

**233rd Meeting of the
National Diabetes and Digestive and Kidney Diseases Advisory Council**

**National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Department of Health and Human Services**

Hybrid Meeting - Held in-person NIH Main Campus (Bethesda, MD), Building 31, C-Wing 6th Floor Conference Center and virtually using web-based collaboration/meeting tools

I. CALL TO ORDER and ANNOUNCEMENTS

Dr. Griffin Rodgers

Dr. Griffin Rodgers, Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), called to order the 233rd meeting of the NIDDK Advisory Council at 8:30 a.m. on May 13, 2026, via a hybrid format. The meeting was conducted using a two-tiered webinar format. The panelist tier included NIDDK Advisory Council members and NIDDK staff members who presented during the meeting. The attendee tier was available via a live stream to the public and allowed them to view and listen to the meeting.

ATTENDANCE – COUNCIL MEMBERS PRESENT

Dr. Jamy Ard	Ms. Davida Kruger
Dr. Richard Blumberg	Dr. Jacquelyn Maher
Dr. Arthur Burnett	Dr. Aylin Rodan
Dr. John Carethers	Dr. Philipp Scherer
Dr. Lilia Cervantes	Dr. Elizabeth Seaquist
Dr. Peng Ji	Dr. Hunter Wessels
Ms. Neicey Johnson	

Ex-officio Members:

Dr. Cindy Davis
Dr. Ian Stewart
Dr. David D'Alessio

Subject Matter Expert:

Ms. Tiffany Jones-Smith

Also Present:

Dr. Griffin Rodgers, Director, NIDDK and Chair of the NIDDK Advisory Council
Dr. Karl Malik, Executive Secretary, NIDDK Advisory Council
Dr. Gregory Germino, Deputy Director, NIDDK
Dr. William Cefalu, Director, Division of Diabetes, Endocrinology and Metabolic Diseases, NIDDK
Dr. Stephen James, Director, Division of Digestive Diseases and Nutrition, NIDDK
Dr. Robert Star, Director, Division of Kidney, Urologic, and Hematologic Diseases, NIDDK

ANNOUNCEMENTS

Dr. Griffin Rodgers

Dr. Rodgers reminded Council members that the lengthy government shutdown last fall had a substantial impact on NIH peer-review operations. As a result, not all summary statements for applications that were received for the May Council round are available for the Council meeting. NIDDK is planning to hold a virtual Council meeting on Wednesday, July 1st from 1-3 p.m. EDT to complete the May Council round business.

Council Member News

Dr. Rodgers recognized two Council members who will soon rotate off the Council: Philipp Scherer will be rotating off Council after the May 13th meeting and Ian Stewart will rotate off Council after the July 1st meeting. He thanked them for their service on the Council.

Recognition of Subject Matter Experts

Dr. Rodgers welcomed a subject matter expert attending the meeting and thanked them for their time and participation in the Council process.

- **Ms. Tiffany Jones-Smith** serves as the President & CEO of The State of Texas Kidney Foundation, Chairwoman and Gubernatorial Appointee of the Texas Chronic Kidney Disease Task Force, and as a Healthcare Consumer Advocate for the Kidney Precision Medicine Project. Ms. Jones-Smith will participate on the Division of Kidney, Urology, and Hematologic Diseases (KUH) Subcommittee.

Extramural Program Operation Overview

Dr. Rodgers gave a brief overview of information pertinent to extramural program operations. He indicated that some of this information might be helpful for Council's discussions with Dr. Bhattacharya or Dr. Lorsch later in the meeting.

The NIH Director has articulated a vision for an NIH-wide approach to support the most meritorious science, while staying aligned with health priorities, and supporting a robust biomedical workforce. At the institute level, this means establishing funding policies that balance several factors, including scientific merit, program relevance, workforce needs, and the need to maintain a well-rounded portfolio. In general, these principles are consistent with NIDDK's historic funding policy approach.

Dr. Rodgers explained that the implementation of the NIH Director's vision is the Unified NIH Funding Strategy, which began with the January 2026 Council round. The strategy explicitly states that many competing and dynamic factors should be balanced when making funding decisions. Ultimately, this is about shaping a research portfolio that is strong scientifically and responsive to emerging opportunities and priorities.

In the Unified NIH Funding Strategy, peer-review scores and comments remain central considerations in the decision-making process. There is also an emphasis on considering peer-review outcomes in a broader context. That means looking at scores and comments

alongside strategic priorities, programmatic needs, and budget realities. This is already a standard process, and NIDDK has always considered peer-review outcomes when making funding decisions. The institute also considers strategic priorities, programmatic balance, workforce needs (for example, Early-Stage Investigator (ESI) and ESI first renewal policies), and other factors when making funding decisions, and has used skips and reaches to help align the portfolio with these considerations.

