



Eunice Kennedy Shriver National Institute
of Child Health and Human Development

NATIONAL ADVISORY CHILD HEALTH
AND HUMAN DEVELOPMENT COUNCIL

MEETING MINUTES

September 21, 2016

**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
September 21, 2016¹**

The National Advisory Child Health and Human Development (NACHHD) Council convened its 162nd meeting at 8:00 a.m., Wednesday, September 21, 2016, 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 12:50 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 3:07 p.m.

Dr. Catherine Spong, Chair, NACHHD, and Acting Director, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), presided.

Council members present:

Ms. Barbara Collura	Dr. Ruth Lehmann
Dr. Patricia Flynn	Dr. Stephen Petrill (virtual)
Dr. Walter Frontera	Dr. Piero Rinaldo
Dr. Melissa Gilliam (virtual)	Dr. Frederick Rivara
Dr. Gregory Kopf	Dr. George Saade
Ms. Wendy Lazarus	Ms. Sheila Zimmet

Council members absent:

Dr. Anne Case

National Advisory Board on Medical Rehabilitation Research Council Liaison

Dr. Richard Shields

Ex officio members present:

Dr. Patricia Dorn, Director of Rehabilitation Research and Development at the Department of Veterans Affairs

Dr. Aaron Lopata, Chief Medical Officer at Health Resources Services Administration

Non-voting Council members present:

Dr. Atul Butte (virtual)

Dr. Richard Krugman

Dr. DeWayne Pursley

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.

Ms. Lesli Rotenberg

Non-voting Council members absent:

Dr. Timothy Shriver

Others present:

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

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

Members of Staff, NICHD

Members of Staff, NIH

Invited Guests:

Ethan Jorgensen-Earp, American Academy of Pediatrics

Craig Fisher, American Psychological Association

I. CALL TO ORDER AND INTRODUCTORY REMARKS

Dr. Spong welcomed Council members, guests, and staff. She announced that the meeting would be open to the public for the morning portion and closed to the public in the afternoon for the consideration of grant applications. The public portion was presented through videocast.

A. Review of Confidentiality and Conflict of Interest

Dr. Hann informed Council members that NICHD implemented a new procedure, an electronic certification of confidentiality and conflict of interest available on the Council member website. Dr. Hann reminded Council that all members were required to certify they had not been involved in any conflict of interest situations during the review of grant applications. Advisors and consultants serving as members of a public health advisory committee may not participate in situations in which any violation of conflict of interest laws and regulations might occur. Therefore, Council members may not perform duties or render advice that might have a direct and predictable effect on the interests of an organization or institution in which he or she has a financial interest. In particular, Council members should not participate in the evaluation of grant applications for federal support that will affect the interests of such organizations or institutions. Dr. Hann also advised Council members that material furnished for review and discussion during the closed portion of the meeting is considered privileged information.

B. Council Minutes

Dr. Hann moved to approve the *Summary of Meeting Minutes* for the June 2016 and August 2016 sessions of Council. The *Minutes* documents were approved unanimously, as written.

C. Future Meeting Dates

Dr. Hann reviewed the future meeting dates:

January 19, 2017	(Thursday)
June 8, 2017	(Thursday)
September 14, 2017	(Friday)

II. NICHD DIRECTOR'S REPORT AND DISCUSSION

News from NIH

A number of new positions have been announced at NIH. Dr. Diana Bianchi was named the director of NICHD. Prior to coming to NIH, Dr. Bianchi was the founding Executive Director of the Mother Infant Research Institute and Vice Chair for Pediatric Research at the Floating Hospital for Children and Tufts Medical Center. She will start November 7, 2016. Likewise, Dr. Joshua Gordon has been named the director of the National Institute for Mental Health (NIMH). He is a psychiatrist and a neuroscientist that studies brain plasticity in mouse visual systems as well as looking at specific disease mutations in mouse models. Prior to joining NIMH, Dr. Gordon was an Associate Professor of Psychiatry at Columbia University.

Over the last 15 months, a number of changes occurred at the NIH Clinical Center that will further strengthen NIH's longstanding commitment to patients, staff, and scientific excellence. A working group, known as the "Red Team," was charged with making recommendations on how to reduce risk and promote patient safety at the NIH Clinical Center. Based on the Red Team recommendations, NIH established a hospital board, the NIH Office of Research Support and Compliance, and retained two companies specializing in quality assurance for manufacturing and compounding. The inaugural meeting of the NIH Clinical Center Research Hospital Board meeting was held on July 15, 2016, and it was open to the public. Upcoming meeting dates for the hospital board include October 21, 2016, and January 13, 2017. Dr. Spong also reviewed a number of new appointments to the Clinical Center.

The Precision Medicine Initiative (PMI) recently made several initial awards for program infrastructure. Vanderbilt University Medical Center, with the Broad Institute and Verily, was selected to serve as the Data Research and Support Center. Mayo Clinic will serve as the biobank for the initiative, and the Scripps Research Institute, with Vibrent Health, will serve as the Participant Technologies Center. The Health Care Provider Organizations (HPOs) that will encourage their patients to participate in the PMI include regional medical centers, federally qualified health centers, and VA Medical Centers. The Foundation for NIH recently published the results of a survey showing broad support for the PMI Cohort Program in PLoS One.

