U.S. Department of Health and Human Services (HHS)
National Institutes of Health (NIH)
Office of the Director (OD)
Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)

Council of Councils Meeting
May 14–15, 2026

Meeting Minutes

DAY 1

I. WELCOME AND OPENING REMARKS

Nicole C. Kleinstreuer, Ph.D., Director, DPCPSI, welcomed participants, NIH staff members, and members of the public to the open session of this Council of Councils meeting. The in-person meeting began at 9:00 a.m. on Thursday, May 14, 2026. Dr. Kleinstreuer then reviewed the day's agenda. The meeting attendees are identified below.

A. Attendance

1. Council Members

Council Members Present

Chair: Nicole C. Kleinstreuer, Ph.D., Director, DPCPSI, NIH
Executive Secretary: Robin I. Kawazoe, Deputy Director, DPCPSI, Acting Director, Office of Research Infrastructure Programs (ORIP), DPCPSI
Monica Gandhi, M.D., M.P.H., University of California, San Francisco, San Francisco, CA
Rafael Irizarry, Ph.D., Dana-Farber Cancer Institute and Harvard T.H. Chan School of Public Health, Boston, MA
Karen C. Johnston, M.D., M.Sc., University of Virginia, Charlottesville, VA
Barbara Kelley, Hearing Loss Association of America, Bethesda, MD
Jean A. King, Ph.D., Worcester Polytechnic Institute, Worcester, MA
Richard D. Krugman, M.D., University of Colorado Anschutz School of Medicine, Aurora, CO
Jennifer Jaie Manly, Ph.D., Columbia University Medical Center, New York, NY
Lauren Silvis, J.D., Tempus, Inc., Washington, DC

Council Members Absent

Kevin C. Kent Lloyd, D.V.M., Ph.D., University of California, Davis, Davis, CA

2. Liaisons

Andrew A. Bremer, M.D., Ph.D., M.A.S., FAAP, Director, Office of Nutrition Research (ONR), and Acting Director, Office of Dietary Supplements (ODS), DPCPSI
Janine A. Clayton, M.D., FARVO, Director, Office of Research on Women's Health, DPCPSI
Josh C. Denny, M.D., M.S., Chief Executive Officer, *All of Us* Research Program Office, DPCPSI
Geri R. Donenberg, Ph.D., Director, Office of AIDS Research, DPCPSI
Matthew W. Gillman, M.D., S.M., Director, Environmental influences on Child Health Outcomes (ECHO) Program Office, DPCPSI

Susan K. Gregurick, Ph.D., Director, Office of Data Science Strategy, DPCPSI
Robin I. Kawazoe, Deputy Director, DPCPSI, and Acting Director, ORIP, DPCPSI
David M. Murray, Ph.D., Director, Office of Disease Prevention (ODP), DPCPSI
Vivian Ota Wang, Ph.D., FACMG, CGC, Acting Director, Office of Strategic Coordination (OSC), DPCPSI
George M. Santangelo, Ph.D., Director, Office of Portfolio Analysis, DPCPSI
Jane M. Simoni, Ph.D., Director, Office of Behavioral and Social Sciences Research, DPCPSI
Marina L. Volkov, Ph.D., Director, Office of Evaluation, Performance, and Reporting (OEPR), DPCPSI
Karina L. Walters, Ph.D., M.S.W., Director, Tribal Health Research Office, DPCPSI

3. ***Ex Officio*** **Member Absent**

Matthew J. Memoli, M.D., M.S., Principal Deputy Director, NIH

4. **Presenters**

Monika Aggarwal, Ph.D., Program Director, S10 Shared Instrumentation Program, ORIP, DPCPSI
S. Sonia Arteaga, Ph.D., Deputy Director, ECHO Program Office, DPCPSI
Jayanta Bhattacharya, M.D., Ph.D., Director, NIH
Andrew A. Bremer, M.D., Ph.D., M.A.S., FAAP, Director, ONR, and Acting Director, ODS, DPCPSI
Yong Chen, Ph.D., Program Director, C06 Construction Grant Program, ORIP, DPCPSI
Michael F. Chiang, M.D., Director, National Eye Institute (NEI)
Josh Denny, M.D., M.S., Chief Executive Officer, *All of Us* Research Program Office, DPCPSI
David Shurtleff, Ph.D., Acting Director, National Center for Complementary and Integrative Health (NCCIH), Acting Scientific Director, Division of Intramural Research, NCCIH, Acting Chief, Sensory Cells and Circuits Lab, NCCIH
Rick Woychik, Ph.D., Senior Advisor to the Director, NIH

5. **NIH Staff and Guests**

In addition to Council members, presenters, and Council liaisons, others in attendance included NIH staff and interested members of the public.

B. Reminders and Procedures

Robin I. Kawazoe, the Executive Secretary for the NIH Council of Councils, reviewed the following:

- Council members are Special Government Employees during the days of Council meetings and are therefore subject to the rules of conduct governing federal employees.

- Each Council member submitted a financial disclosure form and conflict-of-interest statement in compliance with federal requirements for membership on Advisory Councils. The financial disclosures are used to assess real and perceived conflicts of interest, and Council members must recuse themselves from the meeting during discussions of any items for which conflicts were identified.

- Time is allotted for discussion between the Council members and presenters, but time for comments from other meeting attendees is limited. The public may submit comments in writing;

instructions are available in the *Federal Register* notice for the meeting, which was published on April 10, 2026.

- Minutes from the March 24, 2026, meeting are posted on the DPCPSI website. The minutes from this meeting also will be posted there.

C. Future Meeting Dates

The next Council meetings are scheduled to be held September 10 and 11, 2026.

II. DPCPSI DIRECTOR'S REPORT

Dr. Kleinstreuer provided updates on DPCPSI activities, beginning with leadership changes. Dr. Jonathan Green has been selected as the Chief Executive Officer of the NIH Clinical Center. Dr. Bruce Reed, Acting Director of the Center for Scientific Review (CSR), has retired, and Dr. Ray Jacobson has begun serving as Acting CSR Director. Dr. Matthew Gillman, Director of ECHO, will retire at the end of May; Dr. Kleinstreuer noted the dramatic growth of ECHO under his leadership and thanked him for his service. As a new ECHO Director is sought, Dr. Josh Denny will serve as the Acting Director, Dr. Sara Van Driest will serve as Acting Senior Advisor, and Dr. S. Sonia Arteaga will continue to serve as Deputy Director.

Dr. Kleinstreuer noted several initiatives. A number of institutes, centers, and offices (ICOs) are supporting a National Academies of Sciences, Engineering, and Medicine consensus report on early relational health that will focus on the positive impacts of significant interpersonal relationships during early childhood on socio-emotional and physical health and development. Another document, the *NIH Strategic Plan for Disability Health Research Fiscal Years 2026–2030 (FY26–FY30)*, has been released and represents NIH's commitment to advancing research that improves health outcomes for people with disabilities. Additionally, ONR is launching a challenge to integrate nutrition training into health care education.

The Complement Animal Research In Experimentation (or Complement-ARIE) Program has been launched to develop, scale, and validate research methods that better simulate human biology. The first awards under this program have been issued to seven technology development centers and one data hub and coordinating center for new approach methodologies (NAMs) across a range of scientific areas; a validation and qualification network also is available. Another new program, the Science of Science Scholars Program—which aims to bring in experts in the science of science to help NIH staff answer critically important questions and improve NIH policies, processes, and programs—has selected two scholars for the pilot. Finally, the Common Fund's Acute to Chronic Pain Signatures (or A2CPS) study, which aims to identify markers that help predict the likelihood of developing chronic pain after surgery, has completed recruitment.