Dr. Rodgers said that while NIH is implementing the unified funding strategy, they are also taking steps to reinforce fairness and originality in the application process (NOT-OD-25-132). Artificial Intelligence (AI) is getting a lot of attention these days for many different reasons. Regarding the use of AI in generating applications, NIH's position is clear: applications must reflect the investigator's original ideas. If AI substantially develops an application, it will not be considered original. NIH has also introduced a limit of six application submissions per Principal Investigator (PI) or Multiple Principal Investigators (MPI) per calendar year across all Council rounds.

Dr. Rodgers added a short update on Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. These programs have been reauthorized through Fiscal Year 2031, after a program lapse since October 1, 2026. Reauthorization is an important signal of continued commitment to innovation and small business engagement. While there are currently no active SBIR/STTR Notice of Funding Opportunities (NOFOs), future opportunities are expected to be announced; the next standard receipt date is September 5, 2026. In the meantime, along with other NIH Institutes, NIDDK is beginning to make both competing and non-competing SBIR and STTR awards.

Award Recognition

Dr. Gregory Germino

Dr. Germino shared that Dr. Rodgers was named the 2025 recipient of the American College of Physicians' (ACP) John Phillips Memorial Award for Outstanding Work in Clinical Medicine. This national award, presented by the ACP, is one of its most distinguished recognitions, honoring excellence and impact on clinical medicine. He said that this recognition reflects Dr. Rodgers' longstanding commitment to advancing clinical research, improving patient care, and mentoring the next generation of physician scientists. Dr. Rodgers was formally recognized at the ACP Internal Medicine Meeting in San Francisco in April. This honor speaks not only to his individual achievements but also to the broader impact of the work across NIDDK and the professional community he has helped build and nurture.

II. FUTURE COUNCIL DATES

Dr. Griffin Rodgers

As noted previously, Dr. Rodgers told Council that the next meeting to review and approve the remaining May Council round applications will be on Wednesday, July 1st, from 1-3 p.m. EDT and will be held virtually. The October Council meeting will be held on Wednesday, October 28, 2026, and is planned as virtual only.

He added that NIDDK expects, for the foreseeable future, to hold the October and January Council round meetings as virtual only and the May Council round meeting as a hybrid meeting (accommodating both in-person and virtual participation). The institute feels that this plan for two virtual meetings and one in-person meeting per year strikes a balance that manages the travel burden for busy Council members while fostering and maintaining connections among Council members. Additional information will be posted on the Council webpage.

Dr. Rodgers mentioned that NIDDK staff currently working in the Democracy II building will move to a new facility in the fall. The new Shady Grove facility has a conference center and other amenities and advantages that seem likely to tip the balance in favor of holding in-person Council meetings there. The new facility has plenty of staff and visitor parking. Additionally, as the facility is not on the NIH main campus, has its own security, this would reduce some complications and burden associated with security clearance and transportation for Council members and guests.

III. ANNOUNCEMENTS

Dr. Karl Malik

Confidentiality

Council members are reminded that material furnished for review purposes and discussion during the closed portion of this meeting is considered confidential. The content of discussions taking place during the closed session may be disclosed only by the staff and only under appropriate circumstances. Any communication from investigators to Council members regarding actions on an application must be referred to the institute. Any attempts by Council members to handle questions from applicants could create difficult or embarrassing situations for the members, the institute, and/or the investigators.

Conflict-of-Interest

Advisors and consultants serving as members of public advisory committees, such as this Council, may not participate in situations in which any violation of conflict-of-interest laws and regulations may occur. Responsible NIDDK staff shall assist Council members to help ensure that the member does not participate in and is not present during review of applications or projects in which, to the member's knowledge, any of the following has a financial interest: the member, or his or her spouse, minor child, partner (including close professional associates), or an organization with which the member is connected.

At Council meetings when applications are reviewed in groups without discussion, that is, by "en bloc" action, all Council members may be present and may participate. The vote of an individual member in such instances does not apply to applications for which the member might be in conflict.

Multi-campus institutions of higher education: An employee may participate in any particular matter affecting one campus of a multi-campus institution of higher education, if the employee's financial interest is solely employment in a position at a separate campus of the same multi-campus institution, and the employee has no multi-campus responsibilities.

IV. NIH Director Update

Dr. Jayanta Bhattacharya

Dr. Rodgers reminded the Council that last September, NIH Director Dr. Jay Bhattacharya gave a presentation via a pre-recorded video. Following Dr. Bhattacharya's presentation, Council members had an excellent conversation, including some very thoughtful comments and observations. Given the Council's positive response to the presentation and the quality dialogue that it generated, Dr. Bhattacharya was invited to visit the Council meeting again as an opportunity for him to hear directly from Council members, including their comments, suggestions, and insights on issues relevant to diabetes, digestive, and kidney diseases research. Dr. Rodgers stated that Dr. Bhattacharya earned his undergraduate and medical degrees from Stanford University, where he also received a PhD in economics. At Stanford, he was a Professor of Medicine, Economics and Health Research Policy until March of 2025, when he became the Director of NIH. He was also an investigator at Stanford Center for Demography and Economics of Health and Aging, and his research, among other things, focused on the economics of healthcare.