News from NICHD

Dr. Spong presented a brief update on funding the best science. For the past year, NICHD has been examining mechanisms that would allow them to be more strategic and flexible in their investments to ensure they fund the best science possible and to ensure that funding is aligned with NICHD priorities. Discussions about how to fund the best science will be ongoing at NICHD. NICHD was successful in improving the payline for many different types of grants including R01s, R03s, R21s, Ks, F30s, F31s and F32s. NICHD recently announced its funding priorities. In doing so, NICHD will begin to move away from a strict payline so that the institute has the flexibility it needs to fund the best possible science. Approximately half of the NIH institutes have moved away from a strict payline approach.

In light of the impact of Zika virus on pregnant women and children, NICHD provided support for several Zika-related activities. One activity is the ongoing funding announcement for the Rapid Assessment of Zika virus Complications using the R21 funding mechanism. For this funding announcement, the typical timeline from the time of grant submission to the time of award of funding has been accelerated from 10 months to a few months. Applications are

reviewed on a rolling basis. The funding announcement opened on March 20, 2016. A study funded through this rapid funding announcement involves the U.S. Olympic Team. Researchers will monitor potential Zika virus exposure among a subset of athletes, coaches, and U.S. Olympic Committee staff attending the 2016 Summer Olympics and Paralympics in Brazil. Intramural Zika awards include an award to Dr. Leonid Chernomordik and Dr. Joshua Zimmerberg for their grant entitled, “Zika Virus Entry into the Cells: Assays and Mechanism,” and an award to Dr. Leonid Margolis for his grant, “Pathogenesis and Transmission of Zika Virus in Human Tissues *ex vivo*.”

NICHD also partnered with NIAID, NIEHS, and Fundacao Oswaldo Cruz-Fiocruz in Brazil to fund the Zika in Infants and Pregnancy (ZIP) Cohort Study, a large multi-site, multi-country prospective observational cohort study that will follow 10,000 women to assess the risk and outcomes of Zika during pregnancy. This study will enroll participants in five countries. Currently, Puerto Rico and Brazil are enrolling participants. Colombia, Guatemala, and Nicaragua are anticipated to begin enrolling participants between September and November, 2016.

Dr. Spong and Dr. Fauci provided an update to the NIH Advisory Committee to the Director, which included updates on the Zika outbreak and the ZIP study. Dr. Spong presented a public update on Zika through the American Museum of Natural History’s SciCafe and Reddit Science: Ask Me Anything. NICHD will host a workshop on September 22-23, 2016, focusing on understanding how prenatal Zika virus infection affects child development and how to identify strategies for evaluation, management, and treatment.

The NIH Medical Rehabilitation Plan was published on September 14, 2016, with concurrence from 17 participating Institutes and Centers. Communication rollout included Capitol Hill and interested organizations. The NIH Medical Rehabilitation Plan outlines six areas of priorities. Performance will be monitored and reported in the May meeting of the National Advisory Board for Medical Rehabilitation Research.

Dr. Spong provided staff updates at NICHD. Dr. Jean Flagg-Newton, Acting Director of the Office of Health Equity will retire at the end of September 2016. Dr. Spong also acknowledged a number of NICHD staff who recently received NIH Director’s Awards.

Legislative and Budget Update

NICHD provided several legislative updates and briefings. On June 14, 2016, Dr. Alison Cernich presented at the Women and Traumatic Brain Injury Congressional Briefing, and on June 28, 2016, the Friends of NICHD held a briefing entitled, “Research from A to Zika: What Happens During Pregnancy Influences Child Health,” where Dr. Spong and Dr. Cernich presented.

The Freedom of Information Act (FOIA) law became public law 114-185 on June 30, 2016. This law provides the public with access to information under FOIA, including the right to appeal agencies’ decision to withhold information.

Two statutes were added to the National Defense Authorization Act (NDAA) this year that impact NICHD, including an amendment to the Public Health Service Act that would improve, coordinate, and enhance rehabilitation research at NIH and incorporate the World Health Organization’s (WHO) definition of medical rehabilitation research. The second provision would provide coverage of medically necessary food and vitamins for digestive and inherited metabolic disorders under the TRICARE program.

A new bill was also introduced that would require NIH to establish a national pediatric research network. The National Pediatric Research Network Act only allowed, but did not mandate, the NIH to create this network.

Dr. Spong reported that NICHD will likely not have a budget when Fiscal Year 2017 begins on October 1, 2016. There is likely to be a continuing resolution through December 9, 2016 with flat funding.

III. REPORT OF THE DIVISION OF EXTRAMURAL RESEARCH

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. She also acknowledged DER staff who received NIH Director's Awards.

Understanding NICHD Awards

Dr. Hann presented data on R01 awards by research type. She reviewed the characteristic of scored applications at NIH and NICHD on human studies and animal studies, including the requested direct costs. As compared to the rest of NIH, NICHD has a greater number of human studies and fewer animal studies, while the requested direct costs for applications is higher for NICHD compared to NIH. Recent work performed by the NICHD Office of Science Policy, Reports, and Analysis OSPRA demonstrated that the requested direct cost of NICHD, compared to the rest of NIH, were similar for animal research but significantly higher for human studies. When OSPRA examined the amount awarded for R01s, there was no difference in animal studies and a slight, but not a significant, difference in human studies when comparing NICHD with the rest of NIH. In additional analysis, NICHD looked at the number of R01s awarded over the past 25 years at NICHD compared with the rest of the NIH institutes. Compared to the rest of NIH, NICHD has experienced a greater increase in the number of R01s awarded for human research compared to animal research. This trend has been present for a number of years, beginning with the doubling of the NIH budget in 1998.

