branch has expertise ranging across a number of areas such as biomarkers and diagnostic testing and prediction, as well as methodologists who are developing new techniques for the analysis of complex longitudinal data. The Health Behavior Branch has a longstanding research interest in both normative and risky adolescent behaviors, as well as the role of families in managing complex and chronic diseases such as type I diabetes. With the recent addition of Dr. Steven Gilman, the Health Behavior Branch is embarking on a new avenue of research focusing on the early origin of mental health and well-being.

What We Do

Dr. Buck Louis discussed the types of work that DIPHR does during different critical developmental periods. The preconception window is critical and is one area where there is a need for additional data on the pre- and peri-conception influences, both maternal and paternal, that impact reproduction and development.

The BioCycle and EAGeR trials undertaken by DIPHR have examined the role of dietary influences on normal menstrual function and ovulation. A recent discovery was that at a certain level of fiber, ovulation is stopped. This type of information helps the scientific community understand the best type of diet for fecundity in men and women.

Studies lead by DIPHR have also been among the first to identify endocrine-disrupting chemicals that adversely impact human fecundity, fertility and pregnancy loss. This work also underscores the importance of the male factor in driving the adverse impact more so than the female. This work is directly relevant to the recently updated Toxic Substances Control Act (TSCA) legislation that the EPA is responsible for implementing.

The EAGeR trial determined whether low dose aspirin would prevent miscarriage for women with a prior miscarriage, and found that aspirin reduced the amount of time needed to become pregnant. Similarly, the live birth rate was higher among women taking baby aspirin as compared to a placebo among women with high levels of inflammation, as measured by C - reactive protein (CRP). These findings underscore the need for precision medicine to understand the subpopulations where different interventions will be most effective.

DIPHR is also conducting research during pregnancy aimed at understanding the key influences of health and well-being during this critical developmental window. Findings from the NICHD Fetal Growth Study have highlighted factors that can influence fetal growth and underscore that there is no single fetal growth trajectory that can be applied to all individuals in the United States. Factors that can influence fetal growth include race/ethnic-specific differences and twin versus singleton. Dr. Buck Louis highlighted that applying a single fetal growth curve to all fetuses could result in up to 15% of non-Caucasian fetuses being mislabeled as “growth restricted” pregnancies.

Other studies currently underway in the field include the US Collaborative Perinatal Cohort, one of the oldest and largest pregnancy cohort studies from the 1960s. Many of these children have been followed to understand the influences of in utero and early childhood factors on mental health and suicide as adults. Other new pregnancy related research (PEAS) is trying to address the question of excessive weight gain during pregnancy, as well as weight retention after pregnancy. The study aims to move beyond simply looking at maternal diet and includes factors such as satisfaction with food and satiety issues. The goal is to follow the children from the cohort to begin to understand how maternal satisfaction with food may pre-program the developing fetus, as well as infant food likes or dislikes.

DIPHR also recently completed a diabetes and women’s health study aimed at understanding the genetic and environmental factors that are associated with some women that experience gestational diabetes converting to type II diabetes after pregnancy. A follow-on study will follow the children born to affected mothers to understand how exposure to gestational diabetes in utero impacts children’s health and development.

During infancy and childhood, the Upstate KIDS study is the only population-based cohort study in the US that is attempting to answer the question of how treatments for fecundity impairments impact children’s growth. To date, the study has shown that the children show no differences in growth or development through three years of age irrespective of mode of conception (infertility treatment or not). The cohort will be followed through age eight years to examine cardio-metabolic outcomes since there is some evidence from animal models that some of these fertility treatments maybe associated with altered outcomes.

The Health Behavior Branch is also doing research to understand behavioral interventions that can help children and families with type I diabetes. These interventions take place in the clinic where they are administered without interfering with the normal clinic schedule. Both the CHEF and FMOD studies have shown that these interventions are able to improve the management of type I diabetes and quality of dietary intake. The CHEF study demonstrated that it was possible to increase the quality of dietary intake without introducing additional cost for families. Dr. Buck Louis also highlighted the work that the PEAS study is doing to understanding maternal food reward sensitivities and how that will impact their children.

