231st 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 231st meeting of the NIDDK Advisory Council at 1:00 p.m. on January 28th, 2026, 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

Ms. Patricia Birsic
Dr. Arthur Burnett
Dr. John Carethers
Dr. Lilia Cervantes
Ms. Neicey Johnson
Ms. Davida Kruger
Dr. Jacquelyn Maher
Dr. Aylin Rodan
Dr. Philipp Scherer
Dr. Elizabeth Seaquist
Dr. Hunter Wessels

Ex-officio Members:
Dr. David D'Alessio
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

Dr. Rodgers reminded Council members that after the last Advisory Council meeting in September, there was a lengthy government shutdown. The shutdown had a substantial impact on NIH peer-review operations, resulting in the cancellation of many peer-review meetings and a substantial backlog of work. It will take some time to recover from this backlog. As a result, only a subset of applications received for the January 2026 Council

round were reviewed in time to have summary statements available for Council's consideration. Therefore, a "catch-up" Council meeting is tentatively planned for March 11, 2026, to consider the remaining applications that were submitted for the January 2026 Council round, which did not have summary statements available in time for today's meeting.

As with the January Council-round business, the plan is to hold the May Council meeting on May 13, 2026, in person as scheduled. However, not all applications received for the May 2026 Council-round will be reviewed in time to have summary statements available for the May 13, 2026, meeting. Therefore, a "catch-up" meeting for the May 2026 Council round is planned for early July. The NIDDK Advisory Council webpage will provide information as meeting plans are finalized.

II. CONSIDERATION OF SUMMARY MINUTES

Dr. Griffin Rodgers

The Council approved, by a show of hands and verbal vote, the Summary Minutes of the 230th Council meeting, which had been sent to members in advance for review.

III. FUTURE COUNCIL DATES

Dr. Griffin Rodgers

As noted previously, Dr. Rodgers told Council that NIDDK is working through the details to schedule a brief Council meeting on March 11 to consider remaining grant applications from the January round that did not have summary statements available in time for the January meeting. The March 11, 2026, meeting will be virtual and will likely be from 1-2 p.m. EDT. After the March 11 meeting, the next Council meeting is scheduled for May 13, 2026, and is planned to be held in person. The in-person portion of the May Council meeting will be held on the NIH main campus, in Building 31, C-Wing, 6th Floor Conference Center.

There will be a "catch-up" meeting for May Council-round applications that were not reviewed in time to have summary statements available for the May 13, 2026, Council meeting. A virtual "catch-up" meeting is planned for early July.

Finally, there were several policy and process changes in place over the past several years that substantially reduced the need to hold the October Council-round meeting "early" in September. NIDDK can leverage alternative strategies to manage the few "late in the fiscal year" Council review actions that are needed. The logistical challenges and burden of scheduling and holding Council meetings in September now outweigh the benefits. Given these considerations, the plan is to hold the October Council-round meetings in October rather than in September. NIDDK plans to implement this adjustment starting this fall by rescheduling the September 9th Council meeting to Wednesday, October 28, 2026. Council members were advised to put a tentative hold on their calendars and to monitor the NIDDK Advisory Council webpage, which will be updated as the planned meeting dates are finalized.

IV. 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.

Annual Approval of Council Operating Procedures

During its winter meeting each year, the NIDDK Council approves the Council Operating Procedures, which were included for Council review in the pre-meeting materials in the Electronic Council Book. The Council Operating Procedures proposed for 2026 include

minor updates to the 2025 Procedures: active dates were adjusted, and the section on Council advice was revised to align with current practice.

Dr. Malik asked for questions or comments regarding the Council Operating Procedures for 2026, and there being none, called for a motion for concurrence. The Council concurred, by a show of hands and verbal vote, with the Council Operating Procedures for 2026.

V. COUNCIL WORKING GROUP UPDATE

Dr. Will Cefalu, Dr. Yan Li, and Dr. Teresa Jones

Dr. Yan Li provided a presentation on the request to establish an external evaluation panel (EEP) working group of Council. Diabetic foot ulcers represent a major public health and clinical burden. Each year, up to 1.6 million people are diagnosed, resulting in over 100,000 amputations due to non-healing or infected diabetic foot ulcers. People with diabetic foot ulcers face long-term treatments, non-healing ulcers (20-30%), and a 60% risk of infection. Around 20% of infected diabetic foot ulcers ultimately require amputation. Additionally, the 5-year mortality rate of diabetic foot ulcer-related amputations may be comparable with mortality from all cancers.

