Eunice Kennedy Shriver National Institute of Child Health and Human Development

NATIONAL ADVISORY CHILD HEALTH AND HUMAN DEVELOPMENT COUNCIL

MEETING SUMMARY

September 6–7, 2023

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

NATIONAL INSTITUTES OF HEALTH (NIH)

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

NATIONAL ADVISORY CHILD HEALTH AND HUMAN DEVELOPMENT (NACHHD) COUNCIL MEETING SUMMARY
September 6–7, 2023

The NACHHD Council convened its 183rd meeting at 12:00 p.m. ET on Wednesday, September 6, 2023. The meeting was open to the public and held at 6710B Rockledge Drive in rooms 1425–1427 from 12:00 p.m. to 5:00 p.m. The Council reconvened on Thursday, September 7, 2023, at 9:00 a.m. ET, for a session that was closed to the public. 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, sessions for the review, discussion, and evaluation of grant applications and related information are closed to the public. NICHD Director Diana W. Bianchi, M.D., presided.

Council Members Present[1]
Diana W. Bianchi, M.D. (Chair)
Anna Aizer, Ph.D. (pending)
Shari L. Barkin, M.D.
Christina M. Bucci-Rechtweg, M.D.
John P. Coughlin, M.D. (virtual)
Kathleen B. Egan, Ph.D.
Ethylin Wang Jabs, M.D. (virtual, pending)
Lucky Jain, M.D.
Catherine E. Lang, Ph.D.
Missy D. Lavender, M.B.A.
Yvonne Maldonado, M.D.
Genevieve S. Neal-Perry, M.D., Ph.D.
Adam C. Resnick, Ph.D.
David H. Rowitch, M.D., Ph.D.
Ignatia Barbara Van den Veyver, M.D. (pending)

Council Members Absent
Damien Fair, Ph.D.

***Ex Officio* Members**
Patricia Dorn, Ph.D.

Health Resources and Services Administration (HRSA)
Rui Li, Ph.D.

National Advisory Board on Medical Rehabilitation Research Council Liaison
José L. Contreras-Vidal, Ph.D.

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

Executive Secretary
Rebekah Rasooly, Ph.D.

[1]Council 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.

In each section below, the number in parentheses following each heading refers to the time stamp on the NIH VideoCast; go to that point in the recording to listen to the full presentation.

I. CALL TO ORDER AND INTRODUCTORY REMARKS (0:03)

Dr. Bianchi opened the meeting and welcomed the members of the NACHHD Council and all in-person attendees. She asked new Council members to briefly introduce themselves.

Dr. Aizer is the Maurice R. Greenberg Professor of Economics at Brown University. She is a labor and health economist with interests in education and child health and well-being.

Dr. Van den Veyver is a professor of obstetrics and gynecology, maternal-fetal medicine, and molecular and human genetics at Baylor College of Medicine and a clinician and researcher at Texas Children's Hospital. She is the director of both clinical prenatal and reproductive genetics and the Clinical Translational Research Certificate of Added Qualification program at Baylor College of Medicine.

Dr. Jabs is vice chair and professor of genetics and genomic sciences, professor of pediatrics, and professor of developmental and regenerative biology at the Icahn School of Medicine at Mount Sinai in New York City. Her research focuses on understanding the molecular basis of human malformation disorders, especially the craniofacial system. She is currently in the process of moving her clinical and research work to the Mayo Clinic.

Dr. Li (introduced at 1:44:19) was a senior economist at the Centers for Disease Control and Prevention for 16 years before taking a director position at HRSA. Her expertise is in using rigorous methodology to evaluate policy impact.

Review of Confidentiality and Conflicts of Interest (5:00)

Dr. Rasooly reminded NACHHD Council members that they 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 received and signed the required conflict-of-interest certification forms. Dr. Rasooly also reminded Council members that they were required to recuse themselves and leave the 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 any 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. Furthermore, during closed sessions, Council members must turn off cloud-based voice services (e.g., Alexa, Siri) that are capable of capturing confidential information.

Council Minutes (6:16)

Dr. Barkin made a motion to approve the June 6–7, 2023, NACHHD Council meeting minutes as written. Dr. Lang seconded the motion. The minutes were approved by a unanimous vote of the Council members.

Future Meeting Dates (7:06)

Dr. Rasooly announced that the future Council meeting dates and formats are January 22–23, 2024 (virtual); June 3–4, 2024 (NIH Bethesda Campus, Building 31); September 4–5, 2024

(6710B Rockledge Drive, Bethesda, Maryland 20892); January 13–14, 2025 (virtual); June 9–10, 2025 (NIH Bethesda Campus, Building 31); and September 8–9, 2025 (6710B Rockledge Drive).

II. NICHD DIRECTOR'S REPORT (7:51)

In her report, Dr. Bianchi described the fiscal year (FY) 2024 budget, reviewed NICHD's strategic planning goals, shared the NIH Clinical Center's draft pediatric research strategic plan, provided updates on the NIH-wide IMPROVE (Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone) initiative, which supports research focused on reducing preventable causes of maternal deaths and improving health for women before, during, and after delivery, then gave staff updates.

FY 2024 Budget Update (10:34)

The FY 2024 budget that begins on October 1, 2023, has not yet been approved by Congress. The House and Senate appropriations bills range from $43 billion to $49.2 billion for NIH, respectively, and $1.75 billion to $1.76 billion for NICHD, respectively. The Senate bill's additional $10 million for NICHD is a set-aside for the IMPROVE initiative. After the House and Senate vote on their respective bills, the differences between the House and Senate bills must be reconciled in the final appropriations legislation. An approved budget or a continuing resolution is needed by September 30.

NICHD Strategic Planning (12:20)

NICHD's strategic plan, which focuses on research, stewardship, management, and accountability, was last updated in 2020. As the institute gears up to write its 2025 strategic plan, it has been documenting and tracking its activities and achievements. The 2025 plan will be informed by data analysis of achievements on current activities and accomplishments. Leadership will seek NICHD staff input on progress and potential new scientific opportunities, then solicit external feedback from the scientific and advocacy communities and the public. Dr. Bianchi reported progress on 4 of the strategic plan's 10 aspirational goals.

Goal: Accelerate efforts to definitively diagnose, prevent, and treat endometriosis, a disease that affects an estimated 10% of women in the United States and results in chronic pain, infertility, and a higher risk of some cancers.

