Eunice Kennedy Shriver National Institute of Child Health and Human Development

NATIONAL ADVISORY CHILD HEALTH AND HUMAN DEVELOPMENT COUNCIL

MEETING SUMMARY

June 14–15, 2022

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
MEETING SUMMARY
June 14–15, 2022[1]

The National Advisory Child Health and Human Development (NACHHD) Council convened its 179th meeting at 12 p.m. on Tuesday, June 14, 2022, by National Institutes of Health (NIH) VideoCast. The meeting was open to the public on June 14 from 12:08 p.m. to 4:43 p.m. and on June 15 from noon to 1:44 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 on June 15, 2022, from 1:44 p.m. until 5:00 p.m.

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

Council members present:
Diana W. Bianchi, M.D. (Chair)
Shari Barkin, M.D.
Christina Bucci-Rechtweg, M.D.
Michele Caggana, Sc.D.
John P. Coughlin, M.D.
Lucky Jain, M.D.
Catherine E. Lang, Ph.D.
Missy Lavender, M.B.A.
Martin Matzuk, M.D., Ph.D.
Genevieve S. Neal-Perry, M.D., Ph.D.
Carmen L. Neuberger, J.D.
Adam C. Resnick, Ph.D.
David H. Rowitch, M.D., Ph.D.
Alan Thenevet N. Tita, M.D., Ph.D., M.P.H.
Rebeca Wong, Ph.D.
Anthony J. Wynshaw-Boris, M.D., Ph.D.

Council members not present:
Kathleen B. Egan, Ph.D.
Damien Fair, Ph.D.*
Yvonne Maldonado, M.D.*

* Ad hoc Council members

National Advisory Board on Medical Rehabilitation Research Council liaison:
Jose L. Contreras-Vidal, Ph.D.

Department of Defense:
Melissa R. Miller, Ph.D.

[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.

Executive Secretary:
Dennis Twombly, Ph.D.

Others present:
NICHD staff members
NIH staff members
Members of the public

I. CALL TO ORDER AND INTRODUCTORY REMARKS

Dr. Bianchi welcomed members of the NACHHD Council and other participants to this meeting.

Review of Confidentiality and Conflicts of Interest

Dr. Twombly reminded the NACHHD Council that all members were required to read, agree to, and sign the confidentiality and nondisclosure rules for special government employees on the Council member website before evaluating any NIH grant applications. Before the meeting, Council members had received a conflict-of-interest certification form, which they were required to sign. Dr. Twombly also reminded Council members that they are required to recuse themselves and leave the virtual meeting before any discussion involving any organizations or universities for which they are in conflict, in addition to those listed in the Council action document. Council members are not allowed to serve on the NIH peer review panel while serving as Council members, because NIH policy indicates that individuals may not serve on both the first and second levels of peer review.

Council Minutes

A motion to approve the January 11–12, 2022, NACHHD Council meeting minutes carried.

Future Meeting Dates

Dr. Twombly reviewed future Council meeting dates. The next meeting will be on September 13, 2022, at 6710B Rockledge Drive, Bethesda, Maryland.

II. NICHD DIRECTOR'S REPORT

60th Anniversary of NICHD

NICHD will celebrate its 60th anniversary with a scientific symposium, Healthy Pregnancies, Healthy Children, and Healthy and Optimal Lives, on October 17, 2022. This event will probably be virtual. More information on the symposium and other anniversary events is available on the 60th anniversary web page.

NIH Budget

The 2022 Consolidated Appropriations Act, which President Biden signed into law on March 15, provides $45 billion for NIH. The fiscal year (FY) 2022 budget for NICHD is $1.68 billion, which includes $7.5 million for research on the impact of COVID-19 in children. The 2022 appropriation also includes a $30 million increase for the Implementing a Maternal health and

PRegnancy Outcomes Vision for Everyone (IMPROVE) initiative, and this budget was moved to NICHD's base funding. In addition, the NIH Common Fund received $12.6 million for the Gabriella Miller Kids First Research Program. Another $1 billion was allocated to establish the Advanced Research Projects Agency for Health, which will not be part of NIH.

The FY 2023 President's budget request proposes $62.5 billion for NIH, including $1.68 billion for NICHD. NICHD's FY 2023 congressional budget justification includes a fact sheet and several program highlights.

Dr. Bianchi attended a maternal health action plan cabinet meeting led by Vice President Kamala Harris, whose presentation demonstrated her commitment to maternal health and reductions in health disparities. Dr. Bianchi also participated in briefings for the Senate Appropriations Committee staff on IMPROVE and for Congress on the implementation of the Task Force on Research Specific to Pregnant Women and Lactating Women. On May 11, Dr. Bianchi testified before the House Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies. At this hearing, Dr. Bianchi answered questions about maternal health, stillbirth, and youth mental health during the pandemic. Other questions on pediatric issues not directed to Dr. Bianchi were about the future of the NIH Environmental influences on Child Health Outcomes (ECHO) program, drug addiction in adolescents, and firearm violence.

COVID-19 Research

Predicting Viral-Associated Inflammatory disease severity in children with Laboratory diagnostics and artificial Intelligence (PreVAIL kIds) has funding from RADx® Radical to develop translational tools for understanding pediatric SARS-CoV-2 illness, rapidly diagnosing and characterizing multisystem inflammatory syndrome in children (MIS-C) associated with SARS-CoV-2, and predicting the longitudinal risk of severe disease after SARS-CoV-2 exposure or infection.

PreVAIL kIds has made eight awards for programs that are collectively enrolling more than 4,500 prospective participants and collecting data on more than 27,000 retrospective participants in the United States and other countries. These projects are leveraging the NIH Small business Education and Entrepreneurial Development (SEED) program to promote rapid translation and submission of applications to the U.S. Food and Drug Administration for emergency use authorization (EUA).

One PreVAIL kIds study has submitted a pre-EUA application for a diagnostic algorithm to differentiate among MIS-C, Kawasaki disease, and other febrile illnesses. Another project is preparing a pre-EUA package for a machine learning algorithm that can identify progressive disease at initial presentation. In addition, most PreVAIL kIds awardees are part of a pediatric cohort for the NIH RECOVER: Researching COVID to Enhance Recovery program, which is studying the long-term effects of COVID-19.

