229th 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 Meeting - Held virtually using web-based collaboration/meeting tools

I. CALL TO ORDER and ANNOUNCEMENTS
Dr. Griffin Rodgers

Dr. Griffin Rodgers, Director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), called the 229th meeting of the NIDDK Advisory Council to order at 3:00 p.m. on June 17, 2025. The meeting was held virtually and conducted using a two-tiered webinar format. The panelist tier included NIDDK Advisory Council members and NIDDK staff members who were present during the meeting. The audience tier was available via a live stream to the public, allowing them to view and listen to the meeting.

This was the second of two meetings scheduled to consider applications assigned to NIDDK for the May 2025 Council round, focusing on those applications that did not have a summary statement available in time for the meeting held on May 14. Dr. Rodgers thanked Council members for their flexibility with the frequently held meetings over the past few months. He also thanked the NIDDK staff who worked extremely hard to manage operations and work through some systematic complications and associated workload challenges because of having multiple Council meetings in a compressed time frame.

ATTENDANCE – COUNCIL MEMBERS PRESENT

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

Ex-officio Members:
Dr. David D'Alessio
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

Council Member News

Dr. Rodgers recognized two Council members who fulfilled their extended term of service: Dr. Keith Norris and Dr. Philipp Scherer. He thanked them for continuing their service on the Council.

NIDDK 75th Anniversary

Dr. Rodgers reminded attendees that NIDDK is celebrating its 75th Anniversary this year. He played a video titled "Advancing Research and Health for All: NIDDK Supports Research Across America," which highlights the extramural research NIDDK supports.

II. CONSIDERATION OF SUMMARY MINUTES
Dr. Griffin Rodgers

The Council approved, by a show of hands and a verbal vote, the Summary Minutes of the 227th Council meeting, which had been sent to members in advance for review.

III. FUTURE COUNCIL DATES
Dr. Griffin Rodgers

As noted previously, Dr. Rodgers informed the Council that the next meeting of the NIDDK Advisory Council is scheduled for September 17, 2025. It has not yet been decided whether this meeting will be in-person, hybrid, or virtual only. Updates about future meetings will be posted on the Council website.

IV. ANNOUNCEMENTS
Dr. Karl Malik

Confidentiality

Dr. Malik said that 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. 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.

V. CONCEPT CLEARANCE
NIDDK Staff

Dr. Rodgers then turned to Concept Clearance by Council, a step required before Institutes and Centers 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.

Renewal of KPMP/KPMI - Kidney Precision Medicine Project
Dr. Debbie Gipson

The KPMP was started in fiscal year (FY) 2017 with the vision to safely and ethically collect and interrogate human kidney biopsy tissue to discover novel molecular pathways that promote chronic kidney diseases or acute kidney injuries. It was expanded in FY 2022 to enhance participant recruitment and tissue interrogation. Consistent with the recommendation of an External Evaluation Committee (2/14/2025), the NIDDK proposes to extend the KPMP for 5 years. This extension will allow the KPMP to (1) honor its commitment to existing enrollees (~500) by continuing robust longitudinal clinical

molecular interrogation and follow-up, and (2) accelerate the discovery and validation of novel pathways, targets, and disease subgroups by directly supporting the efforts of the broader research community to fully leverage KPMP data.

Renewal of Diabetes Research Centers (DRCs)
Dr. Christopher Lynch

This is a proposal to extend the Congressionally mandated DRC program that has been a prominent catalyst of diabetes research across the country for over 45 years. In 2024, seventeen centers were supported by the program with a FY 2025 budget of ~$27M (total costs). The DRCs promote new discoveries and enhance scientific progress through supporting cutting-edge basic and clinical research biomedical cores for diabetes research, strategies to increase and enhance collaboration and Pilot and Feasibility (P&F) grant programs aimed at elucidating the etiology and complications of diabetes, endocrine and metabolic disorders.

The DRCs are a key component of the overall NIH/NIDDK plan to improve health of Americans with diabetes and related endocrine and metabolic disorders. They are intended to improve the quality and multidisciplinary nature of research on diabetes by providing shared access to specialized and technical resources and expertise. DRCs facilitate progress in research with the goal of developing new methods to treat, prevent and ultimately cure diabetes mellitus and its complications. The centers have a proven track record of increasing cost-effective collaboration among multidisciplinary groups of investigators at institutions with an established, comprehensive research base in diabetes and related areas of endocrinology and metabolism.