Dr. Bhattacharya began by acknowledging Dr. Rodgers, who recently received an award for his work on sickle cell disease, and invited the room to join in congratulating him. He provided a brief overview of recent NIDDK accomplishments. Among the highlighted research advances was new work on treatments to prevent and eliminate kidney stones. He emphasized that kidney stones are frequently underestimated in terms of their debilitating impact, and that NIDDK investments in understanding the underlying biology are beginning to yield meaningful results. An NIH-funded research team, led by Drs. Kymora Scotland and Gerard Wong of UCLA found evidence challenging a long-held belief about calcium-based kidney stones (<https://pubmed.ncbi.nlm.nih.gov/41587311/>). These results could lead to new treatments that prevent or eliminate kidney stones.

The director also highlighted NIDDK's contributions to efforts aimed at ending the HIV epidemic, referencing the long-acting injectable PrEP medication that can provide protection for up to a year with a single injection, combined with advances in viral load suppression. NIDDK is expanding its efforts to help end the HIV epidemic by supporting implementation research in U.S. communities with the highest burden of HIV. He noted that NIDDK's role in this effort is particularly relevant given the intersection of HIV and kidney disease, and the opportunities for patient interaction that can support broader epidemic control goals. Additional areas of progress included research on the biological mechanisms linking obesity and kidney disease, as well as the link between diabetes and kidney failure. An NIH-funded study, led by Dr. Zhenyu Zhong of the University of Texas Southwestern Medical Center, investigated how obesity affects the NLRP3 inflammasome (<https://www.science.org/doi/10.1126/science.adq9006>). NIDDK is also supporting research that investigates the pathophysiology of diabetic neuropathy (DN) in peripheral and autonomic nerves, and the following areas:

- The development of translational animal models and novel methodological approaches.
- The role of factors beyond hyperglycemia that contribute to DN pathophysiology.

- The role of sex differences, socioeconomic status, and sources of heterogeneity in the presentation and progression of DN.

Dr. Bhattacharya presented data on life expectancy trends in the United States from 2006 to 2025, noting that American life expectancy has remained essentially flat between 2009 and 2019. By contrast, comparator countries such as Sweden have continued to see increases throughout nearly the same period, with the exception of a single year during the COVID-19 pandemic. He argued that this stagnation is deeply problematic given the many advances in biomedical science, particularly in areas such as diabetes management and cardiovascular disease, which have occurred over the same timeframe. He stated that NIH must grapple seriously with how its research investments translate, or fail to translate, into longer and healthier lives for Americans. He also noted the significant economic dimension of chronic disease, estimating that Medicare spending is approximately two trillion dollars, much of which is driven by downstream consequences of diabetes and other preventable conditions, and argued that preventing type II diabetes entirely would represent both a public health achievement and a meaningful contribution to reducing the national budget deficit.

Dr. Bhattacharya described research examining how old the ideas are in published biomedical literature and what role NIH plays in supporting the newest science (<https://www.pnas.org/doi/10.1073/pnas.1910160117>). By cataloging all words and phrases introduced into biomedical literature year by year, the researchers were able to construct a timeline of when new ideas entered the field and then assess what proportion of papers containing the newest ideas were NIH-funded. He reported that in the 1990s, more than half of papers featuring zero to two-year-old ideas were supported by NIH funding, but by the 2000s, that proportion had declined to approximately 45 percent. He attributed this shift in part to a culture of risk aversion in peer review, where novel proposals are frequently dismissed as unlikely to succeed, even though every major scientific breakthrough was initially met with skepticism.

Related to this, he presented findings on the career age of scientists publishing the newest ideas, showing that the probability of producing cutting-edge work declines steadily as a researcher's career advances (<https://pmc.ncbi.nlm.nih.gov/articles/PMC6703833/>). He stated that the average age at which a scientist receives their first R01 grant has shifted from the mid-thirties in the 1980s to the mid-forties today, a trend that is even more pronounced for physician-scientists with combined MD and PhD training. He expressed concern that the current ecosystem, which requires multiple postdoctoral positions and penalizes early failure, may be preventing a generation of scientists with genuinely innovative ideas from having those ideas supported and tested in a timely way.

To address the problem of safe, incremental science, Dr. Bhattacharya described a new approach called the unified funding strategy. The central premise is that the current practice of funding grants according to overall priority score, or pay line, causes institutes to overlook proposals with strong innovation scores that nonetheless fall below the funding threshold. Because overall scores correlate more strongly with methodology than with innovation, truly novel ideas are systematically underrepresented in funded portfolios. The unified funding strategy would allow institutes to consider the full narrative of review evaluations and assemble a portfolio that reflects their strategic plans,

prioritizes early-career scientists, and takes calculated intellectual risks. The measure of success would not be whether each individual grant produces publication, but whether the portfolio as a whole advances biological knowledge and improves human health.