The work that DIPHR is doing in adolescence and young adults includes the NEXT Generation Health Study, a national cohort of 10th graders in the U.S. who have been followed into young adulthood. One of the aims was to understand whether individuals can outgrow risky behaviors, or if the risky behaviors observed in adolescence and young adulthood extend across the lifespan. One of the key findings is that there is much alcohol consumption among college students, including blackouts, relative to those individuals who do not attend college. This finding highlighted that these problems extended to problems with work, school, police and personal problems for college students. Another long-standing research interest among

adolescences and young adults is driving behaviors. A recent DIHPR study found that teenage drivers engaged in secondary tasks while driving had 4-8 times the risk of a crash. Further work will be done to understand whether these risky behaviors are either inherited or functions of watching parents engage in similar behaviors.

DIPHR also continues to engage in reproductive health research across the lifespan. Currently there are data coming out at the population level demonstrating that semen quality is associated with mortality. These findings have sparked interest in understanding whether there is a similar association in females between fecundity and mortality.

DIPHR is currently in the process of developing its five-year strategic plan. One emerging area of research interest is in epigenetic reprogramming and fetal resilience. The goal is to improve our understanding of the variability in response among fetuses in different exposures, whether they are dietary or environmental. The well-defined cohorts developed and maintained by DIPHR can be an invaluable resource for basic science research colleagues to begin to understand the underlying factors influencing fetal development. DIPHR is also moving towards more couples-based research in the areas of fecundity and pregnancy, as well as cross-generational research, particularly in behavioral health interventions where the grandparents have a strong interest in helping their children and grandchildren. DIPHR is also looking to develop research that will help understand, in a timely way, how reproductive health is in the pathway to health across the lifespan and development of diseases later on in life. The ultimate goal is to promote health throughout the lifespan whether through targeted interventions or guidance.

Dr. Buck Louis discussed how DIPHR's work fits within the NIH-wide Strategic Plan Framework (2016-2020). The NIH Strategic Plan is a tri-part plan focused on fundamental science, treatment and cures and health promotion/disease prevention. The work of DIPHR is very well-aligned to the health promotion/disease prevention goals. However, the well-defined, well-characterized cohorts developed by DIPHR can also become a critical tool for the fundamental science

Metrics of Leading Discovery and Mentoring

Dr. Buck Louis presented the work that has been done to understand the impact of DIPHR research. During the most recent period of review, 2012-2015, there were 509 publications. The topics where DIPHR had the greatest impact included gestational and type I diabetes, environmental factors of fertility, and pregnancy and birth.

DIPHR is also committed to mentoring and helping to promote diversity from the perspective of gender, ethnicity, geography and academic philosophies. Despite the relatively small size of DIHPR, they have been able to recruit fellows from over 64% of states and summer interns from more than half the states. All DIPHR fellows receive formal media training and learn how to tell their story.

During the most recent period of review, 2012-2015, DIPHR has issued 26 press releases that have been viewed by an estimated 4.5 billion people globally. The gene-based statistical software developed by one DIPHR researcher has been downloaded nearly 9,000 times. In terms of leveraging resources, many of the NICHD Fetal Growth Study extramural collaborators were able to leverage the cohorts they developed as part of this program for the NIH's ECHO initiative. In summary, DIPHR meets the mission of the entire intramural research program at NIH for both original and collaborative research, mentoring and professional services.

Council Discussion

There were no questions from Council members about the presentation.

VII. UPDATE ON PRECISION MEDICINE INITIATIVE

Dr. Stephanie Devaney provided an overview of the Precision Medicine Initiative (PMI) and *All of Us* research program. The PMI was announced by President Barack Obama in January 2015. President Obama's fundamental vision was that the United States could transform medicine over the next 10 years, if work started now, that would leverage new technologies and data sharing. The PMI is a large, collaborative initiative involving more than 10 agencies across the government. The *All of Us* Research Program is a part of the PMI that resides within NIH and seeks to enroll one million or more volunteers within the United States with the goal of creating one of the world's largest biomedical databases to accelerate medical breakthroughs. The intention is that the *All of Us* cohort will reflect the broad diversity of the US population. Data generated from the *All of Us* cohort will be available to all researchers, from citizen scientists to university researchers. The *All of Us* cohort will not be a study on any one disease or condition but a resource to investigate a wide variety of health conditions including wellness and prevention research. The types of data that volunteers will be asked to provide will include information about their health, lifestyle and behavior.

