Eunice Kennedy Shriver National Institute of Child Health and Human Development

National Advisory Child Health and Human Development (NACHHD) Council

Meeting Summary

NIH Bethesda Campus, Building 45, Bethesda, MD

September 9–10, 2025

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 189th meeting at 9:30 a.m. ET on Tuesday, September 9, 2025, at the NIH Bethesda Campus, Building 45, in Bethesda, Maryland. It was a hybrid meeting that was open to the public from 9:30 a.m. to 5 p.m. ET. The Council reconvened on Wednesday, September 10, 2025, for another public session from 9 a.m. to 10 a.m. ET. The Council then met in a session that was closed to the public from 10:15 a.m. to 1:15 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. NICHD Acting 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.
Damien Fair, Ph.D. (virtual)
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 either the Day 1 NIH VideoCast or the Day 2 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 in-person and online attendees.

Review of Confidentiality and Conflicts of Interest (1:10)

Rebekah Rasooly, Ph.D., the Council's executive secretary, reminded NACHHD Council members that they are required to read, agree to, and sign the confidentiality and nondisclosure rules for special government employees on the Council member website before they evaluate 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 are required to recuse themselves and leave the meeting before any discussion that involves 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 on the Council, 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) that are capable of capturing confidential information.

Council Minutes (1:54)

Marcelle Ivonne Cedars, M.D., made a motion to approve the June 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 (3:24)

Dr. Rasooly announced that the future Council meetings are scheduled for January 26–27, 2026 (virtual); June 8–9, 2026 (6710B Rockledge Drive); September 1–2, 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 (3:55)

In her report, Dr. Cernich described the president's and Congress's fiscal year (FY) 2026 budgets, provided updates on key NIH programs and policies, and reviewed several NICHD collaborative programs. Dr. Cernich also expressed her gratitude to the Branches, Divisions, and Offices of NICHD for their flexibility and creativity in handling the realignments and challenges they have faced this year. She extended these thanks to patients, families, advocacy groups, and the extramural community, stating that the work across all of these areas has allowed science and essential supporting processes to be maintained.

NICHD Budget Update (8:45)

The president's proposed FY 2026 budget, released on May 2, 2025, originally suggested an $18 billion cut to NIH and a consolidation of the NIH institutes and centers (ICs), reducing the total number of ICs from 27 to 8. This consolidation would have included

NICHD's merger with the National Institute on Deafness and Other Communication Disorders (NIDCD) to form the National Institute for Child and Women's Health, Sensory Disorders, and Communication, with a proposed budget of $1.4 billion.

Recently, both the U.S. Senate and the U.S. House of Representatives released their FY 2026 Labor, Health and Human Services (LHHS) Appropriations bills. The Senate's bill did not include a proposed consolidation of institutes but did propose a $21.3 million increase in funding for NICHD over the FY 2025 operating level, with $20 million specified for the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) initiative and $1.3 million for the Safe to Sleep® campaign. The House LHHS Appropriations bill proposed flat funding for NIH and NICHD—$48 billion and $1.76 billion, respectively. The bill did not include proposed consolidation of the NIH ICs; instead, it suggested that NIH should consider consolidations in its scientific review processes, and that indirect costs should be limited to 30%. NICHD will continue to monitor this situation for changes.

NICHD Policy Updates (11:30)

NIH Notices of Funding Opportunities to Post Only on Grants.gov (11:31)

Beginning in FY 2026, notices of funding opportunities (NOFOs) will no longer be posted in the NIH Guide to Grants and Contracts. However, the NIH Guide will continue to be used for policy and informational notices. Active and expired NOFOs will remain searchable on Grants.gov. Dr. Cernich directed attendees to NOT-OD-25-143 for additional information. NOFOs will also no longer be included in the weekly NIH Guide Table of Contents subscription emails; instead, they will be issued on Grants.gov subscription services. Dr. Cernich asked attendees to alert their colleagues and institutions about these changes.

Highlighted Topics (12:41)

NIH will also transition to a Highlighted Topics website, which will inform the scientific community about areas of high interest to NIH, similar to notices of special interest (NOSIs). The website will feature descriptions of target areas in the NIH mission, including new or emerging areas not previously highlighted, as well as the institutes, centers, and offices (ICOs) that participate in that area of interest. Dr. Cernich noted that NICHD's Division of Extramural Activities was part of the pilot study that established the website and had helped guide the website's development in a way that makes it more usable and functional.

Supporting Fairness and Originality in Research Applications (NOT-OD-25-132) (14:08)

NIH released a policy announcement, NOT-OD-25-132, that addresses the use of artificial intelligence (AI). It comes after NIH began to receive an increase in applications generated with AI, which enabled investigators to submit more than 40 applications apiece in a year. In response to concerns over plagiarism and falsification of ideas, NIH will not consider applications that have been substantially developed by AI or that contain sections substantially developed with AI. If the use of AI is detected post-award, NIH may refer the matter to the Office of Research Integrity (ORI) while also taking enforcement actions that may include disallowing costs, suspending and withholding future awards, and terminating investigators. In the interest of spreading funding across investigators, NIH will also accept only six

applications a year from an individual investigator, program director, or group of investigators. These new policies will apply to all activity codes except T (for research training and career development) and R13 (for conference grant applications).

Updated NIH Policy on Foreign Subawards (NOT-OD-25-104) (16:25)

NIH needs to report money spent on foreign collaborations transparently and reliably, for both accounting and national security reasons. To this end, NIH will no longer issue new, renewal, or noncompeting continuation awards to domestic or foreign entities that include a subaward to a foreign entity. NIH will use a new award structure that includes a prime awardee with independent awards linked to the prime, so that NIH can track the project's funds individually. This new structure will be implemented no later than September 30, 2025. For current awards, NIH will renegotiate the award structure with the recipient so that foreign subawards are financially removed from the primary award and awarded instead as administrative supplements. Additional details can be found at NOT-OD-25-130.

Limiting Allowable Publication Costs (17:58)

NIH has released a request for information (RFI), available through September 15, 2025, that contains five policy options that maximize funding to investigators by limiting allowable publication costs. Dr. Cernich encouraged the community to submit comments to the RFI through the electronic form or by contacting SciencePolicy@od.nih.gov.

NICHD Collaborative Program Updates (18:59)

Dr. Cernich provided updates on several programs that are collaborations between NICHD and other areas of NIH: the NIH Blueprint for Neuroscience Research, the Environmental influences on Child Health Outcomes (ECHO) Program, the Helping to End Addiction Long-term® Initiative or NIH HEAL Initiative®, the Adolescent Brain Cognitive Development (ABCD) Study®, studies funded with the NIH Common Fund, and the *All of Us* Research Program.

NIH Blueprint for Neuroscience Research (20:48)

This program is a productive continuing grassroots NIH-wide collaboration that has resulted in several advancements in neuroscience. Dr. Cernich highlighted a project aimed at improving speech neuroprosthetics. Typical devices require extensive training for proper calibration and result in poor accuracy for understanding speech. In a study described in the *New England Journal of Medicine*, surgeons supported by the Blueprint Program and investments by NICHD and the National Institute of Neurological Disorders and Stroke (NINDS) have implanted a novel microelectrode array that demonstrates both improved calibration and accuracy.

Blueprint has also led to the development of the NIH Baby Toolbox, a battery of neurodevelopmental assessments designed for infants and toddlers. The toolbox uses computer-assisted item scoring that generates scores on more than 30 validated tests for cognitive, socioemotional, and motor function. The tests are norm-referenced on a nationally representative sample and are designed so that individuals without an advanced degree can reliably administer them. The tests, which are available in English and Spanish, can be found at NIHbabytoolbox.org.

Environmental influences on Child Health Outcomes (ECHO)/Helping to End Addiction Long-term® Initiative (23:41)

Through ECHO, NICHD has developed protocols for the Eating, Sleeping, and Consoling (ESC) for Neonatal Opioid Withdrawal (NOW) trial. So far, the trial has examined 463 infants born to women who took opioids during pregnancy and compared 143 infants treated with the ESC approach with 320 who received usual care. Results published in *JAMA Pediatrics* demonstrate that infants assessed and managed with the ESC approach show substantially less postnatal opioid exposure than infants treated with usual care. Data from this trial will be available on the NICHD Data and Specimen Hub (DASH) when the hub is relaunched, in the fall of 2025.

Through the NIH HEAL Initiative, NICHD has also made new advances in developing programs to study infant pain. Those protocols will be launching soon.

Adolescent Brain Cognitive Development Study (25:24)

In partnership with NIDA, NICHD has invested in the study of digital media and its influence on cognitive development. Findings from this investment, published in the *Journal of Adolescent Health*, have shown differences in technology and digital media use in 9- to 10-year-olds and 13- to 14-year-olds, with differences mediated by technology type, age, sex, and household factors. Time spent with television, movies, video games, social media, and texting generally increased over time, though usage of YouTube did not change. Boys' use of video games was higher, whereas girls more frequently used social media. Children also spent less time with digital technology if their parents were married, had a higher income, and had higher education. Lastly, parents' estimates of their children's technology use was typically lower than what their children self-reported. The study points to a great opportunity to continue measuring these behaviors.

