224th Meeting of the
National Diabetes and Digestive and Kidney Diseases Advisory Council

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

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

I. CALL to ORDER and OPENING REMARKS
Dr. Griffin Rodgers

Dr. Griffin Rodgers, Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), called to order the 224th meeting of the NIDDK Advisory Council at 8:30 on January 10, 2024, via a hybrid meeting (in-person and Zoom video conference). 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 audience 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. Debra Haire-Joshu
Ms. Davida Kruger
Dr. Jacquelyn Maher
Dr. Mark Nelson
Dr. Keith Norris
Dr. David Penson
Ms. Ceciel Rooker
Dr. Kathleen Sakamoto
Dr. Philipp Scherer
Dr. Elizabeth Seaquist

Subject Matter Experts:
Dr. Jamy Ard
Dr. Richard Blumberg
Ms. Neicey Johnson
Dr. Aylin Rodan

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

NIH and NIDDK Panelists and Speakers:
Dr. Noni Byrnes
Dr. Susan Gregurick

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

Recognition of Subject Matter Experts

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

- Dr. Jamy Ard is a Professor of Epidemiology and Prevention at Wake Forest University.
- Dr. Richard Blumberg is 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. Ard and Dr. Blumberg will participate on the Division of Digestive Diseases and Nutrition Subcommittee.
- Ms. Neicey Johnson is the Senior Director for the Association of Black Cardiologists and will participate on the Division of Diabetes, Endocrinology and Metabolic Diseases Subcommittee.
- Dr. Aylin Rodan is an Associate Professor of Internal Medicine at the University of Utah School of Medicine and will participate on the Division of Kidney, Urology, and Hematologic Diseases Subcommittee.

Council Member News

Dr. Rodgers recognized five Council members that agreed, once again, to extend their Council service and participate in the meeting: **Debra Haire-Joshu, Mark Nelson, David Penson, Ceciel Rooker, and Kathleen Sakamoto**. He thanked them for continuing their service on the Council because of the delayed processing of membership slates.

In Memoriam

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

- **Dr. Sandy Garfield** came to NIDDK in 1987 after a long and productive academic career. He obtained his doctorate in developmental biology from the University of Chicago. After postdoctoral training at Case Western University, Dr. Garfield moved to the University of Virginia and then to the University of Cincinnati. He left a legacy of careful and important work on how the mammalian liver is organized and functions in health and disease, particularly

diabetes mellitus. He joined the Division of Diabetes, Endocrinology and Metabolic Diseases at NIDDK as the burgeoning diabetes 'epidemic' was ramping up. Dr. Garfield's stewardship of the Diabetes Centers program earned him the respect of the academic community, and as these Centers grew, the need for clinical trials to build on basic biology was recognized across both the community and the institute. Through the signature Diabetes Prevention Program, complex questions about how to prevent or slow the disease in disparate populations was begun, and the result of this work continues to resonate today. As Dr. Garfield worked with investigators with interests spanning basic and clinical research, he became a valued link to American Indians and Alaska Natives, populations particularly struck by the diabetes epidemic. As Director of NIDDK's Diabetes Education in Tribal Schools Program, he coordinated the development of an innovative set of teaching tools to increase the understanding of science and health (especially pertaining to diabetes) among Native American students from kindergarten through grade 12. His ability to communicate clearly and relate their concerns to colleagues at NIDDK became indispensable to further progress in addressing their needs. Dr. Garfield was a valuable resource for information about clinical trials and at-risk populations. He was a valued colleague for staff across NIDDK and a particularly important asset for newer staff members. Upon retirement, Dr. Garfield left behind a program that had matured under his leadership.

