230th 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

Virtual - Held 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 230th meeting of the NIDDK Advisory Council at 12:30 on September 17, 2025, via a virtual meeting. 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
Dr. Richard Blumberg
Dr. John Carethers
Dr. Lilia Cervantes
Dr. Peng Ji
Dr. Jacquelyn Maher
Dr. Aylin Rodan
Dr. Philipp Scherer
Dr. Elizabeth Seaquist
Dr. Hunter Wessels

Subject Matter Experts:
Dr. Michael Rickels
Ms. Tiffany Jones-Smith

Ex-officio Members:
Dr. Cindy Davis
Dr. Ian Stewart

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

National Institute of Health (NIH) and NIDDK Panelists and Speakers:

Dr. Rodgers noted that NIDDK plans to hold hybrid Council meetings, which accommodate virtual and in-person participation, in the near future. Occasional fully virtual meetings may happen as needs arise or circumstances change. The Council website will have further details in the future.

II. ANNOUNCEMENTS
Dr. Griffin Rodgers

Council Member News

Dr. Rodgers recognized four Council members that are scheduled to rotate off the Council after this meeting: **Dr. John Carethers, Ms. Davida Kruger, Dr. Jacquelyn Maher, and Dr. Elizabeth Seaquist.** He thanked them for serving on the Council over the past several years.

Recognition of Subject Matter Experts

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

- **Dr. Michael Rickels** is the Willard and Rhoda Ware Professor in Diabetes and Metabolic Diseases at the University of Pennsylvania Perelman School of Medicine and Medical Director, Pancreatic Islet Cell Transplant Program. Dr. Rickels will participate in the Division of Diabetes, Endocrinology, & Metabolic Diseases (DEM) Subcommittee.
- **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 in the Division of Kidney, Urology, and Hematologic Diseases (KUH) Subcommittee.

In Memoriam

Dr. Rodgers noted recent losses for the NIDDK research community:

- **Dr. Richard McCallum** was a pioneer and leader in the field of gastrointestinal motility and functional disorders, particularly gastroparesis and its primary symptoms of nausea and vomiting. A native of Australia, Dr. McCallum had a major impact on the field and held positions at UCLA, Yale, the University of Virginia, and finally as the founding Chair of the Department of Medicine at the newly created University of Texas Medical School at El Paso. He was an important leader in the NIDDK Gastroparesis Clinical Research Consortium. Dr. McCallum was the mentor of over 100 trainees, many of whom are now academic leaders, including fellow Australian, Dr. Barry Marshall who won the Nobel Prize for his discovery of H. pylori as a cause of ulcer disease.

- **Dr. Dana Andersen** was a general surgeon with an international reputation for his leadership in research, clinical care, and education in academic surgery. Dr. Andersen's career started with undergraduate and medical degrees from Duke University, where he also completed general surgery residency training. During his residency, he completed a 2-year research fellowship in endocrinology as a Public Health Service (PHS) officer at the National Institute on Aging (NIA) in Baltimore. Dr. Andersen's academic career progression carried him from professorships at SUNY Downstate and then to the University of Chicago, Yale University, the University of Massachusetts, and finally to Johns Hopkins, where he became the Vice Chairman of the Department of Surgery and Surgeon in Chief at the East Baltimore Johns Hopkins campus—returning to the location of his early training at the NIA. His major clinical and research focus was on pancreatitis and pancreatic cancer, for which he earned international acclaim as a surgeon, researcher, and educator. Dana began a second career when he joined NIDDK in 2011, where his leadership established new research programs and clinical consortia that have accelerated research in exocrine pancreatic disease as well as research in many other digestive disease conditions. He promoted research on technical approaches such as minimally invasive surgery, devices, and simulation, in education and training. He was an articulate and compelling speaker, prolific writer, editor, and organizer of symposia. For many years, he was a co-editor of the major textbook of General Surgery. Dr. Anderson was also an active leader in academic surgical societies, including the American Pancreatic Association and the National Pancreas Foundation. His life's work will have a lasting legacy as his many colleagues, trainees, collaborators, and grantees carry on his lifelong commitment to improve the health of people with digestive diseases.