Next, Dr. Bhattacharya discussed the well-documented problem of irreproducibility in biomedical research. A paper published in 2005, citing a widely known 2005 paper arguing that most published research findings are statistically likely to be false, not because of fraud, but because the tools scientists use to distinguish true from false results are inherently imprecise (<https://pubmed.ncbi.nlm.nih.gov/27225100/>). The best tool to determine if something is true is replication. He noted that replication is too often viewed as a threat to a researcher's career rather than a mark of scientific significance, when in fact having one's work replicated should be considered a sign that the ideas are worthy of further evaluation. The problem persists in part because there are no meaningful career incentives for scientists who pursue replication work.

Dr. Bhattacharya outlined goals towards investing in the science of replication. First, NIH will fund replication studies at the R01 level, with peer reviewers identifying the rate-limiting scientific questions most in need of independent verification. Second, NIH will establish a replication platform where such studies can be published with a digital object identifier, providing career credit to researchers who undertake this work. Third, NIH will enhance PubMed to include a replication feature that generates a knowledge graph of related literature, an AI-generated summary of the issues addressed by a given paper, and links allowing readers to verify the AI's conclusions. He also called for new metrics of scientific contribution that go beyond citation counts and publication volume to include dimensions such as data sharing, collaboration, replication, and the novelty of published ideas.

He closed by noting that the concentration of NIH funding means approximately one-third of the portfolio flows to roughly 20 institutions. He acknowledged that these institutions host many outstanding scientists but argued that exceptional researchers at other institutions nationwide face structural disadvantages in competing for NIH support. He described the self-reinforcing cycle in which grants attract facilities funding through indirect costs, and strong facilities attract scientists who can win grants, making it increasingly difficult for institutions outside the top tier to compete. His proposed solution is to separate infrastructure, and facilities support from the research grant competition, allowing facilities funding to be competed independently and at an institutional level, with some consideration given to the cost of providing that infrastructure. He argued that strategic NIH investment in a broader range of institutions could serve as seed funding to attract additional support from foundations and donors, ultimately creating a larger, more geographically distributed ecosystem of biomedical research excellence.

Council Questions and Discussion

Dr. Rodgers, moderator

Comment from Council: *How can NIH best support early-career physician-scientists pursuing career development awards, such as the K23, at a time when their mentors and academic institutions are facing significant funding constraints?*

Dr. Bhattacharya responded that while there has been considerable nervousness about funding uncertainty, NIH was fully funded last year, obligated all funds and continues to make investments across the research pipeline, including T, K, and F awards. However, the distribution of funding may be shifting toward new investigators and institutions. The fact that the age at first R01 award has continued to increase despite significant efforts suggests that something needs to change. He emphasized that the changing funding environment, while harder to plan around, creates new opportunities for early-career scientists with novel ideas and expressed a desire to see mechanisms like the Maximizing Investigators' Research Award (MIRA) program expanded. He also mentioned the structural tension in the K award mechanism, in which outstanding junior faculty are essentially required to argue that their training has been insufficient to qualify, a flawed approach that should be reconsidered. He acknowledged that addressing the challenges facing early-career scientists is a longstanding, complex problem without a simple solution, and welcomed suggestions from Council members.

Comment from Council: *How does NIH plan to invest in career development awards for physicians who come to research later in their careers and require the full protected training time to develop the skills needed for clinical research?*

Dr. Bhattacharya agreed that continuing investment in clinician-scientist training through F, K, and T awards is important. He emphasized that these mechanisms are not going away and noted that a broader shift toward funding cutting-edge ideas will naturally benefit early-career scientists, since they tend to generate the newest work.

Comment from Council: *Has NIH considered building the pairing of junior and senior investigators more explicitly into the R01 review process, given that this collaboration tends to be where the most innovative ideas emerge?*

Dr. Bhattacharya acknowledged the tension between productive junior-senior collaborations, in which senior investigators genuinely support the independence of early-career scientists, versus exploitative arrangements in which junior researchers primarily serve to advance the senior investigator's own work. He said that mentorship is currently neither adequately measured nor rewarded within the funding system. He expressed interest in developing metrics, such as tracking how many trainees go on to independent faculty positions, to identify and reward effective mentors.

Comment from Council: *How does NIH plan to support physician-scientist mentors who are experiencing significant funding delays, given that early-career researchers cannot develop their ideas independently without access to a funded laboratory environment?*

Dr. Bhattacharya acknowledged that while NIH was behind in spending relative to 2024 at certain points last year, institute directors worked to accelerate expenditures and fully distribute the available funds, though the number of grants awarded was lower while the average dollar amount per grant was higher. He explained that under the unified funding strategy, funding decisions will increasingly prioritize innovative ideas over raw priority scores, meaning that a first or second percentile score will no longer serve as a reliable signal of likely funding, and encouraged Council members to provide feedback on what tools and communications would help institutions better plan under this new framework.