Dr. Devaney explained the rationale for initiating the *All of Us* Research Program. The reasons include that there are too many diseases that lack an effective prevention or treatment strategy; the "one-size-fits-all," approach is leaving many behind; and that the advances in data science, bioinformatics and lab technologies coupled with the reduced cost and complexity of generating -omic data are making it easier to achieve significant progress. The widespread adoption of electronic health records (EHRs) through the Hitech Act, as well as the advent of social media and smart phones have also made data more accessible and available for research. The *All of Us* Research Program will tap into the full potential of big data, technology and a talented workforce. Although it resides within NIH, *All of Us* will be a cross-agency effort with involvement from HHS, VA, DOD and DOE.

Dr. Devaney presented the core values of the *All of Us* Research Program. The core values are essential and provide the guiding framework for the research program. The most fundamental core value is that the research program will be open to all interested individuals. The intention is for the Program to benefit all, and in order to do so, the Program will need to reflect the rich diversity of the United States. Importantly, the Program is intended to act as a catalyst for innovative research programs and policies.

The *All of Us* Research Program is approaching diversity with a four-tiered approach that includes people, health status, data types and geography. Dr. Devaney presented an estimated breakdown of the target demographics and geographical representation at Research Program launch based on the health care partners that have come into the program to date. The program is also making a targeted effort to include representation from groups that are underrepresented in biomedical research including sex and gender minorities, race and ethnic minorities, children, individuals from disadvantaged backgrounds, as well as those with physical or mental disabilities, and those that live in geographically or culturally isolated environments.

The research program is also taking a transformational approach to participation by ensuring that participants are involved in each step of the program, from determining the types of data

collected, analyses performed and how data gets returned. The benefits to participants will include an opportunity to learn about their health indicators, and an opportunity to fight disease and improve the health of future generations, and an opportunity to ensure that their community is included in pivotal research studies.

Dr. Devaney described the unique approach that the research program is taking towards data access. Data sharing will be a priority, both for participants and researchers. Participants will have access to study information and data about themselves. Initially, data collection will be limited and grow over time. Privacy and security will be a priority throughout, adhering to the highest standards. The Research Program will also invest in tools that will help level the playing field, ensuring a diversity of researchers can use the data.

Initially, there will be two methods for engaging participants. Individuals interested in participating in the program will be able to enroll directly, either via the internet or the phone. Alternatively, interested individuals can enroll directly through the Healthcare Provider Organizations that are funded by *All of Us*. To date, a broad range of health care provider organizations are partnering with the program. While the experience should feel similar, there will be a difference in where and how the electronic health record data and biospecimens are collected. While the types of data collected will continue to grow overtime, in the first iteration of the protocol, data will be gathered from sources that include participant questionnaires, electronic health records, physical evaluations, blood and urine biospecimens, and mobile/wearable technologies. The Institutional Review Board approval of the proposed data collection methodology is still pending. The Research Program will coordinate closely with both intramural and extramural researchers from across NIH, as well as non-traditional researchers, to ensure that the data collected is useful and relevant for addressing the most pressing health challenges.

Collecting electronic health record data from participants that enroll directly into the program and not through one of the partnering organizations will be more challenging. However, on the policy side, recent guidance from OCR clarifying Health Insurance Portability and Accountability Act rights of access should make it clearer that individuals have the right to request data from their electronic health record, as well as the right to ask that their data be shared with researchers. From a technology perspective, the Office of the National Coordinator for Health IT (ONC) is collaborating with *All of Us* to pilot a standard application programming interfaces (APIs) that will support health IT interoperability and the transfer of electronic health records from providers to the *All of Us* study team.

