

**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
January 29, 2026**

Meeting Minutes

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 virtual meeting began at 10:00 a.m. on Thursday, January 29, 2026. The meeting attendees are identified below. Dr. Kleinstreuer then reviewed the day's agenda.

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, and Acting Director, Office of Research Infrastructure Programs (ORIP)

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

Richard D. Krugman, M.D., University of Colorado School of Medicine, Aurora, CO

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

Jennifer Jaie Manly, Ph.D., Columbia University Medical Center, New York, NY

Lauren Silvis, J.D., Tempus, Inc., Washington, DC

Russell N. Van Gelder, M.D., Ph.D., University of Washington School of Medicine, Seattle, WA

Council Member Absent

Jean A. King, Ph.D., Worcester Polytechnic Institute, Worcester, MA

2. Liaisons

Andrew A. Bremer, M.D., Ph.D., M.A.S., FAAP, Director, Office of Nutrition Research (ONR), DPCPSI, and Acting Director, Office of Dietary Supplements, DPCPSI

Janine A. Clayton, M.D., FARVO, Director, Office of Research on Women's Health (ORWH), DPCPSI

Josh C. Denny, M.D., M.S., Chief Executive Officer (CEO), *All of Us* Research Program Office, DPCPSI

Geri R. Donenberg, Ph.D., Director, Office of AIDS Research (OAR), 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
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 (OPA), DPCPSI
Jane M. Simoni, Ph.D., Director, Office of Behavioral and Social Sciences Research (OBSSR), 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 Present

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

4. Presenters

Jayanta Bhattacharya, M.D., Ph.D., Director, NIH
Michael F. Chiang, M.D., Director, National Eye Institute (NEI)
Geri Donenberg, Ph.D., Associate Director for AIDS Research, NIH, and Director, OAR
Matthew W. Gillman, M.D., S.M., Director, ECHO Program Office, DPCPSI
Adam M. Politis, M.S., Senior Advisor for Disability Health Research, DPCPSI
Stephen Sherry, Ph.D., Acting Director, National Library of Medicine (NLM)
Bruce J. Tromberg, Ph.D., Director, National Institute of Biomedical Imaging and Bioengineering (NIBIB)
Vivian Ota Wang, Ph.D., FACMG, CGC, Acting Director, OSC, DPCPSI

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 January 14, 2026.

- Minutes from the December 9, 2025, 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 May 14–15 and September 10–11, 2026.

II. DPCPSI DIRECTOR'S REPORT

Dr. Kleinstreuer confirmed her full appointment as NIH Deputy Director for Program Coordination, Planning, and Strategic Initiatives and Chair of the Council of Councils and provided an update on DPCPSI. She recognized the extraordinary contributions of Dr. Franziska Grieder, former Director of ORIP, upon her retirement and expressed gratitude to Ms. Kawazoe for serving as Acting Director of ORIP. Dr. Kleinstreuer reported that significant progress has been made in identifying potential new Council members and hoped they could be confirmed before the in-person May meeting.

The recently published *ORIP Fiscal Year (FY) 2026–2030 Strategic Plan* articulates how NIH will strengthen research infrastructure underpinning biomedical discovery. The strategic plan aligns with NIH's priority themes and positions ORIP to remain responsive to emerging scientific needs while maintaining long-term sustainability and impact. The plan's four strategic priorities are (1) model resources to advance the study of human diseases, (2) modern physical infrastructure to accelerate research discoveries, (3) innovative cross-disciplinary research training in model systems for human health and disease, and (4) outreach and awareness of ORIP resources and programs. Dr. Kleinstreuer emphasized that these priorities reflect the consideration of how infrastructure must evolve as biomedical research becomes increasingly complex, data intensive, and interdisciplinary.

Dr. Kleinstreuer pointed to *the Implementation Update Report FY20–22: Strategic Plan for NIH Nutrition Research* as an illustration of how strategic plans are translated into action. This report outlines progress NIH made in FY20 through FY22 toward achieving the goals of the *2020–2030 Strategic Plan for NIH Nutrition Research*, including significant progress in spurring discovery and innovation, investigating the role of dietary patterns and behaviors, and defining the role of nutrition across the lifespan, as well as potentially expanding opportunities in food as medicine, research, and implementation science. Dr. Kleinstreuer pointed to ONR's teaching kitchen work as an example of engaging directly with communities to translate nutrition research into practice.

The Common Fund's Somatic Cell Genome Editing Program recently supported the first successful personalized gene editing therapy administered to a child, which partially reversed a rare genetic condition. The U.S. Food and Drug Administration has released a new regulatory pathway concept for personalized treatment of rare diseases based on this success, exemplifying the broad transformative impact of Common Fund programs. Another Common Fund program, CARE for Health™, aims to address barriers to clinical research participation by integrating innovative research with routine clinical care in real-world settings. Six new study concepts have been approved for network research hubs focused on engaging primary care providers embedded in rural communities and leveraging both technology and community-based approaches. Dr. Kleinstreuer also noted a new NIH challenge webpage that provides a central location for information on challenge and prize competitions, which stimulate innovation and expand participation in biomedical problem solving.

Dr. Kleinstreuer reminded Council members of the recent approval of opening *All of Us* biospecimen access to external investigators using the X01 mechanism, which will be published as a notice of intent in April 2026. *All of Us* also now has a searchable publications directory powered by a large language model that helps demonstrate program impact. *All of Us* data have been used to develop new clinical tools and protocols, and its largest dataset to date will be released in the spring.

The Bridge2AI program also recently released its Year 3 data, covering topics ranging from protein interaction to voice recordings, and electronic health record (EHR) critical care data are expected this month. Bridge2AI datasets are designed to be foundational resources for the research community in lowering barriers to responsible artificial intelligence (AI) development in biomedicine. Dr. Kleinstreuer also noted upcoming events, including the OBSSR Director's Webinar series and ODP's Pathways to Prevention workshop on management of menopausal symptoms.

