Eunice Kennedy Shriver National Institute of Child Health and Human Development

National Advisory Child Health and Human Development (NACHHD) Council

Meeting Summary

January 26, 2026, and March 20, 2026

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)

The NACHHD Council convened its 190th meeting at 12:00 p.m. ET on Monday, January 26, 2026. It was a virtual meeting that was open to the public from 12:00 p.m. to 4:04 p.m. ET. The Council then met on March 20, 2026, in a session that was closed to the public from 1:00 p.m. to 2:51 p.m. ET. 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. Acting NICHD Director Alison Cernich, Ph.D., presided.

Council Members Present[1]

Alison Cernich, Ph.D. (Chair)
Anna Aizer, Ph.D., M.S.
Susan L. Brooks, J.D., M.A.
Marcelle Ivonne Cedars, M.D.
Cynthia Gyamfi-Bannerman, M.D., M.S., FACOG
Ethylin Wang Jabs, M.D.
Yvonne A. Maldonado, M.D.
Ignatia Barbara Van den Veyver, M.D.

Council Members Absent

None

Ex Officio Members

Patricia Dorn, Ph.D.
Reem Ghandour, Dr.P.H., M.P.A.

National Advisory Board on Medical Rehabilitation Research Council Liaison

Linda Ehrlich-Jones, Ph.D., RN, FAAN

Department of War

Gayle Vaday, Ph.D.

Executive Secretary

Rebekah Rasooly, Ph.D.

In each section of this meeting summary, the number in parentheses that follows each heading refers to the time stamp on the NIH VideoCast. Please go to that point in the recording to listen to the full presentation.

[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.

I. Call to Order and Introductory Remarks (0:05)

Dr. Cernich opened the meeting and welcomed the members of the NACHHD Council and all online attendees.

Council Minutes (1:29)

Marcelle Ivonne Cedars, M.D., made a motion to approve the September 9–10, 2025, NACHHD Council meeting minutes as written. Ethylin Wang Jabs, M.D., seconded the motion. Council members voted to approve the minutes.

Future Meeting Dates (3:27)

Rebekah Rasooly, Ph.D., the Council's executive secretary, announced that the future Council meetings are scheduled for July 8–9, 2026 (6710B Rockledge Drive); October 14, 2026 (NIH Bethesda Campus, Building 45); January 25–26, 2027 (virtual); June 7–8, 2027 (NIH Bethesda Campus, Building 31); and September 7–8, 2027 (NIH Bethesda Campus, Building 31).

II. Acting NICHD Director's Report (4:40)

Dr. Cernich opened her report thanking the scientific community for their flexibility while managing various challenges to the current review cycle. Dr. Cernich provided updates on NICHD's budget, policy changes at NIH, and several research highlights.

NICHD Budget Update (6:02)

NIH is currently under a continuing resolution (CR) through January 30, 2026. A recent update to the Consolidated Appropriations bill, released January 20, proposed a $48.7 billion increase to NIH's budget and a $1.69 billion increase to NICHD, directed toward the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) initiative. NICHD is waiting for congressional justification and the president's budget for fiscal year (FY) 2027 and will provide additional updates as those details become available.

NICHD was able to award all appropriations for FY 2025. The institute issued 861 competing awards, reflecting an 8.7% decrease from FY 2024. Comparatively, for competitive awards in NIH appropriations, there was a 19.7% decrease from FY 2024.

NIH has made updates to the grant review process for FY 2026 because of the lapse in appropriations from October to November 2025 that delayed review. To date, colleagues at the Center for Scientific Review (CSR) have gotten through approximately 24,000 of 32,000 applications. By the end of January, only 518 applications will remain, and the expectation is that the last applications will be reviewed on February 10. As of last week, NICHD had received 6,546 summary statements, and the institute expects all summaries to be released by the February 28 deadline. Dr. Cernich gave many thanks to the scientific review officers and extramural community for stepping up to get NIH caught up in its peer review process.

NICHD Policy Updates (9:15)

As discussed in the previous Council meeting, NIH will no longer use the NIH Guide to publish new Notices of Funding Opportunities (NOFOs). NOFOs will only be posted to Grants.gov. Investigators can visit Grants.gov subscription services to receive notifications of new NIH funding opportunities.

NIH's new Highlighted Topics website highlights scientific areas of high interest to NIH. Researchers can then submit applications using parent funding opportunities. Dr. Cernich thanked NICHD staff for their pioneering efforts in putting out the first topics to be featured on the website.

Dr. Cernich reminded attendees of a new policy limiting the number of application submissions. Following concerns about the integrity of a large volume of grant submissions, NIH will only accept six new, renewal, resubmission, or revision applications from an individual principal investigator (PI), program director (PD), or group of investigators in a calendar year. This restriction applies to all activity codes except for T and R13 conference grant applications.

Lastly, per announcement PA-26-002, NIH will be introducing a new funding mechanism for awards with foreign subcomponents. In the short term, investigators can remove a foreign subaward from an existing award and renegotiate it as an administrative supplement. Researchers can also now use the PF5 NIH Collaborative International Research Project mechanism to separate clinical components with foreign collaborators. Separating these components respects the new policies around foreign awards and additionally ensures that NIH can track funding going to foreign sites. Those involved in international awards will be using this mechanism going forward.

Unified NIH Funding Strategy (13:21)

NIH is implementing a new framework that aligns institute, center, and office (ICO) funding policies with the NIH mission and institute priorities. When considering applications, institutes will prioritize scientific merit and take the context of their strategic plans into account. Institutes will also consider investigator career stage, prioritizing early-stage investigators and trainees, and the distribution of awards across geography. Institutes will no longer be using paylines in these considerations. For NICHD, which has already phased out paylines, the review process will remain the same: Peer review staff will give feedback and justifications for considering certain applications for award. The Advisory Council will then provide second-level peer review, and Dr. Cernich will have delegated authority to decide what is funded. She will make her final decisions based on comments and feedback from CSR, program staff, and Council members. This process has allowed and will continue to allow NICHD to balance its portfolio with current and new projects that advance novel areas of science and address needs for replication and stronger evidence.

Average Size of Grant Awards Is Increasing (16:40)

As announced in NOT-OD-26-019, NIH is no longer requiring prior approval for applications requesting more than $500,000 in direct costs. Over the past 30 years, NIH has observed an increase in the overall cost of grants, primarily because of inflation. Applications can also have higher costs if awards are being fully funded in their first year. Regardless of the reason, Dr. Cernich asked participants to be mindful of the fact that

increases in award size will decrease the number of awards NICHD is able to fund. For example, if NICHD is typically able to issue 500 awards at $500,000 each, a 20% increase in award size will reduce the number of available awards from 500 to 417.