Although 1 in 10 women suffers from endometriosis, in 2022 there were no proven, noninvasive, widely available diagnostic tests. A $12.92 million increase in NICHD funding from 2020 to 2022 led to an increase in research projects from 32 to 52. These projects have led to discoveries around genetic factors underlying comorbidity, a drug that reduces endometriosis progression and improves fertility in mice, a promising non-surgical treatment (mouse study), and the potential of using broad AP-1 inhibitors to treat endometriosis. NICHD also plans to host a screening of the PBS series "Below the Belt: The Last Health Taboo," chronicling the experiences of people living with and treating endometriosis.

Goal: Advance the ability to regenerate human limbs by using emerging technologies to activate the body's own growth pathways and processes.

There are 2.1 million Americans living with limb loss, which carries an average lifetime direct medical cost of $878,926 after amputation. A $2.45 million increase in NICHD funding from 2020 to 2022 led to an increase in the number of research projects, from 41 to 44. These projects have led to preclinical discoveries in gene expression patterns and cellular growth and regeneration.

Goal: Enhance the survival and healthy development of preterm infants by exploring the role of environmental factors, such as feeding methods and nutritional support, human touch, and music and lighting.

Approximately 10.5% of U.S. births are premature, and 9% require admission to a neonatal intensive care unit (NICU). From 2020 through 2022, funding remained flat at approximately $163 million, and the number of funded projects fell from 362 to 344. However, significant findings have recently been published in the areas of preterm infant feeding, NICU weight gain, and improving survival while reducing complications.

Goal: Facilitate application of precision medicine approaches in children by capitalizing on advances in genomics and by updating normative data on the growth and development of a diverse population of children, including those with intellectual, developmental, and physical disabilities.

It is now estimated that genetic sequencing is used to diagnose 44% to 50% of rare disorders, including intellectual disabilities, hearing disorders, or vision disorders in children. From 2020 through 2022, funding for pediatric precision medicine stayed at approximately $220 million, and the number of funded projects decreased from 508 to 495. Recent promising findings include a study that identified a genetic influence on dexmedetomidine and fentanyl clearance in children, a way to use electronic health record (EHR) data to identify which children need to be tested for a rare genetic condition, and an analysis that revealed that genetic testing of siblings of newborns with cancer genes could reduce rare pediatric cancer deaths.

NIH Clinical Center Pediatric Research Strategic Plan (22:06)

The Clinical Center Pediatric Research Strategic Plan Working Group's charge was to identify the most impactful scientific areas of pediatric research in which NIH can play a major role to substantially improve child health. The working group is now using that horizon-scanning exercise to perform long-term, strategic planning for intramural, NIH-wide clinical pediatric research (to occur over the next decade and beyond).

Along with identifying the need for cross-cutting infrastructure enhancements to increase efficiency, the working group outlined the following scientific priorities for NIH Clinical Center pediatric research:

- Natural history studies to support research on the continuum from diagnosis to treatment
- Gene therapy, chimeric antigen receptor T-cell therapy, and other cell therapy studies
- Precision medicine pharmacological interventions in rare, non-malignant diseases
- Pharmacokinetic and pharmacodynamic studies to improve medication use and dosing
- Metabolic phenotyping studies across a variety of pediatric conditions
- The development of a cohort of all pediatric patients at the Clinical Center to measure physical and mental health and disease across disorders

- The development of a deeply phenotyped pediatric cohort to establish a standard set of control samples
- Increasingly supported research studies in pregnant and lactating people

Next steps include gaining approval from the Clinical Center's Governing Board followed by implementation planning.

NIH IMPROVE Initiative (27:00)

The maternal health crisis in the United States is worsening, with more than 2.2 million women living in maternity care deserts (across 1,119 counties). Since 2020, there has been a 5% increase in counties with less access to maternity care. For example, the day of the meeting, the *New York Times* reported a dire maternity care situation in Idaho, where five maternal-fetal medicine specialists have recently left the state or retired. Specialty care is not available for many high-risk pregnant people. The majority (65%) of all pregnancy-related deaths occur between 1 and 365 days after the end of the pregnancy.

To confront this public health crisis, the congressionally supported, NIH-wide IMPROVE initiative is funding research focused on reducing preventable causes of maternal deaths and improving health for women before, during, and after delivery. The six components of the IMPROVE initiative are research dissemination and implementation, the Connecting the Community for Maternal Health Challenge, the RADx® Tech for Maternal Health Challenge, Connectathon, the Community Implementation Program (CIP), and the Maternal Health Research Centers of Excellence initiative.

The overall goals of the IMPROVE initiative are to:
- Reduce preventable causes of maternal morbidity and mortality.
- Address disparities in maternal health outcomes.
- Expand implementation of evidence-based maternal health care practices before, during, and after pregnancy.
- Build research capacity in community-based organizations.
- Promote access to maternal health care with innovative technology.
- Enable real-world research with EHR standards.

Connecting the Community for Maternal Health Challenge

This IMPROVE component encourages community-based organizations to compete for funding to develop research infrastructure and capabilities. With a total prize of about $3 million across multiple phases, along with non-monetary incentives (e.g., mentoring, proposal writing assistance), the nine winners of the proposal phase were announced in June. For the research phase, the winning organizations have 1 year to implement project plans, conduct proposed research, and report results. The winners of the final phases will be announced in September 2024.

Maternal Health Research Centers of Excellence

The goal for this component of the initiative is to reduce maternal morbidity and decrease preventable mortality by partnering with affected communities and incorporating their needs and

perspectives into research performed by the Maternal Health Research Centers of Excellence. The key benefits of this program are community partnerships from the inception of each research project and robust training programs to grow a diverse workforce. Projects were awarded in August 2023, and many include robust partnerships. There are 10 centers and two coordination hubs. The projects cover a broad range of topics, medical conditions, approaches, populations, and social determinants of health.

NIH and NICHD Staff Updates (36:48)

Jeanne Marrazzo, M.D., M.P.H., has been named director of the National Institute of Allergy and Infectious Diseases (NIAID). She comes to NIAID from the Division of Infectious Diseases at the University of Alabama at Birmingham. Her research focuses include the human microbiome (specifically related to female reproductive tract infections and hormonal contraception), use of biomedical interventions to prevent HIV infection, and the pathogenesis and management of bacterial vaginosis.