Discussion Highlights

- In response to a question about the focus on menopausal symptoms, Dr. David Murray, Director of ODP, and Dr. Janine Clayton, Director of ORWH, pointed out that the Pathways to Prevention workshop series addresses many topics and is one of NIH's premiere mechanisms for fostering collaboration across institutes, centers, and offices (ICOs) and with federal partners. Dr. Clayton added that this workshop reflects increased attention on the importance of the midlife health of women and the relationship between menopause and chronic disease.
- Dr. Kent Lloyd reminded attendees that successful gene editing therapies were developed based on foundational research conducted in animal models.
- When asked about the security of patient data released through NIH programs, Dr. Josh Denny, CEO of *All of Us*, explained that maintaining trust with participants is a high priority. Although no system is foolproof, *All of Us* uses a number of privacy controls and is working with controlled-access data repositories across NIH to balance ethical and open science.
- In response to a question about a recent article noting the use of Adolescent Brain Cognitive Development (ABCD) data by unqualified researchers to engage in research meant to forward eugenicist ideas, Dr. Denny explained that this incident was addressed by NIH several years ago; *All of Us* currently has more protections than ABCD did at that time. He noted that *All of Us* recognizes this risk and has a formal policy against stigmatizing research. The program also has processes in place that are designed to alert the resource access board to any questionable planned research.
- Dr. Denny emphasized that research participants are included in every phase of governance, including the resource access board, and are informed of the potential risks associated with their participation. A general announcement about the ABCD incident has been made to *All of Us* participants, and the program has distributed talking points to awardees and community advisors. The program is monitoring feedback from participants to determine whether further action is required.
- The *All of Us* stigmatizing research policy is written to address commonly stigmatized categories and recognizes other types of stigma that may occur with certain groups. It also addresses rigor that often is lacking in stigmatizing research. Dr. Denny noted that the resource access board determines whether research is stigmatizing when assessing whether proposals are likely to advance health.
- Dr. Kleinstreuer emphasized that NIH takes participant privacy extraordinarily seriously and does not direct or endorse the independent analyses or conclusions of external researchers. Dr. Lyric Jorgenson, Director of the Office of Science Policy, explained that all research conducted with NIH data aligns with consent parameters and emphasized that the ABCD incident prompted a robust agency review of policies and practices. She added that no protected health data were shared in the incident and that the data were de-identified. Dr. Jorgensen acknowledged that such

nuances do not assuage trust concerns, but she reiterated that data access now requires multiple layers of review, approval, and accountability.

III. PROPOSED DPCPSI REORGANIZATION

Dr. Kleinstreuer described a proposed DPCPSI reorganization intended to improve the coordination of crosscutting activities to address current NIH challenges. The first proposed new office is the Office of Research Innovation, Validation, and Application (ORIVA) which will coordinate NIH activities related to new approach methodologies (NAMs), particularly non-animal and human-relevant research approaches. ORIVA's Division for Accelerating Innovation and Biomedical Research will focus on supporting NAMs and technology development in partnership with ICOs. The Division of the National Interagency Center for the Evaluation of Alternative Test Methods (DNICEATM) will focus on validation of NAMs and coordination with regulatory partners to support applications. Dr. Kleinstreuer pointed out that coordinating NAMs across the research continuum within ORIVA will strengthen the link between NIH-funded innovation and regulatory adoption.

The second proposed new office is the Office of Research Economics, Planning, and Analysis (OREPA) which will strengthen NIH's capacity in strategic planning, evaluation, and portfolio analysis, encourage mission-relevant health economics research, and lead NIH replication and reproducibility efforts. The work of the office will contribute to building a stronger evidence base for leadership decisions and facilitate assessing the effectiveness of NIH policies and funding approaches. OREPA will consolidate two existing DPCPSI offices—the Office of Evaluation, Performance, and Reporting and the Office of Portfolio Analysis—and add a new Office of Replication and Reproducibility (ORR). OREPA will build on NIH's capacity to support and coordinate high-impact health economics research and to strengthen the connection between portfolio analysis and the assessment of real-world impact. ORR will elevate replication and reproducibility as a distinct NIH-wide priority and coordinate replication efforts across ICOs, support innovative funding approaches, and promote a culture change toward increasingly valuing replication and reproducibility.

This reorganization is hoped to be approved in spring 2026. Dr. Kleinstreuer noted that public comments were almost entirely supportive of this proposal but differed in their support for maintaining or replacing animal research. Many commenters stressed the need for a clear, harmonized definition of NAMs, validation, and context of use, and several recommended framing NAMs within the “three Rs” of replace, reduce, and refine animal models. Dr. Kleinstreuer commented that the central message of public comments was that ORIVA and OREPA can be transformative if NIH balances innovation with integration, grounds decisions in rigorous science, communicates clearly and transparently, and equips the offices with adequate resources to deliver measurable outcomes.

Discussion Highlights

- When asked which critical unmet needs necessitated this large-scale reorganization, Dr. Kleinstreuer responded that evolving technology and culture change have moved toward increasing human-based technology and translational relevance, leading more institutes and centers (ICs) to fund NAM projects despite a lack of centralized coordination. OREPA fills a similar role for replication and reproducibility. Dr. Kleinstreuer noted that meta-analyses have suggested a lack of reproducibility across many fields rather than a failure of a single IC. The Council requested the charters of each new office for review; Dr. Kleinstreuer responded that the reorganization packages have been submitted to HHS and will become available after approval. She clarified that ORIVA will function similarly to other DPCPSI offices that coordinate crosscutting research themes. Dr. Kleinstreuer confirmed that the activities of the Science of

Science Working Group would inform the new offices and noted that she hoped to add a report out from that group on the May agenda.

- In response to a question about the status of the Sexual & Gender Minority Research Office, Ms. Kawazoe explained that the office and its functions were not consistent with administration priorities and added that the office had been dissolved.
- When asked to further explain NAMs, Dr. Kleinstreuer responded that they are sometimes referred to as novel alternative methods and are alternatives to animal models, such as organs on chips, microphysiological systems, organoids, AI, computational models, and high-throughput screening. These systems are based on human biology and can be integrated in ways intended to better represent human biology than animal models.
- Dr. Monica Gandhi commented on the tension between reproducibility and replication and innovation and asked how DPCPSI will continue to monitor and promote innovation. Dr. Kleinstreuer pointed out that “innovation” is part of ORIVA’s name and that the office is intended to promote innovation in human-based technologies. She added that the Common Fund continues to invest in high-risk, high-reward research in efforts across the focus areas of multiple ICs and that each IC is firmly committed to innovation in its own portfolio.
- When asked whether changes in funding policies will affect the review of research deemed not to be within political priorities, Dr. Kleinstreuer responded that the practice of not adhering to strict paylines has been standard practice for years and added that IC Directors frequently review their entire portfolio before making decisions.
- In response to a question about the Standardized Organoid Modeling (SOM) Center, Dr. Kleinstreuer explained that the SOM Center is an exciting new effort that will advance the science and provide related technological infrastructure, coordinated by DPCPSI. The center is intended to be a neutral hub for scientific standardization and an intramural and extramural resource for characterization, validation, and standardization of organoid models. It will also serve as a biorepository for those models and a digital repository of optimized protocols associated with them. One novel aspect of the SOM Center is the use of AI and machine learning to assess model success and protocol optimization. The center will be located at the NCI Federally Funded Research and Development Center at Frederick National Laboratories, and represents a very strong DPCPSI partnership with NCI and NIAID, both of which have committed substantial in-kind resources. In addition, DPCPSI is partnering with NCATS which has significant expertise in organoids and tissue chip development, and with NHGRI and ORWH.