Dr. Kleinstreuer outlined updates to the *All of Us* program. The upcoming X01 Biospecimen Access notice of funding opportunities (NOFO) will invite external investigators to apply for access to the more than 14 million aliquots of de-identified biospecimens in the program's biobank and encourage them to propose studies focused on biomarker discovery and validation, novel disease stratification, and multiomics approaches to understanding disease risk and diagnosis and prognosis. All proposals must include a plan to return value to the participants, and resulting data will be returned to the Researcher Workbench. *All of Us* also recently hosted a Science Day, a free virtual event highlighting research already driving real-world health impacts across diverse communities. A partnership with NCCIH, the Your Whole Health Study invites participants to respond to a survey repeatedly over time to track the evolution of their personalized results. The National Institute on Drug Abuse (NIDA) also recently

leveraged *All of Us* data for a challenge on advancing research in substance use and addiction; due to the high number of exceptional submissions, six teams were awarded instead of the planned five.

Dr. Kleinstreuer highlighted upcoming events. The ORIP Workshop on Advancing Research Infrastructure to Study Human Diseases, a 2-day virtual event on novel approaches in biomedical research, will discuss how to advance methodologies to strengthen the understanding and study of human disease. Anticipated outcomes include informing future ORIP strategies to assist in the development and integration of NAMs and building new resources for the community to improve rigor and reproducibility of research models. Finally, the Common Fund Data Ecosystem will host the Incubator for Pan-NIH Resources, a 2-day forum to exchange ideas across NIH and proliferate data standards to increase uniformity, reproducibility, and harmonization.

III. OSC/COMMON FUND CONCEPT CLEARANCE (REVISED): R3PEATS PROGRAM: RIGOR, REPLICABILITY, AND REPRODUCIBILITY TO PROMOTE EXCELLENCE, ACCURACY, AND TRANSLATION IN SCIENCE [VOTE]

Michael F. Chiang, M.D., Director, NEI, presented the revised concept for the R3PEATS Common Fund Program, which aims to integrate research, partnership, engagement, and coordination within R3PEATS and the broader scientific community to foster culture change that will increase rigor, replicability, and reproducibility across biomedical research. Institute and center (IC) directors already have expressed support for the concept, suggesting the potential for significant collaboration. In response to the Council's concerns about the first version of the proposal, rigor was bolstered in all initiatives and culture change was emphasized, with a new Rigor Scholar Awards program to address incentive structures. Outcomes from prior NIH rigor and reproducibility studies have been outlined, and the subcomponents of initiatives have been staggered to address timing concerns, with clearly identified synergies. The new Innovation Awards also have been added to address the Council's comments about the limited number of replication projects and investigators.

Dr. Chiang explained that a landscape analysis conducted in advance of the R3PEATS proposal suggested that insufficient rigor, reproducibility, replicability, and infrastructure impede knowledge acquisition and translation from bench to bedside, ultimately affecting human health. The impacts of experimental factors and transparency on replicability remain unclear, and the current academic culture and high costs of sufficiently powered and well-designed studies disincentivize replications. Systematic and coordinated education, metrics, accountability, and communication are needed for long-term culture change. Although prior NIH replication activities were generally very productive, the underlying issue has not yet been solved, which may relate to the difficulty of culture change across the scientific enterprise. R3PEATS is designed with centralized coordination to support behavior change across the field. The vision of R3PEATS is to enable an adaptable, sustainable research enterprise in which rigor, replicability, and reproducibility are the norm. The goals are to provide comprehensive infrastructure, projects, training, incentives, and public engagement; deliver a knowledgebase of factors and practices that influence replicability, along with optimized resources and incentives for the broader community; and unite broad partners to stimulate culture change.

Initiative 1, Replication Centers, addresses the need to identify factors that affect experimental outcomes and provide coordination and resources. Centers each will focus on a different methodological category, and replication studies after the first year will be selected after merit review by a steering committee of external experts. Each center will be organized as a multisite consortium responsible for replicating studies and developing standard operating procedures to ensure rigor. Replication projects will be proposed by the community, selected by the steering committee, and staggered over time, with each center deciding which projects to replicate. Dr. Chiang emphasized that the goal is not only to replicate

prior studies but to assess why the outcomes occurred, which will maximize the useful information for understanding biological insights or optimizing future experimental design.

Initiative 2, Metascience Testbeds, will focus on culture change in the scientific enterprise. The three testbeds will develop or evaluate scientific support systems for the broader research enterprise. One testbed will focus on quantitative tools, and the other two will leverage cross-sector partnerships. The testbeds will perform landscape analyses iteratively throughout the program to identify ongoing gaps and opportunities that can be integrated into the program as a whole.

Initiative 3, the Education and Outreach Center, aims to build research capacity and communicate best practices. The landscape analysis revealed that significant existing training activities in rigorous research practices are hampered by many gaps and inconsistencies across programs and institutions. He suggested that these gaps are related to the use of the individual paper as a unit of academic currency because papers favor findings that are novel and positive. This initiative will compile existing resources into a foundational rigor curriculum that can be tailored to address specific gaps. The center will collaborate with partners to socialize effective interventions throughout the community. The Rigor Scholar Awards will help hold institutions accountable for providing the necessary training for scientists to integrate rigor into their work. The center also will work to engage the public to improve trust.

Initiative 4, the Coordination and Review Center, will create a web portal to connect all initiatives and collect outcomes and lessons learned. Dr. Chiang noted that the center may need to develop frameworks or ontologies. This initiative also will manage meetings and communications, with a steering committee of external experts from across the research ecosystem that will guide the overall strategic direction and conduct merit review of proposed projects.

Dr. Chiang emphasized that each of the initiatives will occur on their own but will integrate information from the other three initiatives. Many elements will be staggered, so the program can iteratively adapt and learn. He emphasized that the topic of reproducibility resonates with many people because it involves every area of science and medicine, making it a good fit for the Common Fund.

Discussion Highlights

- The discussants, Drs. Jennifer Manly and Karen Johnston, provided their comments. Dr. Manly complimented the revisions but expressed remaining concerns, noting that the proposal establishes NIH as an arbiter of epistemic authority, which presents concerns about concentrated decision-making and increases the stakes for investigators whose work is examined. Dr. Manly suggested that concentrating the usually iterative and distributed process of scientific advancement in a federally structured system risks narrowing the process and amplifying the consequences when the interpretations are incomplete or incorrect. She also expressed concerns about institutional support for the incentives to achieve culture change. Dr. Manly commented that although replication is valuable, it does not resolve scientific questions in the decisive way the program suggests, and she worried that the emphasis on replicating high-impact findings would disincentivize innovation, especially for early career scientists.

- Although Dr. Johnston agreed that replication is a priority, she also agreed with Dr. Manly's comments and expressed additional concerns about concentrating critical aspects of this program's success in a small number of Replication Centers. She also noted that these centers are not an innovative approach to infrastructure that would reach the entire research workforce, which is imperative for changing the culture. Dr. Johnston commented that the previous review should have prompted an approach that distributes funds to investigators, assures them academic credit, and creates an ecosystem in which researchers prioritize their own rigor and reproducibility while sharing information and resources. She expressed concerns that all aspects

of the proposal are too centralized, too traditional, and unlikely to lead to culture change, and she emphasized that creating resources does not necessarily lead to their adoption.

- Dr. Kleinstreuer clarified that the awards for Replication Centers would fund not single institutions but multisite consortia, resulting in a broadly distributed network. Dr. Chiang emphasized the difficulty of changing a longstanding scientific culture and noted the intent is not for NIH to be the arbiter of truth; he emphasized that the team feels strongly that the community will make that determination after R3PEATS provides the mechanism and framework for them to engage in those studies. R3PEATS also plans to partner with groups that engage the community, such as publishers and academia. He also acknowledged that balancing replication and innovation is difficult but emphasized that these concepts are complementary.