The ABCD Study is also examining the link between social media and later depressive symptoms in young adults. Research examining 4 years of data from approximately 12,000 children starting at ages 9 to 10 has shown that children who use social media more than average at the study's 1-year mark are more likely to show greater signs of depression at the study's 2-year follow-up. These patterns are also holding true at the 3- and 4-year follow-up. These findings may suggest that social media use contributes to depressive symptoms more than it serves as a response to feeling depressed.

NIH Common Fund (29:12)

The NIH Common Fund has a Venture Program, which provides short-term initiatives capable of advancing science. This program will administer an award to fund the Newborn Screening by Whole Genome Sequencing (NBSxWGS) Collaboratory, which is led by NICHD's Intellectual and Developmental Disabilities Branch (IDDB) in partnership with the National Center for Advancing Translational Sciences (NCATS). The collaboratory will examine the feasibility of a whole genome sequencing model across states that addresses genetic conditions actionable in the first year of life and may ultimately expand to a national newborn screening (NBS) program. The goals of the collaboratory will be to expand NBS, shorten time to diagnosis for rare diseases, provide earlier interventions, and build state NBS programs that are compatible with new gene therapy technologies as they become available.

All of Us Research Program (30:36)

The *All of Us* Research Program began enrolling pediatric participants in 2024. In July 2025, it enrolled its 500th pediatric participant. NICHD has supported adding enrollment partners on the *All of Us* platform and has been working closely with Sara Van Driest, M.D., Ph.D., the program's director of pediatrics, to continue growing the pediatric data set. *All of Us* initially focused on recruiting young children from birth to 6 years old; now it is working through consent protocols to enroll children up to 12 years of age. These advances in *All of Us* reflect specific NICHD investment in the program's pediatric enrollment, as opposed to general support for the program.

Discussion (32:14)

Ignatia Van den Veyver, M.D., asked for additional details on when DASH will become available. Dr. Cernich said that the hub is down because of contract issues but is expected to be back again in October or November 2025. DASH will be transferred to the NIH Biomedical Research Informatics Computing System (BRICS), which will give DASH more capacity and capabilities, including neuroimaging and enhanced security from the BRICS Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System. Transferring DASH will also be cost-saving, because NICHD will no longer need to maintain DASH's base platform or software developments. Dr. Cernich noted that the original DASH interface will not be migrating; data display will differ, but functionality will largely be the same.

Dr. Jabs expressed her excitement for NICHD's initiatives and asked how these updates will be shared with the public. Dr. Cernich said that NICHD no longer has its own communications team. Instead, it is working with a central, intra-NIH communications team to determine how scientific findings are featured on NIH's web presence at large. At the same time, it is also trying to communicate significant social findings from NICHD with the central office. Research itself is continuing as it always has. NICHD is also working on using social media to share more scientific findings. Dr. Cernich said she hopes to have a more routine process for all of NIH by this upcoming winter.

Cynthia Gyamfi-Bannerman, M.D., M.S., FACOG, asked for additional information on the six-application limit. Dr. Cernich said that this limit applies across NIH and is not IC-specific. NIH is hoping that this limit will drive more distributed leadership across institutions by giving new investigators the opportunity to put forth their first R01s. Dr. Cernich said that while she recognizes the important contributions of established investigators, NIH is interested in supporting younger investigators as well.

Dr. Cedars asked how council members can advocate for the work going on at NICHD and NIH. Dr. Cernich encouraged attendees to speak about the spread and reach of NIH's funding across the country. Science is not always clear and linear, and conveying the value of basic science can be especially challenging. Dr. Cernich said that as she has learned more about basic science, she has come to understand that the mechanisms being studied in those areas drive a wide array of conditions. These mechanisms also play an important role in clinical research, because clinical researchers cannot develop new therapeutics if the target of a disease is unknown. Dr. Cernich encouraged more plain language messaging about the impact basic science has for clinical research and the scientific enterprise as a whole. Dr. Cernich thanked attendees for these efforts, recognizing that NICHD would be in a different

situation without advocacy.

Yvonne Maldonado, M.D., asked for additional information on the *All of Us* Research Program. Dr. Cernich said that the program has a unique way of gathering data and enrolling its participants. Participants enroll and can then donate electronic health records (EHRs) and fill out surveys. The program has been able to transfer consent for these activities to young children through parent proxies. These protocols are currently being piloted at five enrollment centers and will then expand. Dr. Van Driest will eventually work on transitioning these protocols to older children who can directly interact with the program. *All of Us* is also rolling out several ancillary studies, including one on eye health that is piloting retinal scans at certain enrollment centers. The program is also beginning to discuss mother-baby data linkages. Dr. Cernich offered to invite Dr. Van Driest to a future Council meeting.

Patricia Dorn, Ph.D., asked whether the research community is showing the same level of interest in NIH as it has in previous years, in terms of the number of applications submitted. Dr. Cernich said that applications seem to be increasing, which makes funding difficult when the institute is presented with a flat budget. NICHD is discussing other potential funding models and awards to responsibly fund as many new projects as possible. For example, NICHD is not using multiyear funding for clinical trials, because Dr. Cernich believes that there is a responsibility to monitor those studies for both safety and feasibility. NICHD is also assessing its other investments and investing based on impact. An example of this is NICHD's increased investment in the loan repayment program. Dr. Cernich recognizes that these increasing investments mean there is less money available for other areas of NICHD's funding.

Dr. Van den Veyver asked what NICHD is planning to do to make sure that those engaged in pediatric research with the *All of Us* Research Program can continue to access and use the data. Dr. Cernich said that the program regularly has tutorials on how to use its data platform, the Researcher Workbench; it also uses Jupyter Notebooks and other common tools for analysis. Dr. Cernich said that she can speak with Dr. Van Driest about getting the word out to pediatric research communities.

Dr. Cedars asked how collaborative programs are selected for funding. She said that she would love to see similar collaborative efforts for women's health. Dr. Cernich said that NICHD regularly meets with the National Cancer Institute (NCI) about new and ongoing collaborations that address areas of women's health. IMPROVE also involves collaborations with the National Heart, Lung, and Blood Institute (NHLBI) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Dr. Cernich expressed interest in developing more programs to better understand gynecologic conditions and programs focused on basic science. NICHD has the bulk of funding in gynecology research but needs to get other ICs interested as well, especially given that many cell types and molecular drivers of gynecologic conditions are also present in other diseases.

Dr. Cedars said that increasing investments in basic science will help bring those findings to the core of NICHD's mission. Dr. Cernich agreed and said that she is also interested in increasing investments in order to expand NICHD's reach, scope, and lens. To that end, Dr. Cernich is interested in multi-IC programs that can result in greater impact and transformation of science.

Dr. Gyamfi-Bannerman asked how the additional funds generated by increased funding for the IMPROVE initiative will be used. Dr. Cernich said that the use of those funds will depend on the language of the bill. The House bill recommended adding centers of excellence to the initiative, which Dr. Cernich did not think entirely financially feasible. The initiative has been able to use funds in other innovative ways, including giving investigators longer on-ramp periods for their projects. There are a variety of opportunities and ways to use the money, but its exact use will depend on congressional instruction.

Dr. Jabs asked for additional information on NBSxWGS. Dr. Cernich said that the award has not been issued yet, but she will be able to give more updates at a later time. The program's overarching goal will be to improve technology, diagnostics, and whole genome sequencing for the advancement of public health and to return genetic results to people more rapidly.

During a break, Dr. Rasooly offered Council members the opportunity to visit the NICHD zebrafish facility, which supports projects across multiple ICs.

III. Annual Division of Intramural Research Report (1:00:40)

Chris J. McBain, Ph.D., scientific director of the Division of Intramural Research (DIR), provided an overview of the NICHD intramural program, reviewed updates to the budget and personnel, provided updates on the Office of Education (OE), and shared several competitive funding opportunities.

NICHD Intramural Research Program Overview (1:02:10)

NICHD's Intramural Research Program (IRP) is made up of approximately 700 staff members: 66 principal investigators (PIs), consisting of 56 senior investigators, 9 tenure-track investigators, and 1 assistant clinical investigator; 46 staff scientists; and 235 trainees, including graduate, postbaccalaureate, postdoctoral, and clinical fellows. IRP supports basic and clinical research, 59 clinical protocols, and three accredited medical training programs: Pediatric and Adolescent Gynecology, Pediatric Endocrinology, and Reproductive Endocrinology and Infertility.

NICHD's IRP is made up of the following seven divisions:

- Division of Developmental Biology
- Division of Translational Medicine
- Division of Molecular and Cellular Biology
- Division of Neurosciences and Cellular and Structural Biology
- Division of Basic and Translational Biophysics
- Division of Translational Imaging and Genomic Integrity
- Division of Population Health Research

These divisions represent PIs housed in different buildings, as well as different research themes. The DIR is also made up of several offices, various training programs, and four core facilities, which offer their resources to all PIs at no cost. Cores can be used by PIs across intramural programs. For example, NICHD's Imaging Core supports 80 users across 10

ICs, and NICHD intramural researchers can use core facilities housed in other ICs as well.

Researchers in the IRP have also organized themselves across 12 affinity groups, based on commonalities in research interests. Investigators can join as many of the groups as they see fit and attend the different events each group holds. Affinity groups have regular meetings and hold seminar series, both of which provide opportunities for trainees to present to faculty and practice job talks. The affinity groups also contribute to a dynamic research environment that encourages heavy interaction among PIs.