- **Dr. David Badman**, former NIDDK hematology grants program director. Although he officially retired in January 2005 after more than 30 years at NIDDK, Dr. Badman continued to work on a NIH Roadmap drug development project well into 2006. During his storied career, Dr. Badman advanced research on iron overload in children with sickle cell anemia, among his many accomplishments in NIDDK's Division of Kidney, Urology, and Hematology (KUH) division. In May 2006, NIDDK held a symposium and reception in Dr. Badman's honor, hailing him as "a relentless advocate for iron research." He was also proud of his work promoting stem cell research and of innovating the use of zebrafish in research for diabetes and kidney disease. He was well-renowned and loved by the hematology community and all who were lucky enough to work with him.

<u>NIDDK Staffing News</u>

Dr. Rodgers announced recognition earned by several NIDDK staff:

- **Ms. Camille Hoover**, NIDDK Executive Officer, has been honored with the prestigious Distinguished Executive 2023 Presidential Rank Award.
- **Dr. Rob Rivers**, acting Director of the Office of Minority Health Research Coordination Office (OMHRC), has been awarded the Mary Brodie-Henderson Call to Service Award by the Secretary of the Department of Health and Human Services.

Dr. Rodgers announced recognition earned by several NIDDK Intramural Research Program Investigators:

- **Dr. T. Jake Liang**, NIH Distinguished Investigator and Chief of NIDDK's Liver Diseases Branch, received the 2023 Dr. Howard K. Koh Award from the Federal Asian Pacific American Council. Dr. Liang was also selected to receive the 2024 Baruch S. Blumberg Prize from the Hepatitis B Foundation
- **Ms. Elaine Cochran**, pediatric nurse practitioner and advanced diabetes management nurse practitioner in the Diabetes, Endocrinology, and Obesity Branch, won Nurse Practitioner of the Year from the NIH Clinical Center.

Dr. Rodgers announced some staffing changes:

- **Dr. Maren Laughlin**, Senior Advisor for Integrative Metabolism in the Division of Diabetes, Endocrinology, and Metabolic Diseases, has been named the new Co-Director of the NIDDK Office of Obesity Research, where she has served as Acting Co-Director since 2022. Since arriving at NIDDK in 2004, Dr. Laughlin has managed a large portfolio of clinical and basic research grants, serving as a program official for major multi-center clinical trials and consortia that have advanced understanding of metabolism in living systems.
- **Dr. Robert Kuczmarski** is retiring from NIH after 38 years of federal service. Prior to joining NIH in 2001, Dr. Kuczmarski worked for 16 years with the National Health and Nutrition Examination Survey (NHANES) program at the Centers for Disease Control and Prevention (CDC), where he had primary responsibility for topics related to methods for assessment of overweight/obesity and body composition, tracking national prevalence estimates, and development of the CDC growth charts including the body mass index (BMI) charts, instrumental for clinical assessment of overweight and obesity in pediatric populations. Notably, in addition to his other responsibilities at NIH, from 2001 to 2013, he served as Program Officer for the U.S.-Japan Nutrition and Metabolism Panel of the U.S.-Japan Cooperative Medical Science Program, a bilateral program focused on research to increase mutual understanding of the etiology, prevention, and treatment of overweight, obesity, and obesity-associated co-morbidities. Over a period of more than 22 years at NIDDK, Dr. Kuczmarski developed and directed a program of clinical research on the biomedical, behavioral, societal, and environmental approaches to the prevention and management of obesity and inappropriate weight gain in diverse populations and communities at high risk, managing a research portfolio consisting primarily of clinical trials focusing on behavioral interventions across the lifespan. He leaves to his successor a well-established program for clinical research opportunities in the challenging field of developing interventions to effectively prevent and treat obesity.
- **Dr. Najma Begum**, a Scientific Review Officer at NIDDK, is retiring after 20 years at the NIH. Dr. Begum's background is in biochemistry and molecular biology. Her focus includes the molecular mechanisms of insulin resistance and dissection of insulin signaling pathway defects in skeletal muscle, adipose tissue, liver, and vascular smooth muscle. Prior to joining NIH, she was at SUNY Stony Brook for 10 years, where she was an Associate Professor and the Director of the Diabetes Research Laboratory at Winthrop University Hospital, NY. She served as a Principal Investigator on several research grants, including an NIH R01 and grants awarded by the American Diabetes Association and the American Heart