IV. ACCELERATING IMPLEMENTATION SCIENCE TO END HIV

Geri Donenberg, Ph.D., Associate Director for AIDS Research, NIH, and Director, OAR, introduced OAR’s plan for accelerating implementation science to end HIV. OAR coordinates the NIH HIV research program by catalyzing new research, fostering communication across NIH and other federal agencies, coordinating NIH activities, and convening meetings and workshops. Despite effective prevention and treatment, 1.1 million Americans currently have HIV, and more than 39,000 were diagnosed in 2023. Dr. Donenberg emphasized that HIV affects all communities but has disproportionate effects on Black or African American and Hispanic or Latino populations. Nearly one in five new cases of HIV occur in adolescents and young adults, and heterosexual contact accounts for nearly one in four new diagnoses. Nearly one in four people with HIV are women, and more than half are age 50 or older. Gaps in treatment persist—many people with HIV are unaware of their status, not receiving effective HIV care, or not virally suppressed. Dr. Donenberg emphasized that HIV remains a priority for NIH.

Dr. Donenberg explained that implementation research studies the best ways to deliver effective interventions or practices in real world settings, while implementation strategies are the actions taken to enhance the adoption, implementation, and sustainability of evidence-based interventions in practice. Currently, implementation science accounts for 7% of NIH HIV/AIDS research based on the RCDC categorization system and is supported by 14 ICOs. The Advancing Research in Implementation Science to End HIV (ARISE) program aims to increase the NIH focus on implementation research to end the HIV epidemic. Although no specific funding has been allocated to ARISE, the program is intended to catalyze and coordinate collaborations and activities across ICOs to identify factors that will promote the uptake of and access to effective and safe HIV prevention and treatment interventions. Dr. Donenberg also noted that ARISE will facilitate increased investment in research on how to deliver, sustain, and scale evidence-based strategies for prevention and treatment, as well as funding dedicated to increasing training and capacity building in implementation science.

The ARISE steering committee consists of implementation science subject-matter experts within NIH across ICOs and other HHS agencies. Dr. Donenberg pointed out that although NIH supports research, other federal partners, including the Centers for Disease Control and Prevention and the Health Resources and Services Administration, implement any strategies identified. ARISE also has an NIH-wide working group to execute program activities. A new highlighted topic on implementation science to optimize HIV prevention and treatment was published in December, and a notice of funding opportunity is being developed.

Dr. Donenberg reported that the next NIH Strategic Plan for HIV and HIV-Related Research is currently under review and revision. It is grounded in three foundational principles: comprehensive, multidisciplinary research; population-focused health; and multisectoral partnerships. Dr. Donenberg also pointed out that although the HIV field hopes for a vaccine and a cure for epidemic control, these may take time to develop, and recent innovations, such as long-acting lenacapavir, have barriers to access, uptake, and cost. NIH has the infrastructure to address the full continuum from basic discovery to therapeutics and implementation.

Discussion Highlights

- Dr. Lloyd pointed out that basic research conducted at National Primate Research Centers has been critical to all the basic scientific advances related to HIV.
- Drs. Donenberg and Gandhi clarified that promising approaches to a cure have been developed but are burdensome to use and noted that effective vaccines have been difficult to develop.
- In response to a question about funding implementation science without reducing support for cure and clinical research studies, Dr. Donenberg commented that portfolio portions are under discussion but could involve OAR's budget transfer authority, which would shift 3% of the entire AIDS research budget allocation toward this effort. She emphasized that research in the basic sciences will continue.
- Dr. Donenberg clarified that recent changes to the HIV/AIDS application deadlines reflect the current status of the HIV pandemic and the number of research applications received by the Center for Scientific Review across the NIH. This change will reduce the added burden of reviewing HIV/AIDS applications separately while maintaining the same number of submission opportunities at three. Dr. Jayanta Bhattacharya, NIH Director, added that this change is intended to streamline the review process and emphasized that the priority of HIV grants will not change.

V. NIH UPDATE

Dr. Bhattacharya explained the background to, and his thinking about, his priority to increase replication and reproducibility work at NIH. He commented that replication studies are considered less prestigious than original research, and how it will be necessary to develop novel incentives to increase replication and reproducibility studies across the research enterprise. NIH currently has several efforts in this area, including the Common Fund Replication to Enhance Research Impact Initiative as well as a Replication Prize. Dr. Bhattacharya suggested that NIH should support researchers who engage primarily in replication studies. The idea would be that the level of NIH funding would be sensitive to the specific nuances of what replication means in each field because there will be different standards, different methods, and different ideas in each field. NIH also needs to consider where replication studies can be published. A traditional journal could be thought of as serving two purposes: one is gatekeeping of ideas, i.e., the editors—experts in their field—will direct the attention of their field to the key ideas they think are important (gatekeeping), and the second is peer review. A journal that focuses on publishing replication studies needs to have peer review but minimal gatekeeping. Dr. Bhattacharya expressed his interest in trying to establish a journal where people can deposit their replication studies as well as projects where the hypotheses didn't work out. Dr. Bhattacharya stated in science, it is important to talk about both our successful ideas and the ones that didn't quite work out, as well as the replication studies. He also spoke about changing the way we search the scientific literature. In PubMed, for example, it is very different to understand what related literatures say. The idea would be you search in PubMed, a paper comes up, and you have a replication button. The replication button summarizes the relevant literature, including the replication literature, and links are provided to other studies so you can see what the replication studies actually said. This would elevate replication as the standard of truth in science over, "Is it published in a top journal?" Additional efforts could include determining broader ways to measure scientists' productivity rather than the current measures of scientific productivity, e.g., how many citations you have as a measure of how influential you are, rather than including the kinds of activities we want scientists to do, e.g., how innovative you are, demonstrating good scientific behavior, e.g., how often do you share your data, how often do you share your code or your tissue samples, do you write your papers in ways that are sufficiently clear that they invite replication. Those should be metrics of scientific success and of scientific productivity because you're thinking of ideas and writing about them in a way that draws the attention of other scientists because they are potentially important. Development of these metrics is part of the focus of the field called Science of Science. An important part of the new Office of Metascience (OREPA)—will be to oversee our replication efforts, including the development of metrics, conducting metascience studies, and promoting a culture shift in science—to make science more collaborative.