Pediatric Research at the NIH Clinical Center (19:27)

NIH has worked to address gaps in its ability to carry out pediatric research and care at the NIH Clinical Center (CC). In FY 2024, the CC had 21,500 pediatric outpatient visits. Currently, approximately 10% of CC patients are children, and members of staff have expertise in 21 pediatric subspecialties. Given the work at NICHD and other institutes, NIH is trying to increase the infrastructure available to support pediatric services. Specifically, the CC has added a pediatric hospital medicine service, new child life services to enhance the quality of a child's stay, and lowered CC general admission age to 2 years of age.

NIH Director Jay Bhattacharya, M.D., Ph.D., M.A., has led additional improvement efforts with Pius Aiyelawo, M.P.A., acting chief executive officer (CEO) of the CC; Jennie Lucca, M.S.W., CEO of The Children's Inn; and Matthew Memoli, M.D., M.S., Principal Deputy Director of NIH. The CC hosted a day for the World Wrestling Entertainment (WWE) group to engage with children at the CC, and NIH is establishing a pediatric intensive care unit (PICU) within the CC. The PICU will ensure safety and continuity of care by avoiding transfers to other facilities and will enable research in infants and critically ill children. The PICU will also enable first-in-child and higher-risk clinical trials, rare disease research previously not possible at NIH, and stronger national pediatric partnerships.

Finally, NIH has partnered with the National Academies of Sciences, Engineering, and Medicine (NASEM) for the report "Strategies to Enhance NIH-Funded Pediatric Research." The committee was tasked by NIH to review the current NIH pediatric research portfolio and consider ways the CC could advance innovative pediatric research. The report is representative of how agencies can work together to strengthen pediatric research across communities. Those interested in learning more can register for a report release webinar that will take place on January 28, 2026, at 3:00 p.m.

NICHD Research Highlights (24:17)

Dr. Cernich closed her report with several exciting research highlights.

Sensor Devices Can Monitor Placental Oxygen (24:23)

Amir Gandjbakhche, Ph.D., and colleagues from NICHD's Intramural Research Program (IRP) are studying ways sensor devices can be used to monitor placental function noninvasively. This work addresses NICHD priorities to better understand the placenta and the link between poor placental outcomes and adverse pregnancy outcomes. The researchers used wearable noninvasive transabdominal sensors to measure placental oxygen saturation as an effective way to guide clinical intervention. This research has been published in *Biosensors*.

Same-Day Genetic Testing Comes to the NICU (25:34)

Extramural collaborations have led to new knowledge around same-day genetic testing. Rapid genetic diagnoses can be instrumental in guiding care for critically ill newborns, but testing often requires time not available to providers in neonatal intensive care units

(NICUs). In a study published in the *New England Journal of Medicine*, researchers developed a genomic sequencing approach called sequencing by expansion. The technique creates longer, easier-to-read DNA copy that allows machines to read and identify genetic variants in approximately 4 hours, enabling genetic testing to inform same-day medical decisions.

Early Brain Development Linked to Later Reading Skills in Childhood (26:51)

A study currently in *bioRxiv* has used brain scans and test results collected from infancy through late childhood to understand the underpinning of reading skills in childhood. Scientists have found that children with stronger phonological processing skills had more developed brain structures in areas involved in reading and stronger reading skills in elementary school. The study gives exciting insight into interventions to potentially help children succeed in school.

Progress Toward Nonhormonal Treatment for Endometriosis (27:59)

Researchers published in *Advanced Science (Weinheim, Baden-Württemberg, Germany)* examined genome-wide association study (GWAS) data to find genetic targets and potential risk genes for endometriosis. They found genetic changes in M2 macrophage immune cells associated with the development of endometriosis. The researchers then used an organoid model to explore possible treatment approaches and identified a signaling pathway in immune cells that could be a possible target for nonhormonal treatments.

Researchers Identify Genetic Variants Associated with Uterine Fibroid Development (29:26)

Another research group has studied genetic data from approximately 20,000 women with uterine fibroids and 224,000 women without fibroids. From these data, the researchers identified 24 "risk locations" where genetic variations increased the risk of developing fibroids. Published in *Nature Communications*, these findings can focus future efforts to understand how these variations increase risk and provide potential genetic targets for fibroid treatment.

OpenExo: An Open-Source Modular Exoskeleton to Augment Human Function (30:22)

Wearable exoskeletons have the ability to increase mobility, but advancing technology has been difficult because of a lack of standardization. Researchers supported by NICHD created OpenExo, an open-source exoskeleton platform with free detailed instructions and software, allowing users to build exoskeletons at a cost of less than $2,000 in materials. The platform makes it easier for people to participate in exoskeleton research and may help speed up the development of new exoskeleton designs and control systems. The platform is detailed in *Science Robotics*.

U.S. Food and Drug Administration (FDA) Approves First Treatment for Children with Menkes Disease (31:49)

Menkes disease is a rare pediatric neurodegenerative disorder caused by a genetic defect that impairs copper absorption. The disease causes seizures, developmental delays, and intellectual disabilities, and life expectancy is typically less than 3 years. Zycubo is a newly approved copper replacement therapy that was developed by an NICHD intramural lab and underwent

clinical trials at the CC. Children treated within 4 weeks of birth had a 78% reduction in risk of death, with nearly half of them surviving beyond age 6, and some beyond age 12.

Discussion (33:00)

Dr. Cedars asked how the balance of money and number of awards will be considered if NICHD is given a larger budget, given congressional language that NIH will not be allowed to fund fewer grants than in the previous FY if they are given a higher budget. Dr. Cernich said that NIH is waiting to see what language passes, but the institute is used to incremental funding and able to manage it with a variety of approaches. NIH is alerting the scientific community because changes to overarching spending may necessitate renegotiations of budgets.

Anna Aizer, Ph.D., M.S., asked for follow-up on the recent reorganization of NIH. Dr. Cernich did not have any additional updates at this time. NIH is waiting for the president's budget and further recommendations from the administration.

Yvonne Maldonado, M.D., asked whether the Council could receive updates between meetings, potentially through email, to facilitate Council review during this accelerated cycle. Dr. Cernich noted that the Council has another meeting in March 2026 to account for the lapse of appropriations. She will consult with Dr. Rasooly about getting additional updates to the Council.