Concerns have arisen about potential neurodevelopmental effects in the fetuses of women infected with SARS-CoV-2 during pregnancy, even though transmission of the virus from mothers to fetuses is rare. A recent study found that 255 children born during the COVID-19

pandemic had slightly poorer gross motor, fine motor, and social skills at 6 months than infants born before the pandemic, regardless of whether their mothers were infected with SARS-CoV-2 during pregnancy. One possible explanation is the increased level of maternal stress. However, another study found that 1-year-old infants born to mothers infected with SARS-CoV-2 during pregnancy had twice the rate of neurodevelopmental complications as infants whose mothers were not infected during pregnancy.

A study that included more than 1.1 million students and 157,000 school staff members in nine states found that schools with mandatory masking during the surge of the delta variant of SARS-CoV-2 had 72% fewer cases of in-school transmission than schools with optional or partial masking policies.

Other Research Updates

NICHD houses the National Center for Medical Rehabilitation Research (NCMRR), which recently launched the Limb Loss and Preservation Registry with the Department of Defense. In addition, NCMRR is co-sponsoring a Design by Biomedical Undergraduate Teams challenge with the National Institute of Biomedical Imaging and Bioengineering for rehabilitative and assistive technologies for people with physical disabilities. NCMRR also sponsors the Rehabilitation Research Speaker Series.

In 2020, NICHD awarded almost $2.5 million to support research on firearm violence and mortality. NICHD also collaborates with the NIH Office of Behavioral and Social Sciences Research to sponsor two funding opportunity announcements (FOAs) for research on community-level interventions to prevent injuries and deaths from firearm and related violence. In addition, an NICHD grant is supporting a gathering of a multidisciplinary team of researchers and stakeholders (including gun owners and firearm instructors) to develop a research agenda for preventing firearm injuries in children and to conduct pilot studies, including one to develop a new online firearm safety education program for families in rural communities.

NIH-Wide Initiatives with Major NICHD Engagement

NICHD funds only approximately 16% of child health research at NIH. The NIH-wide Pediatric Research Consortium (N-PeRC) brings together the NIH Institutes and Centers (ICs) that conduct pediatric research. N-PeRC's Pediatric Medical Devices Subgroup is drafting a proposal to the Foundation for NIH for a public–private partnership to support the development and commercialization of pediatric medical devices. N-PeRC is also discussing ways to increase the pediatric research workforce.

The IMPROVE initiative focuses on reducing preventable causes of maternal deaths and improving health for women before, during, and after delivery. The $30 million congressional appropriation for IMPROVE in FY 2022 will support the development of research infrastructure with community organizations, acceleration of technology used for maternal healthcare in maternity care deserts, community implementation studies of evidence-based maternal health interventions, creation of longitudinal health records for pregnant persons and children, dissemination and implementation research, and maternal health centers of excellence.

The INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE (INCLUDE) project conducts research on critical health and quality-of-life needs of individuals with Down syndrome. Some projects supported with INCLUDE's FY 2022 $75 million appropriation are supporting early-career scientists pursuing Down syndrome research as well as basic, applied, and clinical trials research. INCLUDE's data hub provides free access to large-scale INCLUDE data resources.

NICHD staff are helping implement the 2020–2030 Strategic Plan for NIH Nutrition Research, including the Nutrition for Precision Health program, powered by the *All of Us* Research Program.

The President's FY 2022 budget request included $100 million for research by the NIH Climate Change and Health (CCH) Initiative. In anticipation of this funding, several IC directors developed a plan for research on this topic. Although the funds were not appropriated for FY 2022, NIH continues to identify priorities for CCH so that the agency is prepared if funding becomes available in FY 2023. NICHD is interested in this research because its populations (i.e., pregnant people, children, and people with disabilities) are particularly vulnerable to the effects of climate change. In addition, NIH has issued several FOAs for research on the effects of climate change on health.

NICHD has been involved in several Helping to End Addiction Long-term® (HEAL) initiative programs, including Advancing Clinical Trials in Neonatal Opioid Withdrawal and Prescription After Cesarean Trial. A potential new initiative, Opioid Exposure and Effects on Placenta, Brain Development, and Neurodevelopmental Outcomes, is also of interest to NICHD.

Several NICHD staff members are involved in working groups of the NIH Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN) Initiative and the NIH Blueprint for Neuroscience Research. Details on the BRAIN Initiative's accomplishments are available on the blog of the initiative's director, John Ngai, Ph.D.

NICHD Staff

NICHD recently filled several leadership positions:

- Rohan Hazra, M.D., director of the Division of Extramural Research (DER)
- Rebekah Rasooly, Ph.D., associate director of the Division of Extramural Activities
- Nahida Chakhtoura, M.D., chief of the Pregnancy and Perinatology Branch

NICHD plans to hire a new clinical director and new chiefs of the Maternal and Pediatric Infectious Disease, Gynecologic Health and Disease, and Fertility and Infertility branches. NICHD is considering four finalists for the position of scientific director of the Division of Intramural Research.

Discussion

Dr. Contreras-Vidal asked about plans for N-PeRC to work with other federal agencies that conduct health research, such as the National Science Foundation or the Defense Advanced Research Projects Agency. Such collaborations could expand the initiative's scope by, for

example, bringing engineers to N-PeRC. Dr. Bianchi said that N-PeRC does work with other federal agencies, but not the two that Dr. Contreras-Vidal mentioned. NICHD can look into partnerships with other federal agencies or at least inform them of N-PeRC activities.

Dr. Lang encouraged NICHD to discuss ways to capture data on the natural experiment on maternal and infant health offered by differences in state abortion laws. Dr. Bianchi said that the Centers for Disease Control and Prevention will capture relevant data on this issue.

Dr. Barkin asked about NICHD mental health initiatives. Dr. Bianchi explained that the National Institute of Mental Health (NIMH) is the lead NIH agency for research on youth mental health, and NICHD co-funds several initiatives with NIMH. Mental health issues might be the most significant long-term effects of the COVID-19 pandemic.

Dr. Jain congratulated Dr. Bianchi on the outstanding new NICHD leaders. Dr. Bianchi reported that NICHD is seeking a new director of its Office of Health Equity. She also noted that NIH offers opportunities to work remotely.

Dr. Matzuk asked about the impact of federal expenditures on COVID-19 relief and assistance to Ukraine on the NIH budget in FY 2023. Dr. Bianchi said that at the hearings she attended, Congress continued to express strong, bipartisan support for NIH.