Discussion Highlights

- Dr. Jennifer Jaie Manly pointed out that threats to rigor and reproducibility arise from such factors as biased sampling, poorly defined denominators, and unquantified uncertainty confidence intervals, which can produce misleading estimates and overconfident conclusions, noting that acting under uncertainty is an unavoidable part of the scientific process but that presenting uncertain evidence as settled science is a preventable failure. She asked how Dr. Bhattacharya distinguishes between research that is genuinely designed to test a hypothesis with a real possibility of falsification versus research that is structured primarily to confirm a hypothesis already favored by investigators. Dr. Bhattacharya suggested that independent replication efforts are the most important protection and added that the scientific community can judge whether an effort is independent.
- Dr. Manly asked what safeguards Dr. Bhattacharya proposed for preventing confirmation-oriented research from being mistaken for hypothesis-testing science and requested assurance that rigor

and reproducibility will not be weaponized by being detached from context or used to delegitimize certain fields. Dr. Bhattacharya responded that normal Center for Scientific Review (CSR) processes will be difficult to target in a biased way and added that he believes the scientific community can determine the most important ideas to reproduce through normal peer-review processes. He hoped that culture change would encourage scientists to consider research that cannot be reproduced to be an automatic failure and investigate why the reproduction failed, which can lead to new science.

- Dr. Gandhi pointed out that rigor and reproducibility is most relevant in basic sciences; replicating large, randomized clinical trials or behavioral science studies in specific groups would be costly and less necessary. Dr. Bhattacharya reiterated that replication standards and costs will differ across fields and commented that he does not differentiate between basic and applied research in this regard. He emphasized that scientists within each field should make decisions about what to replicate. Dr. Bhattacharya acknowledged that resources would be considered in those decisions and planned to charge the scientific community during CSR review with identifying rate-limiting replication steps and eliciting investigator-initiated replication proposals.
- Dr. Rafael Irizarry noted several existing or recent journals publishing or acknowledging reproducibility and commented that education in statistics and coding has not matched the evolution of science toward increased data analysis. Dr. Bhattacharya agreed that improved calculations are needed and that statistical errors may contribute to lack of replication.
- Dr. Karen Johnston commented on confusing language in an executive order requiring review of all scientific proposals by a political appointee and asked how NIH protects against threats of political interference. Dr. Bhattacharya pointed out that the NIH Director has always been a politically appointed position but explained that he uses the Director's final authority as other NIH Directors have and relies on peer review and IC Directors to select highly impactful and innovative science. He added that the NIH portfolio should be judged on whether decisions translate into better health and longevity for the public.
- Dr. Russell Van Gelder emphasized that falsified science is a legitimate issue and noted that high-profile falsifications erode public trust; he asked whether NIH plans to create methods to examine NIH research for signs of falsification. Dr. Bhattacharya replied that NIH has such tools. He theorized that high-profile falsifications were caused by prioritizing publication and suggested that changing status incentives as suggested would shift the culture. Dr. Van Gelder noted that NIH has limited control over promotions in non-NIH institutions.
- Dr. Van Gelder encouraged Dr. Bhattacharya to consider incentivizing studies that combine successful replication with the advancement of the original studies and emphasized that replication-specific studies that do not advance the field will only retard it.
- Dr. Lloyd pointed out that negative characterization of current scientific culture does not improve trust in science and questioned whether educating on and improving practice design would be a more important initial goal. Dr. Lloyd also suggested that the high proportion of studies found to be unreproducible were often published with methods that were not fully described. Dr. Bhattacharya responded that NIH already invests in training and education but that current investments are insufficient.

Dr. Kleinstreuer delivered the NIH update on behalf of Dr. Matthew Memoli, NIH Principal Deputy Director. She noted several staff updates, including the appointment of Dr. Rick Woychik as a Senior

Advisor for NIH's Make America Healthy Again strategy and the permanent appointment of Dr. Jon Lorsch as the NIH Deputy Director for Extramural Research.

NIH has supported several interesting recent advances in research, including a minimally invasive coronary artery bypass, a first-in-human trial of a new gene-editing technology with a next-generation CRISPR approach, and an exposome project to demonstrate the potential impacts of fungicides and industrial chemicals on the microbiome. Dr. Kleinstreuer reiterated that the SOM Center will be a hub for the standardization and characterization of organoid models to create rigorously validated and reliable resources for the scientific community and for use in regulatory decision-making.

Dr. Kleinstreuer noted several targeted budget increases anticipated for DPCPSI offices and programs for FY26, as well as a small increase anticipated for NIH. She pointed out that indirect costs remain frozen at FY17 levels and that multiyear funding has been capped at FY25 levels. She added that this multiyear funding will be effective during the current Council round and commented that this practice is intended to increase consistency; flexibility; IC Director authority; and emphasis on innovation, scientific merit, program relevance, portfolio balance, and opportunity costs. Three full review rounds will occur in FY26. Dr. Kleinstreuer explained that the top third of proposals will be discussed, the middle third will remain eligible for funding but will not be discussed, and the lower third will not be discussed. Simplified summary statements also will be used.

Noted policy updates included the new structure for foreign components categorized as independent subprojects within the main project, the lapsed authority for Small Business Innovation Research and Small Business Technology Transfer awards, and efforts related to reducing administrative burden. Dr. Kleinstreuer commented that NIH currently is very interested in supporting innovation without sacrificing scientific rigor or quality and is prioritizing human-based research and innovative technologies. A policy to cap the number of applications per principal investigator is intended to limit AI-generated content. NIH also is continuing to emphasize transparency, accountability, and public trust.

Dr. Kleinstreuer expanded on the unified funding strategy. She noted that scientific merit is the primary core principle for those funding decisions but that decisions also will account for broadening the portfolio of research areas and career stages, emphasizing and expanding support for young investigators, and ensuring a broad geographic balance and funding for investigators who have not historically received as many NIH funds. She emphasized that moving away from pay lines for transparency involves a comprehensive look at both peer-review scores and strategic priorities at the IC level. Policy modernization remains a core NIH priority. Efforts to simplify policies while advancing science include implementing common forms and enforcing compliance expectations.

Dr. Kleinstreuer explained that NIH is working both internally and across HHS to advance translational science through responsible, ethical use of AI to drive innovation. The technology currently is being used for *in silico* drug design and discovery, target identification and validation, and drug repurposing opportunities. In the short term, AI will be scaled for successful translational models and integrated with emerging technologies. In the longer term, a more predictable and efficient translational ecosystem that aligns with NIH-wide strategic goals is expected.