Budget and Personnel Updates (1:08:12)

The NICHD IRP accounts for 13% of NICHD's overall budget, averaging $230 million to $240 million each year. Half of this money goes toward the Clinical Center (CC) and building maintenance. The other 50% is researcher money allocation, or soft money, which allows the IRP to move funding between personnel allocations to individual PIs and novel research strategies that the IRP wants to initiate.

Dr. McBain announced the following retirements:

- Rena D'Souza, D.D.S., Ph.D., M.S., Director of the National Institute of Dental and Craniofacial Research (NIDCR) and head of the Section on Craniofacial Genetic Disorders, retired on January 21, 2025.
- Richard Maraia, M.D., senior investigator in the Section on Molecular and Cellular Biology at NICHD, on February 28, 2025.
- Francie Kitzmiller, chief of the Administrative Management branch, on March 31, 2025.
- Janice Chou, Ph.D., senior investigator in the Section on Cellular Differentiation at NICHD, on May 31, 2025.
- Anil Mukherjee, M.D., Ph.D., senior investigator in the Section on Developmental Genetics at NICHD, on May 31, 2025.

Expected retirements include:

- Jack Yanovski, M.D., Ph.D., senior investigator in the Section on Growth and Obesity at NICHD, expected to retire on September 26, 2025.
- Robert Crouch, Ph.D., senior investigator in the Section on Formation of RNA at NICHD, on September 30, 2025.
- Karl Pfeifer, Ph.D., senior investigator in the Section on Epigenetics at NICHD, in the fall of 2025.

Honors and awards for NICHD staff include the following:

- David Clark, Ph.D.; Henry Levin, Ph.D.; and Brant Weinstein, Ph.D., were elected to the American Association for the Advancement of Science (AAAS).
- Dr. Levin was also elected to the American Academy of Microbiology.
- Peter Basser, Ph.D., was elected to the National Academy of Inventors (NAI).
- Yun-Bo Shi, Ph.D., was elected to the North American Society for Comparative Endocrinology (NASCE).

Dr. McBain shared analyses of the NICHD IRP's research and the value it has across the

entire NIH IRP. From 2020 to 2024, the NICHD IRP published 3,705 manuscripts, 995 of which included collaborations with 24 other ICs.

Office of Education Updates (1:12:18)

NICHD IRP trainees include 106 postdocs, 92 postbaccalaureate fellows, 12 graduate students, and 9 clinical fellows. Recruitment was on hold from January to April of this year, which included pauses in recruiting visiting fellows and other postdoctoral fellows. The 2025 NIH Summer Internship Program (SIP) was also canceled this year but will be reestablished in 2026.

The OE is run by Megan Bohn, Ph.D., and Erin Walsh, Ph.D. The two of them have worked hard to cater to every aspect of trainees' career trajectory, from trainees' first arrival at NIH to their navigation of life in the lab and to their next career stages.

The office has provided the following events for career development:

- Postbaccalaureate Seminar Series: Career Exploration, Professional Development, & Graduate/Medical School Application Prep
- Science Writing Skills Workshop: "Cut the Clutter"
- One-Day Job Application Boot Camp
- Taking Stock of Your Scientific Career
- 20th Annual Fellows Retreat
- Individual academic job search and application support

The office has also hosted the following grant writing events:

- K99 Cohort Support Series: From Search to Submission
- One-Day Intensive Grant Writing Workshop
- K99 Grant Writing Course (on hold for FY 2025)

The office has also held an Industry Careers Webinar Series, to advise on job searching, support generation of application materials, and develop trainees' leadership skills.

The Office of Education had also launched a Bioinformatics Training Program, in partnership with the Bioinformatics Core. The program launched in 2024 under the leadership of E. Sally Chang, Ph.D., but was put on hold after Dr. Chang was lost to recent reductions in force (RIFs). The IRP is developing training initiatives and working to restart the program at a later time.

The DIR recently joined NCFDD, which opens up new resources for investigators, trainees, and staff scientists. General resources include live and recorded webinars to support faculty development, peer mentoring and accountability partners, 14-day writing challenges, and live training opportunities. The DIR and NCFDD have also hosted the following workshops for DIR investigators:

- Writing & Publishing Strategies, in December 2024
- Career Navigation After Tenure, in April 2025
- Faculty Success Program, in Spring 2025, hosted by Claire Le Pichon, Ph.D.

NICHD also continues to be involved in the virtual Three-Minute Talks (TmT) Science

Communication Training and Awards Program. Presenters convey the importance of their research projects in three minutes or less, with one PowerPoint slide as a visual aid. Participating ICs first hold their own competitions, then move the finalists on to an NIH-wide competition. This year, out of 11 participating ICs, postbaccalaureate fellow Jack Waite in the lab of Pedro Rocha, Ph.D., represented NICHD and placed first in the overall NIH competition. This is NICHD's second win in the competition.

The Biophysics Fellows Research Conference was held August 28–29, 2025, as part of a biophysics training initiative. Travel awards were given to 25 applicants to attend the event, which featured didactic biophysics and poster presentations. NICHD participated in the event with several other ICs, which gave invitees the opportunity to connect with tenure-track and senior investigators at NIH.

Recent trainee awards include:

- Rachel Cosby, Ph.D., from the lab of Todd Macfarlan, Ph.D., won an NIH K99/R00 Pathway to Independence Award.
- Janka Schmidt, Ph.D., from the lab of Gisela Storz, Ph.D., won a German Research Foundation Fellowship.
- Isabella Cisneros, from the lab of Brant Weinstein, Ph.D., won a National Science Foundation (NSF) Graduate Research Fellowship.
- Elissa Moller, from the lab of Doreen Matthies, Ph.D., won a University of Maryland Biophysics Award for Research Excellence.
- Lauren Hewitt, from Dr. McBain's lab, won a Center for Compulsive Behaviors Fellowship.

Competitive Funding Opportunities (1:22:25)

The NICHD Career Development Awards are an internal funding opportunity created by Diana Bianchi, M.D., as part of an initiative of the NICHD Office of the Director (OD), the Office of the Scientific Director (OSD), and the OE. These awards are modeled after the Tufts University School of Medicine's Zucker Grant Program. Now in their fifth cycle, Career Development Awards are open to predoctoral, postdoctoral, research, and clinical fellows, as well as staff scientists and staff clinicians, for outstanding original research proposals. This year 96 applications were received and 45 individual awards of $15,000 were given, for a total of $675,000. Scoring criteria were based on F31 extramural awards, which are excellent opportunities for trainees to receive funding while learning how to write competitively.

Also in a fifth cycle are the NICHD Scientific Director Awards, which provide 2 years of funding and are open to all faculty at the investigator or senior investigator level. These awards were established after a recommendation from the July 2013 Blue Ribbon Panel Report encouraged ways to increase interaction between labs. The awards use a modified application based on R21 funding mechanisms and an expedited review process with NICHD's Division of Extramural Research (DER) and a panel of NIH extramural reviewers. In FY 2025, 8 out of 13 applications were funded, for a total of $2.8 million in awards.

Discussion (1:26:55)

Dr. Cedars asked whether the IRP is trying to bring in more new ideas and investigators to offset the individuals who are leaving. Dr. McBain said that his goal is to have a throughput of a dozen or so tenure-track investigators in the IRP at any time. The historically top-heavy IRP is

even more so now because of the inability to hire this cycle. Once NIH can begin hiring again, Dr. McBain wants to fortify the IRP pipeline by hiring younger and midcareer personnel, and by hiring more clinical staff. Dr. McBain and NICHD Clinical Director Catherine Gordon, M.D., M.S., who hired three new members of clinical staff before the hiring freeze, say they looked forward to hiring more when possible.

Dr. Maldonado said she is interested in viewing the TmT. Dr. McBain said he would send the talks out and encouraged attendees to view them.

Dr. Dorn asked for more information on the IRP's mentoring model and how it supports early-career researchers. In addition to mentorship programs for postdoctoral fellows and trainees, Dr. McBain said, newly recruited tenure-track investigators are assigned a primary mentor when they join the IRP. That mentor helps the new investigator set up a mentoring committee of three to five investigators within six months of onboarding. The committee helps the new investigator ask feasible questions for their research and navigate life in the federal government. The investigator has regular meetings with their mentoring committee and with their tenure committee, both of which submit reports to the Board of Scientific Counselors (BSC). The IRP has also established optional mentoring committees for senior investigators.

Dr. Cedars asked how many members of the affinity groups are gynecologists. Dr. Gordon said that there has been a loss of gynecologists in that affinity group because several people left for positions at prestigious institutions. There are currently three or four members who are adult-trained gynecologists. Dr. Gordon said that this is an area the IRP would like to grow.

Dr. Jabs expressed interest in seeing the number of publications between intramural and extramural researchers. Dr. McBain said that every investigator at the IRP is collaborative with the extramural community. He will request specific publication metrics from the National Library of Medicine (NLM) informatics team for a future Council meeting. Dr. Cernich said that the BSC also tracks these data, in addition to advising IRP researchers through scientific reviews and mentorship.

IV. Scientific Presentation: Developmental Regulation of Recently Discovered *best4*+ Intestinal Epithelial Cells (1:39:15)

Jeffrey Allen Farrell, Ph.D., is an Earl Stadtman Investigator at NICHD and heads the Unit on Cell Specification and Differentiation. He joined NICHD after his doctoral work at the University of California, San Francisco (UCSF) and postdoctoral fellowship at Harvard University. He has been at NICHD for 5 years.