Dr. Wynshaw-Boris emphasized the importance of NICHD involvement in the BRAIN Initiative to ensure that this program studies fetal and childhood brain development. Dr. Bianchi said that several ICs are interested in typical and atypical brain development, which is why they are involved in the BRAIN Initiative.

III. INTRODUCTION TO THE NICHD BUDGET

Alexis Clark, M.P.P., budget officer at NICHD, described the process that NICHD uses to develop its annual budget.

Federal Budget Process

Federal agencies begin developing their annual budget requests at least one year before the beginning of the FY, so agencies are currently working on the President's FY 2024 budget request, which will contain proposals that Congress might or might not implement. Congress typically receives the congressional justification in early February and holds hearings in the spring. Congressional appropriations committees work on their bills over the summer, and Congress's goal is to appropriate funds by the start of the FY on October 1. When Congress does not pass an appropriations bill by October 1, it passes a continuing resolution that provides partial funding to maintain operations while Congress finishes its appropriations work

NICHD Budget Process

Each IC has its own budget office. The NICHD budget office is the Financial Management Branch, which Ms. Clark leads. This branch provides advice to NICHD leaders and staff, helps develop spending plans to support institute priorities, provides information to guide planning

decisions for future years, and monitors the institute's spending to ensure that it is adhering to its operating plan and federal rules.

When it receives a full-year budget or when a full-year continuing resolution is passed, each IC must submit an operating plan to the NIH Office of Budget. At the end of the FY, the IC compares its actual and planned expenditures and submits a mechanism table using a template developed by the NIH Office of Budget. These tables allow comparisons of the expenditures of all ICs in the same categories.

NICHD Budget Components

In FY 2021, research project grants (RPGs) accounted for 55% of the NICHD budget. In addition, NICHD spent $147.7 million on HIV/AIDS research, an amount determined by the NIH Office of AIDS Research, and $46.7 million (another mandated amount) on Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grants.

When NICHD develops its budget each year, it must consider expected spending on nongrant items, including personnel and mandated increases in NIH assessments (e.g., for cybersecurity, rent, and the NIH Clinical Center). Other factors beyond NICHD's control to consider include Department of Health and Human Services (HHS) and NIH taps and assessments, unexpected needs and emergencies, new NIH policies, new congressional mandates, and savings.

In FY 2021, approximately one-third of the NICHD budget for intramural research went to salaries, one-third to assessments, and one-third to other expenses. Although the budget categories were the same for extramural research, the proportions were different: 53% for salaries, 34% for assessments, and 13% for other expenses.

Grant Budgets

NICHD tries to project grant costs for the year to help determine the amount of funding available for new FOAs. These costs include out-year commitments for ongoing grants, co-funding commitments with other ICs, support for early-stage investigators (ESIs), bridge funding for grants affected by delays in competitions, requests for applications (RFAs) that the institute has agreed to support, and funding commitments (e.g., 6.5% of the NICHD extramural research budget for NCMRR and 6% for training programs).

The many considerations used to identify the annual RPG allocation include:

- Spending on administrative and diversity supplements
- Unobligated balances in noncompeting grants that could be offset
- Set-aside funds for taps and congressionally mandated programs (e.g., National Academies studies and COVID-19)

NICHD then estimates the amount available for RPGs and examines the institute's average funding for investigator-initiated grants over the previous 3 years and scores applications to assess their costs. Finally, NICHD calculates allocations to extramural branches that make funding consistent for grants reviewed by the NACHHD Council in October, January, and June.

The process is different for mechanisms other than RPGs. NICHD might not be able to reduce its budget for new grants, but it sometimes uses offsets for certain training awards when grantees do not recruit the planned numbers of trainees. For training mechanisms, NICHD considers the recommendations of the NICHD Training Committee, NIH-wide stipend increases, and the new childcare assistance payment.

Discussion

Dr. Tita asked about the annual budget for NICHD network grants. Ms. Clark explained that NICHD spent a total of $182 million on network grants in 2021, or slightly more than 11% of its total appropriation. NICHD funds some other networks through contracts, not grants, with other ICs. For example, NICHD is one of approximately 20 ICs funding the Pediatric Trials Network. NICHD collects most of this funding from the other ICs.

Dr. Tita asked for a breakdown in costs of networks led by NICHD and those led by other ICs. Ms. Clark was unable to provide this information.

Dr. Jain asked whether NICHD's budgets for administrative expenses (5% of the institute's total budget) and intramural research (14%) are similar to those of other ICs. Ms. Clark replied that most ICs try to maintain their administrative budget at approximately 5% of their total budget. The range for intramural programs is much broader, and the intramural budget at NICHD probably accounts for a higher proportion of the total budget than at approximately two-thirds of other ICs. Congress typically suggests that NIH spend approximately 10% of its budget on intramural research. Dr. Bianchi added that NICHD has the sixth highest intramural research budget of all ICs, and this issue will be a discussion topic for NICHD's new scientific director.

Dr. Lang pointed out that at a recent NACHHD Council meeting, the acting director of intramural research reported that much of the intramural research supported by NICHD could only be done by the Division of Intramural Research. Dr. Bianchi noted that the Council's September meeting usually includes time to discuss the intramural research program.

Dr. Barkin asked how NICHD sets paylines. Ms. Clark explained that NICHD does not set firm paylines for most funding mechanisms. It does establish paylines for K awards at the start of the year, but it revises this number throughout the year. For RPGs (other than R15 awards), NICHD has a zone of consideration rather than a payline. Each extramural branch receives an allocation, and the branch chief decides how to distribute this amount. For example, branch chiefs could either base their funding decisions solely on review scores or also consider institute priorities.

IV. PLANNING FOR NEW INITIATIVES

Caroline Signore, M.D., M.P.H., deputy director of DER, described the steps and timeline to plan and issue a new FOA at NICHD. She used a 2021 RFA for R01 awards as an example.

Planning for this RFA began at a program staff activities workshop in April 2018. The NACHHD Council reviewed this concept in January 2020, and NICHD published the RFA in March 2020. Applications were submitted in July 2020 and, after Council review in January 2021, NICHD issued awards in April 2021. As shown in this example, the planning process for a

new RFA can take up to three years, and the Council is involved twice: when it reviews the concept proposal and when it conducts its second-level review and considers NICHD staff recommendations for funding.

All NICHD initiatives begin with ideas from program officials. These officials identify gaps in the science that NICHD could fill in many ways, such as by reviewing the published literature, hosting NICHD workshops, conducting portfolio analyses, attending scientific meetings, and speaking with scientists.