In response to this burden, the NIDDK established the first national network dedicated to clinical research on diabetic foot ulcers with the mission of improving treatment of diabetic foot ulcers and preventing amputations among the 38 million Americans with diabetes. During the first funding cycle (2018-2022), the NIDDK Diabetic Foot Consortium (DFC) focused on building infrastructure to facilitate high-quality clinical research and developing biomarkers for use in clinical care and research. During the current funding cycle (2023-2027), the DFC focused on expanding the clinical network, continuing the biomarker development and validation, studying social drivers, enhancing community engagement, and supporting early-stage investigators with training.

The DFC has built a comprehensive national infrastructure, including eight clinical sites, multiple biomarker analysis units, and the biorepository and data coordinating center. In 2023, the consortium launched a master protocol platform with broad entry criteria guided by the principle that no patient with diabetic foot ulcers goes unstudied. Enrollment has exceeded 740 participants, aligned with the demographics of Americans with diabetic foot ulcers. The consortium has collected and shared extensive clinical and social data, wound and radiologic imaging, and biospecimens. The DFC has also expanded the database to include omics data. They also advanced biomarker studies for diabetic foot ulcer healing and recurrence.

Given the consortium's scope and progress, NIDDK seeks Advisory Council approval to convene an EEP for this program. The panel would provide an objective assessment of the DFC's accomplishments, progress, and proposed plans to inform decisions on the potential third funding cycle, starting in 2028. The EEP Report will be presented to and discussed with the Council to guide next steps. The evaluation is planned for Spring 2026 with a report delivered at the May Council meeting.

Council Questions and Discussion

Dr. Rodgers, moderator

Comment from Council: *How many people will be on this external panel, and where are they drawn from?*

Dr. Cefalu responded that the EEP will consist of five to six external panel members plus a chair. The DFC will review progress through a formal presentation (1-1.5 hours), followed by an open Q&A session and a closed deliberation. The panel will include experts in complications, biostatistics, and bioinformatics, as well as members who are well versed in clinical trials and research networks but not involved in foot ulcer research or with the project who can provide fresh, unbiased perspectives. Additionally, specialists in foot ulcer research and care, clinical trials, and multi-center consortia will offer guidance on future directions.

Comment from Council: *What process will be used to recruit panelists?*

Dr. Cefalu said that the selection process is internal, drawing on program staff recommendations to identify both subject matter experts in the relevant areas and qualified evaluators with the necessary expertise to assess the work objectively. There was no external request for this review; rather, it's standard practice for any program reaching the 10-year mark to undergo an external evaluation. This ensures informed decisions about proposed aims and provides clear guidance for moving forward.

VI. CONCEPT CLEARANCE

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

Renewal of Epidemiology of Diabetes Interventions and Complications (EDIC) (Renewal)
Dr. Jean Lawrence

The Diabetes Control and Complications Trial (DCCT, 1983-1993) compared intensive (aimed at near-normal glycemia) and conventional therapy in 1,441 participants with T1D, with a mean follow-up of 6.5 years. Results reported in 1993 demonstrated that intensive therapy (mean HbA1c ~7%) reduced the risk of microvascular complications by 35-76% compared with conventional therapy (HbA1c ~9%). As a result, HbA1c <7% was adopted worldwide as the therapeutic target for T1D.

The EDIC (1994-present) study was initiated as an observational follow-up of the DCCT cohort. EDIC has shown that the early beneficial effects of intensive versus conventional therapy on complications persisted for ~10 years after HbA1c levels converged between the two groups. This observation has been termed “metabolic memory.” Prior intensive therapy was also shown to reduce the risk of severe microvascular complications, cardiovascular disease, mortality, and, recently, age-related outcomes including cognitive impairment, bone loss, and reduced mobility.

The DCCT/EDIC cohort is the most extensively studied T1D cohort in history. The participants have been followed and extensively phenotyped for 95% of their diabetes duration and 65% of their lifespan. Throughout its 40+ years, DCCT/EDIC has generated results that guide T1D treatment priorities and led to improved survival and quality of life for millions with T1D worldwide.

Continuation of the National K12 Program for the Career Development of Clinician-Scientists in Diabetes Research (DiabDOCS)
Dr. Hanyu Maggie Liang

The purpose of the DiabDOCS Program is to support the development of physicians committed to a career in diabetes research. The program thus far has supported early career endocrinologists and physicians from other specialties who conduct outstanding, innovative research into diabetes causes, consequences, and treatments. The continuation of the program maintains the organization of a single national program implemented by principal investigators, together with an advisory committee composed of basic and clinical investigators who have a strong record of funded research and successful training of physician-scientists. Although there will be one national administrative center awardee, scholars will be appointed and supported at their home institutions around the country. The program will continue its focus on Type 1 Diabetes (T1D) research with funding from the Statutory Special Diabetes Program. If available, additional funds will be provided for T2D research from NIDDK regular funds. The program is expected to continue to deliver on goals to increase the national representation of physician-scientists with independent research careers in the mission of NIDDK.