Jane Simoni, Ph.D., is NIH's new associate director for behavioral and social sciences research. She was formerly a professor and the director of clinical training in the Department of Psychology at the University of Washington (UW), the founding director of UW's Behavioral Research Center for HIV, and a co-director of the UW/Fred Hutchinson Center for AIDS Research.

Karina Walters, Ph.D., M.S.W., is the new director of the NIH Tribal Health Research Office. She previously served as a tenured full professor, the Katherine Hall Chambers Scholar, and associate dean for research at the UW School of Social Work.

On September 30, after 7 years in this role, Patricia Flatley Brennan, RN, Ph.D., will retire as the director of the National Library of Medicine (NLM). Dr. Brennan was the first nurse, industrial engineer, and woman to lead NLM. She directed the modernization and expansion of mission-critical biomedical and information systems (e.g., PubMed, PubMed Central, ClinicalTrials.gov, GenBank). Dr. Brennan made NLM's Sequence Read Archive the world's largest publicly available repository for high-throughput sequencing data.

Stephen Sherry, Ph.D., who is currently the director of NLM's National Center for Biotechnology Information and NLM Associate Director for Scientific Data Resources, will become acting director of NLM.

Catherine Gordon, M.D., was appointed as the NICHD clinical director with a starting date of September 3. She came to NICHD from Baylor College of Medicine, where she served as professor and chair of pediatrics and conducted research in adolescent medicine and pediatric endocrinology. She also previously served on the NACHHD Council.

Laverne Mensah, M.D., who formerly served as the NICHD acting clinical director, will return to her prior position as deputy clinical director.

Joseph Gindhart, Ph.D., is the new deputy director of the NICHD Division of Extramural Activities and the director of the NICHD Office of Extramural Policy. He was formerly the chief

of the Cell Biology Branch in the Division of Genetics and Molecular, Cellular, and Developmental Biology at the National Institute of General Medical Sciences (NIGMS). Before joining NIH, Dr. Gindhart taught genetics, cell biology, and bioinformatics at the University of Massachusetts Boston and the University of Richmond.

Joanna Kubler-Kielb, Ph.D., has been named chief of NICHD's Scientific Review Branch. She joined NICHD as a scientific review officer in 2013 and was formerly a staff scientist in NICHD's Division of Intramural Research (DIR) Program in Developmental and Molecular Immunity, where her research focused on structural design and immunological properties of pediatric antimicrobial subunit vaccines.

Juanita Chinn, Ph.D., was elected by her peers to the board of directors of the Population Association of America. She is a program director in NICHD's Population Dynamics Branch.

Koji Yoshinaga, Ph.D., who retired in 2018 after a 40-year career at NICHD in the Fertility and Infertility Branch (and its predecessor branches), recently passed away.

NICHD currently has job openings for several DIR and Division of Extramural Research (DER) staff positions, including two branch chiefs.

Discussion (44:00)

Regarding the congressional budgeting process, Dr. Jain asked what the final allocation for NICHD might be when reconciling the differences between the House and Senate bills. Dr. Bianchi said that she had no way to know how it might turn out.

Dr. Jain asked whether the IMPROVE Maternal Health Research Centers of Excellence interacted with NICHD's Maternal-Fetal Medicine Units (MFMUs). Dr. Bianchi said that there is no formal mechanism for the centers to collaborate, but they communicate informally. The MFMUs are part of NICHD's overall investment in maternal health, so data sharing between the centers will be important. RADx Tech for Maternal Health may create technology to improve the sharing and implementation of data from each program.

Dr. Barkin asked how data would be harmonized between the Maternal Health Research Centers of Excellence. Dr. Bianchi said that data harmonization was discussed at the centers of excellence kickoff meeting. Organic networking can lead to collaborative funding partnerships in the future. The intention is to make the whole more valuable than the sum of its parts.

Regarding the Clinical Center Pediatric Research Strategic Plan, Dr. Resnick suggested that NICHD take steps to prevent the intramural data that are collected (e.g., cohort development, natural history progression) from being siloed from its extramural framework. Dr. Bianchi said that data sharing in general is front and center for extramural activities. DIR is currently implementing data sharing requirements. Dr. Resnick said that the Office of Data Science and Sharing has tremendous thought leadership, so there is a great opportunity there. Dr. Bianchi said that the NIH Clinical Center is also in the process of investing in a new EHR system.

III. ANNUAL DIR REPORT (51:00)

Chris J. McBain, Ph.D., the scientific director of NICHD's DIR, provided a brief overview of the intramural program, along with updates on its budget and personnel. He then described DIR's competitive funding opportunities and updates from its Office of Education.

DIR Overview (52:08)

NICHD's DIR has eight divisions that house basic, translational, clinical, and epidemiological research laboratories:

- Developmental Biology
- Translational Medicine
- Molecular and Cellular Biology
- Neurosciences and Cellular and Structural Biology
- Basic and Translational Biophysics
- Translational Imaging and Genomic Integrity
- Obstetrics and Maternal-Fetal Medicine
- Population Health Research (DiPHR)

DIR employs about 830 people, including 70 principal investigators (PIs), 62 staff scientists, and 272 trainees. The basic and clinical programs are divided into 12 scientifically based affinity groups. The three branches and one program within DiPHR include epidemiology, biostatistics and bioinformatics, social and behavioral sciences, and contraceptive development. There are currently 69 clinical protocols and five accredited medical training programs within DIR.

DIR has a two-tiered structure, with investigators assembled into eight geographic locations and 12 scientific affinity groups (which foster communication around a scientific area or theme). The administrative organization of functional groups is loosely based around geographic buildings. Some of the affinity groups are large, and others are quite small.

Budget and Personnel Updates (56:04)

The DIR, including DiPHR, currently receives 13% of the NICHD budget, or about $225 million.

DIR trainees include postdoctoral, postbaccalaureate, and graduate students; clinical fellows; and summer interns. More than half of them are postdoctoral researchers. In 2023, the summer internship program provided research opportunities for 61 new interns, including in-person training for summer students for the first time since before the COVID-19 pandemic.

The following staff changes were announced over the past year:

- Maria Dufau Catt, M.D., Ph.D., a senior investigator and head of the Section on Molecular Endocrinology, retired on November 30, 2022.
- On December 3, 2022, Shyamal D. Peddada, Ph.D., the branch chief and a senior investigator in the Biostatistics and Bioinformatics Branch of DiPHR, moved to the National Institute of Environmental Health Sciences. Recruitment for a new branch chief is underway.