Operational Planning Process

NICHD program staff develop a proposal or pitch for each new initiative, typically in the form of a short document that describes the evidence gap addressed, purpose or goal, reasons for NICHD to lead this initiative, alignment between the proposed initiative and the NICHD strategic plan, and recommended budget. If NICHD has funded the initiative in the past, the document also describes outcomes in previous years and why this field needs continued stimulation. In some cases, NICHD staff deliver oral presentations in addition to written proposals.

For RFAs or requests for proposals (RFPs) that have set-aside funding, operational planning is primarily conducted at an annual meeting 2 years before anticipated funding, although NICHD organizes ad hoc meetings at other times when needed. At these meetings, program staff present 20 to 30 new and recurring initiatives to all NICHD leaders and extramural staff. Initiatives that do not use set-aside funds are discussed at quarterly operational planning meetings attended by staff from DER and the NICHD Office of the Director. Typically, 10 to 15 new and recurring initiative proposals are considered at each of these meetings.

NICHD leaders use the following criteria to evaluate the proposals presented by staff:

- Clarity of goals and objectives
- Extent to which the initiative addresses an important gap or opportunity
- Alignment with the NICHD strategic plan, aspirational goals, and program priorities
- Recommended budget
- Funds available

Funds Available for New Initiatives

In 2021, NICHD allocated about 80% of its annual appropriation to extramural research. Funds remaining after allocations to existing noncompeting commitments (e.g., to support the out-years of existing grants) can be used to pay for new awards, including investigator-initiated, SBIR, STTR, training, early-stage investigator (ESI), and HIV/AIDS grants; recompeting RFAs and RFPs; and new initiatives. Approximately 60% of funds available for new initiatives go to new investigator-initiated projects.

Discussion

Dr. Rowitch asked whether members of the public have opportunities to submit ideas for new initiatives. Dr. Signore replied that NICHD often works with advocacy groups and other stakeholders interested in the institute's science, so it has mechanisms to collect input on

community priorities. For some initiatives, NICHD issues a request for information (RFI) to solicit public comments that it uses in its planning for potential initiatives or programs.

Dr. Wynshaw-Boris asked about the proportion of the FY 2021 appropriation allocated to new initiatives. Dr. Signore replied that 2% of NICHD's FY 2021 appropriation was used for new initiatives.

Dr. Bianchi said that the 3-year interval between initiating the planning for a new initiative and funding awards for that initiative is a concern. NICHD wants to be nimble and issue funding in a timely way, and Dr. Rasooly will be examining ways to accomplish this goal.

V. FUNCTIONAL REORGANIZATION OF DER

Alison Cernich, Ph.D., deputy director of NICHD, explained that functional reorganization involves finding ways for a division's staffing plan to align more closely to the roles and functions needed to support the organization.

The NICHD undertook this reorganization initiative because of the number of direct reports and responsibilities assigned to the associate director of DER, who also manages a $1.1 billion extramural grant budget. NICHD proposes restructuring DER to streamline the associate director's responsibilities; provide career development opportunities for all extramural staff members; provide backup capabilities that enable NICHD to respond to major, unexpected events or emergencies; and plan for succession.

The DER restructuring process began in early 2020 with a functional analysis of the needs and requirements of the structure, function, and staffing of DER. From May to October 2020, Dr. Cernich and colleagues determined whether DER's structure and staffing were optimal to meet the needs identified in the functional analysis. In November 2020, Dr. Bianchi reviewed several options for organizational restructuring and met with all extramural division leaders to gather their opinions of these options.

NICHD proposes streamlining the responsibilities of the associate director of DER to concentrate on the management of the scientific branches. Responsibility for scientific review, grants management, policy and other scientific administration roles will be allocated to the new Division of Extramural Activities (DEA). The associate director of DER will report to the NICHD Director and the and DEA director will report to the NICHD deputy director. In the proposed new structure, all of the scientific branches (e.g., Child Development and Behavior, Contraception Research, Population Dynamics) will report to the DER director. The directors of the Grants Management Branch, Scientific Review Branch, and Office of Extramural Policy will report to the DEA director.

In addition, during this reorganization the Developmental Biology and Structural Variation Branch will be renamed the Developmental Biology and Congenital Anomalies Branch.

NICHD is accepting comments on this proposal at this meeting, at another meeting on July 12 at 1 p.m. ET, and by email to nichdmaps@mail.nih.gov.

Discussion

Dr. Lang asked about the rationale for changing the name of the Developmental Biology and Structural Variation Branch to the Developmental Biology and Congenital Anomalies Branch. She noted that "anomalies" has a negative connotation, and the branch studies many kinds of variations.

Dr. Cernich said that the division's current name does not capture all of the scientific issues that it addresses, and "congenital anomalies" is a more accurate descriptor. Dr. Bianchi added that this division supports both developmental biology research and research on developmental problems that affect structures other than the brain. "Congenital anomalies" is the term commonly used in the field for these developmental challenges. Dr. Wynshaw-Boris agreed that this is the correct term, and the new name clarifies the division's responsibilities. Dr. Cernich confirmed that the division will continue to address congenital structural defects after its name is changed.

Dr. Jain asked how the proposed structure compares with the structures of other ICs. Dr. Cernich said that NICHD is one of the few ICs that does not have a DEA, although the name of this division is slightly different at each IC. Most ICs have one unit responsible for scientific programming and another for scientific review, grants management, training policies, and related activities. The proposed structure would therefore make NICHD's extramural organization more similar to that of other ICs.

Dr. Miller asked whether the proposed structure would fill the gaps identified in the functional analysis. Dr. Cernich said that the new structure does address these needs. For example, the new structure will create new staff assistant positions, which will provide growth opportunities for staff.

A participant in the live videocast asked whether NICHD has enough staff for the new structure. Dr. Cernich said that NICHD has committed the necessary resources to provide the staff needed.

Dr. Wong asked whether NICHD had considered the need for more behavioral and social scientists to support activities related to health disparities. Dr. Cernich replied that NICHD is addressing the need for social scientists and better integration of behavioral and social science staff into many NICHD initiatives. NICHD is seeking a new director of the Office of Health Equity, who will oversee efforts by all NICHD divisions to address health disparities. The NACHHD Council will hear more about these activities at a future meeting.