NIH News

Dr. Rodgers announced a new NIH resource, Highlighted Topics:

- This centralized resource will inform the research community about NIH areas of scientific interest.
- The new resource allows searching for topics by keywords and filtering by participating NIH Institutes, Centers, or Offices.
- The idea is that the resource will help encourage investigator-initiated applications and reduce NIH's use of specific funding opportunities by highlighting topics and allowing applicants to apply through one of NIH's Parent Announcements or broad NIH opportunities posted on Grants.gov.

III. CONSIDERATION OF SUMMARY MINUTES
Dr. Griffin Rodgers

The Council approved, by a show of hands and verbal vote, the Summary Minutes of the 228th and 229th Council meetings, which had been sent to members in advance for review.

IV. FUTURE COUNCIL DATES

Dr. Griffin Rodgers

As noted previously, Dr. Rodgers told Council that future meetings may be held using a hybrid format to accommodate both virtual and in-person attendance. The next meeting of the NIDDK Advisory Council is scheduled for January 28-29, 2026. Although the plan is to meet on January 28, the Council was asked to hold both days open to maintain flexibility. Updates about future meetings will be posted on the Council website.

V. 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.
To ensure that a member does not participate in the discussion of, nor vote on, an application in which he/she is in conflict, a written certification is required. A statement is provided for the signature of the member, and this statement becomes a part of the meeting file.

After today's meeting, Council members will be sent a statement regarding conflict-of-interest in their review of applications. Each Council member should read the statement carefully, electronically sign it, and then return the signed statement by email to Devon Drew (Committee Management Officer) or to Dr. Karl Malik within one day.

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.

VI. NIH DIRECTOR UPDATE

Dr. Jayanta Bhattacharya

Dr. Bhattacharya delivered pre-recorded remarks focused on addressing America's chronic disease crisis, emphasizing that the NIDDK is fundamental to "making America healthy again." He highlighted health trends, including the rise in type 2 diabetes and the stagnation of American life expectancy since 2012, positioning these challenges within a broader chronic disease epidemic that requires transformative approaches rather than incremental solutions. NIDDK's portfolio drives prevention and policy impact, informing guidelines and health system change. Current strategic initiatives include pragmatic clinical trials utilizing real-world data to evaluate interventions, precision epidemiology in nephrology (the Kidney Precision Medicine Project), and research on nutrition and obesity (a collaboration with NHANES to enhance dietary assessment and monitor obesity trends).

Dr. Bhattacharya outlined a five-point strategic vision for reforming the NIH. The first priority involves improving population health by recognizing the interconnected nature of chronic diseases affecting Americans. The second addresses the decades-long reproducibility crisis in biomedicine, acknowledging that unreliable published literature undermines efforts to address population health needs. The third calls for "thinking big" to tackle enormous health challenges with transformative approaches rather than settling for small advances. The fourth emphasizes maintaining safety and transparency in research, particularly by implementing stricter oversight of gain-of-function work, as mandated by presidential executive orders. The fifth priority focuses on restoring academic freedom by reversing pandemic-era speech suppression and establishing concrete policies that allow researchers to publish their scientific ideas freely.

Three major policy implementations were detailed during the presentation. The Novel Alternative Methods Initiative requires researchers to critically evaluate whether animal research is necessary or if alternative methods, such as organoids and computational models, would provide better insights for human health applications. This represents a shift from the routine use of animal models to research approaches specifically aligned with human biology. The Gold Standard Science Plan, implemented following a Presidential Executive Order, embeds scientific integrity across the NIH by requiring research to be reproducible, transparent, collaborative, interdisciplinary, skeptical, subject to unbiased peer review, and free from conflicts of interest. The centerpiece of this plan is a new Replication Initiative launching soon, which will support researchers specializing in replication studies, create a public journal for replication work, link replication results to original papers in databases like Medline, and reward scientists who facilitate replication through data sharing.