New Generation of Type 1 Diabetes Control Technologies Incorporating Artificial Intelligence/Machine Learning Tools/Strategies
Dr. Guillermo Arreaza-Rubín

The purpose of this proposal is to support research addressing barriers that limit progress toward more effective open- and closed-loop diabetes control systems. This may include research that addresses: 1) innovation of sensing relevant analytes/physiologic signals; 2) novel formulation and delivery of hormones; 3) artificial intelligence (AI)/machine learning (ML)-driven tools/algorithms; and 4) digital twin modeling to augment decision support and automated control systems with the goal of improving glycemic control, reducing burden of care, and enhancing quality of life of people with type 1 diabetes (T1D).

Council Questions and Discussion
Dr. Rodgers, moderator

Comment from Council: *A Council member expressed gratitude to NIDDK for facilitating the KPMP project that has significantly impacted the kidney research community by providing helpful resources and insights that have led to new treatments for specific diseases.*

Comment from Council: *What is the target size for the KPMP collection, or will it simply grow as new resources become available?*

Dr. Gipson responded that the target is around 1,000 to 1,200 patients, with sufficient participants in each subgroup (chronic kidney disease, acute kidney injury, with or without diabetes) to enable meaningful precision medicine research and reliable results for specific disease pathways.

Comment from Council: *How satisfied are you with the demographic variety of the samples and how well they represent the at-risk patient populations for these disorders?*

Dr. Gipson said that the demographic variety is strong overall and that the chronic kidney disease population represents typical patients (late 50s-60s) and includes good urban/rural and ancestry variety across multiple sites, though it's currently limited to adults; the acute kidney injury cohort trends younger as expected for that condition.

Comment from Council: *Diabetes P30 centers are much larger with 10 to-200 members—is this intentional growth or a strategic design difference?*

Dr. Lynch replied that the growth to 100 to 200 members isn't an intentional policy; it's happening naturally rather than being mandated by the request for applications. Each center receives approximately $1 million annually, with opportunities for additional funding through regional initiatives, such as regional cores, the Regional P&F Grant Program, or national enrichment programs.

Comment from Council: *Are the regional cores based within a single DRC that then provides specialized services to outside communities?*

Dr. Lynch noted that regional cores vary, with some DRCs expanding statewide to collaborate with multiple universities (such as one covering all North Carolina institutions), while others share specialized resources across states (for example, Penn's DRC utilizes a metabolomics core in New Jersey). Expansion typically aims to broaden research collaboration and resource sharing.

Comment from Council: *Will the technologies developed for patients with (T1D) through this program have potential applications in other disease areas or research fields?*

Dr. Arreaza-Rubin responded that the core components, machine learning algorithms, neural networks, and closed-loop system strategies, could be adapted to other conditions requiring sensor-based monitoring, controllers, and automated delivery systems. However, each disease would need condition-specific customization of the basic framework.

Comment from Council: *There was a suggestion to expand the technology to type 2 diabetes, noting that two companies have already published data on this application, ongoing research is happening, and type 2 patients could benefit from and are already using these devices.*

Dr. Arreaza-Rubin explained that the focus is on type 1 diabetes because the Special Diabetes Program is limited to type 1, but they plan to expand coverage to include type 2 diabetes as well.

Comment from Council: *How does NIDDK determine when research shifts from their responsibility to industry's, particularly as work moves into applied areas with commercial potential, and where NIDDK draws the line between continued support and expecting industry takeover?*

Dr. Arreaza-Rubin stated that the NIDDK collaborates with both large and small industry players, supporting basic academic research that serves as the foundation for current sensor devices and integrated systems. NIDDK focuses on supporting academic innovators who attract industry attention, while also directly collaborating with companies on clinical trials that lead to device approvals.

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

VI. CLOSED SESSION OF THE SUBCOMMITTEE MEETINGS

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

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 FULL 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)(c)(4) and 552(b)(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 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 232 grant applications (21 primary and 211 dual), requesting support of $129,846,376 were reviewed for consideration at the second May Council meeting (held on June 17). An additional 594 Common Fund applications requesting $ 193,034,964 were presented to Council. Funding for these applications was recommended at the

Scientific Review Group recommended level. Prior to the Advisory Council meeting, 237 applications requesting $117,195,272 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 second May Council meeting on June 17.

VIII. 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 229th meeting of the NIDDK Advisory Council was adjourned at 5:00 p.m. on June 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