VI. INVITED DIRECTOR: NATIONAL INSTITUTE OF NURSING RESEARCH

Shannon Zenk, Ph.D., M.P.H., RN, director of the National Institute of Nursing Research (NINR), explained that NINR supports research that develops the basis for clinical practice and policy. What sets NINR apart from other ICs is its focus on health solutions for people in the contexts of their lives and living conditions.

NINR Strategic Plan

NINR's mission is to lead nursing science to solve pressing health challenges and inform practice and policy, while optimizing health and advancing health equity. NINR's new 2022–2026 strategic plan includes guiding principles and the following research lenses for examining health challenges:

- Health equity
- Social determinants of health
- Population and community health
- Prevention and health promotion
- Systems and models of care

These research lenses are complementary and synergistic, and they promote multilevel approaches, cross-disciplinary and cross-sectoral collaboration, and community engagement in research. NINR encourages investigators to apply one or more of these lenses to their study designs and training programs and to view the health equity and social determinants of health lenses as primary foci through which to consider the other three lenses.

NINR's strategic plan is a living document, allowing the institute to respond quickly to emerging issues and crises.

Collaboration

Collaboration is vital to NINR's ability to accomplish its mission and that of NIH. NINR collaborates with partners within NIH and other federal agencies. For example, like NICHD, NINR is involved in the NIH CCH initiative, and it cochairs the new NIH Social Determinants of Health Research Coordinating Committee and the new Community Partnerships to Advance Science and Society (ComPASS). NINR is also cosponsoring two Transformative Health Disparities Research Program RFAs and is participating in several HHS and interagency committees and activities.

NINR and NICHD share many interests (e.g., promoting an inclusive scientific workforce, health equity, disease prevention) and are already collaborating with one another. For example, NINR is participating in the NIH Maternal Morbidity and Mortality Task Force Advisory Cabinet, led by NICHD, the Office of the Director, and the Office of Research on Women's Health. NINR also supports the IMPROVE initiative and several studies of maternal and child health. In addition, NICHD is participating in NINR-led RFAs to advance integrated models of care that improve maternal health outcomes for women who experience persistent disparities.

Dr. Zenk asked the NACHHD Council for suggestions on ways to foster development of interdisciplinary teams and potential partnership opportunities for NINR and NICHD.

Discussion

Dr. Bianchi explained that NINR is one of the smaller ICs. But the proportion of its budget dedicated to research on maternal morbidity and mortality, 3%, is the second highest for all ICs, after NICHD, which spends 5% of its budget on this research.

Dr. Barkin commented that many social determinants of health, such as housing and employment, are outside the healthcare system. Therefore, transdisciplinary research on social determinants of health needs different types of funding mechanisms than those typically used for health research. Dr. Zenk agreed that research on social determinants of health requires more creativity and guidance from research communities. ComPASS supports community-driven research on the social determinants of health.

Dr. Tita asked why only 20% of NINR's budget is devoted to women's health. Dr. Zenk replied that NINR can contribute more to women's health research, and a recent RFA on integrated models of care is one step toward this goal.

Dr. Tita requested information on NINR's global health research activities. Dr. Zenk replied that she is discussing ways for NINR to advance global health with the leaders of the Fogarty International Center.

Dr. Miller asked about NINR investments in research on disability care. Dr. Zenk explained that accessibility is a research priority in NINR's strategic plan and offered to provide information on relevant investments to Dr. Miller.

VII. SCIENTIFIC PRESENTATION: FIRST-IN-WOMEN STUDY OF A HUMAN CONTRACEPTIVE ANTIBODY

Andrea Thurman, M.D., professor of obstetrics and gynecology at Eastern Virginia Medical School, described her NICHD-funded research on a new nonhormonal contraceptive.

Although existing nonhormonal contraceptives for women have several advantages, they also have disadvantages. For example, the copper intrauterine device (IUD) has a low failure rate and is cost-effective, but it can cause menorrhagia and dysmenorrhea. Other nonhormonal options (e.g., condoms, diaphragms, tubal ligation, spermicides) are not reversible, have high failure rates, cause vaginal irritation and other side effects, or require laparoscopic surgery.

Through NICHD funding (P50HD096957 PI = Deborah Anderson PhD Boston University) and private funding (ZabBio), Dr. Thurman performed the first-in-woman clinical study of a vaginal film, which contains an anti-sperm monoclonal antibody. This antibody was developed in a plant model by ZabBio and Boston University. The original antibody is from a woman with infertility. Boston University and ZabBio, incorporated this antibody into the ZB-06 film for use as an on-demand vaginal contraceptive. Unlike other recently approved contraceptives, this film could be available without a prescription, is nonhormonal, has at least 97% efficacy, causes minimal irritation, and has a very low cost.

The ultimate biomarker of contraceptive efficacy is pregnancy. But Dr. Thurman did not want to give an untested product to fertile women. Instead, her team used the post-coital test (PCT), originally developed to measure fertility, to assess functional interactions between cervical mucus and sperm with and without the contraceptive product.

The Phase I first-in-women study of ZB-06 enrolled healthy women ages 18 to 50 who were ovulatory, had undergone tubal sterilization, were not taking exogenous hormones, and were heterosexually active. Their male partners had no history of infertility, vasectomy, or sperm dysfunction. Both female and male partners consented to participate in the study.

Participating women were given a luteinizing hormone (LH) test kit and were told how to apply the film and check their urinary LH levels. Study personnel checked the women's cervical mucus at ovulation, when their fertility was at its peak. The women had sexual intercourse with their partner within 24 hours of ovulation, when the cervical mucus is ideal and most receptive to motile sperm. They returned to the clinic two to three hours later for measurement of the maximum number of progressively motile sperm ascending into the ovulatory cervical mucus.

At baseline, with no product present, the benchmark for the PCT is at least five progressively motile sperm per 400 high-powered fields. The benchmark after intercourse during ovulation with the product present is less than five progressively motile sperm per 400 high-powered fields.

The study enrolled 20 couples, but only eight couples completed the study. These eight couples met the baseline benchmark of at least five progressively motile sperm per 400 high-powered fields. After intercourse during ovulation, the average number of progressively motile sperm was less than one. A third PCT cycle without the product showed no remaining antisperm antibody and normal interactions between the cervical mucus and progressively motile sperm.

None of the couples experienced adverse effects related to the product or study procedures. The women reported that the film was easy to insert, although it left some stickiness on their fingers. The film did not affect their lubrication or sexual pleasure, but some women did not like having to insert the film 30 minutes before intercourse. Men did not feel the film, and the product did not affect their sexual enjoyment, although some noted that the film altered amounts of lubrication.