Dr. Farrell is interested in studying the genetic programs that instruct cells on what type of cell to become and when. He uses the zebrafish as an animal model since it creates an enormous diversity of cell types in 5 days, most of which are the same types of cells that humans make. Dr. Farrell's lab uses both single-cell genomic, staining, and live microscopy techniques to identify the constituent populations of cells within tissues, which sometimes include exciting new populations. His lab then builds developmental trajectories, which identify "paths" through single-cell genomic data that describe the sequence of gene expression events that foreshadow what a cell will become. They then use the structure of those trajectories to predict which genes and transcription factors might determine how cells develop specific functional and morphological features from a common progenitor pool of

cells, and then design experiments to test their predictions.

Dr. Farrell first reviewed his lab's efforts in profiling zebrafish cell specification, which started during his postdoctoral fellowship. In research that was published in *Science*, he generated an RNA sequencing database of 38,000 cells, capturing a sequence of time from the first activation of the genome to 12 hours of the zebrafish's development, when the first rudiments of organs are forming. These sequencing data were then mapped to show the specification of 25 different cell populations in early development and these populations' respective gene expression.

Dr. Farrell expanded this work in his own lab from 2020–2023 by extending these studies with an additional 50 timepoints, spanning the first to 5 days of development. At 5 days, while the zebrafish is not yet fully developed, it possesses most tissues that will be present in adults and can already fully grown, engages in complex instinctual behavior, and exhibits basic learning like hunting for food. Over the course of a year, Dr. Farrell's team developed and annotated a dataset of 451,315 cells by first plotting cells based on gene expression and the tissues the cells arose from. Cells from each tissue were then reprocessed based on cell type. The final dataset had 521 clusters representing approximately 200 cell types from 43 different tissues within the zebrafish. These findings have been published in *Developmental Cell*.

These data have been made available on the Daniocell website, where researchers can view time-resolved gene expression and compare gene expression patterns across cell populations. This resource has been widely used by the field, with more than 1 million page clicks each year. To that end, the lab has also released a software package, called DaniocellDesktop, that lets researchers reanalyze data sets with no programming knowledge required. Researchers can define cell populations, perform custom differential gene expression testing, and generate customizable, publishable plots that show the co-expression of genes. This software has also been well-received, with several hundred users since its release.

From these data, the lab found an unexpected cell type in the zebrafish intestinal epithelium. Zebrafish intestines are similar to mammalian intestines: Both are harsh environments, so their cells have short lifetimes and are constantly replaced, and they are made up of similar kinds of cells. Cells are regenerated from stem cell populations, located at the base of folds within the intestines. The cells divide and get pushed up through the intestines, and at the top of intestinal folds cells are shed and die. Intestinal cells can become absorptive or secretory progenitors, which then are further differentiated into several cell types: Absorptive progenitor cells can differentiate into enterocytes, thought of as typical intestinal cells that absorb nutrients, while secretory progenitors can differentiate into goblet cells, tuft-like cells, and enteroendocrine cells, all of which have supportive functions within the intestine.

When annotating intestinal data, the Farrell Lab found all of these cell populations in addition to a unique population that strongly expressed the gene *best4*+. These best4+ cells were immediately interesting to the lab because they are homologous to a cell type found that had only recently been identified in human intestinal cells in 2019 and have several potential disease connections: Patients with inflammatory bowel disease have fewer of these *best4*+ cells, whereas some patients with colorectal cancer exhibit higher *best4*+ cell expression. In the last five years, these cells have been found in several organisms, including frogs, pigs, rabbits,

monkeys, snakes, and rats. Notably, these cells have not been found in mice, the typical model organism used to study intestinal biology; as a result, these cells are functionally uncharacterized, and the developmental programs that give rise to them are completely unknown.

Dr. Farrell's lab's studies of *best4*+ cells have uncovered their distinct gene expression program that includes ion channels, intestinal hormones, and hormone receptors. From these genes, the lab has hypothesized that these cells are involved in pH sensation and or regulation, hydration of the mucous layer of the intestines to maintain its protective properties, pathogen response, and coordination of behavior among other cell types. Dr. Farrell noted several advantages to studying these in the zebrafish. First, the lab can observe and manipulate cells in a living organism. Second, the genes described above and their relevant developmental regulators are also conserved across species, which will provide insight into how these cells develop and functioned in other animals.

best4+ cells are found in all regions of zebrafish gut. Using transgenic zebrafish lines, the lab can visualize these cells in live fish larvae. They have found that the cells have motile projections that last 2 to 3 hours and touch other cells in the intestinal epithelium before they retract. The lab is now trying to discover which cells are on the other end of this these projections and which processes are being coordinated.

Since *best4*+ cells were only recently identified, the lab has also built a developmental trajectory that describes the development of *best4*+ cells, allowing them to investigate the progenitor pool that become *best4*+ cells, the developmental signals that tell cells to become a *best4*+ cell, and the transcription factors that are then turned on in *best4*+ cells that cement their identity. Their trajectory captured the initial split between intestinal secretory and absorptive progenitors, which led Dr. Farrell's group to predict that *best4*+ cells arise from secretory progenitors, where Notch signaling triggers those secretory progenitors to express meis1b and become *best4*+ cells. The lab is currently testing these predictions using new experimental models. First, the lab has generated new transgenic zebrafish lines that mark secretory progenitors, which they have followed using imaging techniques to confirm that best4+ cells come from secretory progenitors. Subsequent experiments that blocked and increased Notch signaling have respectively showed lower and higher populations of best4+ cells, indicating that Notch is indeed a key signal to specify *best4*+ cells. Finally, the lab has developed another zebrafish line with a complete deletion of meis1b, and initial experiments again show a loss of *best4*+ cells. With these experiments, Dr. Farrell proposed that intestinal stem cells split into absorptive or secretory progenitor cells and undergo further differentiation into *best4*+ cells after exposure to Notch protein signaling. *best4*+ cell identity is then conferred through meis1b gene expression.

Future experiments at Dr. Farrell's lab will include investigating zebrafish where *best*4+ cells have been removed to help determine their function. They have developed a zebrafish mutant line with no *meis1b*, where *best4*+ cells never form, and a second line in which chemical signaling can be used to selectively eliminate *best4*+ cells at any time. These two zebrafish lines will enable the lab to test *best4*+ cell function under different conditions and perturbations to better understand its function and potentially explore its role in gastrointestinal disease.

Discussion (2:07:47)

Dr. Van den Veyver asked whether the Daniocell resources can be integrated with other analysis tools. Dr. Farrell said that Daniocell is integrated with the Zebrafish Information Network (ZFIN) and other zebrafish atlases. Dr. Farrell is continuing to develop canonical references through collaborations. These references will allow new information to be incorporated into existing annotated work. Dr. Farrell has not started to integrate these resources with other animal models but is interested in doing so in the future. Dr. Cernich noted that NLM over time will have more integration across model organisms.

Dr. Jabs praised Dr. Farrell's work and agreed with him about *best4*+ cells' potential for personalized therapeutics. Dr. Farrell said that he is excited about the new zebrafish lines described in his presentation, which will help the lab better understand the cells' roles in pathogenic processes. Dr. Jabs added that, based on the presentation, the cells could be targeted by repurposed drugs that are already FDA approved.

Dr. Rasooly asked why *best4*+ cells are not present in mice. Dr. Farrell was not sure but noted many possible reasons, including potential differences in the mouse microbiota, immune response, or diet. The *best4* channel is a pseudogene in the mouse genome, suggesting evolutionary loss within mice.

Dr. Farrell was asked whether regulatory and T cells may have a role in pathologies in preterm infants. At this stage, Dr. Farrell said, the lab was not sure how *best4*+ cells interact with the immune system. Future experiments introducing pathogens to zebrafish larvae with or without *best4*+ will be informative, but Dr. Farrell has not determined whether the cells communicate with the immune system directly, influence barrier defenses, or change the behavior of immune cells through other means. In response to a follow-up question, Dr. Farrell said he has not yet seen evidence of antigen expression in *best4*+ cells. More work will need to be done before these questions can be addressed.

V. Voice of the Participant: GLP-1 Medications and Polycystic Ovary Syndrome (2:15:52)

Melanie Cree, M.D., Ph.D., a professor at University of Colorado Anschutz Medical Campus, provided background on the trial "Role of Semaglutide in Restoring Ovulation in Youth and Adults with Polycystic Ovary Syndrome (RESTORE Study)." The Council then heard from Grace, one of the study's participants.

Polycystic ovary syndrome (PCOS) affects 6% to 15% of women. The condition includes menstrual cycle irregularities, elevated testosterone, and—in adults only—polycystic ovaries. PCOS also causes reproductive problems that include infertility, miscarriage, preeclampsia, gestational diabetes, giving birth to small or large infants, and increased risk of endometrial cancer. Other complications and symptoms of PCOS include, but are not limited to, obesity, type 2 diabetes, excess liver fat, hyperlipidemia, acne, excessive hair growth, balding, and greater risk of infections. These symptoms can take a toll on women's mental health, resulting in conditions that include anxiety, depression, sexual dysfunction, disordered eating, and general low quality of life.