Dr. Bhattacharya presented research data demonstrating that early-career investigators are the primary drivers of new ideas in biomedicine, yet current systems create significant

barriers to their success. Fellowship recipients are dropping out at high rates, with over 50% leaving within three years of their awards. The median age for receiving the first major NIH grant has shifted from the mid-30s in the 1980s to the mid-40s currently, while multiple postdoc positions are now required before achieving independence. This extended training period is starving the biomedical research enterprise of the fresh perspectives and innovative approaches that early-career researchers typically provide.

To address some of these issues, he announced a unified grant funding strategy that represents a fundamental departure from rigid percentile-based funding toward strategic portfolio management. This approach moves beyond traditional pay lines, where funding decisions are based solely on scientific merit scores, instead considering strategic alignment with the Institute's missions and priorities. The new system emphasizes portfolio balance to ensure representation of new ideas and strategic opportunities, mission alignment by prioritizing proposals that match the Institute's strategic priorities, and workforce sustainability by supporting early-career researchers and innovative approaches. Supporting this policy shift, Dr. Bhattacharya presented research findings suggesting that NIH funding has become increasingly conservative over time (Packalen M, Bhattacharya J. *Proc Natl Acad Sci U S A*. 2020;117(22):12011-12016. doi:10.1073/pnas.1910160117). Data show that papers relying on newer ideas are less likely to receive NIH funding, while the average age of ideas in NIH-funded research has increased significantly. Non-NIH-funded research is more likely to explore cutting-edge concepts, suggesting that the current funding system inadvertently discourages innovation. This conservatism stems from risk-averse approaches that prioritize methodological certainty over transformative potential, resulting in a portfolio that yields reliable but incremental advances rather than breakthrough discoveries.

The comprehensive reforms aim to transform NIH from a volume-focused organization that measures success by publication counts and grant numbers to one that evaluates success based on portfolio-level health outcomes and real-world impact. This transformation involves balancing proven methodologies with promising new approaches, supporting the next generation of researchers who bring fresh perspectives to entrenched problems, and ensuring the reliability of the scientific foundation underlying medical advances. The overarching goal is creating a research ecosystem capable of effectively addressing America's chronic disease burden through innovative, reproducible, and strategically aligned scientific investments that can translate discoveries into meaningful improvements in population health.

Council Questions and Discussion
Dr. Rodgers, moderator

Dr. Bhattacharya provided recorded remarks and Dr. Rodgers responded to the Council's questions.

Comment from Council: How prepared is NIDDK to follow up on some of these initiatives, such as aligning projects with Institution priorities, and how would the Council be integrated into that work?

Dr. Rodgers stated that, while not every NIH Institute publishes a payline, NIDDK has typically published a payline, after the full year budget is passed. NIDDK does not

though make funding decisions solely based on a payline. In our annual FebDoc report, NIDDK has published distribution histograms showing competing R01 applications and competing awards by percentile score. The data show that there are some R01 applications with percentiles in the single digits that didn't get funded, while some others in the 30th percentile range that were funded. NIDDK makes programmatic decisions that consider but are not always strictly based on the payline. NIDDK has a strategic planning document from 2021 that is regularly updated and scored according to these objectives. NIDDK supports young researchers by providing early-stage investigators with a 10-point scoring advantage on their first grant applications and offering additional funding support when they resubmit renewals of their initial grants. He also noted that all review branches have been consolidated within the Center for Scientific Review, and it will take time for the new study sections to establish their reviewing culture and scoring standards for different types of science.

Comment from Council: (1) Who will be responsible for establishing the strategic initiatives, and (2) why would applications that don't align with existing strategic initiatives be allowed to go through the entire review process instead of being screened out earlier to avoid wasting time and resources?

Dr. Rodgers agreed that while peer review and secondary review by the Council should remain the primary factors in decision-making (carrying the most "weight"), other considerations may also be considered. These additional factors would have less influence but should still be considered in consultation with program staff, division directors, and Council input, particularly when dealing with special Council actions. He acknowledged that this is an ongoing process.