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 the newly announced changes in clinical trial policy at NIH and how those changes will impact work supported by NICHD. In 2016, the Government Accountability Office released a report on how NIH is managing and conducting clinical trials. This report, and others, identified three main concerns: poor trial design (rigor and power), inconsistency in federal

oversight and monitoring, and the inability to easily assess clinical trials across NIH Institutes and Centers.

To improve upon the clinical trial pathway at multiple points, a series of policy changes are coming into effect. Effective October 2014, NIH issued a revised definition of a clinical trial. Effective May 25, 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 will come into effect on January 18, 2017. The policy will require 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 will come 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.

Council Discussion

Dr. Patricia Dorn commented that the Department of Veterans Affairs has been using a single IRB for multi-site studies successfully for a number of years and can serve as a resource for NIH as the new policy regarding the use of a single IRB comes into effect.

Dr. George Saade commented that he liked the statistics and information that was presented by Dr. Hann. He then raised a concern about whether NICHD knows how much of this research is actually clinical research versus someone getting a placenta and working on the placenta in a lab. He also commented on the uniqueness of human trials during pregnancy and the costs associated with following two individuals post-partum and following additional special regulations regarding research during pregnancy. He commented that he hopes NICHD and NIH will look upon clinical research during pregnancy with a separate lens than what is used for other types of clinical research and clinical trials.

Dr. Stephen Petrill raised the concern about the new definition of clinical trials and how to differentiate clinical trial research from research that uses experimental designs. His concern was that if the definition of clinical trials is expanded too far, there is a risk of losing the ability to use a particular methodology to understand basic research. Dr. Hann thanked him for raising that concern and explained how the Office of Science Policy, the entity at NIH that refines the definition, has a number of case examples to help articulate what is and what is not considered clinical trial research.

Dr. Richard Shields raised a question about the data elements for studies already on ClinicalTrials.gov and the different data elements that will now need to be reported. Dr. Hann explained that there will be an effective date going forward and the past data will remain as is.

Dr. Ruth Lehmann congratulated NICHD on moving the payline up and expressed concerns about ignoring the scores from peer review. Expert review panel feedback merits consideration. She emphasized the importance of basic research and that it would be sad to see fewer breakthroughs and discoveries because the funding has become too targeted on priority areas.

IV. REPORT OF THE DIVISION OF INTRAMURAL RESEARCH

Division of Intramural Research (DIR) Annual Report

Dr. Stratakis presented an overview of NICHD DIR staff. Currently there are more than 1,100 employees with 65 primary investigators, 59 of whom are tenured and five of whom are tenure-track. There were four retirements in fiscal year 2016 and one additional retirement is planned for 2017. The hiring process of new tenure-track investigators that DIR initiated two years ago is going well and is currently on track with its goals.

There are more than 100 clinical protocols at DIR, approximately two-thirds of which are supported at the NIH Clinical Center.

The graduate medical education training programs include pediatric and adult endocrinology, reproductive endocrinology and infertility, medical genetics, and perinatal research and obstetrics.

Effective October 1, 2016, the Clinical Director will report to the Office of the Director within NICHD rather than the Director of the DIR. However, the Clinical Director will continue to work within the DIR.

As recommended by a report of the Blue Ribbon Panel, since last year the administrative structure of DIR is supported by affinity groups of investigators based solely on intellectual affiliation, that were established to promote additional cross-discipline collaborations. The NICHD principal investigators (PIs) proposed the affinity groups and management verified and validated the titles. NICHD investigators self-assembled with two to ten PIs per affinity group. Each affinity group has developed a mission and vision, research plan and goals, and shared resources and infrastructure. To date, 43 PIs have selected a secondary affinity group, and there are a total of 79 secondary affiliations.

The DIR is overseen by the NICHD Board of Scientific Counselors, a panel of 15 distinguished researchers from across the nation, chaired by Dr. Scott Rivkees, an expert in pediatric endocrinology from the University of Florida. Two new members also joined the BSC to replace outgoing members, Dr. Kate Ackerman from the University of Rochester and Dr. Serdar Bulun from Northwestern University's Feinberg School of Medicine.

As part of the reorganization of the Office of the Clinical Director, three new hospitalists have been hired to help support clinical research at NICHD: Dr. Simona Bianconi, Dr. Jenny Blau, and Dr. Andrew Demidowich. During the past year, NICHD has awarded tenure to two tenure-track investigators, Dr. Mihaela Serpe and Dr. Matthias Machner.

In keeping with the review of the Blue Ribbon Panel, NICHD DIR set aside funds for competitive awards to intramural researchers with a focus on collaboration among investigators to support new research ideas. Two years of funding were set aside, \$3 million in the FY 2014-2015 cycle and \$2 million for the FY 2016-2017 cycle. Of the 25 applications received, eight were funded. Most of the awards were for basic science research. Two awards were also made to internal NICHD investigators as part of the Human Placenta Project for a third year of support. Funding for these awards comes from the NICHD Office of the Director. With funds from the NICHD Director's Office, NICHD intramural investigators also competed for Zika virus research awards. Two awards were made in FY 2016. The DIR also participates in opportunities

for collaborations with the NIH Clinical Center through the U01 program. NICHD supported two awards in the first cycle, two awards in the second cycle, and three awards in the third cycle.