Discussion

Dr. Bianchi asked whether study participants were reimbursed. Dr. Thurman replied that the study was logistically challenging for participants, so they received $75 for each cervical mucus check and $150 for each PCT visit. These women did not need this product, because they had undergone tubal sterilization, but they withstood the study's inconveniences to help provide more contraceptive options to other women and couples.

Dr. Miller asked whether the 30-minute window between application of the contraceptive film and intercourse is realistic for couples. Dr. Thurman explained that some patients thought that the 30-minute interval was too long. For future studies, Dr. Thurman plans to evaluate the film's dissolvability at different time points. Users must be able to insert the product at different times before intercourse if the product is to fit into their lifestyles.

Dr. Neal-Perry asked about the product's side effects and reversibility. Dr. Thurman replied that the product had no product- or procedure-related side effects, and neither men nor women

remembered that the film was in place. The product probably stays in the woman's system for only 24 hours, and its effects are reversible.

Dr. Bianchi asked whether a woman could carry the product in her purse. Dr. Thurman replied that ZabBio has demonstrated that the product is stable at room temperature. She hopes to determine whether women could insert the product before going out on a date, because some women do not want their male partner to know that they have inserted a contraceptive.

VIII. VOICE OF THE PARTICIPANT

Dr. Thurman recorded an interview with Mrs. Tiffany Wright, a participant in the ZB-06 study and an employee in the Department of Obstetrics and Gynecology at Eastern Virginia Medical School. Mrs. Wright reported that she is 40 years old and has two children. She underwent Essure tubal sterilization after the birth of her second child. Mrs. Wright enrolled in the trial because she wanted to be able to recommend more contraceptive options to the women she works with. As a patient care liaison, she desired to learn more about women's health clinical research. Although she has excellent contraception, she wanted to contribute to the development of new contraceptive options for women.

Mrs. Wright had previously used several types of hormonal contraceptives, including patches, pills, rings, and injections. These products affected her menstrual cycles, and she did not like the effects of the additional hormones on her body. Although Mrs. Wright considered a copper IUD, she chose not to use it because of stories of IUD failure. She decided that sterilization was the best option for her.

Dr. Thurman asked what the product's antisperm antibodies meant to Mrs. Wright. Mrs. Wright explained that once she inserted the product, her husband could not feel the product during intercourse, and the product did not affect his pleasure.

Mrs. Wright had to insert the product twice at the screening visit, because the film became very sticky once it was wet. She did not have any trouble using the study product with intercourse during the product use cycle and she thought that insertion of the film would become easier with practice for eventual users in the future. Dr. Thurman explained that study personnel gave participants two films in case they had difficulty with insertion.

A study staff member reminded Mrs. Wright to measure LH in her urine, and Mrs. Wright also created reminders in her mobile phone. She sent in her urinary LH results every morning, and once she received a smiley face (indicating ovulation), she returned to the clinic for a cervical mucus check. Participating in the trial was easy because study personnel worked with her schedule. Mrs. Wright appreciated the opportunity to look at sperm in her cervical mucus under a microscope before and after using the product.

Dr. Thurman noted that the pressure to have intercourse at a pre-determined time made it difficult for some male partners to perform. Mrs. Wright reported that her husband did not have difficulty performing in the study.

When asked what she would tell women about using the product, Mrs. Wright said that she would recommend that they try it. She would suggest spending the 30 minutes between insertion and intercourse on foreplay. She and her husband had no difficulty with this interval, and she was pleased that the product blocks all sperm from the cervical mucus. Mrs. Wright had no vaginal irritation or itching, and the product did not smell.

A benefit of participating in this study was the opportunity to have many questions about women's health answered. Mrs. Wright also appreciated being in a positive environment with other women. She enjoyed participating in the study so much that she is considering enrolling in another clinical study.

Discussion

Dr. Bianchi thanked Mrs. Wright for her altruism, because she was willing to participate in a study that offered her few benefits beyond learning more about her body. This study required a significant investment from both male and female partners.

Dr. Thurman reported that one male partner reported discomfort with oral sex while his partner was using the product. The film dissolves into perhaps a couple of milliliters, so men should not have any problems with it. Study personnel did not instruct male partners to avoid oral sex after their partners had inserted the product.

Dr. Bianchi asked whether the product is contraindicated for women who lack a functioning immune system. Marshall Hoke, M.S., director of regulatory affairs at ZabBio, explained that the product does not have any contraindications that the company is aware of, and some research suggests that the antibody works without complementary immune function. These antibodies are a normal part of the mucosal environment.

IX. STATEMENT OF UNDERSTANDING

Margaret Young, chief grants management officer at NICHD, said that the 2022 Statement of Understanding between NICHD and the NACHHD Council is posted on the Council website and provides a short synopsis of the Council and its membership and structure. Council members voted to approve the statement of understanding.

X. MULTICENTER CLINICAL TRIALS: LEVERAGING NICHD NETWORK INFRASTRUCURE TO ADVANCE RESEARCH AND OUTCOMES FOR WOMEN, CHILDREN, AND PREGNANT AND LACTATING INDIVIDUALS

Robert Tamburro, M.D., M.S., senior advisor for clinical research at NICHD, reported that NICHD formed its first two clinical research networks, the Neonatal Intensive Care Units (now the Neonatal Research Network) and the Maternal-Fetal Medicine Units Network, in 1985. NICHD has since created additional clinical research networks that address other aspects of its mission. This infrastructure has supported hundreds of clinical research projects and led to changes in clinical practice and better outcomes for infants, children, adolescents, pregnant and lactating individuals, and people with disabilities.

In 2016, NIH initiated a series of reforms to enhance clinical trial stewardship and transparency. As part of this effort, NIH asked ICs to develop their own clinical trial FOAs to address their research funding priorities and strategic goals. In response, NICHD reaffirmed its commitment to conducting rigorous multisite clinical trials and established four principles for its network infrastructure for this research:

- Enhance the rigor and reproducibility of clinical trial protocols
- Promote greater availability of multisite clinical trial infrastructure to support trials from a wider range of investigators
- Facilitate data sharing and access to biospecimens to efficiently expand research capacity for all investigators
- Facilitate greater involvement of diverse populations in multisite clinical trials.