- Dr. Amy Bany Adams, the Acting Director of the National Institute of Neurological Disorders and Stroke, emphasized that R3PEATS will signal to the community that NIH is prioritizing rigor and reproducibility. She agreed with the intent to broadly engage the entirety of the academic ecosystem through collaborations with a variety of partners. The program's goal is to inspire a number of grassroots projects in the community, with support from specific ICs. Dr. Richard Hodes, Director of the National Institute on Aging, added that the desired engagement will not occur spontaneously but also will not happen if the program is overly centralized.

- Dr. Richard Krugman commented that replication studies must advance science by recognizing the flaws of earlier studies, such as the absence of questions about child maltreatment in studies of issues known to be associated with it.

- Dr. Rafael Irizarry pointed out that some of the most successful contributions to reproducibility and rigor have come from both NIH data sharing requirements and community computation and data sharing innovations, such as GitHub and data analysis programming. He suggested that by imposing structure and centralization, NIH might miss out on successful grassroots initiatives, and he recommended that NIH set aside funding for unstructured investigator-initiated awards.

- Dr. Monica Gandhi suggested a focus on replicating basic science rather than large clinical trials.

- Dr. Kleinstreuer clarified that all Council feedback will be integrated into the implementation plan for this concept and repeated the commitment to bringing iterations of the implementation plan to the Council for additional feedback as the program is developed. She reminded attendees that the Council could vote to recommend approval, approval with modifications, deferral, or disapproval of a program concept. Dr. Kleinstreuer noted that the Council members had expressed unified support for the goals of the program and reminded them that a vote for approval with modifications would move the concept forward with changes as discussed.

- Dr. Jean King pointed out that technology evolution can make studies impossible to reproduce and suggested that the concept address how to design studies that can be as reproducible as possible in the future, such as by including statisticians early in the project. Dr. Kleinstreuer agreed that this concept is an attempt to more transparently characterize the multifactorial nature of experimental design rather than an attempt to create a concrete measure of reproducibility.

- Dr. Chiang thanked Council members for their feedback and reiterated that culture change will require working with partners across publishing and academia. He pointed out that working with publishers could improve standard practices of knowledge dissemination and address such current problems as the lack of data connected to papers. He agreed that NIH should not be the arbiter of truth but noted that the community will need structure to integrate data from multiple sources.

- Dr. Johnston noted NIH's success in supporting researchers through K awards and asked whether similar mechanisms could be identified that allow researchers to build plans for rigor into their career development. Dr. Kleinstreuer emphasized that R3PEATS is only one way NIH is addressing rigor and reproducibility; mechanisms similar to the K award are under consideration.

- Dr. Manly commented that many of the clarifications provided in this meeting are not apparent in the proposal's written materials. She pointed out that although the multisite nature of the Replication Centers is stated in the documentation, Council members' comments suggest this is an important aspect that was underdeveloped in the proposal, as was the discussion of transparency around factors driving rigor and reproducibility. Dr. Kleinstreuer pointed out that the detailed implementation plan, when developed, will address many of these specifics.

- Dr. Gandhi commented that the 2025 updates to the peer-review process feature an evaluation of rigor and methods and that the reduction in NOFOs has resulted in additional layers of review that could include reproducibility. Dr. Adams responded that NIH is interested in supporting investigator-initiated research across ICs, with many ways to enhance rigorous practices. Highlighted topics allow ICs to signal their research priorities under the Unified Funding Strategy, but culture change must be driven by investigator engagement. Dr. Hodes added that the goal of this effort is to design a system that will help the field understand prospectively what is necessary to optimize testing the reproducibility of results.

- Dr. Kleinstreuer asked Council members about their preferred structure for the multisite Replication Centers, clarifying that most NIH awards currently fund investigator-initiated research, which already integrates rigor and reproducibility measures. Dr. Hodes added that the intent of the centers is to provide core organization for distributed research. Dr. Manly noted that such a structure would be valuable but that it does not match what is written in the proposal. She suggested that the Council needs more details about which groups are critical to improving rigor and reproducibility and how those partners will be engaged in the Replication Centers.

- Dr. Kleinstreuer explained that if the concept was approved with modifications, Council feedback would be used to expand the concept, which then would be turned into a detailed implementation plan that would be reviewed by the Council in September. She noted that the average time from concept approval to a request for applications is more than one year, so multiple opportunities for the Council to review the plan would be available. Dr. Vivian Ota Wang, Acting Director of OSC, clarified that many of the suggestions provided are aspects that are typically included in a detailed implementation plan, which determines how the project is actually implemented, and other concerns can be addressed as the plan is developed.

Vote

A motion to approve the R3PEATS Program concept with modifications was forwarded and seconded. The motion did not pass.

A motion to defer approval of the R3PEATS Program concept was forwarded and seconded. The motion passed with one abstention.

IV. OSC/COMMON FUND CONCEPT CLEARANCE (REVISED): ULTRA-PROCESSED FOODS: INVESTIGATING MECHANISMS, PREVENTION, AND ACTION FOR CHRONIC DISEASE AND TRANSFORMATION (UPF-IMPACT) [VOTE]

David Shurtleff, Ph.D., Acting Director, NCCIH, Acting Scientific Director, Division of Intramural Research, NCCIH, and Acting Chief, Sensory Cells and Circuits Lab, NCCIH, introduced the revised

UPF-IMPACT concept to address the need for research to reduce the adverse health effects of ultra-processed food (UPF) consumption, with a focus on reducing chronic diseases. The goals of the program are to investigate biological mechanisms by which UPFs potentially affect health, disease, and behavior and develop and test scalable interventions to reduce UPF consumption among school-aged children and families at risk for diet-related chronic diseases.

Dr. Shurtleff explained that this concept was presented at the September 2025 Council of Councils meeting and has been revised to address Council feedback. The scope has been refined, achievable deliverables have been identified, elements of the proposal have been clarified, and an initiative has been added to develop and test multilevel interventions consistent with a whole person health approach that targets environmental factors influencing food consumption and contributing to health disparities. The revised concept focuses specifically on school-age children and families with high UPF exposure who are at risk for diet-related chronic disease, and changes have been made to prevent conflicts of interest.

Better understanding the links between UPF consumption and chronic disease and developing interventions to limit UPF consumption is a public health necessity, given the high rates of adults and children in the United States with at least one chronic disease and the significant amount of health care spending related to chronic conditions. The global increase in diet-related chronic disease parallels the population-level shift toward high UPF consumption, and UPFs now comprise approximately 70% of the food supply and approximately 60% of daily caloric intake. Although UPF has emerged as a potential driver of the increased burden of chronic disease, evidence is almost exclusively observational, causality has not been established, and most studies are of low quality.

Food choices result from complex, multilevel factors, and environmental interventions that target barriers to healthy eating are promising but have not been tested specifically to reduce UPF consumption in the United States. Childhood and early adolescence are critical developmental periods for interventions to prevent adverse health outcomes that could persist into adulthood, and children require nutrient-dense foods for development but are especially vulnerable to targeted UPF marketing and availability. Intervening to reduce UPF consumption in school-age children has the potential to reduce obesity and chronic disease and promote long-term whole person health. NIH has supported UPF-specific research in the past, but few studies examined biological mechanisms, included pediatric populations, or assessed food insecurity, access, or the environment.

Andrew A. Bremer, M.D., Ph.D., M.A.S., FAAP, Director, ONR, and Acting Director, ODS, outlined the UPF-IMPACT concept's three initiatives based on a review of the literature and NIH portfolio. The first initiative investigates the biological mechanisms by which UPFs may potentially affect health, disease, and behavior in those who regularly consume UPFs and who are at risk for diet-related chronic diseases. Investigators will examine how specific UPF components and attributes affect physiological processes, with a focus on inflammatory processes and their interactions with microbiome dysbiosis and metabolic regulation. They also could examine neurobiological processes and eating behavior, including the addictive potential of UPFs, or how food presentation and characteristics affect these neurobiological processes. Investigators will be required to identify biomarkers of chronic disease relevant to UPF exposure.