Weight is a primary treatment target of PCOS; about 50% of women with PCOS struggle with their weight and losing 5% of body weight can decrease testosterone and insulin levels. These changes can in turn address infertility, type 2 diabetes, and other PCOS endpoints. However, little has changed in PCOS treatment beyond recommending healthy food and

physical activity to manage weight and prescribing various medications and topical treatments to address specific symptoms. The RESTORE trial has therefore examined the use of glucagon-like peptide-1 (GLP-1) receptor agonists with and without metformin for its efficacy in reducing weight and addressing other endpoints in patients with PCOS. The study began enrolling participants in 2023; after just 14 months, it had already enrolled all control participants. The study is now enrolling participants in the metformin and metformin+GLP-1 arms.

Dr. Cree presented preliminary data from the first 8 participants who have lost more than 10% of their body weight, with median weight loss at 16.5 pounds. These participants have shown a 51.8% median reduction of free testosterone. Of these women, six have had more menses, one has had no change in menses, and one has had fewer menses from losing too much weight.

Grace presented her experiences in the RESTORE trial, which she finished in July 2025. Grace lives in Colorado but grew up in Tennessee. She began menstruating at age 11 and was told that her irregular cycle would regulate within a few years. Though she was not diagnosed with PCOS until the age of 25, Grace began to suspect that she had the condition by the time she was 14. She spent years being tested for hypothyroidism, trying birth control pills to regulate her cycle, and struggling with her weight despite playing basketball, swimming, and eating healthy. Having no friends she could relate to, Grace relied on Google and her own understanding of what could be going on in her body to learn about PCOS. When she was 25, her primary care provider (PCP) finally tested her testosterone levels, and Grace was diagnosed with PCOS.

Grace's mother then found Dr. Cree's study. At first, Grace was scared of injecting herself with the GLP-1, but she eventually reached out to Dr. Cree. Now she feels that the study has changed her life. Before she enrolled, Grace had started powerlifting and learning to play rugby. Yet she still weighed 334 pounds. She also had very irregular cycles, sometimes not having menses for a year and then having menses that lasted 17 to 20 days. Grace finished the study in July 2025. After the control period, she resumed taking GLP-1 medications at a 2.5 mg dose. She now weighs 248 pounds and has regular menses.

Grace is also not taking any medication for her mental health and feels much more confident about her ability to fully participate in her day-to-day life.

She thanked the Council for the opportunity to speak and for supporting the RESTORE study.

Discussion (2:26:05)

Dr. Cernich said she recognizes that there is not enough talk about menstrual cycles in young women, and the assumption that cycles will regulate results in accepting the abnormal. She also recognizes that although Grace's advocacy of her own health paid dividends, it should never have been necessary. Dr. Cernich thanked Grace for sharing her story.

Dr. Gyamfi-Bannerman was struck by the fact that Grace did not receive a diagnosis until age 25, despite knowing about PCOS at age 14. She asked Grace whether there was anything PCPs could learn from her experience. Grace said that as a child, she

knew that she was not the expert and placed her trust in her doctors. She then advocated for herself upon realizing that she was visiting multiple professionals only to be retested again and again for hypothyroidism. She said that health care professionals need to be mindful of what has been done before and test for other conditions. Grace also said that she would have appreciated more transparency; understanding that her PCPs were also struggling to find an answer would have made her feel less alone.

Dr. Van den Veyver asked both Dr. Cree and Grace what the next steps are in order to make this treatment clinically available. Grace said that she is currently in the appeals process of trying to get GLP-1s approved by her insurer. Dr. Cree called for putting greater pressure on the U.S. Food and Drug Administration (FDA) to approve endpoints for the treatment of PCOS. The first FDA meeting that raised this issue was in 2023; since then, there has been very little progress. Drug companies are very interested in GLP-1s, having received approval for their use in metabolic liver disease; they are now being tested as a treatment for sleep apnea. While more trials in PCOS are needed, having endpoints will also make it easier for drug companies seeking approval.

Dr. Cedars noted that the study's inclusion criteria specified that participants should be women who are overweight and have PCOS. She asked Dr. Cree whether she believes that GLP-1 medications would be effective for women who have PCOS but are not overweight, because they are still insulin-resistant. Dr. Cedars also asked whether Dr. Cree had a hypothesis for other drivers of PCOS besides weight. Dr. Cree said that her first trial with oral semaglutide suggested that effects on insulin sensitivity and glucose concentrations are weight-dependent. As women lost more weight, they also showed greater concentration in reproductive hormones. In the current study, participants had to be above the criteria for obesity. Though Dr. Cree did not think there would be effects in women with a body mass index (BMI) of 20 or lower, she was interested in studying lower BMI ranges of 23 to 25.

Dr. Cernich explained to Grace that discussions of hormone-confirmed ovulations are relevant for pregnancy. She asked Grace how, in addition to weight, the diagnosis of PCOS affected her ability to go to school and work each day, and how that experience changed as she got older. Grace said that the lack of a diagnosis primarily affected her mental health. She found it difficult to be with her friends, who were menstruating while she was not, and she had a hard time recognizing that the ways she was taking care of herself were worth it. This experience was very isolating. Hormone irregularities also affected her mental health and ability to deal with daily life. Grace has found that her self-esteem has improved since she joined PCOS communities and began to learn more about the research being done.

Dr. Cernich asked Grace whether she has noticed any differences since she left the trial. Grace said that she is currently paying out of pocket for GLP-1s. Now that she has these medications, a community, and doctors who can effectively counsel her on PCOS, she is not willing to go back to living the way she was before.

Dr. Cedars asked Grace whether there are actions she wished she had taken to get a diagnosis quicker, reiterating that Grace was not responsible for her delayed diagnosis. Grace's experience could inform how physicians speak to their patients and colleagues and prevent a repeat of her situation. Grace said that she wishes her testosterone levels had been tested sooner. She thanked her parents for their support and her mother for her

advocacy, which included finding Dr. Cree's study. Grace's relationship with her parents has changed for the better now that there is understanding of her experience. She encourages parents to listen to their children, advocate for them, and, she jokes, know that time spent on the internet is not always unproductive.

In response to Dr. Cedars' question, Dr. Cree said that considering menstrual history needs to be as much of a priority as checking blood pressure and heart rate. She also called for more PCOS education for PCPs. Ideally, PCOS should be diagnosed in adolescence. Dr. Cree started a special interest group that has published guidelines, which are now being updated. The group is also working on standardizing Epic EHRs, which have been shown to make a difference in diagnosis at Kaiser Permanente locations in Colorado. And Dr. Cree is applying for Patient-Centered Outcomes Research Institute (PCORI) grants while also gathering data on adolescent PCOS from 21 sites.

Dr. Cernich praised the study and the level of engagement for PCOS work. She also thanked Grace for sharing her story. Dr. Cernich reiterated how much strength it took for Grace to continue to pursue her health and recognized how isolating and challenging that experience was. She also acknowledged that it is hard to let go of an answer and a potential solution after struggling for so long. NICHD will charge its teams to work with the FDA and to move progress forward on PCOS.

VI. NICHD Clinical Network Update and the Unified Pediatric Research Consortium Proposal (2:45:36)

Bob Tamburro, M.D., M.Sc., senior advisor for clinical research at DER, provided updates of the Clinical Network Initiative and introduced a new proposal for the Unified Pediatric Research Consortium (UPRC).

NICHD has a long, successful tradition of supporting multisite pediatric clinical research since the 1980s. The creation of the neonatal intensive care unit research network provided NICHD with an even faster system for conducting studies of neonatal and maternal-fetal care. However, in 2016, calls to improve NIH's clinical trial stewardship and transparency began to appear. In response to this charge, NICHD conducted a thorough, multifaceted review of its clinical trial networks including publishing an RFI (Request For Information). As a result of those efforts, the following four principles were identified to guide multisite clinical trial network research:

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

These guiding principles were published in a Guide Notice (NOT-HD-19-034) and presented in a webinar.

To implement these principles, NICHD adjusted its investment in the clinical trial network instituting two fundamental changes. First, access to network resources is now available to

all qualified extramural investigators, and second, all network projects undergo NIH peer review. These changes were operationalized in PAR-23-037, released in November 2022. A robust pre-application process was also put into place, which included the following steps:

1. The researcher sends a letter of inquiry at least 4 to 8 months before the application receipt date.
2. If approved, the researcher prepares and submits a concept proposal.
3. NICHD and the network(s) review the concept proposal, then NICHD makes a final decision on it.
4. If approved, the researcher, network(s), and others develop the grant application.
5. The researcher and network(s) submit the jointly developed application.

As of last month, this process has led to NICHD receiving more than 70 letters of inquiry, approximately 75% of which were approved. Nearly 50% of these letters were submitted from non-network investigators. From these letters of inquiry, more than 40 concepts have been submitted, and approximately 40% have been approved. Dr. Tamburro noted that 40% of submitted concept proposals came from non-network investigators. However, these concepts had a lower approval rate than proposals submitted by Network investigators. Though discouraging, these numbers did make sense, given that in-network proposals are only submitted after multiple opportunities for feedback and revision from the various expert Network investigators participating in proposal development. Consequently, NICHD implemented changes to provide more feedback opportunities for non-network investigators mirroring the Network process more closely, and the number of non-network concept approvals is now improving. In terms of grant applications, one-third of the grant applications submitted to PAR-23-037 have been funded. Grant applications demonstrated similar trends as concept approvals with in-network investigators having much higher rates of success than non-network investigators. Additionally, grant applications were initially less favorably reviewed than anticipated. Consequently, NICHD conducted an analysis of applications and their reviews and identified opportunities for improvement which seemed to be embraced by the Network investigators. Since then, and likely for a number of reasons, applications appear to be more favorably reviewed over subsequent cycles.