Comment from Council: How do investigators decide between a traditional R01, a five-year grant, or a split two- and three-year model when there's no clear guidance on how that decision is made?

Dr. Bhattacharya said that the number of funded investigators has not shrunk dramatically, but it has shrunk. Increased upfront funding (from ~20% to ~39%) is expected to restore grant volume within two years. More broadly, the agency is transitioning away from automatically funding established investigators toward prioritizing high-risk, innovative science and early-career researchers, even if methods are imperfect, because the ultimate goal is to improve American health outcomes, not simply to sustain funding for familiar grantees.

Comment from Council: How does upfront funding actually increase innovation when, in practice, it appears to be reducing the total number of awards and driving junior and early-career investigators out of science?

Dr. Bhattacharya answered that upfront funding should serve as a science policy tool, not merely a budget mechanism. When used strategically, such as helping new investigators cover fixed startup costs or supporting a two-plus-three grant model, it can advance innovation. However, using it purely for budget purposes is problematic, and 100% upfront funding is not the goal. Congressional restrictions on upfront funding last year were likely appropriate, and the emphasis going forward should be on ensuring institutes use it intentionally to advance science rather than as a financial workaround.

Comment from Council: How to ensure sufficient expertise to evaluate novelty in grant reviews, and would simply increasing the weight of novelty scores in study sections be enough to address the problem?

Dr. Bhattacharya answered that responsibility for evaluating novelty ultimately rests with peer reviewers and program staff, as human judgment remains irreplaceable. Study sections generally recognize innovative ideas; the harder question is which are worth funding. Institutes must look beyond overall scores and consider the peer-review signal to build the right portfolio, in close collaboration with the scientific community, because collective expertise is the only reliable guide available.

Comment from Council: How do we direct funding toward scientifically underdeveloped fields that need a push, rather than relying solely on R01s to drive the leaps needed to improve public health?

Dr. Bhattacharya stated that two complementary approaches are needed. The highlighted topics mechanism allows institutes to signal priority areas and attract investigator attention to underdeveloped fields more nimbly than traditional program announcements. At the same time, bottom-up investigator-initiated awards remain essential, as top-down initiatives like the Human Genome Project or BRAIN Initiative should not crowd out innovative individual ideas. The unified funding strategy aims to support both, with peer reviewers helping identify the best proposals from the community.

Comment from Council: Given the alarming decline in life expectancy and the striking health disparities in kidney disease, diabetes, and other chronic conditions across zip

codes, ethnic backgrounds, and socioeconomic groups, why can these disparities no longer be studied?

Dr. Bhattacharya responded that research on health disparities remains fully supported and is explicitly addressed in the agency's priority statement. The concern is not whether to study minority health, but whether past investments have been effective. Rather than continuing to document the existence of disparities, the focus should shift toward actionable research that yields real improvements in health outcomes for minority populations.

V. OFFICE of EXTRAMURAL RESEARCH DIRECTOR UPDATE

Dr. Jon Lorsch

Dr. Rodgers introduced Dr. Jon Lorsch to discuss updates and perspectives on the Office of Extramural Research (OER) at NIH. Dr. Lorsch oversees policies and programs that support NIH's research enterprise. Prior to taking on this role, Dr. Lorsch served as Director of the National Institute of General Medical Sciences from 2013 to 2025, during which he oversaw a broad portfolio of basic biomedical research and training programs. Dr. Lorsch is an accomplished scientist, known for his research on the molecular mechanisms of protein synthesis, particularly the initiation of translation. Dr. Lorsch has extensive experience in NIH leadership roles, including service on multiple NIH-wide committees and efforts focused on improving efficiency, transparency, and impact of NIH-funded research.

Dr. Lorsch explained that the OER is responsible for coordinating extramural research policies and ensuring compliance across NIH's institutes and centers (ICs). OER's core priorities include reducing administrative burden, promoting innovation in funding approaches, strengthening research integrity, enhancing biosafety and laboratory safety, countering foreign interference in U.S. research, and improving access to shared research technologies and infrastructure.

NIH is encouraging its ICs to experiment with new models of supporting research, evaluating the results, and sharing approaches that prove successful. Regarding research integrity, AI-enabled data falsification is a growing concern, underscoring the need for detection methods to keep pace with technological advances. NIH is working to modernize its approach to biosafety, led by the Office of Science Policy, while also pushing for stronger attention to laboratory safety more broadly. Dr. Lorsch said that safety is too often treated as a brief orientation exercise rather than an ongoing institutional priority. He proposed a top-down culture of safety that becomes a routine part of laboratory work. Countering foreign interference in U.S. research is also an ongoing problem and requires continued vigilance from the research community.

Dr. Lorsch said that NIH is prioritizing access to cutting-edge technologies and research resources, regardless of institution or location. A good example of shared research infrastructure is the NIH Common Fund's national cryo-EM centers. Regional or national shared facilities deliver better researcher access, economies of scale for taxpayers, and reduced costs for institutions. He acknowledged that NIH currently lacks a coherent government-wide strategy for shared resources, but it is an ongoing priority.