Initiative 2 focuses on developing multilevel interventions to reduce UPF consumption and exposure in school-age children at risk for diet-related conditions, as well as their families. These may include families with low socioeconomic status, those living in neighborhoods with limited access to healthy foods, and those experiencing food insecurity. Studies should enroll and intervene with the child and the primary caregivers responsible for food purchasing and preparation, and investigators must develop and test a multilevel intervention targeting two or more levels of influence. At least one intervention must target environmental factors. Based on discussions at the last Council meeting, the team believes it is

important that reduced child UPF consumption be the primary outcome, but at least one additional health and behavioral outcome in children and families also should be included. As in the first initiative, investigators will be required to identify biomarkers of UPF exposure and disease relationships. Dr. Bremer noted that several planned federal and state policies affecting school meals and food labeling may provide natural experiment opportunities that can be leveraged to evaluate the impact of these policies on UPF consumption. He emphasized that NIH's goal as an agency is to support biomedical and behavioral research, including research that assesses policy effectiveness.

Initiative 3 will support a Research Coordinating Center that will provide expertise in statistical design and analysis; oversee a central laboratory to develop and maintain standardized protocols for biospecimen collection, processing, and analysis; coordinate a secure, controlled-access biospecimen and data repository; and ensure that data sharing activities are in alignment with NIH data standards.

Dr. Bremer reiterated that the UPF-IMPACT Program is intended to generate actionable evidence to reduce diet-related chronic diseases and improve health. The project will use a phased, milestone-driven approach with a 1-year planning phase and increased funding for the Research Coordinating Center over time, and the program consortium will be governed by a steering committee and will establish subcommittees that must engage in outreach strategies with community partnership.

Discussion Highlights

- The discussants, Drs. Manly and Krugman, provided their comments. Dr. Manly noted several strengths of the revised proposal but expressed concerns that partnerships with industry have been removed from the proposal without being prohibited. She emphasized that this issue is critical because UPF commercially is produced and exposure optimized by the same entities that stand to be affected by regulatory and public health action; she requested clarification of the rules associated with industry influence. Dr. Manly also praised the attention to health disparities by the focus on multilevel approaches with community engagement and a focus on early life for low–socioeconomic status populations but cautioned that the proposal's focus on populations that already consume high levels of UPFs risks locating the problem within those communities rather than in the structural conditions that shape their food environments. Without a stronger emphasis on analyzing upstream drivers, Dr. Manly worried that the program could reinforce an intervention paradigm centered on changing consumption in marginalized populations rather than transforming the systems that produce those patterns. Dr. Manly also noted the proposal does not provide concrete structural protections of publication freedom and questioned whether the revised program still aligns with the Common Fund mission.

    - Dr. Krugman commented that he is generally pleased with the changes that have been made but suggested that the program needs to address physical and sexual abuse in childhood, which has longstanding associations with obesity. Dr. Bremer explained that the program intentionally chose to focus on school-age children and address whole person experiences, including adverse childhood experiences.

    - Dr. Bremer acknowledged Dr. Manly's concerns about industry influence and commented that an improved food environment would necessarily involve partnership with those who generate the food, but the goal of this project is unbiased and independent understanding of the biology as well as focused interventions on at-risk populations, mainly school-aged children and their families.

- Dr. Shurtleff commented that this project meets Common Fund criteria because no single IC could address its initiatives. He noted that the whole person concept requires more than one IC to

work together on multiple components. Dr. Kleinstreuer added that the difficulty of enacting this proposal across ICs is relevant to the Common Fund mission.

- Dr. Nora Volkow, Director of NIDA, commented that other projects studying environmental influences on brain development have required significant coordination. Tools to define and study UPF exposure in the brain are lacking, so the aspects by which UPF components are delivered to the brain, which could have effects similar to drugs, remain unknown.

    - In response to a question about expanding the concept beyond UPF to address nutrition broadly, Dr. Bremer explained that a mechanism focused on increasing nutrition education in medical training is about to be launched, and he sees this concept as another element in the paradigm shift of recognizing the role of diet and nutrition in the chronic disease research ecosystem. He noted that the focus on UPF does not mean they will neglect consideration of the entire spectrum of dietary exposures.

- Dr. King suggested increasing consideration of social factors and emphasized the importance of integrating disparate researchers' knowledge in the Coordinating Center. Ms. Barbara Kelley pointed out that UPF exposure is common regardless of level of food security.

    - Dr. Irizarry expressed a concern that the proposal assumes UPF is a causal driver of chronic disease rather than treating this idea as a hypothesis to be tested, which risks funding studies that are designed to confirm a policy narrative. He also suggested that the proposal should clearly state that well-designed studies finding no independent effect are equally valuable and publishable. Dr. Bremer concurred and reinforced that this program was specifically designed to evaluate what the impact of UPFs on human biology may or may not be and included testing the null hypothesis that UPFs may not be a causal driver of disease. Comments were also made that comparable programs studying dietary exposures with uncertain causal evidence could be designed for other dietary intakes that have increased in popularity, such as nutritional supplements or protein powders.

- Dr. Manly reiterated that the program falls short on innovation and noted that the concept is silent on GLP drugs, which could provide a potential window into some mechanisms that link components of UPF with overeating. She also emphasized the need to consider scientific independence. Dr. Kleinstreuer reminded attendees that NIH prioritizes academic freedom in pursuit of public trust.

- Dr. Bremer agreed that the biopsychosocial lens is important and reiterated that this program intends to address assumptions about UPF that currently do not have data. He noted that incretin therapies are mainstream but treat an issue that may be preventable. Mechanistically, individuals on incretin therapies will be excluded to remove a potential confounder, but in intervention studies, all participants will be welcome to reflect real-world settings. Dr. Shurtleff added that whole person health is aligned with the biopsychosocial model. He emphasized that this program will be conducted in parallel and that biological mechanisms will help identify biomarkers. Dr. Volkow added that one social component is whether individuals have the choice between UPFs and other options.

Vote

A motion to approve the UPF-IMPACT concept was forwarded and seconded. The motion did not pass.

A motion to approve the UPF-IMPACT concept with modifications as discussed was forwarded and seconded. The motion passed with one abstention.

V. REVIEW OF GRANT APPLICATIONS

This portion of the meeting was closed to the public, in accordance with the provisions set forth in Sections 552(b)(c)(4) and 552(b)(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix).[1] Members were instructed to exit the meeting if they deemed that their participation in the deliberation of any matter before the Council would represent a real or perceived conflict of interest. Members were asked to sign a conflict-of-interest/confidentiality certification to this effect. The *en bloc* vote for concurrence with the initial review recommendations was affirmed by all Council members present. During the closed session, the Council concurred with the review of 34 ORIP applications with requested first-year direct costs of $10,171,647 and 1,892 Common Fund/OSC applications totaling $4,382,347,612.

VI. NIH DIRECTOR'S UPDATE

Jayanta Bhattacharya, M.D., Ph.D., Director, NIH, noted that life expectancy in the United States has not increased since 2010 despite significant research discoveries by NIH-funded scientists. Dr. Bhattacharya suggested that these discoveries are not being translated into better health as the basic measure of life expectancy, and thus NIH is not fulfilling its mission. Dr. Bhattacharya suggested that one reason is because NIH funds too much safe, incremental science. The Unified Funding Strategy is one method for addressing this issue and is intended to allow NIH to take larger risks. Dr. Bhattacharya also noted that the Advanced Research Projects Agency for Health (or ARPA-H) was developed in response to a perception that NIH was not funding cutting-edge ideas.

Dr. Bhattacharya commented that a lack of replicable studies leads to challenges for both clinicians and patients in improving health and emphasized that NIH should embrace solving this replication crisis. He also pointed out that NIH funding is concentrated in a relatively small number of institutions. NIH investments in facilities tend to attract other institutional co-funders.