These changes reflect NICHD's approach to implementing new ideas: Start small by implementing new ideas in a step-by-step manner, monitor and evaluate progress, then adapt by implementing changes accordingly. This approach has been instrumental in adjusting the approach to network research and in developing the proposed consortium. The NICHD Clinical Network Operations team have spent 2 years reviewing progress and soliciting feedback. This feedback and lessons learned were incorporated into PAR-25-311 which replaced the initial NICHD network study PAR (PAR-23-037). The new announcement implemented the following changes:

- A biphasic UG3/UH3 mechanism
- Changes to application budgets
- Changes in receipt dates to shorten time from grant receipt to Council decisions
- A list of strong preferences to help align proposals with initiative and NICHD interests and priorities
- Statements that prioritize the participation of junior researchers

Despite the accomplishments of NICHD's networks and researchers, recent data highlight evolving concerns on the health of children in the United States. In addition, studies from NICHD and others highlight the developmental origins of health and disease, with pediatric experiences and even prenatal experiences affecting long-term outcomes into adulthood, demonstrating the need for impactful and longitudinal pediatric research. Effective research is an essential component of a multifaceted approach to addressing these evolving concerns on child health. Important components of this needed research include:

- Collaborative science
- Clearly and consistently defined pediatric outcome parameters
- Longitudinal research that is expanded and expedited
- Successful partnerships with nontraditional stakeholders
- Public–private partnerships that are free of "corporate capture" and that feature rigor, transparency, and open data access
- Coordinated federal efforts that prioritize reproducibility
- A broader approach to research with multiple and interdisciplinary components

In response to these needs, NICHD proposes revising its current approach to network research by creating a unified pediatric research consortium (UPRC), a collection of networks to address the pediatric clinical priorities of NICHD and the extramural community. The ultimate goal of this consortium is to unify efforts within NICHD and across the federal government to address key health issues, accelerate advancements in science, enhance scientific rigor, improve outcomes for children, and reduce costs and burdens.

Given the wide portfolio of NICHD's research, identifying key research priorities for this consortium depends on several parameters including the timing of key institute initiatives. UPRC will therefore begin to build its foundation by first supporting multisite pediatric research in critical care, pharmacology, and medical devices. Dr. Tamburro briefly reviewed NICHD's work in each of these areas.

First, pediatric critical care has been a paramount area of NICHD research, given that injury is the leading cause of childhood death and disability, and that multiple organ dysfunction is a top proximate cause of childhood death. In 2005, NICHD provided support for pediatric critical care research programs that included the Pediatric Critical Care and Trauma Scientist Development National K12 Program and the Collaborative Pediatric Critical Care Research Network (CPCCRN). CPCCRN has led to more than 30 clinical projects (including multisite trials and large-scale cohort studies), approximately 175 publications, and 18 public use datasets. NICHD also established the Pediatric Trauma and Critical Illness Branch in 2014. Since then, CPCCRN has helped develop validated tools to assess pediatric morbidity and outcomes, and is currently conducting precision medicine trials for sepsis-induced multiple organ dysfunction. With CPCCRN's renewal approaching, NICHD is assessing potential ways to enhance investments in this area of research.

NICHD's Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB) has supported the Clinical Pharmacology Training Network. Additionally, and as part of NICHD's implementation of the Best Pharmaceuticals for Children Act (BPCA) mandate,

NICHD has developed the Pediatric Trials Network (PTN) and its affiliated BPCA Data Coordinating Center (DCC). Research stemming from BPCA has led to advances in the care of children with acute and chronic health conditions through 51 clinical studies, including 13,000 participants across 301 sites, 200 publications, and 25 age-specific FDA medication label changes. To further maximize these results, all findings are shared in DASH, and research summaries are available at the NIH Bookshelf. Researchers, health care providers, and the public can also access the BPCA Framework to Enable Pediatric Drug Development.

In addition to these efforts, in 2020, OPPTB established the Maternal and Pediatric Precision in Therapeutics (MPRINT) Hub. The hub is a national resource, expanding knowledge on maternal lactation and pediatric therapeutics, assessing the impact of medication use during pregnancy, and studying its impact on breast milk.

Lastly, NICHD has supported many projects and initiatives in pediatric medical device research. However, a larger ecosystem for this research is virtually nonexistent. From 2008 to 2020, only 5% of the FDA's premarket approvals and humanitarian device exemptions were for medical devices designed for children aged 2 years or younger, whereas 75% of approved medical devices were approved for adults. In response to this issue, the nascent NICHD-led public–private pediatric medical device partnership proposed a self-sustaining pediatric medical device public–private partnership infrastructure, which will de-risk the life cycle of pediatric medical device development. The proposed Unified Pediatric Research Consortium will identify centers capable of conducting multisite device clinical research.

The proposed UPRC initiative will create a framework to which existing pediatric networks, across these and other areas of research, can be joined to leverage resources, increase efficiency, and expand capacity. The proposed consortium will also establish interactions among other NICHD and non-NICHD pediatrics networks, to enable a more timely and cohesive emergency response. Long-term, UPRC will also facilitate longitudinal assessment of study participantsincluding maternal and infant data through data linkages and data sharing.

The establishment of a UPRC will require revising the current approach and structure of pediatric networks. Currently, NICHD supports a number of individual networks with individual data centers and sites. Though these networks have been successful, their current structure does not foster collaboration and sharing of data, resources, or knowledge. An analysis of the pediatric network ecosystem has shown that many of the individual network sites are participating in multiple networks at the same time. This overlap provides an opportunity to restructure and reduce redundancies, better coordinate research efforts, and facilitate collaboration.

The proposed approach features a single data and operations center (DOC) that will support the primary research centers, each of which will be capable of conducting research across multiple fields. The proposed structure is meant to break down barriers, mitigate duplication, enable faster trials, widen the spectrum of interventions, enhance communication and collaboration, and leverage strengths and resources. The proposed structure offers an informed, fungible option that maintains many of the advantages of the current pediatric networks system while offering potential enhanced efficiency. The initiative aligns with the Make America Healthy Again (MAHA) initiative and facilitates

interactions with nontraditional research partners. The proposal also incorporates tenets of NIH's "Leading in Gold Standard Science: An NIH Implementation Plan" report by addressing means to improve rigor, reproducibility, and interdisciplinary collaborations.

The initial plan, and the specific goal of the UPRC proposal, is to establish a DOC that will oversee data collection including assuring compliance with regulatory policies. This DOC will work collaboratively with existing resources. The initial plan will also involve establishing primary research centers that will conduct research across the scientific areas of pediatric critical care, pharmacology, and medical devices in order to lay the foundation for a long-standing consortium. The initiative will establish linked data across these research areas and track participants longitudinally and across disciplines. Other research areas will ultimately join the consortium over time. Dr. Tamburro and the initiative team have shared this idea at various meetings and forums with other NIH and Federal officials. The insight provided by these groups has been highly informative in developing this consortium.

Dr. Tamburro presented data from a recent article published in *JAMA* to highlight the potential value of this collaborative approach. In that report of an analysis of children's cause-specific mortality from 2006 to 2022,the United States has a net difference of approximately 100 more prematurity-related deaths per 100,000 compared with 18 other countries in the Organisation for Economic Co-operation and Development (OECD18). A collaborative research effort could enhance understanding and advance outcomes for this leading cause of death. Additionally, though the current proposal is focused on pediatric health, UPRC could also be linked to a future women's health consortium to study health across the lifespan. Dr. Tamburro closed by thanking his team and reiterating this proposal's alignment with NIH's mission to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce illness and disability.

Discussion (3:20:14)

Dr. Cernich thanked Dr. Tamburro and the initiative team. She also mentioned the NIH-wide Pediatric Research Consortium (N-PeRC), led by Rohan Hazra, M.D. N-PeRC involves all ICs interested in pediatric research. The proposed initiative is being presented to NIH colleagues in the interest of having UPRC as a resource at NICHD, across NIH, and for the extramural community.

Dr. Maldonado applauded the concept but added that her work on the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network showed her and Dr. Hazra that even a single network can be a significant undertaking. She asked what uptake for this idea has been like across NIH, and what obstacles the team foresees. Dr. Tamburro acknowledged the tremendous effort that UPRC will requires. Developing this initiative has involved input from many non-NICHD colleagues who have also expressed interest in disease-agnostic networks. Although this initiative calls for massive effort, research expenses do continue to rise. Dr. Tamburro said that he believes these challenges call for new, multifaceted solutions in order to maintain the same quality and volume of work.

Dr. Hazra reiterated Dr. Tamburro's recommendations on starting with a single project to show feasibility. The concept initially entails the work of the current PTN and the

CPCCRN—two programs that naturally complement each other for their shared focus in pediatric critical care. PTN may also afford long-term follow-up, a feature the CPCCRN has wanted. These types of collaborations may also inform developments in pediatric devices, which will also involve combining resources. The proposal team has considering combining programs that could work together both thematically and administratively.