The DIR also supports diversity initiatives through the NICHD Developing Talent Scholars program for post baccalaureate trainees and graduate students. In FY 2016, the program is supporting two continuing and two new post bacs. The Fellows Recruitment Incentive Award for postdoctoral fellows was awarded to Dr. Anna Roberts-Pilgrim this year in Dr. Sergey Leikin's laboratory. An online annual progress report system for postdoctoral and clinical fellows has also been created that allows trainees and mentors to report progress and set goals for the coming year. The information is made available to reviewers prior to a site visit so that they can monitor trainee progress.

At the end of his presentation, Dr. Stratakis showed two three-minute talks from the Science Communication Training and Awards Program from this year's competition. The first presentation, "Shining Light on the Placenta's Enigma," was given by Afrouz Anderson Ph.D. and the second presentation, "Does Propofol Decrease the Human Stress Response?" was given by Miranda Broadney, M.D.

In closing, Dr. Stratakis, on behalf of all at the DIR, thanked the Office of the Director, NICHD, and the members of the Council for their support of the DIR.

NICHD Activities at the Clinical Center

Dr. Forbes Porter provided an overview of the NIH Clinical Center. Work at the Clinical Center is focused on clinical research, care, and training. The Clinical Center consists of two buildings, the Warren Grant Magnuson Clinical Center and the Mark O. Hatfield Clinical Research Center. The maximum capacity is 240 beds, 22 of which are pediatrics. In FY 2015, NIH-wide, 10,700 new patients were seen at the Clinical Center, of which, 5,400 were inpatient and 100,500 were outpatient visits.

Within NICHD, the Clinical Center supports 85 protocols, 36 PIs, and 122 associate investigators. The majority of the protocols are natural history studies primarily in rare disease and approximately one quarter are clinical trials. The majority of the inpatients seen from NICHD are in general medicine, while in outpatients; there is more balance between adult and pediatric patients. For NICHD protocols in FY 2015, there were 2,449 inpatient days, 5,080 outpatient visits, and 4,481 adjusted patient days at the Clinical Center. The number of outpatient visits at the Clinical Center from NICHD has been constant over the past few years.

As part of the reorganization, the Office of the Clinical Director recently brought on research support, including seven new staff clinicians, five nurse practitioners, and four research nurses/research coordinators. Traditionally these research support staff members have been affiliated with individual PIs, but in an effort to provide more flexibility and efficiency, these individuals will be aligned within the Office of the Clinical Director.

In an effort to promote collaboration between basic and clinical researchers, NICHD participated in a number of NIH-wide programs including the Bench-to-Bedside Award Program. The criteria for this program include utilization of the NIH Clinical Center, and the award was designed to promote basic and clinical collaboration. In 2006, the program was expanded to include both intramural and extramural collaboration. The direct costs provided by this award will increase from \$135,000 to \$150,000 for two years in 2017. Between 2006 and 2015, 27 Bench-to-Bedside awards have been provided to NICHD, primarily in the area of rare diseases.

NICHD also participated in the U01 Grants at the Clinical Center, a program developed to support collaboration between the clinical center, an intramural PI, and an extramural PI. The grants are submitted by the extramural PI and provide \$500,000 in direct support for four years. The program is now in its fourth cycle. During the first two cycles, NICHD supported two awards per year.

NICHD and the Clinical Center also collaborated on four training programs: the Pediatric Endocrinology Inter-Institute Training Program (three fellows per year), the Inter-Institute Endocrine Training Program (two fellows per year from NICHD), the Reproductive Endocrinology and Infertility Training Program (three fellows per year), and the Medical Genetics Training Program, where NICHD provides faculty and participates in the Fellowship Executive Board.

Dr. Porter closed the presentation by providing several examples of the research performed by NICHD at the NIH Clinical Center.

Council Discussion

Dr. Richard Krugman asked a question about what tenure means in the NICHD intramural research program. Dr. Stratakis answered that being tenured at the NIH Intramural Research Program means you have employment for life, and that you are relatively free to pursue your academic queries. He also explained that investigators are accountable for the resources they use when pursuing research. Tenure is reviewed every four years, or more frequently, if necessary.

V. COMMUNICATIONS AT NICHD

Mr. Paul Williams, Director of the Office of Communications, provided an overview of the organization of the Office of Communications which includes two main teams, the News and Science Writing team and the Public Information and Outreach team. The News and Science Writing team is primarily responsible for media relations, website content management, and crisis communications and strategic messaging, while the Public Information and Outreach Team is responsible for communications planning, public health awareness campaigns, and handling FOIA requests.

Mr. Williams reviewed why communication is important at NICHD and discussed recent trends in communications that increase the need for dedicated communications resources. The Office of Communications helps to meet the demand for information with stories of research discovery and process, including where they are and how that information helps NICHD build a more compelling story overall.

NICHD Office of Communications uses a number of vehicles to reach the public. One mechanism is by reaching directly to the news media. The Office monitors scientific articles generated by NICHD intramural and extramural researchers, helps determine the newsworthiness, and drafts, vets, and releases press releases. Other mechanisms for reaching the news media include targeted, personal outreach to reports and podcasts. The Office also handles inbound media inquiries, consultations, and messaging.

The Office of Communications also goes directly to the public, bypassing the media, by using social media and thought-leader blogs. The Office monitors its impact with media mentions and the number of total impressions, which is defined as the total number of people that could have

been exposed to particular content. Additionally, Mr. Williams reviewed several of the top NICHD stories for this year.