Cynthia Gyamfi-Bannerman, M.D., M.S., FACOG, said that early-stage investigators she works with are concerned about funding lines going away and that changes to the review process will result in a more subjective assessment of incoming applications. Dr. Gyamfi-Bannerman asked for guidance and words of reassurance for these investigators. Dr. Cernich said that NICHD has not used paylines as its primary guide for funding decisions, and therefore the application process for this institute in particular is not changing. Catherine Spong, M.D. and Della Hahn, Ph.D., first pioneered the shift from paylines, because they felt that paylines were causing NICHD to fund the same kinds of grants many times over. Diana Bianchi, M.D., the former Director of NICHD, also worked to better align the institute's funding with its strategic plan. Dr. Cernich encouraged younger investigators to think through the institute's strategic plan and align their applications to NICHD's strategy, considering what science is current and what is novel. She also encouraged investigators to reach out to program officers (POs) and staff, who are always eager to help. NIH RePORTER is another helpful resource that shows what is already funded across NIH. Dr. Cernich noted that investigators applying to other institutes that were more payline-heavy will experience more change, but practices at NICHD have remained consistent.

Patricia Dorn, Ph.D., added that this new funding model for NIH is similar to the approach other federal funders use. Agencies such as the U.S. Department of Veterans Affairs (VA) have always used scientific merit as the guidepost to balance appropriation dollars across strategic priorities. Dr. Cernich said that she thinks the shift from paylines will be a good change, and she agreed that other agencies have had the approach Dr. Dorn described.

Rohan Hazra, M.D., added that NICHD staff looks programmatically at all incoming applications and tries to be proactive up front about applications that are not high priority. Even if they score well, PIs can receive feedback that their application is not a high priority

for NICHD but could be reframed and resubmitted to a different institute or center (IC). Dr. Cernich said that NICHD is well aware that applications are key to investigators' careers. She agreed that NICHD staff tries to avoid letting investigators get misguided on how the institute will move forward with its funding.

III. Invited Director: National Institute on Aging (NIA) (45:20)

Richard Hodes, M.D., has served as Director of NIA since 1993. He has supported cutting-edge research that has revolutionized the way scientists think about Alzheimer's disease and related dementias. Dr. Hodes has also been a mentor to Dr. Cernich for many years and has provided support to her as Acting Director of NICHD. Dr. Hodes provided an overview of the NIA portfolio of research and how it relates to NICHD.

NIA was established in 1974 with the goals of understanding the nature of aging and improving the quality of life while minimizing disease and disability. The process of aging begins at birth and transcends generations. NIA therefore does not support just the study of how health manifests in older people but also how health manifests itself across the lifespan. This principle has been the root of collaboration between NICHD and NIA.

NIA has experienced an approximately 4-fold increase in appropriations from 2015 through the present. A large portion of this increase has been targeted by congressional appropriation to address Alzheimer's and related dementias, but untargeted appropriations have increased as well, reflecting continuous bipartisan support for NIA.

Extramural research at NIA is spread across four divisions: the Division of Aging Biology, the Division of Neuroscience, the Division of Geriatrics and Clinical Gerontology, and the Division of Behavioral and Social Research. The Division of Neuroscience in particular has grown to be the largest division at the institute. The IRP has also grown; the NIH Bethesda Campus has intramural labs at the John Edward Porter Neuroscience Research Center and the Roy Blunt Center for Alzheimer's Disease and Related Dementias Research, and more intramural research takes place at the Bayview campus of Johns Hopkins University in Baltimore, Maryland.

Studies across the life course present many opportunities for collaboration between the NICHD and NIA IRPs. Both NICHD and NIA collaborate on initiatives to study Down syndrome, women's health and menopause, and longitudinal studies from adolescence to older age. More recently, palliative care has been a focus of congressional interest, including a targeted appropriation to NIA, which has coordinated research in this area with multiple ICs, including NICHD.

People with Down syndrome are at higher risk of developing Alzheimer's disease, likely because chromosome 21 carries both the gene that encodes the amyloid precursor protein involved in Alzheimer's and the trisomy for Down syndrome. By age 40, most people with Down syndrome will have an abnormal accumulation of amyloid beta and tau proteins, and an estimated 70% or more of people with Down syndrome will develop dementia due to Alzheimer's. Research into the Down syndrome population itself and studies that more broadly inform neurodegeneration are therefore a priority of NIA.

Ongoing research aims to understand how Alzheimer's begins and progresses in people with Down syndrome, understand why only some people with Down syndrome develop Alzheimer's, improve Alzheimer's diagnosis in people with Down syndrome, and evaluate new approaches to Alzheimer's treatment and prevention in people with Down syndrome. To this end, NIA participates in the NIH-wide INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE (INCLUDE) initiative and co-funds the Alzheimer Biomarker Consortium-Down Syndrome (ABC-DS) with NICHD. NIA also supports the Trial-Ready Cohort-Down Syndrome (TRC-DS) to establish a community of potential clinical trial participants with Down syndrome. Lastly, NIA supports ongoing clinical trials studying Alzheimer's in people with Down syndrome, including the Amyloid Lowering for Alzheimer's in Down's Donanemab INvestigation (ALADDIN), and a trial testing the protein homeostasis pathway as a potential therapeutic target for Alzheimer's.

Recent NIA-supported advances in Down syndrome research include identifying twice as much iron and more signs of cellular damage in the brains of people living with Down syndrome and Alzheimer's disease, as detailed in *Alzheimer's & Dementia*. Another publication in *Alzheimer's & Dementia* detailed findings that, in contrast with those for the general population, the *APOE4* gene variant had only a modest association with dementia in people with Down syndrome. Lastly, NIA-supported researchers have published a case report of an individual with Down syndrome who has remained cognitively stable into her 60s, despite having high levels of Alzheimer's disease biomarkers. Additional research into this case study may help uncover mechanisms of cognitive resilience and inform therapeutic and prevention strategies.

NIA also prioritizes the study of midlife health and in fact leads menopause research at NIH. Dr. Hodes provided examples of menopause research at NIA across the four divisions of the institute's extramural portfolio: The Division of Aging Biology has supported research that produced a single-cell atlas of the aging mouse ovary, detailed in *Nature Aging;* the Division of Geriatrics and Clinical Gerontology has led the Study of Women's Health Across the Nation (SWAN), now in its 30th year; the Division of Neuroscience has supported research reported in *Scientific Reports* on how menopause affects human brain structure, connectivity, energy metabolism, and amyloid-beta deposition; and the Division of Behavioral and Social Research has led the Midlife in the United States (MIDUS) study since its initiation in 1995.

Dr. Hodes provided additional details on SWAN, which is a large multiethnic study that has provided a rich, publicly available store of data showing the biological and socioeconomical impacts of menopause and its symptoms. Notable research from SWAN includes a discovery in *JAMA Network Open* that frequent or persistent menopause symptoms, specifically hot flashes and night sweats, are associated with a 50% increased risk of developing diabetes. Another study in *Circulation* has found that persistent insomnia among midlife women predicts higher cardiovascular disease risk.