Dr. Gyamfi-Bannerman asked for additional information on how new networks will be incorporated. She also asked whether combining networks will actually remove barriers, or if this system will drive researchers to become even more specialized. Dr. Tamburro said that he imagines that having standard operating procedures and common data elements across networks will enable easier knowledge sharing. He also said he recognizes that it is unclear at this point what UPRC will look like in the future. But beginning with established networks that have proven successful will help get the consortium started. In the future, new centers will be able to apply to the consortium regardless of capabilities or areas of expertise.

Aaron Pawlyk, Ph.D., clarified that this proposal does not involve dissolving current networks. Rather, networks, subnetworks, and centers will be part of a consortium that builds nimbleness and flexibility, so that they can work together more easily and expand into new areas of research more quickly. Centers will not need to be exactly the same, but there will be systems in place to enable easier collaboration. Building in such flexibility is a subject that has been raised for other projects and will ultimately allow NIH to work with nonclassical partners, such as community health organizations and centers that specialize in rural health. Dr. Tamburro also said that centers will be added through competitions, starting with primary research centers and then moving on to research areas discussed in this proposal and beyond.

Dr. Pawlyk noted that internal processes and structures were not touched on in Dr. Tamburro's presentation, but there is a governance plan. These structures could be discussed further at another time, but the hope is that the proposed network's structure could positively change how these large-scale activities are done at NICHD, across NIH, and throughout the federal government.

Dr. Dorn said that she anticipates passionate individuals from the groups of UPRC will come forward and be the underlying drivers that make this complex, interconnected system work. Dr. Tamburro agreed that UPRC will be a coalition of the willing. He acknowledged the work that different teams have already been doing and praised them for their willingness to work together. Such willingness will be crucial to address future obstacles.

Dr. Cedars expressed interest in UPRC's disease-agnostic approach. She asked how this initiative will handle the DOC's capacity to manage multiple ongoing trials and how projects will be prioritized to avoid study delays. Dr. Cedars also asked how R01s will fit into this network. Current network programs require R01 submissions with long processes that result in delays, so she asked whether the proposed network structure will do away with those processes. Dr. Tamburro said that the DOC was presented as a single entity for the sake of simplicity, but its services could potentially be spread across multiple institutions to manage DOC capacity. In terms of setup, Dr. Tamburro anticipated that NICHD would initially provide infrastructure and some capitation

funding, but subsequent network growth and maintenance would come from program announcements with special receipt, referral, or review considerations (PARs).

Dr. Cedars asked whether that PAR system would delay the start of new studies. Dr. Tamburro said that there would be a slight delay, but that the initiative team has considered ways to shorten it as much as possible. PAR dates have been adjusted so that the time between an application submission and a review decision will be condensed by a month and a half. Providing funding upfront while networks get started and develop other applications should also help reduce delays.

Dr. Maldonado expressed support for having multiple centers with DOC capabilities, potentially in a tiered fashion, and for providing some funding up front. She also recommended that data management systems be both flexible and modular. She recognized that could entail a large undertaking, likely taking 2 to 5 years to build out. Dr. Tamburro welcomed these and any other suggestions from the Council.

Dr. Cernich said that this is a work in progress between NICHD and NIH. NICHD will continue to learn and adjust as challenges arise and will work with the community and the Council to address new challenges.

VII. Concept Clearance (3:47:52)

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. 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 ensures that Council members do not have insider information that would exclude them from applying to any eventual funding initiative.

Unified Pediatric Research Consortium (3:49:43)

Dr. Tamburro presented this concept from DER. Dr. Gyamfi-Bannerman stated the importance of carefully considering the results from the first consolidated group before further network development. Dr. Jabs asked how the network will be funded. Dr. Cernich said that NICHD will fund the initiative; the exact funding mechanism will be determined based on NICHD's financial data. The Council is now being asked to approve an exploration of how this consortium would be developed and funded. Dr. Maldonado expressed support for the concept. She recommended transparency with regard to how this initiative will affect institutions across the United States, so that they can properly evaluate its strengths and resources. **Decision: Approve.**

Autism Centers of Excellence (ACE) (3:57:35)

Alice Kau, Ph.D., presented this concept from IDDB. This concept is evaluated for renewal every 5 years. If approved, ongoing work from the past 20 years will be able to continue. Dr. Van den Veyver asked for more information on how the initiative will expand to address the nation's growing number of autism diagnoses. Dr. Kau said that these centers

represent one opportunity for NICHD to address autism through bigger science than a standard R01, but there are also many other investigator-initiated research projects funded across NIH. Dr. Cernich said that most research efforts come from the National Institute of Mental Health (NIMH). She also noted the Autism Data Science Initiative (ADSI), led by OD—a $50 million initiative using new and existing data to study the driving causes of autism, diagnostics, and etiological factors, which will allow NICHD to do more work in this area. Dr. Cedars asked whether renewing the concept will allow only the same sites to recompete. Dr. Kau said that current grantees will be recompeting with all other applicants. Damien Fair, Ph.D., asked whether there is a plan to integrate or collaborate with ADSI, noting that some called to combine efforts when the Autism Centers of Excellence (ACE) were first announced. Dr. Cernich anticipated many natural collaborations and overlaps. ADSI is relying on data from ACE, the NIMH Data Archive, and other programs. Many investigators entering ADSI have also been part of ACE. Dr. Fair asked how these centers have been affected by the grant disruptions this year. Dr. Kau and Dr. Cernich said that all sites in ACE have been reinstated. **Decision: Approve.**

Data Sharing for Demographic Research (DSDR) Infrastructure Program (4:08:29)

Randy Capps, Ph.D., presented this concept from the Population Dynamics Branch (PDB). Dr. Jabs asked how easy it will be to transfer data to a new database. Rebecca Clark, Ph.D., said that requests for applications (RFAs) under this initiative will stipulate sharing data archives as a condition of the award. Dr. Rasooly said that NICHD recently migrated data on DASH to a new database, thereby demonstrating the feasibility of such data transfers. **Decision: Approve.**

VIII. Comments From a Retiring Member (4:13:36)

Dr. Fair made his comments virtually because of a health concern that prevented him from traveling. He said he has been thankful for the opportunity to serve with the Council, has learned a lot from his position, and has enjoyed meeting new people. Dr. Fair has received funding from NIH throughout his career and said that he appreciates being able to contribute to scientific advancement in new ways. He thanked everyone for their hard work and said that the energy and grit shown this year has been remarkable. He added that he looks forward to seeing the Council's work from the outside, building new collaborations, and continue pushing forward in NICHD's mission areas.

IX. Closing Remarks (4:15:56)

Dr. Rasooly wished Dr. Fair well, hoped for his good health, thanked all the presenters and attendees, and announced the schedule for Day 2.

X. Day 1 Adjournment

Dr. Rasooly adjourned Day 1 at 4:19 p.m. A total of 294 people viewed the live Day 1 NIH VideoCast.

XI. Day 2 Call to Order and Introductory Remarks (0:03)

Dr. Cernich opened Day 2 of the 189th meeting of the NACHHD Council. In each section below, the number in parentheses after each heading refers to the time stamp on the Day 2 NIH VideoCast. Please go to that point in the recording to listen to the full presentation.

XII. Invited Director, National Institutes of Health (0:13)

Jay Bhattacharya, M.D., Ph.D., M.A., assumed his position as NIH Director in April 2025. He comes to NIH from Stanford University, where he was a professor studying population aging and chronic disease, with a focus on vulnerable populations. He also conducted research at the National Bureau of Economic Research (NBER). Before he was at Stanford, Dr. Bhattacharya was an economist at the RAND Corporation and a visiting assistant professor in the Department of Economics at the University of California, Los Angeles (UCLA). He earned his bachelor's and master's degrees, his medical degree, and his doctorate in health economics from Stanford.

Dr. Bhattacharya opened his presentation by praising Dr. Cernich's leadership and noting the importance of NICHD's work in relation to the MAHA initiative. The initiative agenda, which was recently released, essentially gives NIH a warrant to address the fundamental health needs of children in the United States. Key topics in the initiative include:

- Prioritizing lifelong health, starting in childhood
- Addressing the root causes of poor outcomes such as obesity, type 1 and type 2 diabetes, autism, and the use of pharmaceutical treatments for psychiatric conditions through nutrition, access, and equity
- Building strong evidence to guide policies, interventions, and care models
- Partnering with communities, families, and schools to ensure impact

Dr. Bhattacharya highlighted several projects from NIH that align with MAHA goals. On nutrition, there is growing evidence linking processed foods to obesity and chronic disease. NIH aims to clarify the biological pathways and long-term health effects of processed food in order to support innovative interventions that reduce the reliance on processed foods and give families science-based tools that lead to better dietary patterns. NIH has also developed the Autism Data Science Initiative (ADSI), which launches this month. ADSI is a large project that will focus on the etiology of autism. Dr. Bhattacharya noted the sharp rise in diagnoses and prevalence of autism and acknowledged that vaccine use was not a suitable answer to explain this trend. ADSI will provide answers as to why autism diagnosis rates have risen and will offer solutions to parents and families.