Rigor and Reproducibility for Biomarkers in Type 1 Diabetes Clinical Research
Dr. Salvatore Sechi

Despite significant advances in T1D research, there remains an urgent need for reliable, reproducible biomarkers that capture the complexity of autoimmune processes, metabolic dysregulation, and individual patient variability. The overarching goal of this initiative is to advance and facilitate the systematic identification, rigorous validation, and assay harmonization of protein/peptide biomarkers that are important in the prevention, diagnosis, and clinical management of T1D. For this purpose, the NIDDK plans to establish the “Rigor and Reproducibility for Protein/Peptide Biomarkers in Type 1 Diabetes Clinical Research (R2B-T1D)” consortium.

This consortium will leverage state-of-the-art methodologies in clinical chemistry, omics, immunophenotyping, and imaging, and electronic health record mining. Efforts will be devoted to 1) Continue the harmonization of established assays for biomarkers such as HbA1c and c-peptide; 2) Identify and validate other protein/peptide biomarkers that could be used for the prevention, diagnosis, and clinical management of T1D.

The assays for several biomarkers routinely used in clinical research are often not reproducible across platforms or laboratories. The R2B-T1D consortium will work toward having assays for all protein/peptide biomarkers routinely used in T1D clinical research, and for newly identified biomarkers, which are rigorously validated and assessed for reproducibility across laboratories following a metrology approach.

Council Questions and Discussion
Dr. Rodgers, moderator

Comment from Council: *Regarding the DiabDOCS program, what happens to the other 12 scholars in a cohort where 17 scholars are selected but only five receive permanent awards; do the remaining 12 lose eligibility, receive different forms of support, or move to other funding sources?*

Dr. Liang replied that those people would need to revise and resubmit. The number of slots has also increased over time.

Comment from Council: *For the DiabDOCS program, is the pipeline that would lead to that program still robust?*

Dr. Liang noted that the T32 is a strong program and that some people can apply directly for a K-Award at this level. However, some need more time to publish, etc., and the DiabDOCS program can help bridge that period. It can also strengthen the candidate's application for a K-Award. The program connects mentors and scholars from across the country, with primary hubs at Indiana and Stanford. This year, they are partnering with the Endocrine Society and will have their annual meeting at ENDO 2026. This will allow the DiabDocs program, including scholars, mentors and PIs, to engage about 100 additional physicians in training in endocrinology and introduce them to the DiabDOCS program.

Comment from Council: *While the DiabDOCS program is only available to those in the diabetes field, will it be available to other specialties in the future?*

Dr. Liang mentioned that the Division of Diabetes, Endocrinology and Metabolic Diseases (DEM) has had a similar program available to existing NIH grants, Administrative Supplements to Support Emerging Physician-Scientists to Develop Research Expertise in Diabetes, Endocrinology and Metabolic Diseases. Investigators with a funded DEM grant who had identified a candidate for promotion had the opportunity to apply for a supplement that covers the candidate’s salary for two years, similar to previous programs. Dr. Rodgers added that, regarding the generalizability of this program, each division has its own programs, and its training directors meet regularly to discuss successes and challenges.

Dr. Star noted that the Division of Kidney, Urologic, and Hematologic Diseases (KUH) has invested considerable time and resources in revitalizing the TL (formerly T32) program, enhancing it with new features applicable to various early-career stages. The team is also developing the KUH Family initiative to connect all training programs, including postdocs supported by R01s who are not officially in training programs.

Dr. James noted that for the Division of Digestive Diseases and Nutrition, many initiatives are underway and emphasized that all K programs are valued. The primary challenge lies in balancing limited funding with the number of strong, diverse K programs the division would like to support.

Comment from Council: *For the EDIC program, from a kidney-focused perspective, will you also be tracking kidney outcomes, and if so, which specific measures will you include?*

Dr. Lawrence responded that there is interest in continuing to track kidney outcomes. Although the specific measures have not yet been finalized, kidney outcomes are included.

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.

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 772 grant applications (582 primary and 190 dual), requesting support of $340,569,415 were reviewed for consideration at the January 28, 2026 meeting. An additional 0 Common Fund applications requesting $0 were presented to Council. Funding for these applications was recommended at the Scientific Review Group recommended level. 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 January 28, 2026 meeting.

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 231st meeting of the NIDDK Advisory Council was adjourned at 1:52 p.m. on January 28, 2026.

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

2/24/2026

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