NIA-supported researchers have made additional menopause discoveries outside of SWAN. Researchers whose work was published in *Alzheimer's & Dementia* have found that the levels of female reproductive hormones can predict white matter hyperintensity volume (WMHV) in postmenopausal women, with higher estrone levels associated with lower brain WMHV and higher follicle-stimulating hormone associated with higher WMHV. Lastly, NIA-supported researchers have developed My Menoplan, an online tool that women can

use to track menopause symptoms. My Menoplan also connects users to research with implications for how to manage menopause symptoms.

Dr. Hodes closed his talk promoting several upcoming NIA summits and workshops. NIA will host the webinar "Using the Understanding Cohort Effects on Stroke, Vascular Contributions to Cognitive Impairment and Dementia (VCID), and Cognition After Major Epidemiologic Transitions — Centers for Medicare & Medicaid Services (CMS) Linked Data" on February 10, 2026. Another webinar, titled "Using the National Dementia Workforce Study — CMS Linked Data" will be held on March 9, 2026. Additional webinar details can be found on NIA's website. Finally, NIA will be hosting the virtual 2026 Dementia Care and Caregiving Research Summit from March 17 to 19, 2026.

Discussion (1:02:08)

Ignatia Barbara Van den Veyver, M.D., asked for additional detail on the co-funding mechanisms between NICHD and NIA, especially for the study of perimenopause and menopause. Dr. Hodes provided examples of NIA and NICHD collaboration that have contributed to formal solicitations of grant applications, such as the NIH-wide INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE (INCLUDE) . NIA and NICHD also sponsor workshops featuring topics in which there is strong overlap on topics of mutual interest, which can allow for informal funding opportunities. Generally speaking, areas of science examining menopause and its impact on symptoms, morbidities, and diseases of older age will refer more to NIA for funding opportunities, whereas studies of the menopausal transition itself and its impact on women as they approach menopause may be predominantly supported by NICHD. However, the two ICs are in close contact to ensure overlapping interests enable studies across the continuum without silos getting in the way. Dr. Cernich added that ICs frequently coordinate at the program level to ensure funding is complementary to each other.

Dr. Aizer commented that there is a growing body of work linking childhood environments to health later in life. Assessing effects of interventions early in life may therefore require following participants as they age because the benefits of such interventions may not be evident until later in life. Dr. Hodes strongly agreed and said that longitudinal study is a robust area of collaboration between NIA and NICHD. The National Longitudinal Study of Adolescent to Adult Health (Add Health) is one of several examples of NICHD and NIA partnering to cover the entire life course.

From her experience in the rehabilitation field, Dr. Dorn commented that there are distinctions between aging into some form of disability and functional loss. Individuals can also come into aging with functional losses already in place. Dr. Hodes noted that he first met Dr. Cernich through rehabilitation research. He recognized that there is a long-standing sense that all people, as they age, will see a decrease in abilities, but the extent to which these decreases are labeled as "disabilities" can be an abstraction. NIA is dedicated to increasing the length of time free from disability, and rehabilitation is an important aspect of that goal. Dr. Hodes added that rehabilitation for older adults faces different challenges compared with rehabilitation for younger individuals, and NIA spends more time in the area of prevention and resilience than in rehabilitation. Dr. Hodes recognized that both approaches are valuable. Dr. Cernich said that NICHD will be releasing its Strategic Report on Disability, and that will provide some overlap in priorities. She said she also recognized the distinction between encountering a functional limitation and identifying as having a disability, and the implications that can have for research.

Dr. Dorn asked for comments on longevity, especially for younger generations. Dr. Hodes said that longevity is very important to NIA, which looks to extend years of life and years with independence and without disability. This goal becomes more of a challenge as chronic diseases become more prevalent with age, even as people are living longer. The priority of longevity aligns with the Make America Healthy Again (MAHA) initiative, but it also aligns with NIA's preexisting goals.

Dr. Van den Veyver asked for strategies and recommendations for early-career investigators interested in studying menopause, aging, and women's health. Dr. Hodes encouraged researchers with any research interest to get in touch with POs or to even reach out to him through email. NIH staff are all available to give advice on high-priority research areas.

IV. Scientific Presentation: Add Health, the National Longitudinal Study of Adolescent to Adult Health (1:13:47)

Robert Hummer, Ph.D., M.S., is the Howard W. Odum Distinguished Professor of Sociology and Faculty Fellow of the Carolina Population Center at the University of North Carolina (UNC) at Chapel Hill. Dr. Hummer is the Director of Add Health, a longitudinal study of more than 20,000 American adults who have been followed since adolescence and are now in their mid-40s. Dr. Hummer's presentation focused on the development of Add Health's research infrastructure, describing the history, motivations, and evolution of Add Health; the design and data collection of Add Health's Wave VI data; and information on Wave VI data and how to access those data.

Add Health was developed in response to a 1993 congressional mandate. Researchers at UNC applied to the opportunity and were awarded funding by NICHD in 1994. The study was originally funded as two-waves but evolved into a multi-wave design in the early 2000s. The study was also originally named the National Longitudinal Study of Adolescent Health but was renamed when Wave V was funded and the cohort moved into adulthood. The most recent Wave VI has been funded primarily by NIA, with co-funding from NICHD, the National Institute on Minority Health and Health Disparities (NIMHD), the National Institute on Drug Abuse (NIDA), the Office of Behavioral and Social Sciences Research (OBSSR), and the Office of Disease Prevention (ODP).

The innovative design of Add Health gave foundational attention to life course principles, health disparities, social contexts, biological processes, and population representativeness and heterogeneity. Add Health has also yielded so many high-impact publications that it won the Golden Goose Award in 2016, highlighting obscure federally funded studies that have led to high societal impact.

The original design drew from 27,000 high schools, with 80 high schools ultimately chosen based on geography, urbanicity, size, type, and the racial and ethnic mix of students. These high schools helped identify junior high schools that sent at least five graduates to that high school. Recruitment efforts resulted in pairs of schools in each of the 80 communities across the United States. Each student in these school pairs was eligible for the main sample of Add Health and could complete a short in-school survey. From these 90,000 students, approximately 150 adolescents were randomly drawn from each school pair, resulting in 12,000 in-home Wave I respondents. Another 8,000 initial responses were oversamples drawn from 16 schools that included Black students from highly educated families; Chinese, Cuban, and Puerto Rican

students; self-identified students with disabilities; and genetic pairs. These groups contributed the 20,745 participants in Wave I, with in-home surveys of adolescents and their parents. This group represented the roughly 22 million individuals in American schools from grades 7 to 12 during the 1994–1995 school year. As the cohort has aged, Add Health has continued to provide sampling weights at each wave.