Dr. Devaney presented an update on the program status. The established program infrastructure includes:

- Vanderbilt University Medical Center with the Broad Institute and Verily as the Data and Research Center
- The Mayo Clinic as the biobank
- Scripps Research Institute with Vibrent Health as the participant technologies center; and
- Regional medical centers, health centers (including federally qualified health center pilots) and VA Medical Centers as the health care provider organizations

The national network of partners that are onboard for launch, represent diverse geographical locations across the country. Moving forward, the Research Program will seek to recruit partnering organizations from areas that are currently not well represented, as geographic diversity is important. More than fifty awardees are currently involved. The governance structure

is currently being refined to prepare for the launch in 2017. The *All of Us* Research Program is also in the process of working with the IRB to finalize the protocol, including the consent language, participant-facing recruitment materials, and the initial set of questionnaires. The Research Program will also be releasing a funding opportunity shortly for community engagement that will be targeted to non-traditional partners with existing relationships at the community level that can help recruit participants from that community to participate in *All of Us*. The Research Program recently completed the testing of its new name, content and brand. Development of the enrollment website, 1-800 number, smart phone applications and the data center is nearly complete. The IT interfaces for data/sample transfer and document/testing security systems are ongoing, as is the work to build out the biobank capacity. The Research Program is also in the process of setting up a trans-NIH advisory group.

The draft protocol specifies that the program will only recruit individuals over the age of 18 to start, with the enrollment of minors being planned for after the first quarter. Individuals will be able to provide consent electronically or in paper form. The consent form is written at a sixth-grade reading level and will be available in English and Spanish with the hope of expanding to additional languages in the near future. There will also be a separate opt-in and signatures for some modules including electronic health records and genetics.

Dr. Devaney reviewed the eight survey modules that will be included in the initial participant survey. These modules include contact/sociodemographic, overall health/mental health, personal habits, personal health history, medications, family history; health care access, and sleep. The Research Program is still in the process of determining which modules will be rolled out in later iterations and the timing of those roll outs. The data gathering effort planned for the initial launch will also include physical measurements, such as blood pressure and body mass index, as well as biospecimen collection, including blood and urine.

The *All of Us* Research Program is hoping to launch in 2017 but will adhere to the philosophy of launching when ready and right. The Research Program will need to ensure the system is ready and secure prior to launch. The Research Program is also working to ensure that the user experience is outstanding from the outset and will likely do a small, beta launch prior to a larger launch to ensure a positive user experience.

While the focus of this talk was on the first version of the launch, the hope is that this research program will go on for decades and will gradually expand to include additional scientific areas. The goal is to launch a solid platform with the types of data and technology needed for science. As the program continues to grow, one of the areas that will be focused on is the liaisons with the NIH Institutes and Centers, including a liaisons group, performing institute/center strategy syncs and informal groups to provide input on key topics. These inputs will be critical for developing the *All of Us* Research Roadmap for the next two to five years.

Council Discussion

Dr. Gregory Kopf inquired about the types of conversations the *All of Us* Research Program is having with pharmaceutical, biotechnology and diagnostic companies. Dr. Devaney responded that several members of the advisory panel come from industry and have been helpful in reminding the program to focus on collaborating with industry. Dr. Eric Dishman, the Program Director, and Dr. Francis Collins both participated in working sessions with the Biotechnology Innovation Organization (BIO) early on in the planning process, which highlighted many opportunities for the potential to partner with industry. While the exact nature of these potential

partnerships is still being worked out, it is clear that there are a lot of opportunities. Dr. Kopf also asked whether industry partners had expressed any interest in contributing funding to *All of Us*. Dr. Devaney clarified that the Research Program hopes that additional funders contribute to the work later on in the process. Dr. Kopf asked a final question about whether there were any plans to develop similar platforms or programs in other countries, and Dr. Devaney clarified that they are focusing on the US for the time being, although there is certainly interest from others around the globe in doing similar large scale cohorts.

Dr. Anne Case inquired about the plan to recruit and retain participants from diverse socioeconomic backgrounds, particularly those at risk for “falling between the cracks,” in the existing medical system. Dr. Devaney expressed that this is something they are thinking about in an iterative way. The Research Program is working very closely with the health care partners to understand the individuals they serve. Having an online portal will also allow participant demographics to be tracked much more closely. Dr. Devaney acknowledged that it will cost more and take more time to engage the types of individuals the Research Program is most interested in enrolling and closing the research disparities gap. The new Chief Engagement Officer will also help with the process.