- Joan Marini, M.D., Ph.D., a senior investigator and head of the Section on Heritable Disorders of Bone and Extracellular Matrix, retired on December 31, 2022, and was appointed Scientist Emeritus on May 3, 2023.
- Judith Kassis, Ph.D., a senior investigator and head of the Section on Gene Expression, retired on February 28, 2023. She will also be nominated for Emeritus status.
- James Morton, Ph.D., a tenure-track investigator in the Biostatistics and Bioinformatics Branch of DiPHR, departed on April 16, 2023, to start a consulting firm.
- James L. Mills, M.D., M.S., a senior investigator in the Epidemiology Branch of DiPHR, retired on April 30, 2023.
- R. Douglas Fields, Ph.D., a senior investigator and head of the Section on Nervous System Development and Plasticity, retired on May 31, 2023. He was awarded a 2023 Mensa Foundation Prize in recognition of his research on myelin plasticity.
- Catherine Gordon, M.D., was hired as NICHD's clinical director and began this role on September 3, 2023. She is a researcher, adolescent medicine specialist, and pediatric endocrinologist with a research focus on adolescent bone health and reproductive endocrinology. Dr. Gordon previously served on the NACHHD Council.
- Leah Rosin, Ph.D., was recruited as the NIH Stadtman Investigator. She will join NICHD to establish the Unit on Chromosome Dynamics in fall 2023. Dr. Rosin studies how chromosome homologs pair and unpair in meiosis, a process essential for accurate chromosome segregation and development of healthy germ cells. She is an expert in the powerful DNA FISH (fluorescence in situ hybridization) technology oligopaints, which have allowed her to visualize whole chromosomes in multiple species. She plans to use oligopaints as a diagnostic tool to detect chromosomal abnormalities in human developmental disorders.
- NICHD is recruiting a clinical tenure-track investigator to establish an independent translational research program integrating both basic and clinical research. The candidate's clinical and basic science/translational research plans should be aligned with NICHD's strategic plan. Applications will be reviewed on a continuous basis after September 15, 2023. Interviews of qualified applicants will begin in October 2023, and applications will be accepted until the position is filled.

The following investigators received honors and awards during the past year:

- Juan Bonifacino, Ph.D., an NIH distinguished investigator and head of the Section on Intracellular Protein Trafficking, received the American Society for Cell Biology's Keith R. Porter Lecture Award.
- Yun-Bo Shi, Ph.D., a senior investigator and head of the Section on Molecular Morphogenesis, received the American Thyroid Association's Sidney H. Ingbar Distinguished Lectureship Award.
- Sarah E. Sheppard, M.D., M.S., Ph.D., an investigator and head of the Unit on Vascular Malformations, received John M. Opitz Young Investigator Award from the *American Journal of Medical Genetics.*
- Karel Pacak, D.Sc., M.D., Ph.D., a senior investigator and head of the Section on Medical Neuroendocrinology, received the American Association of Clinical Endocrinology's Frontiers in Science and Distinction in Endocrinology Award and the Outstanding Clinical Investigator Award from the Endocrine Society.

- Rena D'Souza, D.D.S., M.S., Ph.D., chief of the Section on Molecules and Therapies for Craniofacial and Dental Disorders at NICHD and Director of the National Institute of Dental and Craniofacial Research, received the Excellence in Research Award from the Edward B. Shils Entrepreneurial Fund.

Competitive Funding Opportunities (1:04:34)

NICHD recognizes the importance of creating opportunities for trainees and staff to compete for funding, so it has launched the following initiatives.

NICHD Early Career Awards

This internal funding opportunity is aimed at promoting the research careers of early-stage intramural researchers in the basic, clinical, and translational sciences. Now in its third cycle, early career awards were launched in FY 2021 as an NICHD Office of the Director (OD), Office of the Scientific Director (OSD), and Office of Education initiative. The program is modeled after Tufts University School of Medicine's Zucker Grant Program. It is open to NICHD assistant clinical investigators, postdoctoral fellows, research fellows, and clinical fellows, regardless of sex or gender. Individual awards of up to $25,000 are made for outstanding, original research proposals to support 1-year research projects. Up to $10,000 can be awarded individually to applications for proposed scientific meeting participation or training that supports scientific or professional development. In FY 2023, NICHD received 38 applications and provided 23 awards for a total of $490,543.

NICHD Scientific Director Awards

Pursuant to a recommendation in a 2013 Blue Ribbon Panel report to support new research ideas, NICHD created Scientific Director Awards to encourage competitive research opportunities with a collaborative focus among investigators across NICHD and NIH to support new research ideas. The program uses a modified application that is based on an R21 and an expedited administrative review process with the support of NICHD's DER and a panel of NIH extramural reviewers. The program began in FY 2014–2015 with $3 million. In FY 2016–2017, 8 of 25 applications were funded with $2 million. In FY 2018–2019, 12 of 26 applications were funded with $3.2 million. The program was reinstated in FY 2023–2024, when 9 out of 14 applications were funded with $3.9 million. These awards have created a lot of excitement throughout DIR.

Office of Education Updates (1:08:55)

The NICHD Office of Education is led by Erin Walsh, Ph.D. It develops activities, programs, and professional development opportunities (e.g., public speaking, teaching, grantsmanship, publishing, interviewing, networking) for career advancement. The office's key activities include the following:

- An annual postbaccalaureate seminar series on career exploration, professional development, and graduate or medical school application preparation
- A K99 grant-writing course
- Ad hoc industry job consulting sessions
- An industry careers webinar series
- The Three-minute Talks (TmT) science communication competition
- One-day grant-writing workshops

- A webinar series on the academic job application and interview process
- NICHD intramural research fellowships
- Launching an individual development plan and annual progress report system for NICHD postbaccalaureate fellows
- The administration and tracking of exit surveys

NICHD Intramural Research Fellowships

Now in its seventh application cycle, NICHD Intramural Research Fellowships provide a grant-writing opportunity for postdoctoral and clinical fellows in their second or third training year. The award of $25,000 for 1 year can be used for equipment, supplies, travel, training, or stipend support. Applications are reviewed by a committee of NICHD investigators, postdoctoral grantees, and tenure-track alumni. The review and scoring process mirrors study section procedures and the NIH extramural F-series scoring system. In 2023, more than 65% of the applications scored in the outstanding or excellent range (within the NIH fundable range), and five awards were given.