Add Health has evolved to address key issues characterizing U.S. society. In Waves I and II, the study collected data on sexual behavior, drug use, and risk factors for human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS). The study has also collected data to address relationships and family formation, the obesity epidemic, midlife health and mortality, drug and alcohol use, suicidality, and cardiovascular risks. More recently, Add Health has also collected data to address the risk and resilience for cognitive health and physical functioning. Throughout these evolutions, Add Health has also aimed to study health disparities along factors of race and ethnicity, socioeconomic status, sexual orientation, geography of residence, and disability status.

Across the six waves of the cohort, Add Health is longitudinal, multilevel, and intergenerational. Dr. Hummer noted that the Add Health Parent Study is about to go into the field next month. The study also features many different data domains, including survey, biological, cognitive, contextual, and environmental data. Nearly 12,000 members of the original cohort have participated in Wave VI. To date, more than 5,000 published papers and more than 900 theses and dissertations have used Add Health data, making key scientific contributions over the years.

The Request for Applications (RFA) for Wave VI was issued February 26, 2020, and was due May 18, 2020. The study team was charged with writing two U01 proposals for Wave VI. The proposals set the overall goal to collect and disseminate high-quality data on life course determinants and trajectories of health, cognition, health behavior, and health disparities among this large, nationally representative cohort aging into midlife. Dr. Hummer emphasized that the data are available for the entire research community. The study team has also considered racial, ethnic, and socioeconomic heterogeneity. Data dissemination also implements quality control in data production and dissemination, while protecting the confidentiality of participants.

Wave VI was funded in 2021, but the study as a whole has faced the challenges of declining response rates, declining trust in institutions, and competition for survey attention. Wave VI in particular faced challenges of busy participants, who were facing longer and more complex survey instruments. Further complications arose from data collection that last took place years before the COVID-19 pandemic. To address costs while ensuring data quality, Wave VI split the cohort into two groups: Participants in Sample 1 answered a 90-minute web survey, and participants in Sample 2 participant data were collected during in-person sessions conducted all over the United States to provide data that included hearing tests, grip strength, and certain cognitive measures. Sample 2 oversampled from different racial and ethnic groups for health disparity research. Consenting Sample 1 and 2 survey completers also had a 45-minute at-home health exam with a blood draw. In the end, Wave VI survey response rates were similar to those for Wave V, and Wave VI home exam rates were significantly higher than those for Wave V.

Dr. Hummer reviewed the data available in Wave VI. Each set of data includes a user guide with information and tips on how to use Add Health data. Wave VI's survey data add new information on work-life balance, mental health, caregiving needs, institutional trust, neighborhood perceptions, discrimination, physical and sensory function, and cognitive

function. The average age of Wave VI participants was 44, meaning the cohort has been followed for an average of 29 years.

Wave VI data show some positive health trends such as decreasing rates of people without health insurance, lower rates of smoking, and lower rates of suicidal ideation. However, Wave VI also has higher percentages of participants who report having poor or fair health, obesity, and reported hypertension.

Cognitive, sensory, and physical functioning data for Wave VI were collected through the Add Health Cognitive Assessment, Physical, and Sensory Functioning (Add CAPS) Protocol, developed by Allison Aiello, Ph.D., and Robert Hummer. The protocol features in-person and web-based assessments of cognition, as well as in-person tests of hearing and grip strength. The cognitive tests selected for the protocol were designed to expand on Waves I to V. Tests were also chosen to reduce ceiling effects, be repeatable for longitudinal assessments, align with other large studies to enable comparative and integrative research, and work for both the web-based Sample 1 and in-person Sample 2. Preliminary analysis of Add CAPS cognitive data shows that data can be compared with similar studies for integrative life course research. Analyses also suggest trends in global cognition, with cognition scores increasing with education but also declining with age.

Next, Dr. Hummer reviewed data from Wave VI in-home exams. These datasets will be fully processed and disseminated within the next few months. Measured obesity and hypertension rates were higher than self-reported measures.

Finally, Wave VI data include contextual and environmental data on domains ranging from social and policy contexts to local area estimates of pollutants and noise. Add Health is also collecting decedent records, birth records state by state, and college educational records. Dr. Hummer noted that the number and rate of deaths were higher than anticipated. Updated mortality data will be released in spring or early summer of 2026.

Dr. Hummer provided information on Add Health's tiered, two-way data access. Restricted use data include all Add Health data. This tier requires an approved 5-year contract with UNC. Contracts are renewable and free of charge. There are approximately 400 established contracts, each with an average of five or six users attached to the contract. Researchers can access data through a secure research workspace (SRW) at UNC or through a secure server at their home institution. Dr. Hummer directed attendees to Add Health's website for more information. Public-use data are accessed through data use agreements with either the Inter-university Consortium for Political and Social Research (ICPSR) at the University of Michigan or Dataverse at UNC-Chapel Hill.

Dr. Hummer closed his presentation by thanking the Add Health team and NIH, NIA, and NICHD for funding support. Most of all, Dr. Hummer thanked the Add Health participants for giving so much of themselves for the goal of scientific advancement.

Discussion (2:07:47)

Dr. Van den Veyver asked whether Add Health could inform policy change if it has not already done so. Dr. Hummer shared several examples of Add Health's influence on society and population health. Data from Wave I led to a highly cited paper showing the importance of family context for adolescent health. Wave IV data showed that levels of pre-hypertension and

pre-diabetes were both higher than anticipated, leading to changes in family medicine with earlier blood pressure and blood sugar monitoring for adolescents. Finaly, Add Health data have also been used to assess the effects of major societal shocks, such as the 2008 recession, on health and wellness.

Dr. Gyamfi-Bannerman asked whether pregnancy data are collected in Add Health. Dr. Hummer said that pregnancy data are collected with support from NICHD. Childbearing has occurred throughout all waves of data collection, enabling the study to assess fertility, the timing of early versus late childbearing, and childbearing's effects on social and family contexts. Dr. Hummer said he anticipated that more data on pregnancy and childbearing will be available in Wave VII. These data come from questionnaires asking how many children a participant has had and the birth outcomes. Add Health is also working state by state to collect participant birth records and child birth records. In response to a question from Dr. Aizer, Dr. Hummer said that pregnancy and childbirth data are collected only from female participants. There are currently no plans to start a separate Add Health study for children.