Dr. Bhattacharya noted that NIH support for the newest ideas has declined over time and suggested that study sections are less likely to give high scores to new ideas. Early career scientists, who often have newer ideas but are less experienced at writing effective grants, are disadvantaged by a funding system in which new ideas are not scored highly, and researchers now are older when they win their first R01 grant than in the past. The Unified Funding Strategy is a way to potentially address this issue by supporting the review of all comments on an application rather than making funding decisions based only on the final review score. He suggested that IC staff reviewing the applications would prioritize different values (e.g., potential impact) than study section reviewers, who might judge based on likelihood of publication.

Dr. Bhattacharya commented that science is determined to be true or false based on authority, such as publication in a leading journal, but many papers are not easily replicable, which reduces trust in biomedical literature. He suggested that this problem is caused by insufficient reward for replication. Funding replication studies as identified by peer-reviewed committees could change the culture of replication and make it more valued. Dr. Bhattacharya noted the intent for NIH to establish a replication platform on which to publish these studies with minimal gatekeeping. Replication work visibility also will be enhanced by adding metrics to PubMed to show related papers and discussion.

Dr. Bhattacharya reiterated that about one-third of NIH funding goes to about 20 institutions. Facilities funding requires scientists who are able to win grants for projects, and the indirect funding is attached to project funding. However, superior facilities are needed to attract scientists with the skills to win grants.

[1] For the record, it is noted that members absented themselves from the meeting when the Council discussed applications (a) from their respective institutions or (b) in which a conflict of interest may have occurred. This procedure applied only to applications that were discussed individually, not to *en bloc* actions.

Dr. Bhattacharya suggested that NIH could use some funds to build biomedical research excellence in places outside the top 20 without impacting those institutions. He suggested a need to disconnect indirect funding and project funding and compete research facility support separately from project competition. He also suggested that there should be more competition for researchers.

Discussion Highlights

- Dr. Bhattacharya suggested that a new set of rules related to reproducibility is needed because the existing ones have become too easy to break. The effort to disconnect direct and indirect costs will be centered on pilot studies.

- Dr. Bhattacharya commented that the NIH budget can accommodate both reproducibility and innovation because new ideas must be able to be validated.

- In response to a question about the impact of systemic issues on limiting implementation of NIH research, Dr. Bhattacharya explained that although NIH does not have authority over implementation, it can fund biomedical research including implementation science. He suggested that all NIH research should be actionable, rigorous, and within the scope of NIH's mission.

- When asked about the current status of spending, Dr. Bhattacharya pointed out that the 2-month shutdown set NIH behind, but it is now caught up and on track to identify enough excellent science to spend the budget this year.

- Dr. Bhattacharya clarified that the changes in international research, with sub-projects rather than sub-awards, will be slow to implement but provide more secure footing.

- In response to a request for transparency regarding screening of grants and how that might contribute to lower U.S. life expectancy, Dr. Bhattacharya commented that no lists of banned words are used and that the decrease in life expectancy is a longstanding problem. He suggested that IC-level funding decisions illustrate each IC's priorities. Applications are screened after review to identify proposals that are not actionable, rigorous, or in scope.

- When asked about unequal distribution of research discoveries across populations, Dr. Bhattacharya responded that price is a greater limiting factor than inequity. He proposed that NIH could reduce the price of life-saving discoveries by investing in research that lowers the cost of care.

- In response to a question about the renegotiation of grants focused on equity, Dr. Bhattacharya suggested that applications had used equity as a strategy to secure funding and added that diversity, equity, and inclusion–related applications have decreased.

- When asked about the appeal of replication studies when most scientists are driven by curiosity and discovery, Dr. Bhattacharya suggested that young scientists being mentored by senior scientists in well-resourced institutions would have increased opportunities.

- Dr. Bhattacharya confirmed that the search for replacement Directors at ICs is ongoing. When asked about term limits for IC Directors, he replied that his opinion has changed since he became NIH Director, and he now thinks there should be a mix of senior and junior Directors. He advocated for turnover without a formal rule.

- In response to a question about declining funding for early career investigators, Dr. Bhattacharya pointed out that the Unified Funding Strategy is new and its effects will require several years to appear in the data. He emphasized that NIH is committed to K, F, and T awards.

- When asked whether changes to international research requirements should be seen as a commentary on international research, Dr. Bhattacharya responded that fostering international collaborations is an important part of the NIH investment in American science. The long-overdue changes to the system allow for better auditing of where American tax dollars are sent.

- Council members emphasized the need to continuously communicate NIH's support for young investigators to ensure they feel supported in the scientific community.

VII. NIH MAKE AMERICA HEALTHY AGAIN (MAHA) IMPLEMENTATION STRATEGY AND GOVERNANCE STRUCTURE

Rick Woychik, Ph.D., Senior Advisor to the Director, NIH, explained that the MAHA initiative includes 33 scientific mandates focused on identifying the root causes of chronic disease. NIH already engages in many relevant activities, but additional coordination is required to overcome silos. The implementation strategy focuses on leveraging and aligning the existing research projects, improving coordination, and generating actionable results. Dr. Woychik noted the importance of establishing synergistic relationships among experts with complementary skill sets across ICOs.

Chronic diseases arise from interacting genetic, environmental, behavioral, dietary, and social factors. Dr. Woychik emphasized that implementation of the MAHA mandates would occur within the existing ICO infrastructure, and he planned to build on his experience with a collaborative project called Health Effects of Extreme Weather (HEW), which recognized a problem that extended beyond the focus of a single IC and brought collaborators together. The MAHA initiative will embrace the whole person health framework, which recognizes that health and disease exist on a bidirectional continuum, with opportunities to prevent disease and restore health through integrated health care with individual and social support.

The implementation strategy will center on thematic coordination groups (TCGs), which will focus efforts on a specific area, and implementation platforms (IPs). A steering committee composed of ICO Directors will provide strategic oversight, review NOFOs, and oversee the performance of the TCGs and IPs. The TCGs were formed by grouping related MAHA mandates, with IC Directors co-chairing each group and nominating subject-matter experts. Subject-matter experts will meet regularly to identify areas for improved communication and coordination and make recommendations to the steering committee, but TCGs will not have budget authority.

IPs will apply their capabilities across all TCGs. IP1, the Real World Data (RWD) and Artificial Intelligence (AI) Platform, will address the current lack of RWD and the use of AI to analyze any data created. IP2, Clinical and Community Networks That Integrate The Whole Person Health Framework, will ensure the principles necessary for whole person data collection are applied across TCGs. Dr. Woychik pointed out that the CARE for Health program, which centers on integrating NIH research in rural primary care settings, is relevant to this IP. IP3, Life-Course Cohort Integration, will address cohort-based chronic disease research across the life course and will develop strategies to use such resources as the AoU, ECHO and the Adolescent Brain Cognitive Development (ABCD) cohort.

Dr. Woychik described seven TCGs: (1) nutrition, metabolism, and health promotion as it relates to chronic disease; (2) environmental and chemical exposures, using the concept of the exposome to assess how the environment interacts with genes to contribute to chronic disease or promote wellness; (3) oral systemic health, physiologic resilience, and inflammation, which will assess factors that affect systemic

inflammation that can contribute to chronic disease; (4) neurodevelopment, mental health, and cognitive resilience, which will focus on such elements of the MAHA agenda as autism, mental health, and addiction; (5) substance use, prescribing, and therapeutic safety, which will combine utilization research with pharmacogenomics and addiction-risk prediction; (6) immunologic interventions and differential responses, which will assess vaccine effectiveness and safety over the life course; and (7) cancer etiology, early detection, and survivorship, which will investigate the recent increase in colorectal cancer or many other cancers.

IC Directors have reviewed the framework and SME's have been nominated for all groups. The next steps are to conduct a portfolio analysis to identify current research aligned with the TCGs and develop a narrative, followed by identifying knowledge gaps and potential projects.