Association. Dr. Begum joined the NIH in 2003. She began her NIH service at the Center for Scientific Review, within the Digestive Sciences Integrated Review Group of the Division of Physiological and Pathological Sciences (DPPS). While at Center for Scientific Review (CSR) she managed two chartered study sections and several Special Emphasis panels between 2003 and 2010. Dr. Begum joined the NIDDK Review Branch in September of 2010. Her responsibilities over the years have included overseeing many different types of complex review including the Diabetes Research Centers (P30s), NIDDK Biorepository Samples Access (X01s), Editorial Board style review of DP3 and DP1 Catalyst Awards, and COVID-19-associated RFAs.

NIDDK's *Recent Advances and Emerging Opportunities* (2024)

Dr. Rodgers announced the publication of the 2024 edition of *NIDDK's Recent Advances and Emerging Opportunities* report, now in its 24th year. The report highlights examples of NIDDK-supported research advances during Fiscal Year 2023. It also includes "Personal Perspectives" of people who have given time and effort to support NIDDK-sponsored clinical research. Special features this year celebrate the 50th anniversary of the Diabetes Research Centers and the 25th anniversary of the Special Diabetes Program. Also included is a feature highlighting the recent *Pathways to Health for All* report from the Health Disparities and Health Equity Research Working Group of this Council. The report and a companion Executive Summary are posted on the "Strategic Plans and Reports" section of the NIDDK website.

Dr. Rodgers noted that the production of this report was an Institute-wide effort. He acknowledged the Office of Scientific Program and Policy Analysis for developing the content and managing this project, and the extramural divisions and offices, as well as the Division of Intramural Research, for providing input and guidance. Dr. Rodgers welcomed comments regarding the report.

II. CONSIDERATION OF SUMMARY MINUTES
Dr. Griffin Rodgers

The Council approved, by electronic poll, the Summary Minutes of the 223rd 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 future meetings will 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 May 8-9, 2024. Although the plan is to meet May 8, the Council was asked to hold both days open to maintain flexibility. Updates about future meetings will be posted on the Council website.

IV. ANNOUNCEMEMNTS
Dr. Karl Malik

Confidentiality

Dr. Karl Malik reminded Council members 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

Dr. Malik reminded Council members that 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.

Prior to today's meeting, Council members were sent a statement regarding conflict of interest in their review of applications (members who attended in-person had the statement in their table folder). Dr. Malik directed each Council member to a statement in their meeting folder regarding the conflict of interest in review of applications. He asked each Council member to read it carefully, sign it, and return it to NIDDK before leaving the meeting.

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.

Regarding multi-campus institutions of higher education, Dr. Malik said that 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 2024 are unchanged from the Procedures in 2023, the only update was the active dates.

Dr. Malik asked for questions or comments regarding the Council Operating Procedures for 2024, and there being none, called for a motion for concurrence. The Council concurred, by electronic poll, with the Council Operating Procedures for 2024.

V. UPDATE: OFFICE OF DATA SCIENCE STRATEGY and NIH STRATEGIC PLAN FOR DATA SCIENCE

Dr. Susan Gregurick

Dr. Rodgers opened the session by stating that NIH released its first Strategic Plan for Data Science in June of 2018 as a roadmap for modernizing the NIH-funded biomedical data science ecosystem. Aligned with broader NIH planning, Dr. Rodgers noted that the NIDDK Strategic Plan specifically recognizes data science as an integral feature for several of its scientific goals.

Dr. Susan Gregurick was invited to the Council meeting to give an update on the Office of Data Science Strategy's (ODSS) activities and its recent release for public comment of an updated NIH Strategic Plan for Data Science for 2023-2028. Dr. Gregurick was appointed Associate Director for Data Science and Director of the ODSS at NIH in 2019.