Dr. Diana Bianchi noted that pregnancy was not included in the presentation and wondered whether there are any plans to include data on pregnancy in the data gathering effort. Dr. Devaney clarified that there are questions about pregnancy in the participant questionnaire but is not certain what aspects of pregnancy are covered in the current questionnaires. She clarified that they would like to see pediatrics, obstetrics and individuals with physical or mental disabilities incorporated into other research programs wherever possible. Dr. Devaney clarified that the Program will begin by enrolling children in the next iteration and plans to enroll prisoners and individuals with mental and/or physical disabilities in future iterations.

Dr. George Saade commented that it is important to include existing, available data from childhood and infancy. For research participants that have agreed to be re-contacted, Dr. Saade encouraged the Research Program to follow up with those individuals and assess their willingness to participate in the *All of Us* Research Program.

Dr. Fredrick Rivera inquired about how the *All of Us* Research Program will incorporate the lessons learned from the NCS. Dr. Devaney discussed that program staff are familiar with the NCS and that many, including individuals on the IRB, were intimately involved in the NCS and will be able to offer their advice and guidance on how to avoid the same pitfalls. The *All of Us* Research Program leadership are all familiar with the report issued by the National Academies on the NCS and are committed to avoiding similar problems.

VIII. OFFICE OF HEALTH EQUITY REVIEW REPORT DISCUSSION

Dr. Melissa Gilliam provided a brief review of the OHE Review Report. One of the panel’s fundamental findings was that the OHE should position itself as a “think tank” on issues of diversity. NICHD has a large footprint and covers many topic areas. Diversity is a complex, multifaceted issue in the United States. Given the complexities, OHE needs to think about the breadth of issues encompassed in diversity, including disabilities, race, ethnicity, gender, sexuality and pregnancy. The second high-level recommendation finding of the Report was to address diversity within NICHD. While NICHD has done an excellent job of maintaining diversity among its workforce, it is something that requires constant attention to ensure that the pipeline of investigators reflect the diversity inherent in our nation. The findings of the report

highlight the importance of being strategic to ensure that OHE is addressing unmet needs and is not duplicative of other ongoing activities within NIH. The panel also recommended thinking more broadly across NIH and encouraged OHE to look for opportunities to collaborate with community partners to improve diversity issues. The work that NICHD does to reduce health disparities is important, and there is a need to ensure that community partners know about the work that the Institute is doing. Lastly, while it is difficult to measure health disparities, the panel recommended identifying goals and establishing metrics for measuring progress.

Other key points of the report include that OHE should become a leader in the discussion on health disparities at NICHD and serve as a coordinator of the NICHD health disparities portfolio. Several datasets that have been generated through NICHD-funded studies could be re-evaluated through the lens of health disparities, and OHE can play a role in helping to drive the reuse of these datasets to address questions of health equity. The panel also recommended that OHE take on an education role. Health diversity and issues of diversity and inclusion touch many portfolios indirectly, and OHE can be a leader in educating colleagues on these issues and how they can be incorporated into their research.

The panel was also asked to touch on the role of OHE in promoting workforce diversity in its report. The panel recommended that OHE should lead the discussion on NICHD workforce diversity and take on the issues such as bias, implicit attitudes, cultural competency and health equity. OHE should set goals for workforce diversity and create the programs and practices needed to achieve this vision. The panel also recommended that OHE work to ensure that NICHD stays abreast of research on inequities of funding and to create appropriate trainings and policies to enhance equity of the granting process. OHE should also play a role in linking NICHD to NIH-wide diversity efforts, particularly those lead by the National Institute for Minority Health and Health Disparities, as well as external collaborations that will help enhance the diversity of the scientific workforce. The panel also recommended creating more diversity supplements to bring in a new, diverse generation of researchers.

The panel also recommended a role for OHE in health communications. OHE should play a role in leading health communications to help increase the awareness of health disparities. These communications should move away from simply documenting disparities and focus on understanding the root cause of differences and how to create a more equitable future. OHE should lend their expertise to incorporate health disparities into the NICHD communications plan, as well as identify and promote external partners and collaborators to assist with the communications and strengthen the impact of NICHD's work.