Next, Dr. Lorsch discussed reducing administrative burden. In January 2025, NIH had more than 800 active NOFOs. A goal was set to reduce that number by 50 percent within a year, and that target was met. He added that a substantial share of NIH NOFOs over the years received zero applications, and an even larger share received only a handful. The office is also working to simplify and shorten the remaining NOFOs, with an HHS-wide "Simpler NOFOs" initiative now producing templated, plain-language documents. The first NIH example, a NIGMS MIRA award for early-stage investigators, was recently released (<https://simpler.grants.gov/opportunity/59c3ea57-ba49-4e96-9706-0528937de746>). The office is also moving away from the current confusing designation system; going forward, all NOFOs will follow a single, uniform set of rules. The NIH is shifting toward investigator-initiated research versus NIH-directed research. The Highlighted Topics webpage is replacing NOFOs that focus on specific research areas: <https://grants.nih.gov/funding/find-a-fit-for-your-research/highlighted-topics>.

Dr. Lorsch mentioned that the NIH no longer requires letters from applicants requesting more than \$500,000 in direct costs per year. He mentioned that only about half of those who submitted letters of intent ultimately applied, making the letters of intent an ineffective screening tool. Pre-approval requirements for conference grants (R13) have also been dropped.

Dr. Lorsch offered a detailed history of the long-misunderstood modular budget system, launched as a pilot in 1994 with a threshold of \$250,000 in direct costs that was never intended as a cap but was widely treated as one. By Fiscal Year (FY) 25, only 7.6% of R01 applications used modular budgets, a clear signal that the experiment had run its course. NIH is considering an update to application budget guidance that going forward, detailed budgets will no longer be required for most grant types, including R01s. A brief budget justification would still be required so reviewers can assess overall reasonableness, and full detailed budgets would only be requested as just-in-time information for applications that are likely to be funded.

The existing two-page Data Management and Sharing Plan requirement is being replaced with a streamlined pilot consisting of four yes/no questions. For example, whether applicants intend to share data underlying their publications. Applicants who answer yes move forward without further elaboration. Only those answering no must provide an explanation. There was also difficulty in standardizing this approach, given the variety of fields involved, different data types, and multiple ways of generating data. Additionally, NIH staff had begun developing an AI tool to evaluate data management plans at the same time the University of California was building one to write them for grantees, which would have left no human to write or review these plans. The previous approach contained a significant loophole: researchers were only held accountable for sharing the specific data types they had listed upfront, even though most labs generate multiple data types over the course of a project.

NIH will no longer consider Basic Experimental Studies in Humans (BESH) to be clinical trials. BESH studies examining fundamental biological or behavioral processes in human subjects had been folded into the clinical trials category under a 2014 policy change. The reason for the policy was to make sure that the results were shared. However, once the data management and sharing policy addressed the original concern driving that classification, the clinical trials designation became an unnecessary burden.

BESH studies have now been formally removed from the clinical trials category, though they remain subject to human subjects research requirements. NIH has a webpage that helps applicants determine the type of study: <https://grants.nih.gov/policy-and-compliance/policy-topics/clinical-trials/clinical-trial-besh-or-observational-study-involving-humans>.

NIH issued new guidelines clarifying reporting requirements for the humane care and use of laboratory animals, without changing the underlying policies. The agency also standardized the use of the eRA prior approval module for prior approval requests, replacing a patchwork system in which each IC handled these requests differently. Researchers will now follow the same process regardless of which IC their grant comes from. NIH has adopted common forms for the biographical sketch and other support documents as part of a government-wide effort, requiring researchers to use the Science Experts Network Curriculum Vitae (SciENCv) system at the National Library of Medicine. After an initial grace period to accommodate early technical limitations, the system is now required for all applicants.

Future plans include consolidating the 26 existing K-series career development award activity codes into five, covering the same range of activities in a far simpler structure. NIH is also aligning more closely with NSF on application requirements, including adopting NSF's model of limiting letters of support to brief, boilerplate letters of collaboration from unfunded collaborators only, and combining separate facilities and equipment sections into a single section. NIH is also planning a request for information seeking additional burden-reduction ideas from the research community once these initial reforms are in place. The National Science and Technology Council is working on a government-wide approach to reducing administrative burden.

Council Questions and Discussion

Dr. Rodgers, moderator

Comment from Council: *Has NIH considered involving patient communities and advocates more formally in the grant review process, similar to the UK model in which people living with a condition and their families provide direct input during review?*

Dr. Lorsch responded that some study sections already incorporate community input, particularly those working with Native communities, and there is room to expand that practice more broadly. NIH has historically used its advisory councils as a forum for this kind of public engagement, though this is an area worth developing further.