Dr. Rodgers also reminded the Council that the RFI inviting comments on the NIH Strategic Plan for Data Science (announced in NOT-OD-24-037, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-037.html) is open for public comment until March 15, 2024. He welcomed the Council's input on the plan and how to harmonize implementation of NIDDK's Strategic plan with the goals and principles in the NIH Strategic Plan for Data Science.

Dr. Gregurick provided the accomplishments of ODSS as well as the strategic plan moving forward. The top priority over the next five years is to improve capabilities to sustain NIH policy for data management and sharing. Some of the other goals include developing programs to enhance human-derived data for research; providing new opportunities in software, computational methods, and artificial intelligence (AI); generating support for a federated biomedical research data infrastructure; and strengthening a broad community in data science. Dr. Gregurick encouraged the Council to read and submit comments on the NIH Strategic Plan for Data Science, 2023-2028.

Next, Dr. Gregurick described the Office of Data Science and Science Strategy. The Office is situated within the Division of Program Coordination Planning and Strategic Initiatives (DPCPSI). The mission of DPCPSI is to identify emerging scientific opportunities, to raise public health challenges and scientific knowledge gaps that merit further research. One of sixteen offices, ODSS provides NIH-wide leadership and coordination for a modernized NIH data resource ecosystem. The budget for 2022 was mainly invested (90%) in supporting NIH Institutes, Centers, and Offices through the focus areas of AI, enhancing data infrastructures, supporting data sharing, developing tools and analytics, and training data science workforce development.

ODSS, in keeping with Goal 1 of the Strategic Plan, has developed objectives to address the challenge of developing capabilities to sustain the NIH data management and sharing policy. These include supporting the biomedical community to manage and share data,

enhancing Findability, Accessibility, Interoperability, and Reusability (FAIR) data and greater data harmonization, and strengthening NIH's data repository and knowledge ecosystem. Over the past 3 years, ODSS has supported NIH's investigators to use FAIR data. Dr. Gregurick provided an example of this work. Dr. Jingchuan Guo, University of Florida, has a R01 that aims to leverage real-world data (RWD) to identify patient subgroups that would benefit from new glucose-lowering drugs and to improve the quality-of-care and health equity of type 2 diabetes (T2D) care. Through a supplement provided by the Office of Data Science and Science Strategy, Dr. Gao can improve the FAIR and AI-readiness of the data. She is developing pipelines and associated documentation to standardize RWD into a common data model with a focus on the social determinants of health and make the RWD into AI/machine learning (ML) ready data sets in preparation for the development of T2D digital twin models.

Data needs to be shareable in both general and community-derived repositories. The TRUST principles are Transparency, Responsibility, User community, Sustainability, and Technology. To support FAIR and TRUST data resources, 21 awards have been awarded over the past 3 years to support these principles. There are two new funding announcements (PAR-23-236 https://grants.nih.gov/grants/guide/pa-files/PAR-23-236.html and PAR-23-237 https://grants.nih.gov/grants/guide/pa-files/PAR-23-237.html) to support early stage and established data resources.

Dr. Gregurick said that ODSS has a plan to support data management and sharing over the next 5 years. In keeping with Goal 1, they plan to support the biomedical community to manage, share, and sustain data; enhance FAIR data and greater data harmonization, and strengthen NIH's data repository and knowledgebase ecosystem.

With Goal 2 of the Strategic Plan, ODSS seeks to enhance human-derived data for research to improve access to and use of clinical and RWD, adopt health IT standards for research, and enhance the adoption of social and environmental determinants of health for health equity.