Mr. Williams provided a brief explanation of why NICHD uses social media, including that it allows the Institute to interact directly with the public, it is fast and inexpensive, and allows for the sharing of messages in a variety of formats including graphics and videos. NICHD currently has a presence on Facebook, Twitter, Pinterest, and YouTube. Currently, NICHD has 18,900 followers on Facebook and 6,600 followers on Twitter. On average, NICHD posts receive 10 and 2.5 re-posts on Facebook and Twitter, respectively. Experimentation with other social media sites include an, "Ask Me Anything," chat that Dr. Spong participated in on September 9, 2016 on Zika virus and pregnancy.

The NICHD monthly newsletter, NICHDdevelopments, provides an overview of news and funding opportunities. It currently has 4,637 subscribers thus far in 2016 and an average open and click rate of 35% and 9.1%, respectively. This exceeds the respective government averages of 21% and 2.5%.

The NICHD website is the anchor for all communications and contains information on the latest news, organizational updates, funding opportunities, and intramural laboratories. The most popular section is the A to Z Topics, which provide centrally located information about mission-related issues and conditions. The website has been fully responsive on mobile devices as of early 2016. Approximately 75% of website traffic comes from search engines. The most popular topics include Safe to Sleep, Sexually Transmitted Diseases and Infections, Contraception, and Adrenal Gland disorders. The top referrer is the National Library of Medicine and of the social media sites, Facebook, refers the most individuals followed by Pinterest. The NICHD website consistently exceeds the Federal Government and private sector healthcare provider customer service scores on the ForSee Site Satisfaction Survey. The website is also available in Spanish.

The types of outreach supported by the Office of Communications include evidence-based campaigns to disseminate health messaging to target audiences, including the general public and healthcare providers. Such programs include Safe to Sleep, National Child and Maternal Health Education Program, and Media-Smart Youth. The NICHD Information Resource Center also performs outreach, which includes interacting directly with the public, ordering NICHD publications, and engaging the public at health fairs, conferences, and meetings.

Mr. Williams also reviewed the FOIA requests received by NICHD. On average, each FOIA request is 200-400 pages. Larger requests can be as much as 1,500-2,000 pages and include photos and video. The largest request was 30,700 pages. The NICHD Office of Communications works to efficiently to capture, review, and release documents.

NICHD also uses videos for communications. Videos highlight the human side of NICHD and helps put a face to a name. Videos are less taxing on the user, can be made in-house at a much lower cost, and work well for both intramural and grantee research. These videos are available on the NICHD YouTube channel. In closing Mr. Williams showed an example video produced by NICHD on the topic of Disease Research at NICHD: Niemann-Pick Disease Type C.

Council Discussion

Dr. Gregory Kopf asked how the Office of Communication confirms the accuracy of the information that NICHD and others produce. Mr. Williams replied that he and his team work

very hard on accuracy, and that if they see any falsehoods in any of the information produced, they correct the record.

Dr. Barbara Collura expressed her thanks and appreciation for all the work performed by the Office of Communications.

Dr. DeWayne Pursley inquired about what, if any, metrics are available to monitor public goodwill for federally-sponsored research. Mr. Williams replied that not for lack of trying, but they do not have a central metric to do that. They do, however, try to get as much information out there and make it positive. Dr. Spong also added that Mr. Williams and his team have tried to reach out to all these new methods of getting communications out to people who may not participate in traditional news media, and that the team is always willing to work on the next new type of media.

VI. ENVIRONMENTAL INFLUENCES ON CHILD HEALTH OUTCOMES (ECHO) PROGRAM

Dr. Matthew Gillman provided an overview of the Environmental Influences on Child Health Outcomes (ECHO) program including the theory, its goals, the organizational approach, themes, and components funded through NIH. The underlying theory for ECHO is that by intervening earlier in life during infancy and childhood, when plasticity is highest, health outcomes for chronic diseases will be better than if intervention occurs later in life because of inadequate responses to new challenges.

The overarching goal of ECHO is to understand the effects of early environmental exposures on child health and development. The program will focus on high-impact conditions in four areas: pre/peri/post-natal outcomes, upper and lower airway, obesity, and neurodevelopment, including cognition and behavior. ECHO differs from the National Children's Study in that it leverages extant cohorts and cooperative agreements to bring those cohorts together. The ECHO organization includes a Steering Committee, Data Analysis Center, Coordinating Center, Children's Health Exposure Analysis Resource (CHEAR), Pediatric Cohort sites, Genetics core, Institutional Development Award (IDeA) States Pediatric Clinical Trials Network (ISPCTN), and Parent/Person Reported Outcomes (PRO) Core. ECHO funding is \$165 million per year for seven years via an annual appropriation, with the exceptions being the IDeA States Pediatric Clinical Trials Network, which was multiple year funded for four years, and the CHEAR resource, also funded for 4 years.

Some of the challenges that ECHO will address include balancing the need to hit the ground running while building a culture of collaboration and allowing time to develop best practices. By leveraging extant cohorts, fewer challenges of recruitment are expected, but ECHO must develop solutions to address the challenge of combining existing studies and strategies to integrate many moving parts, including the ISPCTN. Another challenge ECHO will address is how to distinguish modes of intergenerational transmission critical for intervention design. Cross-cutting issues for the ECHO program include heterogeneity (geographic, social and demographic), explaining disparities (racial/ethnic and socio-economic), replication, and prevention strategies.