Comment from Council: How will NIH implement a funding mechanism that balances the need for reproducibility research (including confirmatory studies that haven't been historically prioritized) with innovation priorities, and what will be the actual decision-making structure; will program directors have final authority as Dr. Bhattacharya suggested, or will there be an additional layer of oversight from the Office of the Director?

Dr. Rodgers responded that he would share these concerns with leadership. He clarified that decision-making generally remains within individual Institutes, with the NIH Director only involved in joint initiatives. Specifically, the rigor and reproducibility initiative will be funded through the Common Fund (approximately $500 million controlled by the Director), where Institutes provide input, but the Director makes final decisions. Dr. Rodgers agreed that there's a potential inherent conflict between promoting innovation and ensuring rigor and reproducibility and will forward these concerns to the appropriate parties.

Comment from Council: There were two concerns mentioned: (1) how will academic researchers doing reproducibility studies advance their careers when novel research is traditionally valued for promotions, and (2) if pay lines are no longer the primary funding driver of decisions, the second review may be more critical since decisions won't be based solely on scientific scores but will need to balance scientific merit with feasibility and critical priorities.

Dr. Rodgers commented that this is an interesting point and that reproducibility initiatives require a fundamental culture change in academia. Currently, universities prioritize novel discoveries for tenure and promotion, but if we want researchers to specialize in reproducibility work, institutions must recognize this as equally valuable for career advancement. Until academic departments develop evaluation criteria that give "reproducibility experts" equal standing with those making clinical or fundamental science breakthroughs, it will be challenging to attract top researchers to this field, regardless of the availability of NIH funding.

Comment from Council: The proposed second layer of funding decisions, based on Institute mission alignment, must maintain transparency by providing scientists with clear explanations and guidance; otherwise, researchers will be unable to effectively steer their work toward strategic priorities.

Dr. Rodgers said that this was an insightful economic point about marginal decision-making. Rather than completely overhauling the current system, the proposed changes likely involve slight adjustments, where traditionally fundable applications continue to be funded based on scientific merit, but decisions at the funding margins incorporate strategic mission alignment alongside scores. This approach would preserve the transparency and scientific rigor of peer review while allowing program flexibility to prioritize certain research areas when choosing between similarly scored applications. This marginal effect model seems more feasible and transparent than completely abandoning scientific scoring as the primary funding criterion.

Comment from Council: This proposed approach mirrors the Department of Defense's established model, particularly the Congressionally Directed Medical Research Programs dual-review system, where grants undergo peer review, followed by programmatic review for strategic alignment and prioritization. CDMRP reviews could serve as a valuable resource for NIH implementation, as they have successfully operationalized this process.

Dr Rodgers will pass along the CDMRP feedback to Dr. Bhattacharya, noting that since this dual-review system has been operational for some time, there should be data on its effectiveness.

Comment from Council: There was a question on whether there would be an opportunity to submit additional questions to Dr. Bhattacharya for future response.

Dr. Rodgers suggested that Karl Malik collect questions from Council members to send as a batch to Dr. Bhattacharya, although there is no guarantee when he will respond due to his busy schedule. He also encouraged members to send any specific questions they would have asked if he had been present.

Comment from Council: How will the review process address cross-disciplinary research that spans multiple Institute missions, given that science is increasingly moving into gray areas that don't fit neatly within traditional institutional boundaries?

Dr. Rodgers recognized that this was a valid concern about cross-disciplinary research and mission boundaries, noting that he cannot provide a specific answer or speak for Dr.

Bhattacharya, but suggested formulating it as a question to be included in the batch of inquiries being collected and forwarded to him.