Dr. Aizer was impressed by Add Health's pollution data and asked when those data are collected in the participant life cycle. Dr. Hummer said that pollution data are estimates based on residential context, going all the way back to Wave I. Dr. Hummer's colleague Eric Whitsel, M.D., M.P.H., could provide more detail on these data. Dr. Aizer cited evidence linking exposure to pollution early in life with later poor health outcomes, highlighting the importance of such data.

Dr. Aizer also commented that the Social Security Administration could provide important administrative data, such as those for earnings and retirement. Dr. Hummer said that this partnership is being explored for Wave VII.

Dr. Maldonado asked whether Add Health is interested in particulate tracking, which could be useful in areas that have been affected by wildfires, such as California. Dr. Hummer said that Add Health has latitude and longitude coordinates for each wave, but not every time a participant moves. Add Health will look for ways to continue improving these data as the study continues.

Dr. Jabs asked what data on twins are available, what kinds of omics the study collects, and whether Add Health is working together with the NIH *All of Us* Research Program. Dr. Hummer said that Add Health is not connected to *All of Us*, but Add Health's data have been compared with the National Health and Nutrition Examination Survey (NHANES) and datasets from the National Institute of Environmental Health Sciences (NIEHS). Researchers have also integrated Add Health data with MIDUS and the Health and Retirement Study (HRS). On twins, Wave I innovatively included approximately 1,500 twins and many sibling pairs. Add Health also has GWAS data from approximately 11,000 participants, available through NIH's database of Genotypes and Phenotypes (dbGaP). Omics data include epigenetic data, biological clocks data from Wave V, and microbiome data.

Dr. Cernich asked whether adolescent data include other data on social and community enrichment, such as volunteering activities or participation in sports. Dr. Hummer said that Add Health was heavily influenced by social and behavioral sciences, with rich social data going back to Wave I data collection. School-based data facilitated collecting information on close friendships, enabling researchers to study those connections. Researchers also asked adolescents about their relationships with parents and parental figures, and asked parents about their relationships with their children. As cohort members aged into their 20s and 30s, questionnaires

added items about religious involvement, volunteering, and spousal connections, which have aided longitudinal study of social isolation.

Dr. Cernich praised Add Health and its evolution over the life course. She noted that having early data, even in imperfect form, paints an important picture of how to support health over the life course in a number of ways—and not all having to do with medical care. She echoed Dr. Hummer's appreciation for both the Add Health team and the study participants.

I. Scientific Presentation: The Role of Early Motor-Based Problem-Solving in Physical Therapy Interventions for Infants: A Synthesis of Two NICHD-Funded Clinical Trials (2:11:52)

Stacey Dusing, Ph.D., P.T., FAPTA, is the Sykes Family Chair of Pediatric Physical Therapy, Health, and Development and a professor at the University of Southern California's Division of Biokinesiology and Physical Therapy. Following her talk, Dr. Dusing introduced Kylie Macnab as the Voice of the Participant.

Developmental cascades describe the ways in which multiple domains of development can influence each other. For example, in the context of motor skills and communication, advancement in motor skills can have cascading effects on an infant's communication system, improving the infant's ability to engage with both objects and their social partners. As an infant begins to explore their environment, their social partners can provide new opportunities for learning by engaging with them in different ways. However, in rehabilitation, providers are trained to rehabilitate in one given domain, limiting opportunities for more global development.

As a physical therapist, Dr. Dusing was taught how to support movement, posture, and stability. Informed by her physical therapy practice and supported by funding from NICHD, Dr. Dusing has been able to develop two different interventions that provide infants with rehabilitation for movement and posture while encouraging them to find different ways of navigating and engaging with the world.

Dr. Dusing shared the Supporting Play Exploration and Early Development Intervention (SPEEDI) multisite clinical trial. The aims included assessing SPEEDI's efficacy supporting parents and infants during early development and assessing how timing affected intervention efficacy. Infants born preterm can exhibit impaired motor control and signs of stress with interaction, and they can have biological risk factors that limit how they engage with the world. These infants are also at high risk for developmental delays or disabilities that can affect long-term achievement and their ability to explore and move independently. In the short term, SPEEDI was designed to enrich the motor and cognitive environment while educating caregivers to improve reciprocal communication and give infants more opportunities to engage with their environment. Ultimately, Dr. Dusing aimed for SPEEDI to reduce the risk of developmental delay and disabilities.

Dr. Dusing enrolled infants in Virginia, where infants born at less than 29 weeks (11 weeks before full-term gestation) are eligible for early intervention regardless of whether they show developmental delay. Infants are eligible for rehabilitation at the time of NICU discharge; however, many families do not start intervention until at least 3 to 4 months after

arriving home. Dr. Dusing compared standard care with two versions of the SPEEDI intervention: one in which SPEEDI bridged the gap between NICU and home (SPEEDI-early), and the other in which SPEEDI was delivered during the typical 3 to 4 months after returning home (SPEEDI-late). Dr. Dusing performed up to six assessments during the infants' first 2 years of life. She hypothesized there would be additional benefits with SPEEDI-early because the early intervention would be able to take advantage of enhanced plasticity during that earlier time frame. The study sampled data on 83 infants, all born around 26 weeks. Risk of disability was assessed based on medical records, and the general movement assessment. Nine children went on to have cerebral palsy and were described separately from the rest of the study participants.

SPEEDI was designed in two phases. In Phase 1, parents and infants go through five guided participation sessions over 21 days to create an improved connection between parent and infant. In Phase 2, parents provide 20 minutes of the SPEEDI intervention per day, based on five specific activities that improve learning opportunities and social engagement. A physical therapist continues to see the family for five visits over 12 weeks to monitor progress and help parents know when to advance the intervention. The study outcomes included gross motor and cognitive outcomes, rated on the Bayley Scales of Infant and Toddler Development and the emotional availability scale of parent-infant interaction during a 5-minute free play session.

Collapsed SPEEDI groups showed no difference when compared with standard care; however, differences emerged when comparing early and late SPEEDI treatments. Gross motor skills, cognition, and emotional availability all improved across groups and with each session of intervention. However, the greatest differences were observed in the SPEEDI-early group. Dr. Dusing speculated that greater emotional availability may have been a driving force in improving motor and cognitive outcomes for the SPEEDI-early group. However, she noted that the COVID-19 pandemic presented challenges to seeing families in person and may have influenced the study's results.

Dr. Dusing also shared findings from the SIT-PT Project, a follow-up to a previous study funded by the U.S. Department of Education comparing the Sitting Together And Reaching To Play (START-Play) intervention against usual care. The first study showed that START-Play was more effective than usual care at improving motor and cognitive skills in infants with moderate to severe disability. The SIT-PT Project added to the initial study by performing dose-matched comparison of the two interventions. Usual care involved alignment and strength training, repetition of movement, motor skill improvement, and caregiver education. START-Play consisted of child-led, play-based sessions, with motor-based problem-solving and brainstorming with the caregiver. Infants were motivated to move through play.