Discussion Highlights

- Dr. Woychik clarified that hearing health is part of the initiative but could be spelled out more specifically in the second IP. Ms. Kelley suggested that data are needed to justify screening asymptomatic adults over 50, which could be used to ask for a U.S. Preventative Task Force Services mandate.

- Dr. Woychik planned to emphasize infectious disease as a driver of health outcomes in TCG6.

- When asked how to ensure the IPs do not duplicate existing efforts, Dr. Woychik emphasized that the strategy is not intended to build a new organizational design, but rather to identify and build on existing efforts.

- Council members encouraged Dr. Woychik to consider NIH's long-term mission and goals when implementing this broad strategy. Dr. Woychik explained that he is planning to use a matrix approach, in which work is conducted in collaborative working groups. This will build the framework for more cooperative efforts across NIH that will be sustainable over the long term.

- Dr. Krugman asked where child abuse and neglect are addressed. Dr. Woychik replied that there are elements in TCG4 related to neurodevelopment and mental health.

- Dr. Woychik reiterated that the HEW project is a successful example of this approach; its small amount of funding was used as a catalyst, with most funding provided by ICOs.

- When asked how aging fits the agenda, Dr. Woychik explained that IP3 includes longevity, and he emphasized that aging is an important part of the life-course perspective that the framework supports. He also noted that Dr. Hodes has been an active participant in developing the strategy.

- In response to a question about postnatal maternal mental health, Dr. Woychik noted that the narrative developed to encompass the strategy will expand upon elements not addressed in the presentation. He noted that Centers for Disease Control staff have suggested potential areas for collaboration, including postpartum mental health.

VIII. CLOSING REMARKS, DAY 1

Dr. Kleinstreuer expressed gratitude for the input and discussion provided by Council members.

IX. ADJOURNMENT FOR THE DAY

Dr. Kleinstreuer adjourned day 1 of the meeting at 4:30 p.m. EDT on May 14, 2026.

DAY 2

X. WELCOME AND RECAP OF DAY 1

The meeting began at 9:01 a.m. on Friday, May 15, 2026. Dr. Kleinstreuer welcomed participants and reviewed the previous day's proceedings.

XI. OVERVIEW OF THE ORIP S10 SHARED INSTRUMENTATION PROGRAM AND THE NIH C06 CONSTRUCTION GRANT PROGRAM

Monika Aggarwal, Ph.D., Program Director, S10 Shared Instrumentation Program, ORIP, DPCPSI, presented an overview of ORIP's S10 program, with a focus on how S10 funds enable cutting-edge biomedical research and how the program aligns with NIH-wide strategic priorities. NIH established the S10 program in 1982 to support the purchase of scientific instruments for shared use.

The S10 program supports the acquisition of state-of-the-art, commercially available, costly scientific instruments to be used on a shared basis for NIH-funded research. Awards are issued for 1 year to purchase and install the instrument and make it available to the users. NIH mandates institutional support and internal advisory committee oversight of the instruments, and ORIP provides administrative oversight for 5 years.

Dr. Aggarwal stated that each S10-funded instrument supports an average of 17 NIH-funded research grants, enables broad research for tens of thousands of investigators at hundreds of institutions nationwide, and generates data for thousands of publications each year, maximizing the return on NIH investment by fostering efficient and cost-effective research operations. ORIP has produced educational videos and has recently initiated a weekly office hour to promote communication with prospective applicants.

Between FY21 and FY25, ORIP-funded 640 S10 instruments that supported more than 14,000 research projects across nearly all NIH ICOs. Dr. Aggarwal emphasized that the S10 program has supported research across a broad range of scientific areas and with a wide geographic distribution. S10 awards have been granted to both research-intensive and under-resourced institutions. Dr. Aggarwal emphasized that the S10 program ensures fair access for all institutions across the nation.

The S10 program has funded many types of instruments, including spectrometers and resonance systems, optical instruments, biomedical imagers, cell analysis instruments and robotics, computer and data storage systems, non-optical microscopes and detectors, molecular interactions systems, and X-ray irradiators. These instruments have enabled more than 20,000 publications from FY21 to FY25. ORIP tracks these publications through its website. Dr. Aggarwal briefly highlighted examples of S10-funded instruments that have enabled highly impactful science.

ORIP supports the acquisition of instruments and technologies that align with NIH-wide strategic priorities, including the NIH Director's initiative to prioritize human-based science. As part of this effort, ORIP will provide a wide range of advanced instruments that are essential for driving progress across all areas of biomedical research. Additionally, ORIP will respond to evolving modern scientific instrumentation needs of the scientific communities at all levels of academic and research institutions nationwide. Furthermore, ORIP will facilitate the adoption of novel and emerging technologies that accelerate innovation and scientific discoveries.

Dr. Aggarwal explained that ORIP has initiated two S10 sub-programs that are currently under review: a premium S10 instrument sub-program and a seed instrument support (SIS) sub-program. The premium S10 instrument sub-program will expand regional impact, fill gaps in regional infrastructure, and promote

collaboration beyond the applicant's institution. The SIS sub-program will promote innovative research activities by supporting the acquisition of instruments that are currently unavailable at the applicant's institution and help develop sustainable research programs and technical expertise while supporting research capacity building.

Dr. Aggarwal concluded by emphasizing that many biomedical research fields have benefitted from the S10 program. Additionally, the S10 program will continue to play a critical role in ensuring that the biomedical research community has access to state-of-the-art instrumentation that drive innovative research. Strategic investment in shared infrastructure will continue to be essential for maintaining the nation's competitiveness in biomedical research.

Discussion Highlights

- Dr. Gandhi noted that Dr. Bhattacharya spoke about infrastructure grants to under-resourced institutions in his remarks on the previous day of this meeting. She wondered whether the S10 program is aligned with these efforts. Dr. Aggarwal agreed, noting that ORIP's Basic Instrumentation Grant and SIS programs promote broad and equitable access, spanning both research-intensive and under-resourced institutions. Dr. Gandhi also noted that the S10 mechanism and other NIH funds helped enable the development of the drug lenacapavir and would like to ensure that NIH receives direct benefits from these efforts.

- Dr. King remarked that her research has benefitted from S10 funding. She spoke on the importance of this mechanism for the biomedical research community. She wondered about support for early stage investigators who do not yet have NIH funding. Dr. Aggarwal stated that S10 principal investigators are not required to have NIH funding. She also noted that the S10 program is highly engaged in community outreach activities, including informational webinars and an S10 symposium. Dr. Xiang-Ning Li added that ORIP and the National Institute of General Medical Sciences co-established an S10 sub-program for resource-limited institutions, which supports institutions that have established training and educational programs.

- Dr. King also pointed out that it can be challenging for investigators to identify available S10-funded instruments in their region. Dr. Li responded that ORIP is developing an S10 network with search functionalities for available instruments, a prototype function is available. He stated that ORIP's long-term goal is to ensure that investigators in every region of the United States have access to such instruments.

- Dr. Johnston commented that the SIS sub-program is enabling the creation of infrastructure at institutions that previously lacked these capabilities. She noted that this program enables both training and collaboration. She asked whether the program is aligned with NIH's priorities regarding decoupling direct and indirect costs. Dr. Kleinstreuer remarked that the S10 program is an excellent example of NIH's dedicated and directed infrastructure support for the research community, but Dr. Bhattacharya's priorities relate to a broader vision to address the issue of indirect costs under research project grants. In response to a follow-up question from Dr. Gandhi, Dr. Kleinstreuer noted that more discussions are needed to fully understand this decoupling.

- Dr. Irizarry questioned the separation of funding metrics by state, noting that disparities exist within states. Dr. Kleinstreuer noted that this point could be considered in the context of geographic distribution and distribution of funds in a data-driven manner.