Next, Dr. Gregurick described the work of ODSS in Fast Healthcare Interoperability Resources (FHIR), which is a standard of specifications for the exchange of electronic healthcare data. ODSS has conducted training for researchers on how to set up a FHIR resource and how to implement FHIR. In FY22 and FY23, ODSS supported IC efforts in FHIR-enabled exchange of clinical data across systems. Over the next 5 years, ODSS plans to enable researchers to gather and integrate data of interest to address health-related questions. NIH will support approaches to enhance clinical data science, increase the use and utility of health care-derived data for research, with proper security and privacy safeguards, and integrate clinical data and RWD, including data from wearables and data originating from health care settings.

With Goal 3, ODSS plans to address the challenges of new opportunities in software, computation methods, and AI with new opportunities to improve biomedical AI analysis, develop innovative software technologies, and support FAIR software sustainability. NIH has supported software to enhance open science. Examples include enhancing software engineering of valuable scientific tools, encouraging new collaborations between biomedical and clinical scientists and software engineers, making research tools reliable and sustainable across multiple computing environments, and improving reuse and

effectiveness of NIH-developed software for open science. NIH is supporting significant research in AI and a few examples were shared by Dr. Gregurick. The Bridge2AI program aims to generate new "flagship" datasets and best practices for machine learning analysis. The AIM-AHEAD program aims to enhance participation of under-represented communities in AI/ML research. The ScHARe program to test AI bias mitigation strategies and to advance health disparities research. The DEMONSTRATE program guides healthcare providers and systems in safe opioid prescribing. The CARD program extracts insights on disease risk and protective factors from large networks of data. And lastly, the Improved operations in health program aims to improve screening through developing AI computation tools.

Dr. Gregurick explained that new opportunities can be created to support collaborations in developing socio-technical solutions, such as guidelines and principles for ethical AI. These solutions include new technologies and methods for foundational models. There are plans to develop social and technical solutions for ethical AI, create and validate an approach for using synthetic clinical datasets for AI, leverage new technologies and methods for AI and foundational models to accelerate biomedical and behavioral research, develop new AI technologies to enable the translation of data to knowledge, and enhance NIH capabilities in AI through partnerships across federal agencies and communities.

With Goal 4, ODSS plans to support a federated biomedical research data infrastructure to develop, test, validate, and implement ways to integrate NIH data and infrastructure; ensure a robust and connected data resource ecosystem that includes collaborative data management platforms, curation, analysis, and sharing of data and metadata; and develop new capabilities for data search and discovery. Support for the NIH Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) Initiative provides several benefits to participants including competitive pricing, expert support, and training along with a number of other benefits. The NIH has also provided a Cloud Lab to NIH-funded researchers to become more efficient and comfortable in leveraging the cloud for their research purposes.

Supporting FAIR data is critical for biomedical research and the NIH has invested significant resources into the generation of large-scale datasets, such as human genomic, clinical, and imaging data. Many of these data are stored in different cloud-based repositories that are stewarded by many ICs and can cause researchers to struggle to find, access, aggregate, and co-analyze datasets across different data repositories. To provide a solution to this problem, NIH has created the NIH Cloud Platform Interoperability (NCPI) effort to establish and implement guidelines and technical standards to empower greater data sharing and end-user analyses across participating NIH cloud platforms. The NIDDK Central Repository will implement NIH's Researcher Auth Services (RAS) integration activities to enable research data access across a federated NIH system. The NIDDK Central Repository Data-Centric Challenge is enhancing NIDDK datasets for future AI applications. Over the next 5 years support for data infrastructure is critical for biomedical research and NIH is taking steps to connect NIH's many data systems.

With Goal 5, ODSS plans to strengthen a broader community in data science to increase training opportunities in data science, develop and advance initiatives to expand the data science workforce, broaden and champion capacity building and community engagement

efforts, and enhance data science collaboration within the NIH Intramural Research Program. ODSS supports many efforts toward and has standalone programs in training, workforce, and community engagement. One example is a partnership between ODSS and NIDDK that is funding the Hawaii Advanced Training in Artificial Intelligence for Precision Nutrition Science Research (AIPrN). This is a co-funded 5-year T32 training program to develop individual-level dietary and nutritional intake by accounting for individual variability in genes, phenotype, environment, and lifestyle. This novel concept includes the assessment of biological, clinical, social, and environmental parameters including multi-omics, genomics, proteomics, metabolomics, and sustainability.