Dr. Gillman reviewed the current status of different components of the ECHO program. CHEAR was funded in FY 2015 and again in FY 2016 through supplements. The Genetics Core will be funded in FY 2017. There is currently one PRO Core, 35 cohort sites, and 17 clinical sites in the IDeA States Network. The Cohort Sites go through two phases, a two-year UG3 pilot phase and a second, five-year UH3 phase after they have met "proof-of-concept" milestones.

The Pediatric Cohort Sites have hallmarks of good cohorts, including quality measures and good retention. They maximize sample size overall within the four focus areas and bring together a diverse group of participants. Many have repeated measures early in the life course and employ innovative analytic approaches. The cohorts incorporated into the ECHO program balance the strengths of one-off studies with the need to combine studies and include both mature and newer cohorts. To date, 35 applications have been funded at institutions in 38 states, the District of Columbia and Puerto Rico. The initial estimate of the cohort size is >50,000 children.

The Data Analysis Center will create and maintain a database and interfaces, conduct sophisticated statistical analyses, oversee data harmonization across disparate cohorts, and promote public data sharing while maintaining data security. John Hopkins University, with the Research Triangle Institute, is the awardee for the Data Analysis Center.

The Coordinating Center focuses on policies, communication, coordination, and quality control. It is also charged with managing biospecimens and the biorepository. The awardee is Duke University and its Clinical Research Institute.

The IDEa States Pediatric Clinical Trials Research Network presents an opportunity for children in rural and medically underserved locations to participate in clinical research. It creates a national network for pediatric clinical trials and targets states that have historically low rates of NIH funding. It is co-led by NICHD and the National Institute General Medical Sciences (NIGMS) and includes a Data Coordination and Operations Center and 17 clinical sites.

CHEAR includes six national exposure assessment laboratory sites that form a Resource Core. CHEAR also includes a Data Repository Analysis and Science Center, as well as a Coordinating Center. It was funded in FY 2015 to support the academic community, and in FY 2016, CHEAR received administrative supplements to support readiness for analyzing ECHO biospecimens.

The PRO Core will play an important role in developing and validating new instruments and providing research services and resources to all ECHO components. It will collaborate with other NIH programs, including PROMIS and PhenX. The awardee for the PRO Core is Northwestern University.

Council Discussion

Ms. Wendy Lazarus asked how childhood physical and/or emotional trauma exposure will be incorporated into the ECHO study.

Dr. Gillman stated that it was a very important psychosocial exposure, which occurs between conception and age five. There are several cohorts focusing on that area as an exposure.

A Council Member asked whether any of the cohorts will track whether the births were the result of *in vitro* fertilization. Dr. Gillman mentioned that there are strengths and challenges to having individual cohorts. Whether there is enough power in ECHO as a whole to do that, is unknown because it will take several cohorts having more detailed information about infertility and its treatments to make that as a key exposure within ECHO. It may be done on an individual cohort basis, but whether it can be done as a synthetic cohort is unknown.

Dr. George Saade asked whether the ECHO program will consider how data were obtained during pregnancy. Dr. Gillman stated that he thinks of data harmonization as fitting squared off pegs into rounded off holes. Not every cohort is going to have the best measure of everything. Dr. Gillman stated that he believes the cohorts are going to approach this by having some

measures that are definite, some measures that are probable, and some measures that are possible. Dr. Gillman mentioned, whenever ECHO harmonizes, analyzes, and publishes, the quality of the measures and what can be inferred must be discussed.

VI. OFFICE OF HEALTH EQUITY (OHE) REVIEW REPORT

Dr. Melissa Gilliam presented recommendations regarding the Office of Health Equity (OHE). A panel convened to review the charge of OHE and the role it plays at NICHD. The panel is composed of a diverse group of experts, including experts from within and beyond NIH. The panel was asked to consider the following questions:

- What areas should NICHD focus on to address and eliminate health disparities?
- To address these areas of focus, what activities should NICHD consider? How can the OHE assist in promoting or enhancing these activities?
- What opportunities exist for OHE to enhance collaboration within NICHD DER and DIR, and NIH Institutes, Centers and Offices?
- How can OHE assist the DER/DIR to increase the number of underrepresented individuals participating in the scientific workforce? Are there opportunities to collaborate with other organizations, such as professional societies, nonprofits, universities, or other government agencies?
- In what ways should the OHE inform and educate the public about issues related to health equity?

Dr. Gilliam discussed the three focus areas that the panel was asked to make recommendations on: health disparities in research, creating a diverse workforce, and communications. The panel recommendations therefore are organized around these three areas. Each area of recommendations is divided into “Role of OHE” and “Ideas for OHE to consider”.

The panel’s main idea was to position OHE as a “think tank” for NICHD with a role to address diversity within NICHD itself. The office would work across NICHD and link the Institute with other diversity activities across NIH and in the external community. The panel also thought that OHE should create strategies to increase diversity among investigators. The panel also felt that OHE should adopt a metric-driven approach.

In the area of health disparities research, the panel recommended that OHE should lead the discussion of health disparities at NICHD and serve as a coordinator across the NICHD portfolio. OHE should have a leadership role in the process for identifying the needed studies with the goal of reframing the portfolio to realize health equity as a cross-cutting theme. The panel also discussed the need to identify innovative ways of propelling health disparities research forward and integrating these ideas into NICHD.