TmT Science Communication Training and Awards Program

The 2023 TmT competition included fellows from 11 NIH Institutes and Centers (ICs). A postdoctoral fellow from NICHD, Jong Park, Ph.D. (Weinstein lab), placed first overall. TmT challenges presenters to convey the excitement and significance of their research projects in 3 minutes or less using only one slide. NICHD initiated the TmT program, but it quickly grew to include a large number of ICs.

Funding Opportunities: Recent Fellow Successes

NICHD encourages its research fellows to pursue external funding sources. In 2023, the fellows were successful in securing the following opportunities:

- NIGMS Postdoctoral Research Associate Training Fellowship (two NICHD awardees)
- NIH K99/R00 Pathway to Independence Award (four new NICHD awardees who also receive a DIR incentive award adding $20,000 for a consumables budget and a postbaccalaureate slot for the K99 phase)
- NIH Center on Compulsive Behaviors (CCB) Seed Grant (one NICHD awardee)
- NIH CCB Postdoctoral Fellowship (four NICHD renewals)
- Brain & Behavior Research Foundation Young Investigator Grant (one NICHD awardee, 2-year award)
- NIH Fellows Award for Research Excellence (FARE), a $1,500 travel grant (11 NICHD awardees)
- NIH Intramural Postbaccalaureate Poster Day Awards (16 NICHD awardees scored in the top 20% in judged presentations)

Graduate Partnerships Program (GPP)

The NIH Office of Intramural Training & Education established the GPP as a collaborative program in which Ph.D. students could complete all or part of their graduate research at NIH in the Intramural Research Program. The degree is conferred by the student's attending university, and the student must complete all academic components required by their extramural graduate program. The GPP has historically provided positive mentoring experiences, but administrative

costs and logistical support limited recruitment. To encourage recruitment of graduate students to complete their research training in the NICHD DIR, two new funding paths were created in FY 2023. One path provides central funding of tuition and fees for all DIR graduate students, and another path provides full central coverage of fees, tuition, stipend, and health insurance for up to four DIR graduate students at a time, including two students in FY 2023.

Summer Internship Programs and Social Events

In 2023, after a break from its in-person training during the pandemic, NICHD welcomed 61 students back to the summer internship program (6 high school, 48 undergraduate, 3 graduate, and 4 medical students). Three NICHD PIs also continued to provide a successful virtual summer internship program for 15 undergraduate students. The virtual program is especially important for students who cannot travel to or live in Bethesda. The PIs received a large number of applications for this program, so it will hopefully be expanded over the next few years. Additional social events over the summer invigorated the laboratory teams.

DIR Diversity Initiatives (1:23:56)

DIR diversity initiatives bolster the DIR's commitment to recruit, train, support, and sustain a diverse group of talented young scientists, including those from groups traditionally underrepresented in science. Dr. McBain highlighted two programs: one for postbaccalaureate students and one for postdoctoral students.

NICHD Developing Talent Scholars Program

Three postbaccalaureate scholars were selected for FY 2023, including one returning scholar. The alumni group includes about 30 scholars, many of whom are currently in professional school, M.D., and Ph.D. programs.

Fellows Recruitment Incentive Award

One postdoctoral student was selected for FY 2023, bringing the total to six currently funded trainees since FY 2017.

Howard University Partnership (1:24:43)

NICHD continues to partner with Howard University to provide secondary mentors for College of Arts and Sciences biology honor students (five new sophomore students in spring 2023, first cohort completed honors theses and graduated in May 2023); clerkship research mentors for the College of Medicine OB/GYN students and residents (mentor-mentee matching in progress for FY 2023); and residency research mentors and lecturers for Howard University Hospital OB/GYN (one mentor match and two guest lectures in spring 2023).

Discussion (1:26:00)

Dr. Maldonado said that it was remarkable to see the list of trainees at all levels. She asked whether there were opportunities for the virtual trainees to travel to Bethesda to present a poster. Dr. McBain said that some of the 15 virtual summer interns were able to present a poster in person this summer, but he would like to expand that travel capacity to more students in the future.

Dr. Neal-Perry asked for more details on the grade levels of the summer interns. Dr. McBain said that the vast majority are undergraduate students, but it is open to high school students who are at least 18 years old. Dr. Neal-Perry suggested opening the program to younger students, especially those from diverse backgrounds, because they might lose interest in science earlier in the pipeline. Dr. McBain said that NIH sets the parameters for the summer internship program, but NICHD was investigating new K–12 educational opportunities (e.g., science fairs). Dr. Neal-Perry suggested providing opportunities for current NICHD trainees to present their work at their elementary and high schools.

Dr. Miller asked whether the Office of Education grant training workshops provided information on how to apply for non-NIH grants. Dr. McBain said that most of the training is currently focused on obtaining K99 grants, National Research Service Award grants, and small foundation awards, but the DIR website contains a list of more than 80 different types of grants for which fellows can apply. The general focus of the training is on how to write the grant application narrative. Dr. Miller added that writing for NIH is quite different from writing for the Department of Defense, Veteran's Affairs, or small foundations.

Dr. Contreras-Vidal suggested inviting K–12 instructors to NIH to learn about the training opportunities and share them with their students. He said that several teachers visited his institution over the summer and that the response was phenomenal.

Dr. Contreras-Vidal asked whether DIR planned to track its trainees over time. Dr. McBain said yes and noted that Dr. Walsh brings trainees back to serve on panels twice each year to show "the face of success."

Beyond intramural training, Dr. Jabs asked whether NICHD planned to provide similar (or different) opportunities for extramural training. She also asked whether intramural applicants were different from extramural applicants and whether the outcomes were different for intramural and extramural trainees. Dr. McBain said that his office was sensitive to the falling number of postdoctoral fellows looking for positions in both intramural and extramural settings (e.g., there were 40 more postdoctoral fellows before the COVID-19 pandemic). He does not see a difference in opportunities between intramural and extramural training. Intramural trainees do not usually have opportunities within NIH for longer than 5 years, so they must be prepared to enter the extramural community.