Yong Chen, Ph.D., Program Director, C06 Construction Grant Program, ORIP, DPCPSI, then provided an update on the C06 Construction Program. He explained that the construction program was established at

NIH through the Health Research Facilities Act of 1956. Under current federal law, only the NIH Director and National Institute of Allergy and Infectious Diseases Director have the authority to make grants and contracts to renovate existing or construct new research facilities. The construction budget requires annual congressional appropriations, and 25% of the budget is allocated for institutions of emerging excellence.

The first installment of the 1956 legislation was $90 million for a 3-year program, equivalent to $1 billion in today's purchasing power, after adjusting for inflation. And the construction programs continued to contribute to major construction projects through the late 1990s and early 2000s, significantly expanding NIH's health research infrastructure. A record $1 billion investment through the American Recovery and Reinvestment Act of 2009 funded 148 projects for research facilities nationwide. In the past, the construction programs used the C06 mechanism for construction of new facilities and the G20 mechanism for renovation of existing facilities. These programs were merged into a single C06 program in 2019. Dr. Chen remarked that the budget has been steady in recent years.

The C06 program can be divided into three sub-programs: Special Disaster Relief, Biomedical Research Facilities (BRF), and HIV Research Facilities (HRF). The current NOFO includes two of the sub-programs: BRF and HRF. The NOFO will be active for 3 years; each year's budget requires congressional appropriation. Dr. Chen briefly described the review and funding process.

For awarded projects, ORIP oversees the design and construction and holds federal interest to ensure that the facility will be used for the proposed research for either 10 or 20 years, depending on the program. Dr. Chen explained that a C06 project must be completed within 5 years; most projects can be completed within 4 years. The Office of Research Facilities oversees the technical reviews of design and environmental policy compliance. The Office of Grants Management provides guidance on grant policy and financial compliance. Soon after construction is complete, ORIP conducts a closeout site visit to ensure that the facilities were built as designed and are operational. Near the end of the federal oversight period, ORIP conducts a final site visit to evaluate the facility's impact and accomplishments. Dr. Chen also noted that ORIP developed the extramural Construction Award Management and Early Risk Alert (known as eCAMERA) system, a unified documentation and communication platform that allows users to track project progress and take action as needed.

Dr. Chen briefly highlighted examples of representative facilities that were supported by C06 funds. He remarked that these facilities have supported grantee institutions in expanding their research portfolios, securing additional funding, recruiting new faculty and researchers, and forming new collaborations. As a result, the C06 program has made a lasting impact on grantee institutions, regional economies, and the NIH research enterprise.

Discussion Highlights

- In response to a question from Dr. Gandhi, Dr. Chen clarified that the NIH construction budget requires congressional appropriation. He also explained that the funds can support the construction of a new research building, the fit-out of a shell space within an existing building, or the renovation of existing facilities.

XII. ECHO PROGRAM: PROGRESS, POTENTIAL, AND *ALL OF US* PARTNERSHIP

Dr. Arteaga provided an overview of the ECHO program. The ECHO program began in 2016 to fulfill two congressional mandates, the Children's Health Act of 2000 and the Pediatric Research Initiative. The program's objective is to address the factors that affect child health to improve the health of children. Observational and intervention research allows the ECHO program to inform policies, practices, and programs to promote this goal. The ECHO program comprises the ECHO Cohort and the ECHO Institutional Development Award (IDeA) States Pediatric Clinical Trials Network (ISPCTN), and it is

present across 42 states, the District of Columbia, Puerto Rico, and two Tribal nations. Five pediatric areas—including pre-, peri-, and postnatal outcomes; upper and lower airways; and obesity—are the focus of the ECHO program.

The ECHO Cohort is the largest longitudinal study of children in the United States, with data being collected from 60,000 active participants from before conception to age 21. A broad range of data is collected—including medical, societal, psychosocial, and chemical exposures. Blood, urine, hair, and deciduous teeth biospecimens are collected from the children. The ECHO Cohort is recruiting 30,000 new pregnant participants. Enrollment is at 91%, and the retention rate is 96%. Blood and urine biospecimens are collected from pregnant participants. If available, data and biospecimens are collected from the father of the child, as well. The ECHO Cohort has resulted in approximately 2,200 publications. Dr. Arteaga highlighted findings from several publications. Wildfire smoke and phthalate exposure during pregnancy are linked to an increased risk for preterm birth. Social media use is linked to poor mental health outcomes, particularly for adolescents with weaker peer relationships, and the quality of peer relationships is a strong predictor of mental health. These large-scale population research studies can inform prevention strategies.

The ECHO program is fostering the next generation of researchers. Through the ECHO Opportunities and Innovation Fund, early stage investigators (ESIs) can receive $200,000 over a 2-year period to conduct research. During the first cycle, 51 ESIs were funded, and at least 50 awards will be provided to ESIs in this current funding cycle. Dr. Arteaga noted that ESI achievements are tracked; many ESIs are publishing their research and obtaining R01 grants. The program also supports predoctoral and graduate students.

ISPCTN provides access to state-of-the-art clinical trials in IDeA states to build the pediatric research capacity in states with historically low levels of NIH funding. Dr. Arteaga highlighted that ISPCTN is the only clinical trials network to conduct pediatric research in these underserved populations, with 28% of ISPCTN's participants located in rural communities. ISPCTN research includes obesity treatment, indoor air quality, and the opioid crisis. Dr. Arteaga highlighted several clinical trials, including the feasibility of a HEPA filter intervention to improve indoor air quality for babies and the implementation of safe and effective treatment strategies for neonatal opioid withdrawal.

Dr. Arteaga emphasized that the program has a rapidly expanding data platform and biorepository that serves as a national research resource; the program harmonized data from more than 170,000 participants by incorporating preexisting longitudinal studies. By sharing data and biospecimens with the broader research community through ECHO Cohort ancillary studies, the program is maximizing its impact. The program is a major investment in understanding the prenatal and early childhood factors that are involved in child health outcomes, and the program fills knowledge gaps about factors that cause chronic disease. The ECHO program supports the nation's research priorities—including the Autism Data Science Initiative—and MAHA's public health priorities.

Dr. Arteaga discussed the *All of Us* partnership to retain participants after they turn 21 and are no longer eligible to participate in the ECHO program. Integration of the ECHO program's data platform with the *All of Us* data repository will create a unified national data resource, which will allow earlier prevention and better health outcomes across a person's lifespan.

Discussion Highlights

- Dr. Gandhi expressed concerns about the program's overlap with the UPF initiative. She questioned whether additional surveys related to UPF could be included in the ECHO program for cross-initiative collaboration and stewardship of funds. Dr. Arteaga explained that the ECHO program collects diet information, including UPFs, from the fathers and pregnant mothers, and during childhood. Principal investigators can use these data to understand outcomes and how

factors interact with each other to create health outcomes. Dr. Kleinstreuer continued that DPCPSI is considering how to optimize initiatives and coordinate across research programs in a resource-constrained landscape. The ECHO cohort can be a catalyst for other research initiatives.

- Dr. King noted that additional partnerships are needed to minimize duplication of effort. She commented that factors—including environmental toxins where children play—can cause epigenetic changes, which should be studied. Dr. King continued that the ECHO program should consider other parameters, such as noise level, which affects sleep and causes stress. Dr. Arteaga responded that geocoding data are a part of ECHO research, which has resulted in publications about green space and mental health. Additional research is needed to understand the comprehensive impact of environmental exposures.
- In response to a question from Dr. Krugman about data collection on childhood abuse, Dr. Arteaga explained that this information is collected when participants are of age to discuss these experiences. She noted that this is an important topic being studied to understand how it impacts a variety of health outcomes.
- Dr. Johnston commented that ECHO is a model program. She appreciated its partnership with *All of Us* and data collection across a person's lifespan. Dr. Johnston commended the program for its efforts in data harmonization and whole person health.