Comment from Council: *What progress has been made with regards to AI and research integrity?*

Dr. Lorsch said that addressing AI's impact on research integrity is an evolving challenge. NIH has already taken some steps, including issuing a guidance notice reminding applicants that AI should not substantially write a grant application, since that would compromise the originality of the work, and capping the number of applications on which a PI can be named in a single year at six. Those measures were prompted in part by cases in which single groups submitted unusually large numbers of applications in a short

period, in at least one instance as many as 41 in a year. The agency is also investing in better tools to detect AI use in both grant writing and figure generation.

Comment from Council: *How can researchers stay informed about the funding models and priorities that individual institutes are experimenting with, and how those decisions are being made?*

Dr. Lorsch replied that researchers can start by reviewing the high-level priority statements and the individual mission statements that each IC posts publicly on its website. Beyond that, the highlighted topics pages that NIH has recently launched offer a practical signal of where institutes would like to see more applications. These are not formal funding opportunities but rather expressions of interest intended to encourage researchers who are already working in a given area to submit their ideas.

The absence of a topic on the highlighted topics pages should not be read as a lack of interest from the institutes. The lists are meant as gentle nudges in a few selected areas, not a comprehensive map of NIH priorities. Researchers working on something that does not appear there should not be discouraged. In fact, some of the most valuable science may be in areas NIH has not yet thought to highlight, novel work that no one has anticipated but that could turn out to be critically important.

Comment from Council: *Will the reduction in NOFOs come at the expense of complex networks and collaborative research structures, given that investigator-initiated research tends to produce smaller, self-selected groups rather than the broader collaborations that targeted funding opportunities are designed to support?*

Dr. Lorsch responded that targeted funding opportunities remain appropriate in certain contexts, particularly for complex clinical trials networks that require coordinated structures and agreed-upon parameters. Some Common Fund initiatives organized from the top down have also proven highly effective. He suggested the model may have been applied too broadly over the past decade, and that some recalibration is warranted. Drawing on research into team science, Dr. Lorsch pointed out that most truly innovative work tends to come from smaller teams, while larger teams are better suited to applied advances. This distinction may help guide decisions about when directed funding opportunities are the right tool and when investigator-initiated research is more likely to yield something new.

Comment from Council: *For NOFOs that are needed but have been slow to come out, such as specialized center grants, what can the community do to follow up or advocate for their release?*

Dr. Lorsch acknowledged the delay, explaining that a new review process for NOFOs that extends beyond NIH took time to establish but is now running. More NOFOs are expected to appear on grants.gov in the coming weeks. Much of the reduction has targeted NOFOs that simply solicited R01 applications in a specific scientific area, which tended to attract few applications. With the parent R01 mechanism and the new highlighted topics available, those narrowly focused NOFOs are largely unnecessary.

Comment from Council: *When the K activity codes are consolidated, will the same number of awards still be made and the same career stages still be supported, or will some categories of investigators find fewer opportunities available to them?*

Dr. Lorsch answered that the five consolidated K activity codes will cover the same ground as the current 26, including postdoc-to-faculty transitions and clinical researcher development. However, pointing out that K awards have sometimes become de facto holding patterns for junior investigators rather than genuine career development tools. With the average age of a first R01 now at 42, Dr. Lorsch argued that the system has inadvertently delayed independent research careers by making K awards an expected prerequisite for R01 funding.

Comment from Council: *When reviewers in a study section lack expertise in a specialized field like implementation science, can NOFOs help address that gap by enabling institutes to convene special emphasis panels with the right expertise?*

Dr. Lorsch said that while NOFOs were historically used to convene institute-specific review groups, all reviews have now been centralized at the Center for Scientific Review, so that rationale no longer applies. Specifically, regarding implementation science, the director cited the strong enthusiasm for the field as grounds for expecting better representation on review panels going forward.

Comment from Council: *Could a checklist or checkbox approach be applied to other sections that reviewers currently spend significant time on but that may not meaningfully influence scoring?*

Dr. Lorsch welcomed the suggestion, saying that this kind of feedback from the community is what the office is looking for. Some of these requirements are statutory, meaning reviewers are obligated to consider them, but he pointed out that does not necessarily dictate how the information is collected or presented. A just-in-time approach could work here as well, asking for a streamlined version at the review stage and requesting fuller detail only for applications that are likely to be funded.

Comment from Council: *While a national or regional model may make sense for expensive specialized equipment like cryo-EM, what is the vision for local core facility programs like the P30 centers that have long supported research communities at the institutional level?*

Dr. Lorsch answered that core facilities remain valuable and that the push toward regional and national models is not meant to replace them across the board. Some technologies are well-suited to local core facilities and do not warrant a national infrastructure. That said, the director identified a real problem: NIH has no coherent strategy for supporting core facilities. Different institutes run their own programs independently, and a previous attempt to even inventory NIH's support for core facilities across the country ran into significant obstacles. That lack of coordination is something NIH would like to address.

Comment from Council: If NOFOs are reduced, how will institute priorities be communicated and applied consistently, and is there a risk that without a formal codification process, those priorities become opaque or unevenly implemented?