NICHD believes that adhering to these principles ensures proper stewardship of public funds, increases accountability, and helps NICHD maintain the public's trust. To operationalize these principles, NICHD issued an RFI to solicit feedback from the public on its vision for supporting multisite clinical trial infrastructure. Common themes identified in the 79 responses were:

- Support multiple models of clinical trial infrastructure
- Sponsor many clinical sites to ensure diversity of enrollment
- Fund core sites with well-trained staff
- Increase the diversity of researchers who have access to network infrastructure
- Train and mentor young investigators
- Enable follow-up beyond the traditional 5-year grant period
- Use a centralized approach that supports network infrastructure

NICHD planned to ask the NACHHD Council, during the concept clearance portion of this meeting, to consider a concept to solicit clinical trial applications that address the four principles in the following ways:

- Enhance study rigor and reproducibility using a new protocol proposal and selection process to increase the transparency and rigor of network study selection processes. For future trials conducted within this network infrastructure, investigators will submit individual applications that will undergo NIH peer review, and NICHD will make funding decisions.
- Promote greater availability of multisite clinical trial infrastructure to support trials from a wider range of investigators by allowing investigators from outside the network to propose studies to be conducted in the network. Investigators from network clinical centers will also be eligible to propose studies via the proposed FOA. Studies will need to align with the purpose, goals, and objectives of the network and NICHD.
- Facilitate data sharing and access to biospecimens by requiring networks to share data and biospecimens in accordance with the NIH Policy for Data Management and Sharing. Study consent forms will be modeled to allow broad sharing and future use of study data. The use common data elements will be a priority for network studies.
- Facilitate greater involvement of diverse populations in multisite clinical trials and continue to increase workforce diversity.

The most significant innovations include giving access to the network infrastructure to investigators from outside the network, using the NIH peer review process for all network

clinical trial applications, and extending network funding cycles to 7 years instead of the traditional 5 years.

NICHD plans to start this initiative with only a few of its clinical trial networks, including some that are undergoing re-competition. The institute will monitor the initiative and make adjustments as needed. NICHD will develop similar RFAs for other networks as it learns from its experiences.

The approach will require a rigorous pre-application process. This process will include a feasibility assessment to determine whether the network can successfully complete the proposed trial. In addition, this assessment will address the trial's relevance to current scientific and societal needs, the network's mission, and NICHD priorities.

This initiative, with the goal to be grossly cost-neutral, holds the potential to expand the breadth and diversity of NICHD's science and investigators, enhance the rigor and transparency of network clinical trials, enable clinical trials to be conducted in the most efficient and cost-effective manner, and foster flexibility to address emerging health crises.

Discussion

Dr. Tita congratulated Dr. Tamburro and the team that developed this concept and asked whether funding decisions could be made within 4 months of the application deadline. Dr. Tamburro replied that NICHD must balance the need for rigorous peer review with the desire to make timely decisions. NICHD is reviewing approaches used by other federal programs to speed up the peer review process.

Dr. Tita asked how the initiative can be cost-neutral when this infrastructure will support studies by investigators outside the network. Dr. Tamburro explained that NICHD will not increase its total investment in multisite clinical trials, and external investigators will submit their applications through a separate FOA.

Dr. Resnick was enthusiastic about this concept, which is very timely. He asked how this centralized infrastructure will interact with other NICHD data management initiatives, such as the NICHD Data and Specimen Hub (DASH). Rebecca Rosen, Ph.D., director of the NICHD Office of Data Science and Sharing, explained that the proposed FOA will require a data coordinator to curate and submit study data to an NIH-designated repository. If, for example, a study collects imaging data that are not suitable for DASH, NICHD will identify an appropriate NIH- or NICHD-designated repository to store the data. The data coordination center will be responsible for data curation and management.

Dr. Bianchi reported that in the past, investigators believed that they owned the biospecimens collected in their studies, but NICHD is complying with NIH policy requiring investigators to share biospecimens and data. Dr. Rosen added that DASH can be expanded to accommodate rapid data-sharing cycles, and investigators will not need to wait until their studies are complete to share their data. Dr. Resnick said that the new initiative provides an opportunity for NICHD to lead a new approach to multisite clinical trial infrastructure.

Dr. Neal-Perry asked how NICHD will let the research community know about this new opportunity. Dr. Tamburro explained that NICHD will publish the proposed FOA in the *NIH Guide to Grants and Contracts,* just as it does for all FOAs.

Dr. Neal-Perry asked whether the initiative will provide opportunities for ESIs. Dr. Tamburro said that some members of the public who responded to the NICHD RFI emphasized the importance of training and mentoring, and investigators will have diverse ages and levels of professional experience. NICHD is enthusiastic about including ESIs in this initiative.

Dr. Rowitch suggested using the initiative goals listed toward the end of Dr. Tamburro's presentation as performance indicators for measuring the initiative's impact. Dr. Tamburro said that NICHD will monitor and reassess the initiative frequently.

Dr. Caggana asked whether clinical trial networks will be required to engage ESIs who are not part of the network but want to use network resources for a clinical trial. Dr. Tamburro explained that NICHD is still determining how to best engage ESIs in the network. Dr. Caggana suggested requiring networks to facilitate connections with external ESIs through research portals or professional societies.

Dr. Jain praised the concept, which offers the best of both worlds by leveraging the resources of networks and centers while inviting innovative applications to bring the results of the best clinical trials to the bedside. He asked whether clinical trials from centers outside the network will have access to network resources and noted that participating in NIH networks is a major recruiting tool for clinical trial experts. Dr. Tamburro agreed that participating in an NICHD or NIH network is prestigious. He believes that being part of this new type of network will be even more prestigious, because it will offer more effective ways to conduct clinical research. NICHD will continue to fund clinical trial network infrastructure, and participating networks will be able to submit applications in response to the proposed FOA.

Dr. Bianchi noted that this concept has been discussed for several years at NICHD. Dr. Tamburro and his team engaged in a major effort to balance the needs of various stakeholders and come up with a solution to many different problems.

Dr. Miller asked about the process to evaluate the feasibility of potential protocols during the pre-approval stage. Dr. Tamburro explained that NICHD is still developing this process, but it is likely to involve the network steering committee, external scientific groups, community engagement boards, and NICHD.