Dr. Gilliam concluded her presentation by remarking upon what an exciting opportunity it has been to convene a panel that thinks about the role that OHE could fill in promoting diversity and equity within and beyond NICHD. It is important to ensure that OHE has the resources it will need to empower and lead NICHD on issues of health equity. Establishing good systems and processes internally will also be important for OHE to have maximal impact. OHE will also need to focus on developing metrics and ensuring that there is accountability. Dr. Gilliam thanked her fellow panel members for their contributions to the effort and to the report.

Council Discussion

Dr. Patricia Dorn inquired about the most promising opportunities or programs the panel found when it surveyed other diversity programs within NIH. Dr. Gilliam responded that the small

amounts of funding that exist to allow for mentorship and to engage individuals at a young age, such as high school, in order to expose them to science, seem to be particularly effective.

Dr. Timothy Shriver thanked the panel for their work on this important topic. He expressed concerns, though, that the panel report gives very little mention to the issue of development and intellectual disabilities and the inclusion of these individuals within the workforce. While it is challenging to ensure that all relevant stakeholders are mentioned, the report repeatedly mentioned issues of cultural and ethnic diversity without making mention of individuals with developmental disabilities. Dr. Shriver noted that this is an issue of personal importance. Dr. Shriver also noted that as the Institute is designed to combat health care research bias against individuals with intellectual and developmental disabilities, this stakeholder group should be called out explicitly in the report.

Dr. Bianchi called for a vote on the report and informed panel members that they could concur, disagree, or call for modifications to the report recommendations. Dr. Bianchi inquired whether the Council wanted to recommend a modification to explicitly mention individuals with mental or developmental disabilities. Dr. Shriver suggested the Council approve the report pending revisions and stated that he does not feel comfortable approving it the way it is written. Dr. Bianchi indicated that it would be possible for Council members to vote electronically on a revised version once the revised version is available. Dr. Gilliam inquired about the best way to make the changes needed, and Dr. Bianchi suggested that Dr. Gilliam communicate Council's concerns back to the panel and that the individuals that drafted the report make the revisions. Dr. Patricia Flynn mentioned that as a panel member she agreed that the panel should revise the report and indicated that the panel would be willing to work with Dr. Shriver on the language. Dr. Stephen Petrill concurred with the recommendation to amend the report as the parent of a child with autism and emphasized that intellectual disabilities are a central focus of NICHD.

IX. CONCEPT CLEARANCE AND DISCUSSION

The Council discussed and unanimously endorsed seven concepts as detailed below.

Dr. Tonse Raju requested approval for the recompetition of the Global Network for Women and Children's Health Research Program. This initiative focuses on improving pregnancy outcomes for populations from low and middle-income countries. In spite of major advances in perinatal care in the western world, regions Sub-Sahara Africa and Asian counties suffer the burden of high perinatal and infant mortality. These regions of the world account for more than two-thirds of global stillbirths, maternal death, and infant mortality. A network established in 2001 aimed to conduct observational and randomized control trials to develop evidence-based interventions and therapies in those countries. In the latest round, seven international sites were funded. Each of these sites has a partner at a university from the United States. The Global Network has made significant accomplishments over the years, including 15 individual and five multi-site studies, studying interventions to reduce postpartum hemorrhage, neonatal resuscitation, pre-term infants, and interventions to improve infant growth. The World Health Organization has developed practice guidelines for the whole world using findings from the Global Network.

Dr. Bill Kapogiannis requested approval for Adolescent HIV Prevention and Care Continuum in resource-limited settings. This initiative aims to increase behavioral, community, and biomedical intervention research using different prevention and treatment methods to address adolescents impacted by HIV, in such settings. This initiative will also aim to improve the knowledge base in

this area and ultimately to inform guidelines on the clinical management of at-risk, uninfected, and HIV infected young people in these regions.

