227th 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

Meeting held virtually using web-based collaboration/meeting tools

I. CALL TO ORDER AND OPENING REMARKS Dr. Griffin Rodgers

Dr. Griffin Rodgers, Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), called to order the 227th meeting of the NIDDK Advisory Council at 4:30 pm on April 24, 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 presented during the meeting. The audience tier was available via a live stream to the public and allowed them to view and listen to the meeting.

The meeting focused on completing the remaining business from the January 2025 Council round and was brief.

Dr. Rodgers announced that the next meeting of the NIDDK Advisory Council, scheduled for May 14, 2025, would have a longer open session of the full Council to provide more time for announcements and a presentation from a working group of the Council. The May 14th meeting would begin the consideration of applications reviewed in the for the May 2025 Council round. However, Dr. Rodgers noted that not all initial peer review scores and summary statements for applications received for the May Council round would be available in time for the May 14th meeting. Because of this, an additional Council meeting in the late-June or early-July timeframe was being planned to complete review of the remaining applications for the May 2025Council round. The additional meeting date would be announced soon on the NIDDK Advisory Council webpage.

New Council Members

Dr. Rodgers welcomed nine new Council members who were joining the meeting as full members of the Council for the first time.

- **Dr. Jamy Ard** is a Professor of Epidemiology and Prevention at Wake Forest University. Dr. Ard will participate on the Division of Digestive Diseases and Nutrition Subcommittee.
- **Ms. Patricia Birsic** is a co-founder and on the Board of the National Pancreas Foundation. Ms. Birsic will participate on the Division of Digestive Diseases and Nutrition Subcommittee.
- **Dr. Richard Blumberg** is the Jerry S. Trier Professor of Medicine at Harvard Medical School and Chief of the Division of Gastroenterology, Hepatology and Endoscopy and Senior Physician in Medicine and Gastroenterology at Brigham and

Women's Hospital. Dr. Blumberg will participate on the Division of Digestive Diseases and Nutrition, Subcommittee.

- **Dr. Arthur (Bud) Burnett** is a Professor of Urology at Johns Hopkins University School of Medicine and on the Urology Care Foundation Board of Directors. Dr. Burnett will participate on the Division of Kidney, Urology, and Hematologic Diseases Subcommittee.
- **Dr. Lilia Cervantes** is a Professor in the Department of Medicine and the Director of Immigrant Health at the University of Colorado Anschutz Medical Campus. Dr. Cervantes will participate on the Division of Kidney, Urology, and Hematologic Diseases Subcommittee.
- **Dr. Peng Ji** is a Professor of Pathology in the Division of Experimental Pathology and of Pathology in the Division of Hematopathology at the Northwestern Feinberg School of Medicine. Dr. Ji will participate on the Division of Kidney, Urology, and Hematologic Diseases Subcommittee.
- **Ms. Neicey Johnson** is the Senior Director for the Association of Black Cardiologists, Inc. Ms. Johnson will participate on the Division of Diabetes, Endocrinology and Metabolic Diseases Subcommittee.
- **Dr. Aylin Rodan** is the Dialysis Research Foundation Presidential Endowed Chair, Associate Professor of Internal Medicine, Chief of the Division of Nephrology & Hypertension, and Investigator within the Molecular Medicine Program at the University of Utah School of Medicine. Dr. Rodan will participate on the Division of Kidney, Urology, and Hematologic Diseases Subcommittee.
- **Dr. Hunter Wessels** is a Professor and Nelson Chair of the Department of Urology at the University of Washington School of Medicine. Dr. Wessels will participate on the Division of Kidney, Urology, and Hematologic Diseases Subcommittee.

ATTENDANCE – COUNCIL MEMBERS PRESENT

| Dr. Jamy Ard | Dr. Davida Kruger |
|----------------------|------------------------|
| Ms. Patricia Birsic | Dr. Jacqueline Maher |
| Dr. Richard Blumberg | Dr. Keith Norris |
| Dr. John Carethers | Dr. Aylin Rodan |
| Dr. Lilia Cervantes | Dr. Philipp Scherer |
| Dr. Peng Ji | Dr. Elizabeth Seaquist |
| Ms. Neicey Johnson | 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

II. CONSIDERATION OF SUMMARY MINUTES Dr. Griffin Rodgers

The Council approved, by a show of hands and verbal vote, the Summary Minutes of the 226th Council meeting, which had been sent to members in advance for review.

III. FUTURE COUNCIL DATES Dr. Griffin Rodgers

The next meeting of the NIDDK Advisory Council is scheduled as a virtual meeting for May 14, 2025. 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.

Annual Approval of Council Operating Procedures

Every 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 2025 are unchanged from the Procedures in 2024, the only update is the active dates and some updated links.

Dr. Malik asked for questions or comments regarding the Council Operating Procedures for 2025, and there being none, called for a motion for concurrence. The Council concurred, by a show of hands and a verbal vote, with the Council Operating Procedures for 2025.

Triennial Report on Inclusion of Women and Minorities in Clinical Research

NIH has had a policy for inclusion of women and minorities in clinical research since the 1980s. To ensure that NIH rigorously implemented its inclusion policy, Congress included in the NIH Revitalization Act of 1993 a section entitled Women and Minorities as Subjects in Clinical Research. In 1994, NIH revised its policies to harmonize with the statutory language.

More recently, *The 21st Century Cures Act of 2016*, established a revised requirement for a Triennial Report (a change from biennial reporting) on Inclusion in our clinical research. For these reports, it is required that each Institute's Advisory Council and Institute Director concur with the report before it is submitted to Congress.

Dr. Malik also noted that in 2017 NIH revised its Inclusion of Children Policy to Inclusion of Individuals Across the Lifespan, which requires reporting on participant age at the time of enrollment in annual progress reports. This policy went into effect for awards made to applications submitted on or after January 25, 2019, and age data are now also included in our Triennial Report. A copy of the Triennial Report on the Inclusion of Women and Minorities in Clinical Research FY 2022-2024 was included in the Electronic Council Book for review.

Dr. Malik asked for questions or comments regarding the Triennial Report on the Inclusion of Women and Minorities in Clinical Research FY 2022-2024, and there being none, called for a motion for concurrence. The Council concurred, by a show of hands and a verbal vote, with the report.

V. CLOSED SESSION 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 552b(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.

VI. 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 31 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 1,314 grant applications (366 primary and 948 dual), requesting support of \$524,879,778 were reviewed for consideration at the April 24, 2025, meeting. An additional 1,315 Common Fund applications requesting \$1,491,990,424 were presented to Council. Funding for these applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, 1,453 applications considered in the first Expedited Concurrence process requesting a total of \$591,371,249 in direct year one costs, and 26 applications considered in the second Expedited Concurrence process requesting a total of \$12,572,750 in direct year one costs were reported. All Expedited Concurrence applications were recommended level. The expedited concurrence actions were reported to the full Advisory Council at the April 24, 2025, meeting.

VII. 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 227th meeting of the NIDDK Advisory Council was adjourned at 5:30 p.m. on April 24, 2025.

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

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