Discussion Highlights

- Dr. Lloyd pointed out that multiyear funding will continue to decrease the number of grants and will by default continue to slow scientific progress.
- Dr. Jorgenson confirmed that the gain-of-function research policy has not yet been published but noted that the executive order prohibiting dangerous gain-of-function research remains in effect. She explained that it is an interagency initiative led by the White House.

- When asked whether the SOM Center would validate organoids *in vivo* before moving findings into human use, Dr. Kleinstreuer theorized that this would be considered on a case-by-case basis.
- Dr. Manly noted that recent data show a divergence between NIH’s longstanding mission to foster the next generation of biomedical researchers and actual outcomes for early career scientists, noting that the lack of success undermines NIH’s strategic goals and investments and has serious consequences for the research ecosystem. She asked what analyses NIH conducted to assess the downstream effects of its recent funding and policy decisions, particularly on early career investigator success rates, and how those analyses failed to anticipate the observed declines. Dr. Kleinstreuer responded that the unified funding strategy is intended in part to provide more flexibility for supporting early stage investigators and improving their success rates and added that the impact of funding policies and resource allocation on the success rate of early stage investigators will be studied by OREPA.
- Dr. Gandhi pointed out that prorated multiyear funding at FY25 levels will result in much lower funding amounts and asked how to encourage trainees to apply for T or K programs without paylines. Dr. Kleinstreuer suggested that T and K applications could be encouraged by publicizing NIH’s intent to support early stage investigators. She confirmed that prorated multiyear funds would be significantly lower and noted that NIH follows direction from the Office of Management and Budget on multiyear funding levels.

VI. 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 and return a conflict-of-interest/confidentiality certification to this effect, following the closed session. 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 225 ORIP applications with requested first-year direct costs of \$180,285,220.

VII. ENVIRONMENTAL INFLUENCES ON CHILD HEALTH OUTCOMES (ECHO) PROGRAM OFFICE STRATEGIC PLAN FOR 2026–2030

Matthew W. Gillman, M.D., S.M., Director, ECHO, introduced the ECHO Program Office *2026–2030 Strategic Plan*. The ECHO program aims to enhance the health of children for generations to come through observational research on early environmental exposures and intervention research through clinical trials. ECHO follows approximately 30,000 children and is recruiting an estimated 30,000 new pregnancies, including partners when possible. The ECHO data platform and biorepository contains harmonized data from more than 170,000 participants, and ECHO’s Institutional Development Award (IDeA) States Pediatric Clinical Trials Network (ISPCTN) studies issues that disproportionately affect children in rural communities. The ECHO Program Office Strategic Plan aims to guide the office’s efforts from 2026 through 2030. ECHO is a mature research program, now in its 10th year, with robust infrastructure and team science collaborations. The cohort has been established as a national resource

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.

through its early impact, and from 2026 through 2030, ECHO aims to reinforce its organizational effectiveness and high-impact research to expand its reach as a national resource.

The first goal of the new plan is to enhance organizational effectiveness. Objectives under this goal are to promote a mission-driven organization, refine operational resources, and strengthen interpersonal cohesion. The second goal is to enable high-impact research. The objectives are to empower investigators with research awards, implement practices for innovative research, and support ECHO research dissemination. Under this goal, ECHO has a number of research priorities. For the ECHO cohort, priorities are to (1) detect modifiable early developmental exposures, (2) explore pathways to ECHO health outcomes, (3) examine resilience or susceptibility factors, (4) identify periods of development most sensitive to exposures, and (5) measure the effects of natural experiments or new innovations. For the ISPCTN, priorities are to (1) address prevention and treatment of common pediatric conditions; (2) conduct efficacy and effectiveness trials where kids eat, sleep, learn, and play; (3) implement shovel-ready interventions in rural or underserved communities; and (4) expand reach through scalable interventions.

The third goal is to expand ECHO's reach. Objectives are to promote ECHO as a national research resource, cultivate broad awareness of ECHO, and translate ECHO science into action. Activities planned under this goal include enabling ancillary studies for access to data and biospecimens, collaborating with ICOs to advance health across areas of NIH interest, and engaging interested parties by providing regular briefings to interested parties and training ECHO investigators to present findings to local and state leaders. ECHO also hosts annual translation symposia to bridge the gap between cutting-edge research and solutions to enhance children's growth and development.

Discussion Highlights

- Dr. Richard Krugman asked how ECHO collects information on the physical and sexual abuse of children in this cohort. Dr. Gillman replied that the program has implemented questionnaires on adverse childhood experiences, which have resulted in a number of high-impact papers. ECHO also collects data on positive childhood experiences and resilience factors. He noted that both adverse and positive childhood experiences have been shown to have effects that can be passed from mother to child.
- When asked about data security, Dr. Gillman explained that ECHO communicates with other large studies on this topic. The external scientific community accesses data and specimens in highly secure data storage areas, and the data analysis center uses only cloud-based computing, with many safeguards for data access. Researchers' ideas also are thoroughly vetted, and the most sensitive data are not included in all datasets. Dr. Gillman noted that although ECHO cannot guarantee that data will not be used inappropriately, the program makes the best effort possible to ensure privacy while facilitating studies that will improve child health.
- Dr. Gillman confirmed that ECHO has a policy against stigmatizing research similar to the one used by *All of Us*, and the program provides principles for data use to avoid group harms. Enforcement largely centers on NIH-based consent processes, but Dr. Gillman suggested that the prevention of inappropriate use through multilayered security is more useful than detection and management. He emphasized that during the informed consent process, the program is as transparent as possible about the risks of data contribution and noted that participants have the right to rescind the authorization to share their data at any time. Dr. Manly suggested that ECHO leadership think deeply about how risks are explained in light of the ABCD incident.

VIII. OSC CONCEPT CLEARANCE (NEW): BRIDGE2AI PROGRAM STAGE 2 [VOTE]

Vivian Ota Wang, Ph.D., Acting Director, OSC, introduced the Bridge2AI Program Stage 2 by reminding attendees of the principles of Common Fund research. Bruce J. Tromberg, Ph.D., Director, NIBIB, explained that Stage 2 of the Bridge2AI program aims to use the AI-ready databases and tools developed in Stage 1 to accelerate the development of AI solutions and scientific methods for a range of grand challenges. When the Bridge2AI program began in 2020, AI-ready biomedical datasets were urgently needed but almost nonexistent. Now such datasets are common, and the current need is to use them to make trustworthy, replicable, transparent, and explainable discoveries. This effort complements AI's rapid growth in industry and will reduce the gap in fields lagging in development.