Dr. Louis De Paolo requested approval to continue the Reproductive Scientist Development Program (RSDP). The goal of the RSDP is to provide career development support for clinicians who wish to commit to a career conducting fundamental and biomedical research in reproductive health in an academic setting. Since 1988, 97 scholars participated or are participating in the program. Nearly 80% of former scholars remain in faculty or research-related positions. Scholars pursue training in two distinct phases. Previous research fields of the scholars included reproductive biology, endocrinology, and oncology. Given that challenges remain regarding development of clinician scientists, the branch seeks to recompute the RSDP to continue making strides and preparing the next cadre of physician-scientists to pursue cutting edge research careers in the reproductive sciences.

Dr. Valerie Maholmes requested approval for the initiative CAPSTONE Centers for Multidisciplinary Research and Child Abuse and Neglect. This initiative seeks to develop more effective screening approaches that help physicians, nurses, and other health professionals to recognize the signs and symptoms of abuse and neglect, and to disrupt the stability of abusive and/or neglectful behavior at times of critical risk. High-impact studies conducted via transformative research opportunities for collaboration would build upon existing momentum and create national research resources for the field. Continuation of this initiative will underscore NICHD's strong interest and commitment to this field of research and stimulate the next generation of research in child mistreatment through multi-disciplinary approaches.

Dr. Lisa Freund requested approval for Baby Toolbox, a set of tools to measure the neurodevelopmental assessment of infants and children from one month to three years of age. There is a great need for this in the biomedical and bio-behavioral fields for establishing standard measures of neurodevelopment for young ages that are efficient to administer, low in cost, and useful in research settings. Such assessments could be conceptually connected with the current NIH Toolbox, which starts from three years of age through age 85. The Baby Toolbox would complement the NIH Toolbox in terms of evaluating neuro-cognitive development during early childhood, which is a period of rapid development.

Dr. Enrique Schusterman presented a low-cost intervention to improve fertility outcomes and requested approval for an initiative to improve pregnancy rates and live births among racially and ethnically diverse women with chronic inflammation. This initiative focuses on a pre-conception and inflammatory therapy that will improve pregnancy rates and live births among women with low-grade inflammation and who are undergoing low-tech infertility treatments. Successful improvements in pregnancy rates attained from ovulation inductions and intrauterine insemination treatments may be significantly improved for the first time in decades, while also improving couples' outcomes during the first length of treatment. This would also reduce the need for more expensive and invasive treatments.

Dr. Tonja Nansel requested approval for Sprouts: Eating Behaviors in Early Childhood, an initiative that addresses the knowledge gap in understanding of early life developmental processes that influence eating behaviors. The goal is to investigate the development of neural behavioral factors and the influence on eating behaviors and growth in young children. This initiative would leverage research from the Pregnancy Eating Attribute Study (PEAS) to one year postpartum and would extend the follow-up of families from children aged two through age

five. This initiative aligns with the NICHD areas of developmental origins of health and disease and behavior and cognition.

Council Discussion

Regarding the Global Network, Dr. Case asked, if it's at the concept stage, if we should think about adding a United States site where there has been a doubling of maternal mortality, given that it's still in a fluid stage. Dr. Case explained that this may be a place here where they could actually help women within the United States, given that this disparity is growing here as well. Dr. Raju responded by saying that he was unsure if they could add another site, but NICHD has been working on a workshop and a conference which is in the planning stages. NICHD is working to understand why maternal mortality rates are rising domestically.

Regarding Dr. Maholmes's CAPSTONE Centers for Child Abuse and Neglect, Dr. Richard Krugman noted that this is the first effort to try to do some NIH funding and research to build the infrastructure for research in the field that is now a subspecialty to pediatrics. Dr. Krugman also notes that there is 50 years behind every other subspecialty.

Regarding the Baby Toolbox, Dr. Atul Butte asked how you would ensure that awardees of this do not also create another set of difficult to use and high-cost tools. Would you issue this as an RFA or as a contract where the government then owns the full intellectual property? Dr. Freund expects that the government owns this and can be copyrighted, but it would be freely available to the research public.

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 565 HD-primary applications requesting \$150,114,949 in direct costs and \$206,345,177 in total costs.

XII. ADJOURNMENT

There being no further business, the meeting adjourned at 4:00 p.m. on Tuesday, January 31, 2017. The next meeting is scheduled for June 8, 2017.

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

/S/

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

5/30/2017

Date

Ms. Kimberly A. Witherspoon
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.