VII. COUNCIL WORKING GROUP UPDATE

Dr. Cefalu

Dr. Cefalu provided an update on the report, Pathways to Health for All, from the Working Group of the NIDDK Advisory Council. The final report was complete and provided to Council before the meeting. The NIDDK Advisory Council approved the creation of a new Working Group of the Council (WGOC) in January 2023 to examine the understanding of diabetes heterogeneity. This was based on the fact that significant heterogeneity exists in diabetes within countries and across the globe and that multiple metabolic pathways that contribute to the risk of diabetes are not captured in current definitions of diabetes. The current classification system is inadequate, with a major limitation being its reliance on a single clinical marker (i.e., elevated glucose) for the diagnosis and management of the disease. The goal for the working group was to provide recommendations and research opportunities across all phases of research to fully elucidate the understanding of heterogeneity of diabetes. A better understanding of the pathophysiology of the heterogeneity will aid in future reclassification efforts and move the field towards precision medicine (Franks PW, et al. *J Clin Endocrinol Metab*. 2025;110(3):601-610. doi:10.1210/clinem/dgae844).

The steering committee created five separate subgroups: Engagement, Pre-clinical, Clinical, Innovation, and Lifestyle. Two additional cross-cutting theme subgroups, "Health for All" and "Data Science," were added. Two additional cross-cutting themes may be added later: partnerships and cost-effectiveness. These groups worked on the report for over two years.

Each group provided broad recommendations. For example, the pre-clinical subgroup recommended increasing the genetic diversity of animal and human models to study diabetes and making these available through repositories that are accessible to the research community. Under this broad recommendation, additional opportunities are described. Other recommendations included standardizing and benchmarking assays widely used for metabolic phenotyping, as well as characterizing diabetes-related tissues from the same individuals and benchmarking them against human induced pluripotent stem (IPS) cell models. The last recommendation is already receiving funding through administrative supplements.

The innovation subgroup recommended advance research to increase understanding of the diagnostic, prognostic, and therapeutic value of individual continuous glucose monitoring profiles in individuals with or at risk of dysglycemia. Another recommendation was to develop strategies to elucidate the clinical relevance of molecular biomarkers for understanding the heterogeneity of type 2 diabetes. Lastly, to promote research using wearable technologies for real-time monitoring of behavioral and physiological parameters to understand the heterogeneity of diabetes.

This effort took 33 months and included 50 investigators from 12 countries who participated as subgroup Chair/Co-Chairs or subgroup members. Over 27 NIDDK program staff participated as Program Leads, subgroup members, and Program Analysts.

The five subgroups provided 25 broad recommendations and 107 specific research opportunities. The two cross-cutting focus groups provided nine broad recommendations and 34 research opportunities. These opportunities have varying timelines, with some already being implemented, others under consideration, and some long-term opportunities that may take several years to develop. Many of the opportunities will depend on the success of the early projects, with the efforts lasting through the next 10 to 15 years.

Dr. Cefalu introduced a proposal to establish an External Evaluation Panel for the Collaborative Islet Transplantation Registry (CITR).

External Evaluation Panel Review of the Continuation of the CITR
Dr. Thomas Eggerman

The CITR has collected comprehensive data on islet transplantation for type 1 diabetes treatment over the past 25 years, documenting procedures from 47 sites, including islet allografts, auto-transplantation, and pancreatectomy outcomes across diverse patient populations. Despite advances in transplantation techniques and immunosuppressive protocols, type 1 diabetes remains a chronic, severe disease requiring lifelong insulin therapy, with traditional islet transplantation activity declining significantly while newer approaches emerge. The field lacks standardized integration of rapidly advancing diabetes monitoring technologies and predictive biomarkers for transplant success, remission, and long-term outcomes. The landscape is quickly evolving with the success of stem-cell-derived islet transplantation trials utilizing immunosuppression, promising gene-edited islet approaches without immunosuppression, and the transition from academic-only research to commercial entity involvement, creating complex challenges in data standardization and collaboration frameworks. This initiative seeks guidance from an External Expert Panel to renew CITR's mission by leveraging technological advances in diabetes monitoring and emerging transplantation methodologies to develop integrated data collection strategies and collaborative frameworks, to advance precision medicine for all diabetes patients. To achieve these goals, CITR will build on its extensive registry data from 23 active sites across North America, Europe, and Australia, and establish optimal approaches for integrating traditional and innovative transplantation strategies while fostering collaboration between academic investigators and commercial entities in this rapidly evolving field.