In the SIT-PT Project, both interventions were provided through 24 visits over 12 weeks, with usual care continuing during the study. Outcome assessments took place every 3 months for 1 year. Interventions were dose-matched to 94 infants with high risk of having cerebral palsy, as measured by the Hammersmith Infant Neurological Examination (HINE). Groups were matched by age, gender, and severity and type of impairment. Approximately 40% to 50% of children in the study went on to have a cerebral palsy diagnosis at 2 to 3 years of age. Dr. Dusing noted that children were enrolled in the study when they could sit up for 3 seconds, which occurs at different ages, leading to a mixture of ages within the groups.

Preliminary data suggest cognitive function and gross motor function improvements both favor START-Play. Dr. Dusing played a video of a child 3 months after START-PLAY intervention who is now able to balance, sit upright, and explore to find their caregiver on their own. Relating these findings back to the concept of developmental cascades, Dr. Dusing said that these two studies demonstrate the importance of supporting clinicians, researchers, and families with proper intervention at accessible cost. Dr. Dusing noted that SPEEDI takes place over 10 visits, an approach that costs less than long-term special education later in a child's life. Providers also need to educate families and get them thinking of development across these cascades. Finally, Dr. Dusing said that providers need to prioritize evidence-based therapies that enable children to explore their world on their own, with appropriate support from their families.

Discussion (2:40:45)

Dr. Van den Veyver asked which family members take part in these interventions. Dr. Dusing said that families choose a primary person for the intervention, but anyone who is interested can join the sessions. One person needs to be listed as a primary member, which is usually the child's mother, but families have also invited nurses and other caretakers to sessions.

Dr. Van den Veyver asked how the study accounts for the presence or absence of siblings. Dr. Dusing said that siblings are rarely present in the NICU, but they are scaffolded into the interventions.

Dr. Cernich asked for more information on the standard of care for infant physical therapy. Dr. Dusing gathered information on standard of care through provider surveys and, more rarely, taped rehabilitation sessions. Videos allowed Dr. Dusing's team to set the dose and assess standard care and test interventions by recording how long families stayed on task. The study team also assessed principles they observed across both the test intervention and standard of care. Dr. Cernich said these methods were great examples of standardizing early interventions.

Dr. Maldonado asked whether Dr. Dusing thought her work could have a long-term impact on cognitive decline. Dr. Dusing said that reducing long-term cognitive decline is the team's primary goal. So far, she is observing that the rate of decline in preterm infants with START-Play is slower, and these children do not fall as far behind. Dr. Dusing noted that this intervention may not be able to cure cerebral palsy, but it may reduce developmental delay.

II. Voice of the Participant (2:48:58)

Kylie and her son participated in the SIT-PT Project. Kylie and her husband have four children ranging from 8 to 2 years of age. She used to be a pediatric oncology nurse and then stayed at home following her last pregnancy. Her water broke at 17 weeks, and she was then placed on bed rest for 119 days. Kylie was initially told her son would not survive. Her son lived, but then his pediatrician began noticing developmental delays at 34 weeks of life. Kylie also realized that her son was not reaching his usual milestones. Her son then started early intervention, based on eligibility guidelines in Nebraska. After he had been seeing a therapist for 4 months, the family was notified of this study. Kylie noted how different START-Play was from her son's usual therapy, appreciating its emphasis on play and the lack of manipulation he needed during sessions. Her son has come very far with the new intervention.

Kylie also described the experience of having her other children involved in her son's therapy and said that she valued having the extra support for her son. She said she hopes that her son will not need as much intervention as he gets older. Kylie said she was also grateful to have 10 free visits, recognizing that not all families will be able to pay for interventions out of pocket. The physical therapist who worked with Kylie's family gave advice on how to help her son outside of sessions and kept the interventions parent centered. The play aspect also meant that there were fewer tears compared with typical early intervention treatment, which Kylie and her other children appreciated.

Discussion (2:254:59)

Dr. Cernich thanked Kylie for sharing her story and asked her to share more about what participation was like and what researchers could take away in terms of how she and her family were cared for during the study. Kylie said that the developmental red flags were a catalyst for starting the study, and she likely would not have taken part on her own. Kylie said that making pediatricians aware and getting them involved in assessing the need for early intervention were very valuable, and she recommended having more connection between therapists and health care providers.

Dr. Cernich asked whether, in addition to the engagement of the researchers, anything else helped Kylie stick with the study. Kylie said that she knew what research looked like, which prepared her for the commitment. She also acknowledged that participation was easier for her as a stay-at-home mom; she was able to schedule appointments around nap time for her older child. Kylie said that families with fewer developmental delays may feel like the study would be a lot to commit to, but Kylie and her family were encouraged to continue because they could see improvements early and easily. The therapists were also very encouraging, which helped the family stay engaged.

Dr. Van den Veyver asked what has happened since the study's end and whether Kylie is receiving any continuing support. Kylie's family has finished the study and the follow-up period, which includes visits every 3 months for the year after concluding the study. She said that she is not sure whether there will be any additional follow-up.

Dr. Gyamfi-Bannerman asked whether health care professionals can do more to identify delays and connect families to interventions sooner. Kylie said that delays were noticed at well-baby visits with the pediatrician, and the pediatrician helped her get a referral for therapy. However, the pediatrician kept assuring Kylie that her son would catch up. It took Kylie's pointing out red flags for interventions to be recommended, but that advocacy came from experience that not everyone has. Dr. Dusing has heard from other families that it is hard for developmental delays to be identified early. Children in the NICU tend to get identified earlier, but there is also a heavy "wait and see" attitude that is problematic and not equitably applied across the country. Dr. Dusing said that providing any intervention between the NICU and returning home can help families get education and look out for early signs if nothing is immediately apparent.

Dr. Maldonado said that it is disturbing to hear that the squeaky wheels are the ones that get service. She said that in her experience in working with the American Academy of Pediatrics (AAP), most pediatricians try to follow national guidelines. Dr. Maldonado asked Dr. Dusing whether therapists can work with AAP to build better

policies so that pediatricians are not relying on the tendency to "wait and see." Dr. Dusing said that a paper published in 2017 helped establish guidelines around the world for identifying cerebral palsy within 3 to 5 months of life, but the United States has been slow to adopt them. Children at risk for cerebral palsy can also be identified for other cognitive and motor dysfunction with reliable assessment tools, but families face issues with access, and many pediatricians are not aware that these services exist. Dr. Dusing is working on a training initiative with early detection guidelines, based on the argument that early treatment saves money and hardship for families. In her field of infectious disease, Dr. Maldonado said, preventing even one or two dire disease episodes is related to improved IQ across the population, which then translates into more money for the economy. She suggested that this message could be very exciting to policymakers in this space as well.