XIII. ADVANCING CROSS-NIH SCIENCE THROUGH SHARED GENOMIC AND REAL-WORLD DATA INFRASTRUCTURE: UPDATES ON *ALL OF US* AND COORDINATION WITH THE ECHO PROGRAM AND ACROSS NIH

Dr. Denny explained that *All of Us* has enrolled about 880,000 participants and collected 15 million aliquots of biosamples, 500,000 electronic health records (EHRs), and 3 million survey responses. *All of Us* is nearing the end of its first 5-year strategic plan, which included a goal of 10,000 researchers using the data by the end of 2026; currently about 23,000 researchers participate, and Dr. Denny expects the program may reach 30,000 by the end of the year.

One of the program's major principles is returning results to participants, and it currently has returned health-related genetic results to more than 200,000 people, 5,500 of whom have learned about potentially life-saving results. Another 150,000 have learned pharmacogenetic traits that would be actionable if they receive any of about 50 common medications. A new clinical test for polygenic risk scores was trained on the diverse population of *All of Us*. Top priorities for 2026 are to reassess, reactivate, and re-engage the cohort in the wake of the program's platform transition. The next data release will be the largest broadly accessible deep research dataset of this type in the world, and by far the most diverse in terms of genetic ancestries represented, with about half of participants of non-European genetic ancestry.

Dr. Denny noted several efforts currently active in *All of Us*. The Exploring the Mind dataset involves quantitative measures of various behavioral aspects. The program has the largest longitudinal dataset of wearable data in the world. Long-read sequencing data, including methylation data, will be released soon, as will proteomic and transcriptomic data. Some metabolomic data have been collected, and the first pilot with clinical narrative data is in progress, which will extract concepts and context from clinical notes.

Dr. Denny commented that program staff believe that making "doing the right thing" easier helps people "do the right thing," so researchers are given easy on-ramps to access the data and describe (and update, when necessary) their research projects and planned studies. A researcher from an institution with a master agreement already signed can start using the workbench within 2 hours. A growing number of researchers also have been writing grants that use *All of Us* data in their research, with many currently published papers using the program's genetics information; intramural researchers from 21 ICs also use

the data. The program is developing a large language model to identify publications using *All of Us* data and to categorize the publications in a filterable way.

Dr. Denny noted several methods of participant engagement and explained how results are returned for pathogenic or likely pathogenic genes. The Genotype to Phenotype program invites individuals with a rare genetic variation of unknown meaning to the Clinical Center for deeper phenotyping, which could lead to the discovery of new genetic syndromes or further understanding of the penetrance of actionable conditions. Additional efforts include the Genomic Variant browser, a Disability Health and Functioning survey, and the opening of biospecimen access for outside researchers through the X01 mechanism as approved by the Council in September 2025.

Dr. Denny emphasized that data security is a top priority for *All of Us* and that balancing the protection of participants' data with making them useful for researchers is critical. Encryption and removal of identifiers, as well as computing within the cloud and on *All of Us* environments, help preserve security, and education and monitoring add to the security.

All of Us just started a reassessment of its participants that have been with the program for several years. This is the first time participants have been asked to updating the data collected on their original surveys. The program had originally planned to recollect biospecimens but is unable to do so due to budget reductions.

Dr. Denny elaborated on the *All of Us* collaboration with ECHO, thanking Dr. Gillman and recognizing his incredible contribution as the inaugural ECHO director. He noted that both ECHO and *All of Us* are longitudinal cohorts and pointed out that *All of Us* has more EHR integration and ECHO has more surveys and in-person assessments, especially focused around key outcomes in children. The programs have significant overlap between chronic disease and the ability to understand health through the lifespan. Dr. Denny noted that data integration is an important starting place for collaboration between the programs, because making data available to researchers quickly in a harmonized platform will accelerate progress.

The *All of Us* program has successfully met many of its 5-year goals, although it has not met its goal for total number of participants, which Dr. Denny suggested was affected by budget constraints. It has already more than doubled the number of expected researchers. He emphasized that enrollment remains open and encouraged people to join the program.

Discussion Highlights

- Ms. Lauren Silvis suggested that the next *All of Us* presentation include information on how the program has advanced understanding in specific areas. She also asked whether the program works with the Veterans Administration (VA) Million Veterans Program. Dr. Denny explained that although they meet with the Million Veterans Program regularly, a tighter collaboration would be helpful. He pointed out that that MVP typically requires an investigator from the VA to participate in all studies and the data are not as broadly accessible. The first step is to co-host precalculated data on each platform. He added that any VA researcher can use the *All of Us* platform.

- Dr. Denny clarified that blood is the only biosample currently available for the X01 for biospecimen access. Methylation studies will be collected from ethylenediaminetetraacetic acid tubes, and RNA-seq data are generated from the PAXgene tube. He also explained that the same participants receive both short-read and array sequencing because these tests have different speeds and levels of information. The amount of variation is very valuable, and the data are available on the Genome Variant browser.

- Dr. Denny reiterated that the environment is designed to support computing in the cloud. The program recently moved to a new version of its workbench platform with a visual data explorer and high-scale, powerful analysis. Dr. Kleinstreuer added that the platform supports a diverse range of researchers and computational analytics capabilities and expertise.

- In response to a question about integrating genetic testing from other sources, Dr. Denny explained that because of how each clinical system stores their data, sequence results typically are not available in the medical record.

- Dr. Denny clarified that the Exploring the Mind initiative involves interactive measurements of risk tolerance, emotional processing, reaction time, and other such considerations that could help illuminate factors that influence neurodegenerative diseases and behaviors that could influence or be influenced by health.

- Council members expressed concerns about the decreases in budget and suggested that ICs could contribute support. Dr. Denny agreed that the budget has been a challenge, with a >70% reduction to date with more expected for FY27, and noted that further reductions would affect core capabilities. Dr. Kleinstreuer noted that DPCPSI is working across NIH to position *All of Us* as a centralized resource that could support a range of studies, including studies of environmental exposure supported by the partnership with ECHO.

- A Council member asked about a recent news story about ABCD and whether the data were de-identified. Dr. Denny explained that the HIPAA definition of de-identification has certain legal implications and does not formally apply to the way *All of Us* removes identifiers since its participants are not legally governed under HIPAA. However, the program does remove identifiers from the data in the researcher workbench. He clarified that the misuse of ABCD data that was reported several months ago was unrelated to *All of Us*, which began collecting data several years after ABCD and uses more protections. He explained that researchers' descriptions of their research projects can be reviewed for appropriateness and noted that researchers are very responsive to reviews conducted by the *All of Us* Resource Access Board. In rare cases, the program can revoke a researcher's access to the data. Contracts also are in place to ensure data are used appropriately. Dr. Denny commented that the program is exploring AI tools that can help with security.

XIV. CLOSING REMARKS

Dr. Kleinstreuer thanked the Council members for their engagement and reiterated that DPCPSI takes their feedback seriously. An *ad hoc* closed session will be scheduled to review ORIP applications.

XV. ADJOURNMENT

Dr. Kleinstreuer adjourned the meeting at 11:30 a.m. EDT on May 15, 2026.

XVI. CERTIFICATION

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

Kleinstreuer, Nicole (NIH/OD) [E] Digitally signed by Kleinstreuer, Nicole (NIH/OD) [E] Date: 2026.07.21 07:01:02 -04'00' July 21, 2026

Nicole C. Kleinstreuer, Ph.D.
Chair, NIH Council of Councils
Director, DPCPSI, OD, NIH

Date

ROBIN I. KAWAZOE -S Digitally signed by ROBIN I. KAWAZOE -S Date: 2026.07.21 06:22:24 -04'00' July 21, 2026

Robin I. Kawazoe
Executive Secretary, NIH Council of Councils
Deputy Director, DPCPSI, Acting Director, ORIP, DPCPSI, OD, NIH

Date