Council Questions and Discussion
Dr. Rodgers, moderator

Comment from Council: There was a question about how much industry relies on data from CITR and how NIH could leverage this reliance into something that can be monetized.

Dr. Eggerman replied that there already is a fee to access the CITR data. CITR is also interested in including data from industry, particularly the results of stem-cell transplants and gene therapy, to help inform the broader community. Nothing is definite yet, but talks are ongoing with various companies.

There being no further questions or comments from the Council, Dr. Rodgers proceeded to request a motion for concurrence in establishing an External Evaluation Panel for the CITR. The motion was made and seconded and approved by Council vote.

VIII. CONCEPT CLEARANCE

Dr. Rodgers then turned to Concept Clearance by Council, a step required before Institutes and Centers (ICs) can publish notices of funding opportunities. To streamline this process, summaries of the concept were supplied to Council members for their review prior to the meeting. Cleared concepts will be made publicly available on the NIDDK website. He then introduced each speaker.

Support Services for the Epidemiology Coordinating Committee
Dr. Jean M. Lawrence

This current NIDDK-wide initiative provides support services for the Epidemiology Coordinating Committee activities pertaining to the development and analysis of public health surveillance data for NIDDK-related topic areas. The epidemiology support services contractors, under the supervision of NIDDK Program Directors, support the publication of data collected by the National Center for Health Statistics (NCHS) for original scientific research on NIDDK diseases, including the occurrence, risk factors, natural history, prevention, management, and public health implications. Additionally, the Support Services for the Epidemiology Coordinating Committee initiative will cover the development and publication of two major compendia on the epidemiology and burden of NIDDK diseases, Diabetes in America, published in 1984, 1995, 2018, and 2023- present, and the Burden of Digestive Diseases in the United States, published in 1994, 2008, and currently in preparation. Publication of content for these compendia are planned for the next 5-year contract to accompany public health surveillance data releases in diabetes, physical activity, nutrition, body composition measures informing obesity research, and digestive diseases. Funds from this initiative will also support the acquisition and maintenance of several data sources used for these publications.

Renewal of the NIDDK Inflammatory Bowel Disease Genetics Consortium (IBDGC)
Dr. Ludmila Pawlikowska

The NIDDK IBDGC has led international efforts resulting in the identification of >300 inflammatory bowel disease (IBD) risk loci across different patient populations and the characterization of underlying biological mechanisms. Despite advances in biological understanding and the development of a range of biologic therapies, IBD remains a chronic, severe and heterogenous disease with no cure and a need for multiple medical interventions over the life course. Diagnostic biomarkers and accurate predictors of critical outcomes such as disease remission, recurrence, and response to specific therapies are lacking. Identification of as many sources of biological variance in disease as possible is necessary to fully understand the interactions of environmental and genetic effects in the disease course, and to integrate these interactions in predictive models. This initiative seeks to renew the NIDDK IBDGC with a continued mission to leverage advances in biological understanding and data science towards development of disease predictors and biomarkers with the goal of improving medical management and advancing precision medicine for all IBD patients. Toward these goals, the IBDGC will build on extensive

patient cohorts enrolled across the US, banked biospecimens and advances in molecular analysis and data science, and continue follow up and enrollment of IBD patients into longitudinal studies and mechanistic studies in biospecimens and experimental models.

Limited Competition: Continuation of the Physiology of the Weight Reduced State Study (POWERS)
Dr. Mary Evans

The purpose is to issue a request for application (RFA) for the competing continuation of the Data Coordination Center of the POWERS clinical trial consortium, to complete the clinical trial and conduct limited discovery research using biospecimens. POWERS is focused on elucidating the metabolic, behavioral, and molecular mechanisms underlying individual variability in maintenance of reduced weight following weight loss. The POWERS study was originally awarded in 2021 with the requirement to collect biospecimens (blood, urine, feces, muscle and adipose tissue), but the funding for analysis of these specimens was not included.