Dr. Jabs asked Dr. Dusing whether she is using virtual visits and whether artificial intelligence (AI) could improve the scalability of this treatment. Dr. Dusing said that she has a current collaboration in Australia implementing SPEEDI with mental health components through virtual visits, which will allow her to compare usual care with telehealth. She said that she has a small foundation grant to look at treatment implementation in urban and rural contexts to also have a direct comparison of in-person and telehealth services. Dr. Dusing said she expected that providing basic services in the NICU and then bridging to telehealth would be more successful, but she anticipated more delays if providers wait for patient discharge before bringing up interventions with the family. Dr. Dusing typically sees families within 1 to 2 days after NICU discharge, and the intervention is made more feasible because it requires only 10 visits.

Dr. Cedars praised the intervention, especially the efforts to educate primary and pediatric caregivers, but emphasized the need for capacity among physical therapists. Dr. Dusing agreed with this point. She said that therapists put a lot of time and care into interventions for older children that are not as effective, and she suggested that shifting resources toward earlier interventions may help capacity.

Dr. Cernich thanked Kylie for sharing her experience and said that the naturalistic way intervention was delivered was very important. She said that the earlier families can access scalable therapies, the higher the likelihood that children will have better outcomes throughout their lives.

III. Concept Clearance (3:12:40)

Dr. Rasooly led the Council through the review of three concepts. She explained that these concepts represent early stages of potential grant or contract solicitations. The NIH policy is that experts in the field must approve the concept before an initiative can be announced or developed into a funding initiative. Council members are asked to review, comment on, and approve concepts for their scientific merit and relative priority. Not all concepts are developed into formal initiatives. Those that are developed further may include details that are not in the original proposal. Concepts are presented in open session and specifically do not include details about future funding initiatives, which prevents Council members from having insider information that would exclude them from applying to any eventual funding initiative.

ORACLE 3C: Chronic Conditions, Coinfections, and Comorbidities in HIV (3:14:17)

Samantha Calabrese, M.P.H., presented a concept from the Maternal and Pediatric Infectious Disease Branch. The proposed concept aligns with all five of NICHD's strategic plan goals, branch priorities, and HIV and AIDS research priorities. Dr. Maldonado asked whether applicants will be able to define what comorbidities they study or whether there will be specific conditions outlined in the initiative. She also pointed out that the HIV and AIDS researchers are aging up and that there is unfortunately less emphasis in the young investigator category. She asked whether the initiative would allow young investigators to study diseases outside of HIV if relevant to a comorbidity. Ms. Calabrese said that the concept team is open to suggestions and ideas. She said the team hopes that other ICOs will participate in the initiative and that this initiative will engage the next generation of researchers. Dr. Maldonado asked whether this initiative would make existing datasets and biobanks available to researchers. Ms. Calabrese said that the initiative emphasizes advancing lines of inquiry through data-driven approaches, which can support using existing data or new data collection. Dr. Gyamfi-Bannerman noted the low burden of HIV and AIDS in the United States and asked whether other concepts from the branch should be considered. Ms. Calabrese said that the concept is in line with branch priorities because it has the potential to address evolving challenges in adolescent and maternal populations. Dr. Van den Veyver asked whether the concept will only focus on pregnancy or whether researchers will be able to study other aspects of fertility and how comorbidities affect it. Ms. Calabrese said that the concept is aimed at covering the life course, and so researchers will be able to study various reproductive stages. Dr. Jabs asked whether clinical trials will be allowable under this initiative. Ms. Calabrese said that the concept team will consider them.
Decision: Approve.

The Council additionally discussed the concept clearance process. Dr. Maldonado asked whether Council members will have the opportunity to provide additional feedback before this initiative is released. Dr. Rasooly said that Council members become ineligible to participate in an initiative as soon as NICHD begins planning it. Council members cannot plan the specificities of applications, but they can provide input and discussion on gaps and potential areas to pursue during the concept stage. Dr. Cernich added that the concept presentation offers an opportunity to share Council input and thoughts before moving to a vote. Members of the Council can comment on areas of focus, the potential to expand scope, and how a program can move forward with possibilities for inclusion. However, after moving past the larger concept, Council members are not eligible to apply. Concept presentations try to balance the general idea of what NICHD is planning to do and how the concept aligns with priorities and addresses research gaps, without sharing the funding mechanism or number of awards. After the presentation, program staff takes Council feedback into account when writing the initiative.

IV. Closing Remarks (3:29:00)

Dr. Rasooly noted that Council members will receive Conflict of Interest forms at a later time because of the unusual schedule for this Council's closed session. She asked Council members to fill out these forms promptly and thanked everyone for their flexibility.

Dr. Cernich thanked all attendees and expressed her appreciation for their dedication to the Council. She also thanked NICHD staff who made this meeting possible and then thanked the

presenters and guests. She said that she looked forward to seeing everyone for the closed session.

V. Day 1 Adjournment

Dr. Rasooly adjourned the open session at 4:04 p.m. A total of 173 people viewed the live NIH VideoCast.

VI. March 20, 2026 – opening announcements preceding Closed Session

Rohan Hazra, M.D., introduced himself as the new Acting Director and Acting Deputy Director of NICHD following the departure of Dr. Alison Cernich. He also introduced David Clark, Dr.P.H., M.P.H., who is now serving as Acting Director of the Division of Extramural Research, and Theresa Cruz, Ph.D., who is now serving as Acting Deputy Director of the Division of Extramural Research.

VII. Closed Session

The meeting was closed to the public in accordance with the provisions set forth in Section 55f2b(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 extramural applications.

VII. 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 949 NICHD-primary applications requesting $318,797,265 in direct costs and $445,541,800 in total costs.

VIII. Adjournment

There being no further business, Dr. Hazra adjourned the meeting at 2:51 pm. The next Council meeting is scheduled for July 8, 2026, as an in-person meeting.

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

Rohan Hazra -S
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Date: 2026.04.14 16:06:18 -04'00'

Rohan Hazra, M.D.

NACHHD Chair

NICHD Acting Director

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Date: 2026.04.14 11:27:13 -04'00'

Rebekah S. Rasooly, Ph.D.

NACHHD Executive Secretary

Director, NICHD Division of Extramural Activities