Dr. Tromberg explained that Bridge2AI initially intended to define AI-ready data and address its rarity; activities were centered around the pillars of people, ethics, and data. Ethics have been integrated throughout all activities, and training and mentorship for the next generation of AI-capable clinicians and researchers has been implemented. The program has recently begun its fourth year of data generation and has produced a large volume of multimodal AI-ready data from four flagship data-generation projects related to significant challenges in health: a broadly sourced voice database, critical care data from EHRs, retinal imaging data from diabetics returning to health, and functional genomics data. The program also has developed tools for collecting and working with these data.

Stage 2 is based on two new initiatives: the Innovation Funnel and the Network for AI Health Science. The Stage 1 datasets will be the primary sources for these initiatives, but additional datasets will be welcomed as appropriate. Dr. Tromberg explained that NIBIB has gained significant experience with the Innovation Funnel model since its initial deployment to increase U.S. COVID-19 testing capacity and has used it across NIH, but unique features have been developed for this program that make it easy for many stakeholders to enter the program quickly. Projects moving through the funnel will address open questions about how to define and optimize AI data quality and readiness for delivering trustworthy algorithms that meet performance requirements specified by the challenge topics. The funnel provides a low-barrier, fast-review process for submitting an idea, and accepted investigators receive modest funds and expert guidance to develop their concept. If the idea reaches Phase 1, investigators receive additional funding and wraparound support for viability and risk assessment. Teams that advance to Phase 2 will implement Bridge2AI tools for validation, verification, and readiness. Dr. Tromberg explained that one funnel for each Stage 1 dataset will be run simultaneously for a year.

Stephen Sherry, Ph.D., Acting Director, NLM, explained that substantial work is needed to ensure trustworthy AI for health sciences. In Stage 2, Bridge2AI will introduce a research network to advance AI health science methods across high-priority, crosscutting, methodological topics to develop and test resources that strengthen how AI is designed, evaluated, and used in biomedical and behavioral research. Each center will focus on one methodological theme, and a coordinating committee will coordinate cross-training across user communities, disseminate ethical and technical frameworks, and link the work to other NIH efforts. The network will address broad methodological questions relevant to Innovation Funnel topics, allowing the program to move from a single promising dataset to a validated framework for multimodal AI that can be reused across many neurological and behavioral conditions, and the network also will produce a roadmap for future NIH AI projects.

Dr. Sherry emphasized that trustworthiness is not an abstract concept but rather a measurement of when, for whom, and under what conditions an AI system is effective. The network coordinating committee will connect centers with standards organizations, community partners, users, and subject-matter experts to ensure that products developed endure beyond the network's lifespan. Key outcomes include practical frameworks for complex AI-enabled science, a broad and trained AI research community, and increased trust in AI-based research tools. By aligning the Innovation Funnel and the Research Network, ideas and

investigators can enter the system from either side; some ideas will mature into solutions and others will receive seed funding for refinement. Dr. Sherry added that Stage 2 meets the Common Fund criteria and aligns with national and NIH priorities around AI and data science. He noted that Innovation Funnel will be supported by adding to an existing contract. The four outcomes of Stage 2 will be: (1) an AI-ready dataset characterized for reuse, (2) risk mitigation and evaluation frameworks, (3) trustworthy solutions deployed for patient care and knowledge generation, and (4) a national workforce trained in trustworthy biomedical AI. The program requests \$90 million over 5 years, which includes funds to sustain Stage 1 through the life of Stage 2.

Discussion Highlights

- The discussants, Drs. Lloyd and Krugman, provided their comments. Dr. Lloyd supported the concept but provided several recommendations. He suggested clearly defining the four challenges in notices of funding opportunities, including the rationale for selection and quantifiable benchmarks of success expected from applicants. He also recommended strengthening the details on funnel implementation with clear plans for selection governance, milestone gating criteria, external validation partnerships, and data sharing reproducibility requirements. Dr. Lloyd suggested establishing a mechanism for early and midterm project review and adjustment and requested that the program incorporate a formal AI health training module in workforce development plans. Dr. Krugman agreed with Dr. Lloyd's comments.
- Dr. Tromberg explained that the four databases built in Stage 1 are aligned with the grand challenge concepts. Regarding sustainability, he commented that ICs reviewing these databases identify opportunities to solve different challenges and that NIH support will be built broadly over time. He emphasized that AI is developing too quickly to implement long time courses, so the Innovation Funnel provides database accessibility to many people who have ideas.
- In response to a question from Dr. Lloyd about public involvement, Dr. Tromberg commented on a partnership with the disability community during the development of COVID-19 tests and suggested that similar partnerships with specific communities could be designed for Bridge2AI.
- When asked about coordination between the network and the funnels, Dr. Tromberg replied that many parties across NIH are excited about this concept, and Dr. Sherry added that the Bridge2AI team could facilitate expectations around transfer and dissemination within a bidirectional communication forum. Dr. Lloyd recommended adding a formal coordinator position to provide more structure to the coordination between the components.
- In response to a question about the long-term prospects for additional dataset generation, Dr. Tromberg explained that the overall idea of this project is to tap into the creativity of many communities, so ancillary dataset growth and coupling is expected. Dr. Van Gelder pointed out that the levels of funding used to build the Stage 1 datasets are not accessible to many ICs and encouraged the program to return more valuable datasets.

Vote

A motion to approve the Bridge2AI Program Stage 2 concept was forwarded and seconded. The motion passed with no abstentions.

IX. NIH STRATEGIC PLAN FOR DISABILITY HEALTH RESEARCH FY26–FY30

Adam M. Politis, M.S., Senior Advisor for Disability Health Research (DHR), DPCPSI, introduced the *NIH Strategic Plan for Disability Health Research FY26-FY30*. Mr. Politis provided an overview of

disability and noted that one in four people in the United States has a disability as defined by the Americans with Disabilities Act of 1990. He briefly reviewed conceptual models of disability and remarked that disability is increasingly being understood through interactional models, which posit that disability results from the dynamic interplay between individual medical conditions and biological, behavioral, sociocultural, and environmental factors. Mr. Politis explained that DHR is focused on understanding and addressing the effects of medical conditions, non-medical factors, and their interaction on the health and well-being of people with disabilities. DHR centers the person rather than the disability and emphasizes that disabled people have health needs and goals both related and unrelated to their disabilities, the latter of which historically have been overlooked.

NIH ICOs support a broad range of research related to disability, from basic science to clinical, translational, and implementation research. In FY24, NIH invested more than \$619 million in disability research, including investigations into the biological mechanisms underlying physical and mental impairments, medical rehabilitation interventions to improve function and quality of life, and efforts to address disparities in health and healthcare outcomes experienced by people with disabilities. Mr. Politis noted, however, that NIH's previous efforts have typically focused on specific conditions or impairments rather than addressing people with disabilities as a population with unique health and health care needs. As understanding of disability has evolved, influenced by interactional models of disability and informed by the experiences of disabled people, there has been growing recognition that NIH needs a more harmonized, coordinated, and person-centered approach to disability health research.