XI. CONCEPT CLEARANCE

The NACHHD Council reviewed the following 10 concepts and voted to approve each one:

- **Multicenter Clinical Trials: Leveraging Network Infrastructure to Advance Research and Outcomes** (Robert Tamburro, M.D., M.S., DER)
- **Coordinating Center for the NICHD Population Dynamics Centers Research Infrastructure Program** (Rosalind King, Ph.D., Population Dynamics Branch)

- **Opioid Exposure and Effects on Placenta Function, Brain Development, and Neurodevelopment Outcomes** (David Weinberg, Ph.D., Pregnancy and Perinatology Branch)
- **Advancing Methods for Safe, Noninvasive, Real-Time Assessment of Placenta Development and Function Across Pregnancy** (David Weinberg, Ph.D., Pregnancy and Perinatology Branch)
- **Maternal Health Research Centers of Excellence** (Nahida Chakhtoura, M.D., Pregnancy and Perinatology Branch)
- **NICHD Laboratory of Developmental Biology** (Ravi Ravindranath, D.V.M., Ph.D., Fertility and Infertility Branch)
- **Reproductive Scientist Development Program** (Esther Eisenberg, M.D., M.P.H., Fertility and Infertility Branch)
- **Small Research Grants for Analyses of Gabriella Miller Kids First Pediatric Research Data** (James Coulombe, Ph.D., Developmental Biology and Structural Variation Branch)
- **Biological Testing Facility** (Dan Johnston, Ph.D., Contraception Research Branch)
- **Chemical Screening and Optimization Facility** (Christopher Lindsey, Ph.D., Contraception Research Branch)

Multicenter Clinical Trials: Leveraging Network Infrastructure to Advance Research and Outcomes

Dr. Tita supported this concept but suggested that NICHD try to shorten the pre-application and peer review processes. Dr. Barkin recommended that NICHD consider the comments submitted in the Zoom chat box during the earlier discussion of this concept.

Coordinating Center for the NICHD Population Dynamics Centers Research Infrastructure Program

Dr. Wong asked whether NICHD had a coordinating center for this program in the past. Dr. King explained that NICHD released the first RFA for this coordinating center in 2017, and this initiative must be cleared every five years.

Dr. Wong asked whether the coordinating center must be an academic institution. Dr. King said that any institution with the appropriate capacity, environment, and investigators is eligible to apply for this award. Dr. Wong explained that experts in new technologies are most likely to come from outside academia, and she encouraged NICHD to be open to such applicants. Dr. King agreed that new technologies are more likely to be found outside academia.

Opioid Exposure and Effects on Placenta Function, Brain Development, and Neurodevelopment Outcomes

Dr. Barkin asked about the connection between this concept and the BRAIN Initiative. Dr. Weinberg explained that this initiative synergizes with the BRAIN Initiative and is part of an aggressive NIH attempt to address the opioid crisis. Dr. Bianchi added that this initiative is linked to the NIH HEAL Initiative Healthy Brain and Child Development Study and will focus on the effects of opioids on the placenta and whether they result in abnormalities in placenta development that affect neurodevelopment. Many NIH HEAL Initiative program staff members

are also involved, so some indirect connections will be made. Dr. Barkin emphasized the importance of cross-linking initiatives where possible to maximize their collective output.

Dr. Rowitch expressed support for this concept, especially because of concerns about trends in the fentanyl crisis. Addressing this issue is critical.

Maternal Health Research Centers of Excellence

Dr. Tita said that this concept offers a fantastic opportunity and asked how these centers of excellence will work with the Maternal-Fetal Medicine Units Network. Dr. Chakhtoura replied that she hoped that the centers of excellence will collaborate with the Maternal-Fetal Medicine Units Network.

Dr. Bianchi reported that NICHD has scheduled a tribal consultation about this concept, because rates of severe maternal morbidity and mortality are almost as high among American Indian and Alaska Native (AI/AN) women as among African American and Black women. The Maternal-Fetal Medicine Units Network does not necessarily include AI/AN women. Dr. Bianchi added that NICHD will coordinate and integrate the resources of different networks whenever possible.

Dr. Barkin asked about the point in the life course at which maternal health begins. Dr. Chakhtoura explained that the initiative focuses on the period starting at pregnancy and ending 1 year after delivery, when risk of maternal morbidity and mortality is highest. Other NICHD initiatives use a life course perspective.

Dr. Barkin asked whether the community-engaged approach will include partners that can provide housing, food, and other needed services. Dr. Chakhtoura replied that community members will be true partners with researchers from the start of the centers of excellence, and NICHD is considering partnerships with other agencies within HHS. Dr. Barkin strongly encouraged NICHD to form such partnerships.

NICHD Laboratory of Developmental Biology

Dr. Matzuk asked how often this laboratory requires NACHHD Council approval. Dr. Ravindranath replied that approval is required every five years.

Dr. Wynshaw-Boris asked whether the laboratory will identify a backup repository, because redundancy is useful in the event of an emergency. Dr. Ravindranath said that the laboratory uses only one repository. Dr. Wynshaw-Boris encouraged NICHD to ensure redundancy.

Reproductive Scientist Development Program

Dr. Matzuk has trained two scientists who completed this program, and both are conducting research and have obtained NIH grants. He was pleased that the initiative is being renewed.

Small Research Grants for Analyses of Gabriella Miller Kids First Pediatric Research Program Data

Dr. Wynshaw-Boris supported this concept because very few genome sequencing projects around the world involve children, and the Gabriella Miller Kids First Pediatric Research

Program is unique in its focus on children with birth defects. If NICHD does not support this initiative, this research will not be done.

Chemical Screening and Optimization Facility

Dr. Barkin asked about the difference between this initiative and the proposed Biological Testing Facility. Dr. Lindsey explained that the Biological Testing Facility will conduct *in vivo* studies, whereas the Chemical Screening and Optimization Facility will conduct chemical optimization studies.

XII. ADJOURNMENT

Dr. Twombly closed the open session on Day 2 at 1:44 p.m.

XIII. CLOSED SESSION

This portion of the meeting was closed to the public in accordance with the provisions set forth in Section 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

XIV. 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 553 HD-primary applications requesting $207,095,359 in direct costs and $288,297,463 in total costs.

XV. ADJOURNMENT

There being no further business, the meeting adjourned at 5:00 p.m. on Wednesday, June 15, 2022. The next meeting, scheduled for September 13, 2022, will take place at 6710B Rockledge Drive in Bethesda, Maryland.

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

Diana W. Bianchi, M.D. Date

[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.

Chair, National Advisory Child Health and Human Development Council
Director, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

_____ _____

Dennis Twombly, Ph.D. Date
Executive Secretary, National Advisory Child Health and Human Development Council
Deputy Director, Office of Extramural Policy, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development