Additional ideas from the panel included integrating health disparities into the continuum from basic and translational research with a focus on maternal health and pregnancy, fetal and childhood origins of adult-onset disease, perinatal health disparities, violence, disabilities, adolescent health, and reproductive and gynecological health. Additionally, the panel also recommended that OHE encourage secondary data analyses for relevance to health disparities.

On the topic of workforce diversity, the panel recommended that OHE should lead the discussion on workforce diversity within NICHD and a focus on diversity within NICHD, providing training to members of NICHD on topics such as bias, cultural competency, and health equity.

OHE should also set goals for workforce diversity and create the programs and practices to achieve it. OHE should also have a role in ensuring that NICHD stays abreast of research on inequities in funding and to create appropriate trainings and policies to enhance the equity of the grant making process. The panel also recommended that OHE link NICHD to diversity efforts across NIH, particularly those underway at the National Institute for Minority Health and Health Disparities. The panel recommended using external collaborations to enhance the scientific workforce and creating more diversity supplements while reducing the challenges to obtain them.

Additional workforce ideas included expanding intramural training opportunities and offering grant writing trainings, including programs for grant administration and management to increase the capacity of institutions with diverse faculty and students, and to consider creative methods to recruit and retain funded faculty at minority institutions.

Around the third topic area, Communications, the panel recommended that OHE lead the Institute in increasing awareness of how health disparities research is shifting from solely documenting health differences towards understanding the root cause and lending expertise to incorporate health equity into the NICHD communications plans. The panel also recommended that OHE should have a role in identifying and promoting partnerships to strengthen the collective impact of NICHD's work. OHE should also have a role in assisting DIR and DER with dissemination of their research findings related to health equity beyond the academic community. OHE could play an important role in amplifying the impact of NICHD's work on health disparities and health equity.

Additional ideas on how OHE could contribute to health disparities communication include representing NICHD in collaboration with other agencies and state sector partners on health disparity activities, building on relationships with advocacy groups and community groups to encourage their involvement in NICHD's health disparities, and participating in a knowledge generation by participating in research collaborations, event sponsorship, and community tie-ins to support and reinforce comprehensive communication efforts from NICHD. This includes establishing and maintaining effective communication channels, fostering accountability by reporting on relevance, impact, effectiveness, efficiency and sustainability of pro-equity interventions, and creating social media activities to communicate priorities and emerging direction for NICHD health disparities activities.

In conclusion, the panel thought that there is tremendous opportunity to build on NICHD's commitment to health equity and that OHE should be positioned and empowered to lead. The panel recommended that OHE should address NICHD's daily operations, its research, the current and future workforce, and health communications. Throughout the process, the panel recommended that OHE establish goals, metrics, and accountability.

Council Discussion

Dr. Richard Krugman inquired about how the panel recommendations will be operationalized.

Dr. Gilliam stated that the Office of Health Equity is being completely rethought and at this point does not have staffing. So the first thing will be to populate the office and then this report would become the beginning of a strategic planning process. The new team will have the benefit of all of the data that Dr. Sara Glavin and colleagues pulled together, as well as a series of recommendations. Dr. Gilliam stated that she believes that these are three important channels to

work though: thinking about the content of the research, issues of workforce, and how to communicate that and, additionally, creating an inclusive culture around this work.

Dr. Spong added that NICHD had previous reviews of different aspects of its programs and part of the opportunity is how those reviews are implemented. Dr. Spong mentioned that sometimes a recommendation cannot be done, so staff has to work with the report to prioritize actionable recommendations. Additionally, Dr. Spong reminded Council members that NICHD will recruit for an OHE director, but she believes that NICHD is poised to move forward and benefit from this report that has so thoughtfully put together.

Ms. Wendy Lazarus inquired about the plans for resourcing this office.

Dr. Spong stated that she would not be able to give a definitive plan at this time because it depends on what the actionable priorities will be from the report. Dr. Spong stated that they are committed to ensuring the success of this office and addressing these goals as best they can.

Dr. DeWayne Pursley indicated that he is currently leading a taskforce at the Association of American Medical Colleges to increase diversity and expressed that it would be great if OHE could play a role in coordinating diversity efforts nationally.

Dr. Richard Krugman suggested that since the Council has only had 24 hours to review the report that it should be revisited at the January 2017 Council Meeting. Dr. Krugman also expressed that as recruitment progresses it would be helpful to know whether the charge of the office will be spiritual or financial.

VII. CONCEPT CLEARANCE REVIEW AND DISCUSSION

The Council discussed and unanimously endorsed nine concepts as detailed below:

Dr. Tonse Raju requested approval for a Data Coordinating Center for the NICHD Neonatal Research Network that consists of 15 clinical sites. The Data Coordinating Center would provide logistical support, the development and monitoring of network protocols, statistical support, preparation of the data for data monitoring and preparation of the data for public access.

Dr. David Weinberg requested approval for an initiative titled, “Moving Beyond Standard Imaging: Applying Novel Tools to Assess the Human Placental Structure and Function in Real Time.” To date, NICHD has been very successful in drawing researchers from many sectors to advance imaging and assessing circulating factors as part of the Human Placenta Project, but only touch on a small fraction of the technology available. The goal of this initiative is to stimulate the development of novel tools such as, biosensors and nanotechnology to improve our understanding of the human placental structure and function.