Dr. Jain said that it was wonderful to see all the effort being put into the pipeline to develop young investigators. He asked how productivity was tracked for DIR PIs. Dr. McBain said that extramural productivity metrics were not used to measure the success of intramural researchers, but each intramural PI undergoes a review every 4 years. In that review, the parameters that are examined include past 4-year productivity (quality of science), future 4-year program aims, mentoring skills/mentee success, institute and NIH-wide contributions, and service.

Regarding the virtual intern data science training opportunity, Dr. Resnick asked whether there was an opportunity for additional partnerships or collaborative pediatric projects. Dr. McBain

described some of the genetic work that was done virtually and how it fit well into a virtual internship setting. He agreed that expanding this type of learning could be valuable for many PIs.

Dr. Jain asked for clarification on the percentage of the DIR budget. Dr. McBain said that it was close to 13.5% of the entire NICHD budget, which is slightly higher than the 11% budget suggested by Congress. NICHD is in the mid-range for size of all ICs.

IV. INVITED DIRECTOR: NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS) (1:45:25)

Joni L. Rutter, Ph.D., director of NCATS, presented "Research at the Intersection of Translational Science and Children's Health." She noted that the quick response (QR) codes on her slides contained links to additional information and encouraged attendees to scan them with their smartphones.

NCATS Overview

NCATS is focused on 10,000 diseases, 5% of which have treatments or cures. Drug development typically takes 10 to 15 years and millions of dollars, and 9 out of 10 promising therapeutic candidates that enter clinical trials fail. NCATS' mission is to turn research observations into health solutions through translational science. NCATS is advancing translational science by addressing long-standing bottlenecks in the translational pipeline so that new treatments reach people faster. Its three audacious goals are to create a five-fold increase in the number of diseases with treatments, dramatically increase inclusivity across every area NCATS supports, and enable diagnostics and therapeutics to reach people twice as fast. To meet these goals, NCATS seeks to:

- Understand what is similar across diseases to spur multiple treatments at a time.
- Develop models that better predict a person's reaction to a treatment.
- Enhance clinical trials so the results more accurately reflect the patient population.
- Leverage real-world data and data science approaches to address public health needs.

The NCATS FY 2023 budget of $923,323,000 is divided into Clinical and Translational Science Awards (CTSA, 68%) and all other NCATS activities (32%). The CTSA program funds a nationwide network of 63 research institutions with consortium-wide resource centers and collaborative initiatives, including some translational science (preclinical, clinical, and data science) efforts for children's health.

Supported Research

Preclinically, NCATS is supporting research to revolutionize drug development approaches because there is a need for new technologies and better predictive tools across the translational pipeline (e.g., studies using 3-D tissue bioprinting and tissue chip to improve health in pregnancy, the tissue chips in space program). NCATS is using resources, funding, and data-driven solutions to develop new ways to understand and treat rare diseases. The economic burden of rare diseases was investigated by NCATS, finding that people with rare diseases face significantly higher health care costs (up to a trillion dollars per year total costs). There is a significant gap between scientific research and translation to therapies for rare diseases. The

current Rare Disease Clinical Research Network (RDCRN) is a network of 20 different consortia (a network of networks) with the support of a Data Management and Coordinating Center. NCATS partners with 10 NIH ICs, including NICHD, for this program. Over the past 13 years, RDCRN efforts have led to eight U.S. Food and Drug Administration (FDA)–approved treatments for nine rare diseases.

Over the past 3 years, NCATS has developed an extensive cloud-based data ecosystem. Next steps are to turn this operational environment into a shared environment, and it is currently being built to eventually allow extramural and controlled public access. Furthermore, several ICs are collaborating to develop RARe-SOURCE™, a data tool to unlock novel insights into rare disease commonalities through multimodal data integration. NCATS is also issuing awards for artificial intelligence (AI) and machine learning (ML) studies as ways to shorten the diagnostic odyssey (it takes 7 years, on average, for a patient to be diagnosed with a rare disease).

Targeted Gene Therapy Initiatives

Targeted gene therapies also hold promise for treating rare diseases:

- The NIH Targeted Genome Editor Delivery Challenge will award up to $6 million in prize money and provide independent testing for the most promising delivery vehicles in two target areas (a programmable target area and a target area across the blood-brain barrier).
- The Accelerating Medicines Partnership® Bespoke Gene Therapy Consortium (BGTC) is a public-private partnership that is working to streamline regulatory frameworks to accelerate gene therapies for rare diseases.
- On May 16, 2023, NCATS announced a new clinical portfolio, which focuses on rare diseases that are not under investigation by commercial entities, so all discoveries will be freely available for public use.
- Orphan drug designation (ODD) and Rare Pediatric Disease Designation (RPDD) programs provide financial incentives for the development of diagnostics and treatments of diseases that affect small patient populations and for which commercial development is challenging.
- NCATS initiated a collaboration to start the Platform Vector Gene Therapy (PaVe-GT) program to develop gene therapies for four rare disorders. PaVe-GT publicly shares the scientific and regulatory experience gained during the implementation of its platform.
- An NCATS Therapeutics for Rare and Neglected Diseases (TRND) project in Taiwan led to the first disease-modifying treatment for aromatic L-amino acid decarboxylase (AADC) deficiency. For this project, the TRND group collaborated with NCATS' Therapeutic Development Branch. The AADC treatment has now received several regulatory approvals.

NCATS and NIH celebrate Rare Disease Day on the last day of February each year.

The CTSA Network

CTSA's nationwide network of 63 research institutions addresses clinical and translational science roadblocks by identifying processes and innovations that feed clinical and translational science; developing new approaches, technologies, resources, and models and demonstrating

their utility; disseminating data, analysis, and methodologies to the community; and supporting the next generation of clinical and translational science researchers through institutional career development and training grants. Each institution uses its local strengths to enable nimble, rapid, and robust responses to national public health challenges.