Dr. Lorsch said that institute priorities are not meant to be a black box. Every five years, each institute is required to publish a strategic plan, which is publicly available and provides a formal account of its priorities. The highlighted topics pages offer a nimble complement to that, allowing institutes to signal emerging areas of interest on a shorter time horizon without waiting for the next strategic planning cycle.

Comment from Council: Has NIH considered a two-stage application process, similar to the PCORI model, in which investigators submit a brief letter of intent or preliminary proposal that is reviewed before they invest the time and effort of a full application?

Dr. Lorsch agreed that a two-stage process was appealing and noted that it has worked well in some contexts. However, the NSF's experience with a similar model in its molecular and cellular biology directorate was unsuccessful. The low barrier to submitting a short letter led to an overwhelming volume of submissions, and, perhaps more surprisingly, the ability to write a strong letter of intent did not predict the ability to write a strong full application. For those reasons, Dr. Lorsch expressed skepticism about applying the model broadly across the NIH portfolio, while leaving open the possibility that it could work well in specific contexts. In the meantime, he encouraged investigators to reach out to the relevant program officer before applying to gauge whether their idea fits the institute's portfolio. Program officers can flag high-priority areas, suggest a better-fitting institute, or point toward a different funding agency, without passing judgment on the idea itself.

VI. CLOSED SESSION OF THE SUBCOMMITTEE MEETINGS

This portion of the meeting was closed to the public, in accordance with the determination that it concerned matters exempt from mandatory disclosures under Sections 552(b)(4) and 552(b)(6), Title 5, U.S. Code, and Section 10(d) of the Federal Advisory Committee Act as amended (5 U.S.C. Appendix 2).

Members absented themselves from the meeting during discussion of and voting on applications from their own institutions, or other applications in which there was a potential conflict-of-interest, real or apparent. Members were asked to sign a statement to this effect.

VII. CLOSED SESSION OF THE COUNCIL

This portion of the meeting was closed to the public, in accordance with the determination that it concerned matters exempt from mandatory disclosure under Sections 552(b)(4) and 552(b)(6), Title 5, U.S. Code, and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

Members absented themselves from the meeting during discussion of and voting on applications from their own institutions, or other applications in which there was a

potential conflict-of-interest, real or apparent. Members were asked to sign a statement to this effect.

CONSIDERATION OF REVIEW OF GRANT APPLICATIONS

A total of 1,585 grant applications (1,168 primary and 417 dual), requesting support of \$ \$682,897,653 were reviewed for consideration at the May 13, 2026 meeting. An additional 1,918 Common Fund applications requesting \$4,388,219,546 were presented to Council. Funding for these applications was recommended at the Scientific Review Group recommended level. There was no Early Concurrence Review held for this session.

VIII. EXECUTIVE CLOSED SESSION OF THE COUNCIL

IX. ADJOURNMENT

Dr. Rodgers expressed appreciation on behalf of the NIDDK to the Council members, presenters, and other participants. He thanked the Council members for their valuable input. There being no other business, the 233rd meeting of the NIDDK Advisory Council was adjourned at 3:50 p.m. on May 13, 2026.

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

Griffin P. Rodgers, M.D., M.A.C.P.
Director, National Institute of Diabetes and Digestive and Kidney Diseases, and
Chairman, National Diabetes and Digestive and Kidney Diseases Advisory Council

Karl F. Malik, Ph.D.
Director, Division of Extramural Activities, National Institute of Diabetes & Digestive &
Kidney Diseases, and
Designated Federal Official/Executive Secretary, National Diabetes and Digestive and
Kidney Diseases Advisory Council

May 13 NIDDK Advisory Council Meeting Attendance

NIDDK Staff

Name

Beena	Akolkar
Guillermo	Arreaza-Rubin
Raj	Basu
Olivier	Blondel
Eric	Brunskill
Henry	Burch
Bonnie	Burgess-Beusse
Arthur	Castle
Rebecca	Cerio
Kevin	Chan
Diana	Cummings
Edward	Doo
Emily	Duggan
Thomas	Eggerman
Mary	Evans
Minnjuan	Flournoy Floyd
Debbie	Gipson
J. Rafael	Gorospe
Daniel	Gossett
Raquel	Greer
Camille	Hoover
Kayla	Hurd
Teresa	Jones
Chris	Ketchum
Ziya	Kirkali
Peter	Kozel
Maggie	Liang
Dominique	Lopez-Piper
Christine	Maric-Bilkan
Saul	Malozowski
Susan	Mendley
Chris	Mullins
Sarah	Neser
Deepak	Nihalani
Jenna	Norton
Heidi	Otradovec
Matthew	Portnoy

Tracy	Rankin
William	Reynolds
Cindy	Roy
Anna	Sadusky
David	Saslowsky
Ivonne	Schulman
Aliecia	Shepherd
Pamela	Thornton
Aynur	Unalp-Arida
Xujing	Wang
Theresa	Woo
Norann	Zaghloul