Continuation of the NIDDK Consortium to Investigate Gastrointestinal Disorders of Interoception in Children and Adults
Dr. Patricia Shea-Donohue

A major accomplishment of the Gastroparesis Clinical Research Consortium (GpCRC) was the creation of a large database with information on patients with symptoms of either delayed or normal gastric emptying. The GpCRC had the foresight to include pediatric patients with gastroparesis forming the first comprehensive registry of children and adolescents with gastroparesis in the US. The GpCRC conducted four clinical trials providing clarity and insight in our understanding of gastroparesis, but the symptoms of greatest concern to patients continue to have inadequate treatments. Gastroparesis, irritable bowel syndrome, and functional dyspepsia are among the gastrointestinal (GI) motility disorders associated with shared symptoms including nausea, vomiting, and altered bowel habits. These symptoms have poor specificity, little correlation with functional changes, and overlap with other GI conditions. Recent NIDDK-sponsored workshops identified altered GI interoceptive awareness and processing as characteristic of these motility disorders. This continuation initiative will realign research priorities to concentrate on the mechanisms underlying patient symptoms and new interdisciplinary research opportunities to focus on GI disorders associated with impaired interoception in adults and children. The collaborative effort will lead to the discovery of cellular and molecular mechanisms of interoceptive signaling in the gut and accelerate progress towards more effective therapies.

Continuation of the CITR
Dr. Thomas Eggerman

The CITR began in 2001 after the successful “Edmonton Trial” in 1999. It has pooled data from 47 programs. Through 2025, there were 1,517 allograft recipients, 1,363 autograft recipients and 3,557 islet preparations in its databases. CITR prepares comprehensive periodic reports about every two years on allograft islet transplantation and another on autoislet transplantation after pancreatectomy. The latter had its first report in 2018 and a third is planned for 2025. Additional data are now beginning to be

collected on pancreatectomy patients who do not receive islet auto- transplantation to allow a safety and efficacy comparison with islet autografts. The CITR islet transplantation data this cycle will have been presented at five international meetings by summer 2025. Two virtual international CITR meetings will have been held, one in 2022, another in 2025. These meetings provide a forum for islet transplantation investigators and coordinators to meet and compare approaches and provide guidance on problems occurring at their sites. Key results from islet efforts are also provided via annual reports and in peer-reviewed publications stemming from specific data analysis of registry information. Licensure of human islets occurred in 2023 and is expected to increase islet transplantation activity in the US. As allograft islet transplantation will no longer be considered an experimental therapy, it is important that CITR monitor results to ensure continued safety and efficacy.

Continuation of the Cardiovascular Biorepository for Type 1 Diabetes (CARE-T1D) - Resource Center (Limited Competition)
Dr. Teresa Jones

Individuals with type 1 diabetes have a 2- to 4-fold higher risk of cardiovascular disease (CVD) compared to the general population. The mechanisms driving elevated risk are complex and multifactorial with critical gaps in understanding how risk factors, such as hyperglycemia, dyslipidemia and inflammation, interact to promote CVD in type 1 versus type 2 diabetes. NIDDK, in partnership with National Heart, Lung, and Blood Institute (NHLBI), created the Cardiovascular Biorepository for Type 1 Diabetes (CaRe-T1D) program in 2022 to better understand the pathogenesis of CVD for type 1 diabetes and the differences with type 2 diabetes. CaRe-T1D established a biorepository from organ donors with type 1 diabetes, type 2 diabetes or no diabetes that includes heart, kidney and arterial tissue that are annotated with careful clinical phenotyping. The tissue undergoes thorough quality control procedures and characterization with imaging for vascular calcification and microscopic evaluations. In 2024, investigative teams were added to the consortium and began performing hypothesis-driven research with CaRe-T1D resources. The renewal of the CaRe-T1D Resource Center will support research that will continue to leverage the outstanding infrastructure that has been built during the first grant cycle and will drive groundbreaking discoveries to foster the development of novel, targeted therapies for CV and renal diseases in type 1 and type 2 diabetes.