Mr. Politis outlined the efforts underlying the development of the strategic plan. In December 2022, the NIH Advisory Committee to the Director Subgroup on Individuals with Disabilities issued a report to NIH that highlighted the necessity for an NIH-wide strategy for DHR. In September 2023, NIH formally designated people with disabilities as a population with health disparities. The NIH Director charged DPCPSI with the strategic coordination of DHR in spring 2024 and this resulted in the establishment of the Disability Health Research Program (DHRP). In September 2024, the DHRP began the DHR strategic plan development process in partnership with the NIH Disability Health Research Coordinating Committee (DHRCC), which is composed of more than 60 members from 40 ICOs.

Community engagement and feedback were vital for the development of the strategic plan. A series of roundtable discussions and a town hall were held to obtain input from the community, including disabled people and organizations interested in DHR. More than 1,000 attendees participated in these events. A request for information also was issued to obtain feedback on the draft strategic plan framework. In addition, the DHRP met with more than 12 ICO Directors to discuss how their research priorities align with DHR. The external Council of Councils Disability Health Research Working Group (CoC DHRWG) also provided input and feedback. Using information, data, and feedback from a variety of sources and stakeholders, the DHRP and DHRCC developed and refined the strategic plan. The strategic plan's purpose is to identify agency-wide strategic goals and objectives to advance innovative and responsible research that promotes the health and well-being of people with disabilities.

Mr. Politis outlined the DHR strategic plan's crosscutting themes: whole person health, inclusion of people with disabilities in research, interdisciplinary collaboration, and technology. Whole person health involves considering the whole person—not just separate organs or body systems—and examining the multiple factors that influence health and disease. Rather than focusing solely on treating specific conditions, whole person health focuses on promoting health and well-being across the lifespan for everyone, including those with disabilities. Promoting inclusion of people with disabilities in research is needed, as disabled people are often excluded from being participants in research, including clinical trials, without adequate scientific justification and this undermines the generalizability of research findings. DHR spans a wide range of scientific disciplines, and interdisciplinary collaboration will enable a more comprehensive understanding of the complex factors that affect health outcomes for disabled people and

foster innovation in research design, methods, and interventions. Technology can play a transformative role in promoting the health and well-being of people with disabilities but also raises important ethical considerations. To ensure responsible innovation and broad access to these technologies, disabled people must be key contributors and decision-makers throughout the technology development lifecycle to ensure that potential harms unique to people with disabilities are mitigated and benefits are realized.

The DHR strategic plan includes four major goals: (1) advance the science of disability health by supporting innovative, rigorous, person-centered research, (2) foster a highly skilled, multidisciplinary, and sustainable disability health research workforce, (3) support accessible, state-of-the-art disability health research resources and infrastructure, and (4) engage in collaborative, responsible, and ethical management of disability health research activities. Mr. Politis reviewed the objectives for the first goal: catalyze advances in conceptualizing, defining, and measuring disability for health research; promote research that examines the biological, behavioral, sociocultural, and environmental factors that influence the health and well-being of people with disabilities across the lifespan; support research to reduce disparities in health outcomes for people with disabilities; and foster research on health promotion and disease prevention for people with disabilities.

Mr. Politis outlined the next steps for the DHR strategic plan. The plan was submitted to NIH leadership for approval and will be available to the public soon. Implementation and ongoing evaluation of the strategic plan will be overseen by the DHRP in partnership with three subcommittees of the DHRCC. These subcommittees will focus on research; policy, planning, and evaluation; and community engagement. Recommendations for disability health research priorities, opportunities for collaborations, strategies for increasing the DHR workforce, and approaches for optimizing outreach to disability communities will be obtained from the CoC DHRWG.

Discussion Highlights

- Council members noted their support for the DHR strategic plan. Dr. Van Gelder expressed his gratitude for being involved in the CoC DHRWG, noting that he was previously unaware of how disabilities could affect the life expectancy of his patients. Dr. Van Gelder highlighted that whole person health for people with disabilities is an important and understudied research area. Ms. Barbara Kelley stated that a person-centered approach is critical.
- When asked how DPCPSI will implement the DHR strategic plan, Mr. Politis responded that the internal committee within the DHRP will facilitate strategic coordination efforts. The CoC DHR WG will evaluate progress on the strategic plan initiatives. Mr. Politis noted that additional implementation resources could be added.
- Mr. Politis explained that standard NIH metrics would be used to assess progress. Metrics to accurately define community engagement and impact are being developed, and annual progress reports will be published.

X. OSC CONCEPT CLEARANCE (NEW): RESEARCH, RIGOR, AND REPLICATION TO PROMOTE EXCELLENCE, ACCURACY, AND TRANSLATION IN SCIENCE (R3PEATS) PROGRAM [VOTE]

Michael F. Chiang, M.D., Director, NEI, introduced the Common Fund proposal for the R3PEATS Program. He defined the terms “replicability” and “reproducibility” as a spectrum of behaviors encompassing the ability to do the same experiment using the same method and get the same result and the ability for different people to test the same hypothesis using independent data and methods while achieving consistent results, and he noted that research rigor is an important part of replicability and

reproducibility. The R3PEATS proposal aims to increase rigor and reproducibility in biomedical research with a multipronged approach that will help foster scientific culture change.

Dr. Chiang emphasized that replication is foundational to establishing the credibility of scientific findings and understanding when science is ready to move forward, but he noted that determining why replication fails is difficult. The R3PEATS initiative is intended to create a scientific ecosystem with frameworks for more rigorous replication studies and a culture that better incentivizes them. Dr. Chiang noted that previous NIH replication initiatives have not been centralized but will inform this effort.

The R3PEATS proposal includes four coordinated initiatives. The first is to fund five national Replication Centers based on methodological expertise that will perform direct, independent replication of high-impact studies as well as test which experimental variables contribute to heterogeneity and replicability. To do this, they will develop standard operating procedures for rigorous experimental design, statistical planning, and data management across multiple sites. In this initiative, suggestions from ICOs or the external community would undergo merit review and ranking by the steering committee. The second initiative is a Metascience Testbed that will develop and test replicability metrics and coordinate rigor-enhancing interventions across scientific sectors to measure and incentivize replication, which will require public-private partnerships. The third initiative is an Education and Outreach Center that will collaborate with the other initiatives to disseminate the lessons learned and best practices gleaned from the Replication Centers and Metascience testbed via various training and communication efforts; this center will engage bidirectionally with the scientific community. The fourth initiative is a Coordinating Center that will connect all initiatives, create a public website to compile a knowledgebase of replication factors, share program outcomes, and develop a replication ontology framework. The Coordinating Center also will manage a steering committee of non-NIH experts and the internal consortium of members across the program.