Dr. Esther Eisenberg requested approval for an initiative titled, “Application of Technologies to Improve Diagnosis, Monitoring and Treatment of Diseases and Disorders in Infertility and Reproductive Health and in Obstetric, Pediatric and Neonatal Critical Care Settings.” The goal of this initiative is to advance research using advanced technologies such as, biochips, microfluidics and mobile technologies to develop novel point-of-care devices for the treatment of infertility and reproductive disorders and obstetric, pediatric, and neonatal critical care settings.

Dr. Candace Tingen requested approval for an initiative titled, “Integrative Research in Gynecological Health.” The application would fund research on fibroids and endometriosis for

gynecological pain syndromes. These disorders are highly prevalent and most women will experience at least one of these at one point in their lifetimes. The initiative will promote bench to bedside collaboration and accelerate the development of novel treatments.

Dr. Daniel Johnston requested approval for an initiative titled, “Identification of Non-Steroidal Targets for Male and Female Contraception.” The goal of the initiative is to analyze bioinformatics data to provide a comprehensive identification of putative contraceptive targets for subsequent validation. A similar study was conducted by industry 15 years ago, but the data was not made publicly available and technology has advanced substantially since then.

Dr. Nahida Chakhtoura requested approval for an initiative titled, “Zika in Infants and Pregnancy.” This initiative will extend the follow up for mothers and children enrolled in the first international cohort study of Zika and pregnancy. The purpose is to provide additional support for extended follow up of the infants over a three-year period that were born in the Zika cohort to determine the full spectrum of outcomes, short-term and long-term.

Dr. Eric Lorenzo requested approval for an initiative titled, “NICHD International and Domestic Pediatric and Maternal HIV Studies Coordinating Center.” The goal of this initiative is for the development of improved therapies for HIV infection and associated complications in children and pregnant women and further reduction of perinatal transmission.

Dr. Sonia Lee requested approval for an initiative titled, “Interaction of HIV and Neurodevelopment in Children in Resource Limited Settings: Improving Their Assessments.” We do not have an understanding how the advancement of HIV prevention and treatment has impacted the neurocognitive development of children due to a lack of psychometric resources and tools that can be used effectively in resource-limited settings. The goal of this initiative is to support research focused on improving assessment of neurodevelopment and neurocognitive functioning of children in resource-limited settings with a focus on children who have been exposed to and/or are living with HIV and AIDS.

Dr. Denise Russo requested approval for an initiative titled, “The Female HIV/AIDS Cohort Study.” Currently NICHD supports the Pediatric HIV/AIDS Cohort Study which includes over 3,000 HIV positive women of child-bearing age with an additional 250 new enrollees per year. NICHD would like to leverage this cohort to launch a more intensive study of their natural history, reproductive, and overall health status after HIV diagnosis and treatment.

Council Discussion

Regarding the Data Coordinating Center for the NICHD Neonatal Research Network, Dr. Frederick Rivara inquired as to whether there has been a Data Coordinating Center in the past. Dr. Raju responded that there has and that the current contract will expire in two years. Dr. Richard Krugman inquired if it would be possible to obtain information on past concepts and Dr. Hann indicated that NICHD would make sure Council had access to that information as it is public information.

Regarding Dr. Weinberg’s concept for the Human Placenta Project, Dr. Ruth Lehmann inquired about how many placental RFAs are currently out. Dr. Weinberg responded that none are currently available.

For the Zika in Infants and Pregnancy concept, Dr. Rinaldo asked what is being done to develop a vaccine for Zika. Dr. Spong replied that NIAID is funding Zika vaccine development efforts,

including a phase 1 study that started in August, 2016. There are other vaccines being developed by NIAID, BARDA and by industry. Dr. Patricia Flynn asked what the targeted age would be for follow up. Dr. Chakhtoura would like to follow the infants up to three years of age.

VIII. RETIRING COUNCIL MEMBERS

Dr. Spong thanked the four retiring members for their contribution to the NICHD Advisory Council. Each retiring member provided comments on their tenure as a member of the NICHD Advisory Council.

Dr. Walter Frontera thanked Dr. Spong and stated that his area of interest and expertise was in rehab medicine, and although most of the topics brought up in Council were out of his area of expertise, it has been enjoyable to listen to the scientific discussions.

Ms. Lazarus expressed that this has been a rewarding experience, both to see what is on the frontier of children's health and development and to learn about and have a voice in some of what is going on at NICHD.

Dr. Ruth Lehmann commented that even though she has been continuously funded by NIH for the past 30 years, she has learned a lot while on Council. She also expressed that she is incredibly supportive and impressed with the spread of work at NICHD.

Dr. Piero Rinaldo stated that it has been an amazing experience serving on Council and noted that NICHD has a great combination of intramural and extramural research. Dr. Rinaldo closed his thoughts by thanking NICHD for his opportunity to serve on Council.

IX. 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).

X. 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 618 HD-primary applications requesting \$196,081,262 in direct costs and \$255,772,530 in total costs.

ADJOURNMENT

There being no further business, the meeting adjourned at 3:07 p.m. on Wednesday, September 21, 2016. The next meeting is tentatively scheduled for January 19, 2017.

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

_____/S/_____
Catherine Y. Spong, M.D.
Chair, National Advisory Child Health and
Human Development Council
Acting Director, *Eunice Kennedy Shriver*
National Institute of Child Health and
Human Development

Date

Kimberly Witherspoon
Committee Management Officer, NICHD

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.