- The pediatric reach of the CTSA network includes 53 institutions with an associated children's hospital, 10 institutions with children's hospital partners, and 13 institutions with pediatrician PIs, plus a variety of training and career scholars.
- Notably, a group of pediatric trainees at the University of Arkansas for Medical Sciences who were funded by its Health Sciences Innovation and Entrepreneurship (HSIE) training program started a company called Pediatrica Therapeutics and improved a drug that was already FDA-approved to produce less fetal and neonatal opioid exposure.
- During the pandemic, CTSA institutions created the National COVID Cohort Collaborative (N3C) as a national health data ecosystem. The N3C data enclave is the largest collection of real-world COVID-19 data in the United States. N3C is being used to study COVID-19, identify potential treatments, and validate existing therapies. Its pregnancy clinical domain team aims to leverage N3C data to gain insights into pressing COVID-19 questions around pregnancy.
- With the idea to collect data to inform newborn screening options, the CTSA "BabySeq Project" is the first randomized clinical trial to conduct whole genome sequencing (WGS) in a diverse cohort of healthy newborns. Dr. Rutter gave an example where a physician used WGS to quickly diagnose a 5-week-old infant presenting with infantile encephalopathy. Within 13 hours of starting the WGS, the gene for thiamine metabolism dysfunction syndrome 2 was found, and the infant's symptoms were relieved within 6 hours.

In conclusion, Dr. Rutter shared upcoming plans for NCATS' strategic planning process, which is open for stakeholder engagement. She reminded the group that NCATS seeks to solve a large public health challenge.

Discussion (2:26:03)

Dr. Barkin asked how to stay ahead of the best use of AI, ML, and other advanced tools for pediatrics. Dr. Rutter said that it was a work in progress and further complicated by data missingness. More data transparency is needed to understand biases. Wearables, telehealth, and telemedicine could be useful for reaching underserved communities and creating decentralized clinical trials. Wearable devices should become more sophisticated over time. Dr. Barkin suggested that NICHD create guardrails for designating good and less desirable uses of AI and ML. Dr. Rutter said that validation would be needed before using any AI/ML algorithms.

V. SCIENTIFIC PRESENTATION: YOUNG WOMEN'S HEALTH – SUPPORTING ADOLESCENTS, YOUNG ADULTS, AND THEIR FAMILIES (2:31:35)

Catherine Gordon, M.D., M.S., the new clinical director of NICHD's DIR, described her background, scientific interests, and leadership vision. As clinical director, Dr. Gordon aims to develop scientific initiatives and programs that align with NICHD's strategic plan.

Dr. Gordon said that her scientific interests are in pediatric and adolescent bone health, abnormal skeletal morphology, and high-resolution peripheral quantitative computed tomography (HRpQCT), a noninvasive imaging modality for assessing both volumetric bone mineral density and the microarchitecture of cancellous and cortical bone. She also studies anorexia nervosa, Hutchinson-Gilford progeria syndrome, pubertal blockade in transgender youth, premature ovarian insufficiency, and postpartum depression.

To support the clinical research pipeline, Dr. Gordon believes that the key to success is attracting outstanding trainees and junior faculty who grow into scientific leaders. Building infrastructure that allows trainees and junior scientists to succeed is critical, as is targeting people from groups that are underrepresented in medicine (e.g., women, minorities, groups who do not have the same early opportunities). To tackle the research pipeline and prevent it from leaking, students must be engaged in high school or earlier and at all levels (undergraduate, medical school, residency, subspecialty fellows, junior faculty). Brainstorming about existing opportunities and new ventures with new schools and colleges, along with building on the partnership with Howard University, should be the starting point for developing a pipeline of new talent.

Dr. Gordon's vision for clinical research at NICHD is grounded in NICHD's mission and vision statements. She sees all employees of DIR working to advance the health and well-being of children, adolescents, and their mothers by engaging in cutting-edge research that advances care. Training the next generation of scientists and leaders is also part of the vision, along with seeking out opportunities to advocate for the broad community served by NICHD: infants, children, adolescents, and women (inclusive of pregnancy and lactation).

As clinical director, Dr. Gordon's broad goals are to:

- Invest in and support people.
- Manage change and bring stability.
- Encourage open dialogue and transparency.
- Foster justice, equity, diversity, and inclusion.
- Promote research excellence.
- Attract talent and promote top-notch training.
- Promote well-being and professionalism.
- Strengthen local and global partnerships.
- Foster faculty, trainee, and staff development.

Themes that resonate with Dr. Gordon include advancing safe and effective therapeutics and devices for pregnant and lactating women, children, and people with disabilities (including clinical trials that enroll these populations at the NIH Clinical Center); advancing equity, diversity, and inclusion initiatives; and improving child and adolescent health and the transition to adulthood.

Dr. Gordon will prioritize programs for faculty development and wellness, career development, and workforce development for both early career and senior investigators. She will expand research on the transition of care, build clinical and research infrastructure, lead community engagement, support innovation for clinical and translational research, and make NICHD the premier research center, or "destination center," for premature ovarian insufficiency.

To begin her tenure as clinical director, Dr. Gordon is starting a listening tour over the next few weeks, tackling several major research challenges, developing and nurturing the talented teams at NICHD, and making a commitment to hiring and retaining talent to realize the goals in the NICHD 2020 Strategic Plan. She looks forward to striving together to develop a top-notch and diverse team.

Discussion (3:01:49)

Regarding the reorganization of DIR's research affinity groups, Dr. Rowitch suggested comparing priorities between the clinical program and the intramural program and then building the new groups on overlapping inter-program synergies.

Dr. Aizer asked whether firearm-related injury or violence was a key challenge for Dr. Gordon. Dr. Gordon said yes, especially because it is an important problem in adolescent medicine.

Dr. Aizer asked whether Dr. Gordon planned to incorporate social and economic outcomes (e.g., for treating postpartum depression) in her framework. Dr. Gordon said yes, and gave an example of tying ZIP code information to outcomes in a recent interventional study.

VI. VOICE OF THE PARTICIPANT (3:04:17)

Dr. Bianchi introduced Carolina (the participant) and Nereida Rodriguez (the participant's mother) from Houston, Texas. Carolina was a participant in a research study conducted by Dr. Gordon in the USDA/ARS Children's Nutrition Research Study in Houston.

Dr. Gordon said that the clinical research study investigated physical health and quality of life outcomes in childhood cancer survivors. Participants were 10- to 24-year-old girls with a new diagnosis of premature ovarian insufficiency but had not yet begun estrogen therapy. Carolina was 10 years old when she was enrolled in the study. She is now 11 years old and in fifth grade. Her favorite subjects are math and science, and she would like to be an engineer when she grows up.