The deliverables for this initiative are the replication efforts, including the identification of important experimental factors previously unknown to influence replicability; the development of replication best practices, metrics, and educational resources; and a network of strategic partnerships. The program is intended to facilitate scientific culture change and improve how research is communicated. Dr. Chiang suggested that this proposal aligns with Common Fund criteria.

Discussion Highlights

- The discussants, Drs. Manly and Johnston, provided their comments. Dr. Manly commended the work required to develop this concept and noted that the Coordinating Center, public web portal, and Metascience Testbed are strengths of the proposal. She expressed a number of concerns, including the overemphasis on reproducibility relative to original research rigor; the indirect focus of the Metascience Testbed, which appears to be the only element that addresses processes related to new independent science; the lack of explicit practice-level interventions that would address identified gaps; and the absence of initiatives that intervene in original studies. Dr. Manly also noted that the Replication Centers initiative does not mention that the most successful rigor and reproducibility practices already have been instituted within research laboratories and published. She pointed out that the landscape analysis used to identify gaps recommends preregistration and registered analyses, standardized reporting protocols, and data/code sharing with stronger journal oversight but that the materials presented for this concept do not mention these practices. Dr. Manly recommended that R3PEATS prioritize testing and scaling institutional incentives and enforcement mechanisms through the Metascience Testbed and embed those requirements in program governance to ensure that rigor is expected and reinforced where research actually takes place. She pointed out that rigor and reproducibility guidance was added

to NIH in 2014, but the concept does not articulate which elements of this guidance were successful or unsuccessful and how R3PEATS will evaluate and update that information. Dr. Manly commented that NIH recently has participated in issuing claims not grounded in established evidence and emphasized that the promotion of those claims by federal platforms causes disruption. She added that NIH has engaged in actions that undermine continuity, institutional memory, and expert vetting, which are prerequisites for reproducible, high-quality science. She also noted that reducing equity-relevant research also decreases the generalizability and reproducibility of evidence.

- In response to Dr. Manly's comments, Dr. Chiang explained that this proposed program would help develop and scale infrastructure to improve rigor in original research and would include incentives at the institution or investigator level. He noted that infrastructure is required to confirm that scientists are as rigorous as they believe they are.
- Dr. Manly asked how R3PEATS will ensure that program outputs remain rigorous, reproducible, and generalizable across populations even when external political or external pressures work against evidence-based practice. Dr. Chiang noted that part of the R3PEATS effort is to help identify why research in one population does not always translate to other populations.
- Dr. Kleinstreuer asked whether a staged approach would help in which the Metascience Testbed determines which studies to advance into the Replication Centers. Dr. Manly agreed that a staged approach would strengthen the concept but noted that, although the Metascience Testbed seemed to address some cultural and institutional issues more than other components, it was still quite vague and the lack of detail did not suggest it would ensure progress in these areas. Dr. Chiang pointed out that the Metascience Testbed and Replication Centers are intended to be parallel initiatives that can learn from each other.
- Dr. Johnston agreed that the Metascience Testbed was a strength of this proposal and commended the focus on collaboration, culture change, and replication options for the entire workforce. She pointed out that the description of the Replication Centers suggests that only select groups would be invited to have their work replicated, which would not advance culture change for early career researchers. She expressed doubts that the program as described would have the impact intended, noting that the incentives for researchers are not aligned to best practices and that lessons learned from previous NIH efforts were not identified. Dr. Johnston pointed out that academic researchers already have incentives to be rigorous to secure grants and publish, but few have incentives to replicate their studies. She also expressed skepticism about the Education and Outreach Centers, stating that the scientific workforce already is formally trained in scientific rigor and that the obstacles preventing them from replication are cost and lack of academic credit, not lack of knowledge. Dr. Johnston conveyed that this concept is not ready to be launched and suggested that the team incorporate ideas from the discussions of reproducibility during this meeting that occurred prior to this presentation. She identified key issues to address, including lessons learned from previous NIH programs, barriers identified by the research community, incentives that would lead to culture change, methods to improve data sharing while ensuring privacy, and ways to identify non-rigorous results prior to dissemination.
- In response to Dr. Johnston's comments, Dr. Chiang reiterated that researchers are disinclined to share data appropriately because they are not incentivized to do so. He noted that an NIH Data Sharing Index competition to develop a metric to recognize and reward sharing is in progress. Dr. Chiang commented that scientists are incentivized to write papers, but there is not an established ecosystem for synthesizing knowledge in ways that advance the field.

- Dr. Van Gelder suggested using the Metascience Testbed to create a toolbox for measuring reproducibility and noted that AI could be used to identify replications of landmark studies that are embedded within other studies. Tools also could be built to identify rigor and reproducibility issues for specific domains and questions, which could inform a second round of replication studies. Dr. Van Gelder emphasized the many opportunities available to facilitate rigor and reproducibility through existing mechanisms or with slight modifications to existing mechanisms. Dr. Chiang agreed with the value of creating such a toolbox but emphasized the challenges in parsing out the desired information from prior studies.
- Additional Council comments noted the need to define reproducibility at multiple levels, the importance of identifying examples of research practices that would be emphasized by training initiatives, and the difficulty of changing the “publish or perish” culture.
- Dr. Kleinstreuer noted the consensus that this concept is not ready for a vote. The concept will be edited and reviewed again at the May Council meeting. Dr. Manly recommended that the updated proposal be specific about how this program will deliver durable culture change and how lessons learned from prior NIH efforts are integrated into the proposal. She suggested that institutional change could be tied to funding eligibility and added that incentives could be identified to explore why older studies are not replicable today, which would lead to innovation.

XI. CLOSING REMARKS

Dr. Kleinstreuer elaborated on the nomination and approval process for new members, explaining that the field of candidates has been widened at the IC level; when IC Councils are filled, DCPCSI can work with IC leadership to nominate members to this Council. Council members reiterated that filling the Council positions before the May meeting is critical to ensure this Council remains a robust entity with a depth and richness of expertise.

Dr. Kleinstreuer thanked Council members for their input, discussion, and feedback.

XII. ADJOURNMENT

Dr. Kleinstreuer adjourned the meeting at 5:25 p.m. EST on January 29, 2026.

XIII. CERTIFICATION

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

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

Date

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

Date