Dr. Bhattacharya's vision for NIH includes several goals, but he focused on the goal of ensuring reliable results. The recent "Restoring Gold Standard Science" executive order calls for science that is reproducible, transparent, communicative of error and uncertainty, collaborative and interdisciplinary, skeptical of its findings and assumptions, structured for falsifiability of hypotheses, subject to unbiased peer review, accepting of negative results as positive outcomes, and without conflicts of interest. Dr. Bhattacharya said that many findings do not meet these criteria, citing research published in *PLOS Medicine*. The publication argues that it is difficult to find true discoveries about how the physical world

works. While there are true discoveries, many research studies have negative results that are difficult to publish. This aversion to negative results creates two problems: researchers have a harder time establishing their scientific career, and science as a whole cannot easily determine which findings are truly reproducible. Dr. Bhattacharya said that this is an area that NIH can and should fix by supporting replication studies and rewarding scientists for replicating their work. Such practices can lead to a healthier ecosystem of scientific thinking and publishing. The scientific community also needs to revise its view of replication studies, he said, by viewing replication as an honor rather than a threat. These changes could lead to new standards that improve people's lives, instead of simply rewarding publications in top journals.

As NIH Director, Dr. Bhattacharya is also increasing support for early-career researchers in order to drive new ideas in science. Citing research he published in the *Journal of Human Capital*, Dr. Bhattacharya has found a monotonic decline in the probability of publishing new ideas as researchers move forward in their careers, demonstrating the importance of early- to mid-career researchers. To test these new ideas, these researchers need access to resources, training, and funding. However, support for early-career researchers has been declining since the 1970s, with many investigators now receiving their first R01 in their 40s. These trends have contributed to more than 60% of trainees—those with the highest potential for new ideas—leaving academia.

Compounding this issue is an increase in the average age of ideas that receive NIH funding. From research he published in *Proceedings of the National Academy of Sciences of the United States of America*, Dr. Bhattacharya showed data that indicates a collapse in NIH support for the earliest, newest ideas. From 1990 to 1999, approximately 55% of ideas that received funding from NIH were new. As ideas aged, the probability of funding decreased. However, an analysis of funding from 2000 to 2009 shows that the average age of ideas supported by NIH increased from 1 to 2 years old to 7 to 8 years old. Dr. Bhattacharya suggested that these data indicate more conservative trends in NIH funding that punish failure and lead to a research portfolio less able to advance health.

To address these issues, Dr. Bhattacharya is interested in implementing a new unified grant funding strategy that removes paylines as a primary driver of funding decisions. NIH will still hold scientific reviews, but ICs will be able to select projects that match the strategic vision of each institute. Dr. Bhattacharya said he hopes that this strategy will allow ICs to award projects that score well while also selecting newer ideas that may not score as well by traditional standards but show innovation.

Discussion (24:32)

Dr. Maldonado expressed her support for Dr. Bhattacharya's goals. She asked how supporting replication and new ideas will be balanced at the institute level, noting that these things need not be in conflict with each other. Dr. Bhattacharya agreed that replication and innovation are not conflicting ideas, saying that a portfolio with new ideas needs independent scientists who ensure that those results can be replicated. The drive for replication should not come solely from the government; universities should respond to this goal by promoting researchers interested in replication work and giving them a place to pursue grants and publications.

There was additional discussion on how NIH can support team science. Dr. Bhattacharya said that he recognizes the difficulty that team science has traditionally faced in terms of getting support. He said that the unified strategy will allow institutes to prioritize team science. Dr. Bhattacharya said that cross-fertilization is fundamental to scientific advances, and that he welcomes other ideas to further improve the funding landscape.

Dr. Fair expressed his support for Dr. Bhattacharya's comments. He noted that researchers are becoming more open to implementation science but making changes to support it is still difficult. Dr. Fair asked what kinds of incentives NIH can put in place to encourage a culture shift. Dr. Fair added that many of the changes Dr. Bhattacharya is interested in will also involve changing tenure guidelines and academia's focus on promotion. Dr. Bhattacharya said he believes that NIH could influence tenure practices. By encouraging creative replication work, institutions will respond by supporting scientists interested in such work. Dr. Bhattacharya also noted the critique that money in replication is money taken away from original science. He argued that original science that cannot be replicated is not worth the investment. In order to drive replication and prosocial behaviors in science, and in response to calls from the U.S. House of Representatives, Dr. Bhattacharya will establish an office within OD that will reevaluate how quality science is measured. To drive positive change, it will also assess different methods for measurement and reward in collaboration with the scientific community.

Dr. Gyamfi-Bannerman expressed her appreciation of Dr. Bhattacharya's support for NICHD. She asked Dr. Bhattacharya about his goals on pregnancy and women's health research, citing U.S. statistics on maternal mortality. Dr. Bhattacharya said that he has heard about these concerns during his discussions with families around the country, and that they highlight a need for research to meet these challenges. Dr. Bhattacharya said he is interested in continued investment in women's health across the lifespan and seeing it broadened across IC portfolios.

Dr. Gyamfi-Bannerman asked about NIH's goals to incentivize physician–scientists. Dr. Bhattacharya said that NIH will be key in this space by providing more support to clinicians who are interested in research. Though funding mechanisms are currently available, many people ultimately choose to go into practice over research because of the complications around current mechanisms and the decreased support as individuals enter their midcareer stage. Dr. Bhattacharya said he is interested in a greater shift toward institutional K awards, which will allow universities to hire new professors and support them in their independent research. Once those clinician–scientists receive their first R01 award, the K award can then be transferred to other researchers. Dr. Bhattacharya said he recognizes that he does not have all the answers at this time, but he agrees with Dr. Gyamfi-Bannerman that this issue will cause science to stagnate if it is not addressed. Dr. Gyamfi-Bannerman noted that even with institutional K awards, physician–scientists often receive half the pay their colleagues do. Dr. Cedars added that institutional K awards present their own problems, which include the additional burden on institutional departments. Dr. Bhattacharya said he hopes that the unified plan can also help address some of these issues, though he recognizes that these changes will be experiments, and that strategies may therefore need to be adjusted.

Dr. Cedars said that NIH has decreased its investment in research on diseases that primarily affect women. Such research now represents less than 10% of NIH's budget. She asked

how Dr. Bhattacharya will address this issue, listing potential options that include increasing funding to NICHD and providing greater support for cross-disciplinary, cross-institute women's health initiatives. Dr. Bhattacharya expressed interest in refreshing the Women's Health Initiative (WHI) cohort. Longitudinal follow-up of the ECHO cohort—which could inform a vast range of policies, ideas, and treatments—will require involvement of ICs beyond NICHD. Though NIH has made great strides in improving the representation of women in heart disease studies and clinical trials for a variety of general conditions, Dr. Bhattacharya agreed that research on women's health is an area that needs to continue improving. He noted that MAHA has been led mostly by mothers, which reflects a political movement behind an increase in interest for women's health research. Dr. Cernich said that she can provide a briefing on the NICHD portfolio, which funds 70% of women's health research.

Dr. Dorn expressed her support for Dr. Bhattacharya's emphasis on team science. She asked whether there are exemplary areas of NIH's efforts with respect to building data sets, training, and mentorship. Dr. Bhattacharya said that NIH's work has led to a cure for sickle cell anemia, disease-modifying drugs for type 1 diabetes, and advances in basic science translation to clinical medicine. He added that rehabilitation medicine needs to continue to be part of the NIH portfolio, especially as the population ages. He also reiterated his desire to support early-career research.

Anna Aizer, Ph.D., M.S., asked how NIH research can be used to inform policy, especially in areas of MAHA such as nutrition and eliminating food deserts. Dr. Bhattacharya said that unlike the Director of the Centers for Disease Control and Prevention (CDC) or the U.S. Surgeon General, the NIH Director's focus is not on public health or providing health advice. Instead, Dr. Bhattacharya's main goal is to structure NIH's portfolio so that the research NIH supports advances the health of the public. He recognizes that part of that goal requires communicating and translating scientific results—an area that needs attention. Dr. Bhattacharya hopes that instead of having NIH be the main driver of policy translation, it can be part of a larger team that includes FDA, the Centers for Medicare & Medicaid Services (CMS), the Center for the Biomedical Advanced Research and Development Authority (BARDA), and other branches of the federal government.

Linda Ehrlich-Jones, Ph.D., RN, FAAN, asked Dr. Bhattacharya about his priorities for funding disability research. He said that this research does not belong just at NICHD. As the population ages, there will be greater need for research that informs innovations that improve daily living. Many families are also currently struggling with the stresses of properly caring for a child with disabilities. Supporting research on disabilities will be an important part of the NIH portfolio. Dr. Cernich said that NICHD includes disability research in its strategic plan, with input from Theresa H. Cruz, Ph.D., director of the National Center for Medical Rehabilitation Research (NCMRR).

XIII. Closing Remarks (59:42)

Dr. Cernich thanked all attendees and concluded the open session. A total of 256 people viewed the live Day 2 NIH VideoCast.

XIV. Closed Session (September 10, 2025)

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.

XV. 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 707 NICHD-primary applications requesting $243,468,091 in direct costs and $341,565,096 in total costs

XVI. Adjournment

There being no further business, Dr. Cernich adjourned the meeting at 1:00 pm. The next Council meeting is scheduled for January 26, 2026, as a virtual meeting.

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

ALISON N. CERNICH -S

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Date: 2026.01.14 19:47:23 -05'00'

Alison Cernich, Ph.D.

NACHHD Chair

NICHD Acting Director

REBEKAH S. RASOOLY -S

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Rebekah S. Rasooly, Ph.D.

NACHHD Executive Secretary

Director, NICHD Division of Extramural Activities