Council Questions and Discussion
Dr. Rodgers, moderator

Comment from Council: There was a question on whether the islet collection discussed in the concept clearances was similar to the earlier presentation on CITR.

Dr. Eggerman replied that the first presentation requested an expert panel review of all current changes, whereas this one is a concept clearance presentation for renewing and continuing the registry.

Comment from Council: The POWERS study excludes GLP-1 users, but since roughly 90% of weight regain involves people coming off these medications, is there any way to adapt the study to include them, given that the mechanism is likely not fundamentally different?

Dr. Evans replied that the POWERS study was launched before the wide availability of GLP-1 agents. The study design and procedures are already established, so the study needs to be completed as designed. However, this raises an excellent point: the same mechanisms likely apply broadly, and the findings could translate to people using those drugs. This suggestion is currently under active discussion within NIDDK and the research community, although the current study cannot be modified.

Comment from Council: Is tissue collection from the type 1 diabetes study only available to sites participating in the Consortium, or can researchers from the broader scientific community also obtain tissue samples?

Dr. Jones said that researchers can now access samples and data from this study through an ancillary study application process. Application information is available on the website, and submissions from the broader scientific community are welcome. This approach helps maximize the value of research investments by making resources available beyond just the original study sites.

Comment from Council: Given the success of the NIDDK IBD genetics consortium and the current limits on discovering new genes with significant effect sizes, what is the next phase or next generation of this program? Additionally, how many requests for access to tissues, samples, and data is the consortium receiving, and how is this benefiting the broader research community?

Dr. Pawlikowska replied that while significant progress has been made in understanding the genetic underpinnings of IBD, the consortium is pivoting in its next cycle toward studying factors and biomarkers for disease course and progression. This represents a separate but overlapping set of questions where very little is currently known. Researchers are now prioritizing the prediction of heterogeneous outcomes in Crohn's disease, such as clinical course and treatment response, over causal mechanisms, adopting strategies proven effective for diabetes and other common conditions.

Regarding the second question, the consortium has deposited genetic information in the database of Genotypes and Phenotypes (dbGaP) through the NIDDK repository, and both data and biospecimens have been utilized by ancillary studies within the consortium as well as by the broader research community. However, specific numbers on requests and usage aren't immediately available, but that information can be provided separately.

Comment from Council: How do you envision translating this research into community-based initiatives that can reach neighborhoods, barrios, and rural communities?

Dr. Rodgers stated that this aligns with the NIDDK's 2021 strategic plan, which emphasizes enhanced community participatory efforts that have already begun to be implemented, particularly in kidney disease research. We've adopted the principle "nothing about us without us," which recognizes that patient-involved research often identifies different priorities than investigators initially consider. Increasing community involvement in understanding and participating in research is a key strategic direction for the NIDDK, with updates on these activities potentially available during the sub-council meeting.

The CARE for Health initiative targets rural and historically underrepresented communities to conduct community-driven research studies. It focuses on federally qualified health centers and aims to involve communities in research they want to participate in.

There being no further questions or comments from Council, Dr Rodgers proceeded to request a motion for concurrence with the concepts presented. The motion was made and seconded and the concepts approved by Council vote.

IX. 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.

X. 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 1041 grant applications (349 primary and 692 dual), requesting support of $445,901,434 were reviewed for consideration at the September 17, 2025, meeting. An additional 149 Common Fund applications requesting $187,096,239 were presented to Council. Funding for these applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, 1280 applications requesting $542,393,645 received second-level review through expedited concurrence. All of the expedited concurrence applications were recommended for funding at the Scientific Review Group recommended level. The expedited concurrence actions were reported to the full Advisory Council at the September 17, 2025 meeting.

XI. EXECUTIVE CLOSED SESSION OF THE COUNCIL

XII. 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 230th meeting of the NIDDK Advisory Council was adjourned at 3:15 p.m. on September 17, 2025.

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

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Date

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