Nereida shared that when Carolina was diagnosed with a stage 4 Wilms tumor in 2018, she underwent kidney surgery followed by chemotherapy and radiation over the course of a year. The family was referred to endocrinology when Carolina started showing signs of delayed puberty. Nereida was immediately interested in having Carolina participate in the research study when Dr. Gordon reached out to her. She stated that she saw her daughter participating in a research study as an opportunity to make something positive out of a difficult situation.

Discussion (3:14:50)

Dr. Dorn asked Carolina whether she had the opportunity to talk to other children who had been diagnosed with cancer. Carolina said that she was able to talk with other children in a community room while she was in the hospital. Dr. Gordon said that patient support groups would be a good addition to the clinical study protocol.

Dr. Barkin asked Carolina what "research" means to her. Carolina said that research means learning more about an object or a thing and how it works. Nereida added that research is very important and that, as a parent, she would be interested in learning more about what symptoms to watch for in the future.

Dr. Neal-Perry asked what researchers should know to make the participant experience better. Nereida said that the day she learned that her daughter had cancer was the hardest day ever. She believes in science and research and has faith in God but did not know what it meant to be diagnosed with stage 4 cancer. She knew that she was in a good place at M.D. Anderson Cancer Center and believed that everything would be okay.

VII. COMMENTS FROM RETIRING MEMBERS (3:20:15)

The retiring members expressed gratitude to their fellow Council members, Dr. Bianchi, and NICHD staff. Beyond messages of thanks, the retiring members spoke about the topics below.

Dr. Coughlin (3:21:10)

- Learning about the important work of NICHD, especially the Harvard mother's milk study [https://www.nichd.nih.gov/sites/default/files/inline-files/Belfort_NACHDD_Council_012320.pdf] and the study on anesthetic complications of appendicitis [https://reporter.nih.gov/project-details/]
- Praising Dr. Bianchi for communicating when it was safe for children to return to school during the COVID-19 pandemic

Dr. Egan (3:23:33)

- Learning new scientific information about medicine, pharmaceuticals, and biogenetics
- Enjoying the diversity of the group
- Showing the impact of NICHD funding to Congress and others

Dr. Jain (3:26:09)

- Graduating from high school 50 years ago and being told to observe others in life because you will need all of them in some way
- Appreciating the stops in life, including a consequential stop at NICHD

Ms. Lavender (3:29:34)

- Being impressed by NICHD processes for accomplishing its broad mission
- Learning about implementing basic, yet important initiatives

Dr. Resnick (3:31:30)

- Participating on the Council during such a momentous time (e.g., the COVID-19 pandemic, changes in reproductive health policy)
- Watching NICHD take the lead during the explosion of data sharing and big data in research and medicine

- Being inspired by the way that NICHD nimbly adjusts to change and takes the lead in pediatric health, maternal health, and health care in general

VIII. CONCEPT CLEARANCE (3:35:24)

Dr. Rasooly led the Council through the review of four concepts.

Centers for Collaborative Research in Fragile X and FMR-1 Associated Conditions (3:36:08)

Tracy King, M.D., M.P.H., presented this concept from the Intellectual and Developmental Disabilities Branch (IDDB). IDDB was seeking approval for renewal of this funding opportunity. Dr. Barkin asked for additional commentary on the advancements from this program, which has been in place since 2000. Multiple gene targets have been found to be responsive to therapeutic and pharmacological treatments in studies of cellular and animal models. . **Decision: Approve.**

Optimizing Health of Children and Adolescents with Perinatal HIV Exposure (3:39:34)

Sonia S. Lee, Ph.D., presented this concept from the Maternal and Pediatric Infectious Disease Branch (MPIDB). MPIDB was seeking approval for this funding opportunity. A Council member expressed support for this concept. **Decision: Approve.**

Women's Reproductive Health Research (WRHR) Program (3:42:07)

Steven C. Kaufman, M.D., presented this concept from the Contraception Research Branch (CRB). CRB was seeking approval to renew the WRHR program for another 5 years. A Council member asked whether WRHR addressed the significant maternal health care deserts. A Council member asked whether the impact and outcomes of WRHR had been measured over time. A scholarly review of this successful program (since inception) will soon be published. Dr. Bucci-Rechtweg suggested that the funding mechanism include innovative industry partnerships or collaborations in the future. **Decision: Approve.**

Population Dynamics Research Infrastructure Program (3:56:22)

Ronna Popkin, Ph.D., presented this concept from the Population Dynamics Branch (PDB). PDB was seeking approval to renew support for research infrastructure at population dynamics research centers. Dr. Lang asked for more information about this program. **Decision: Approve.**

Discussion

Dr. Barkin said that future concept clearance renewal requests might include outcomes updates. Dr. Egan asked for additional background on the concept clearance process, and this was provided by Dr. Rasooly and Dr. Bianchi. Dr. Lang suggested developing partnerships to allow virtual NICHD summer interns to participate in projects at population dynamics research centers. Dr. Aizer said that linked datasets are playing an increasing role in population dynamics research, and creating and maintaining large datasets require a lot of resources.

IX. CLOSING REMARKS (4:03:20)

Dr. Bianchi thanked all attendees and announced the logistics for Day 2.

X. DAY 1 ADJOURNMENT

Dr. Bianchi adjourned Day 1 at 4:25 p.m. A total of 97 people viewed the live VideoCast of the open session.

XI. DAY 2 CALL TO ORDER AND INTRODUCTORY REMARKS

Dr. Bianchi opened Day 2 of the meeting.

XII. CLOSED SESSION

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). NACHHD Council members provided second-level review of NICHD intramural and extramural applications.

XIII. 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 665 HD-primary applications requesting $209,299,336 in direct costs and $297,253,865 in total costs.

XIV. ADJOURNMENT

There being no further business, Dr. Bianchi adjourned the meeting at 12:15 p.m. on Thursday, September 7, 2023. The next Council meeting, which will be virtual, is scheduled for January 22–23, 2024.

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

Diana W. Bianchi -S

Digitally signed by Diana W. Bianchi -S
Date: 2023.10.27 16:47:45 -04'00'

Diana W. Bianchi, M.D.
NACHHD Chair

Date

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

NICHD Director

Rebekah S. Rasooly -S

Digitally signed by Rebekah S. Rasooly -S
Date: 2023.10.27 11:50:57 -04'00'

Rebekah Rasooly, Ph.D. Date

NACHHD Executive Secretary
Director, NICHD Division of Extramural Activities