In conclusion, Dr. Gregurick explained that the goal of ODSS is to strengthen a broader community in data science and to develop and nurture data science talent from a diverse array of scientific interests.

Council Questions and Discussion
Dr. Rodgers, moderator

Comment from Council*: When considering training and the workforce pipeline, how do we keep data scientists within biomedical research?*

Dr. Gregurick responded that this is something that ODSS has considered, and the biomedical research community cannot compete with other opportunities based on salary. However, NIH can compete on mission. A compelling mission focused on biomedicine and health research can draw in data scientists. Another mechanism is to offer a clear career pathway, such as offering R01 or other funding opportunities.

Comment from Council*: How are AI initiatives, both within and outside the government, impacting ODSS?*

Dr. Gregurick replied that there are challenges and uncertainties particularly relating to generative AI and the ability to generate new content. However, it is hard to differentiate between what is a hallucination in AI versus what is real. ODSS sees a need for ethical and transparent development of AI. There is a need to create open and transparent training models and datasets and make the code available to other researchers. NIH will be working with the Food and Drug Administration (FDA) on looking into the need for the regulation of AI for drug development as part of an HHS AI task force.

Comment from Council*: With an increased emphasis on cloud computing, will extramural program investigators be able to access some of the resources that are part of the STRIDES initiative for long-term data storage?*

Dr. Gregurick shared that NIH encourages the use of community-derived data sharing resources. Another option is generalist repositories. The STRIDES Cold Deep Data Archive is a cold-storage solution that can bring data out when needed and push it back into storage when not needed for deep preservation. This is a money saving option for long-term preservation. There is also a partnership between Amazon Web Services (AWS) and the National Library of Medicine (NLM) on the open data platform for archiving data that is held in the supplemental materials of publications. The challenge is that if there is not a unique identifier it may be difficult to find the data in the future.

***Comment from Council**: There are a number of regional health-data warehouses, especially in the central U.S. Are there plans or interest to integrate these regional databases and university systems into a national database?*

Dr. Gregurick stated that this is one of the goals of the NIH Director, Dr. Bertagnolli. She would like to integrate electronic healthcare across the U.S. into a health platform. This would be a long-term effort across the U.S. Department of Health and Human Services (HHS) to integrate, find, and access electronic healthcare data.

VI. REPORT FROM THE NIDDK DIRECTOR
Dr. Griffin Rodgers

Budget Update

Dr. Rodgers updated the Council on recent budget events.

The FY24 budget cycle began with the release of the President's Budget Request on March 9. The House Appropriations Subcommittee held a budget and oversight Hearing on April 19, focused on both COVID-19 oversight, as well as the budget for the public health agencies under the Department of HHS. The Senate Appropriations Subcommittee held a NIH budget hearing on May 4. Both the House and Senate, on July 13 and July 27, respectively, released their FY24 Labor-HHS-Education appropriations bills.

On September 30, after much speculation of a government shutdown, Congress passed, and President Biden signed a 45-day continuing resolution into law; this first continuing resolution (CR) was set to expire on November 17. However, due to the removal of Speaker Kevin McCarthy and a lengthy race for a new Speaker, the appropriations process was delayed in the House. With Mike Johnson of Louisiana as the new Speaker in place, the House voted on November 14 to pass a second CR, with the Senate following suit on November 15. On November 16, President Biden signed this CR into law. This CR funds four appropriations bills through January 19 and eight appropriations bills through February 2 at the FY23 levels.

Dr. Rodgers noted that the President's Budget Request includes $48.270 billion for the NIH, which is about $811 million over the FY23 enacted level. The budget also includes a proposed $2.303 billion for NIDDK, maintaining FY23 funding levels.

The House bill proposes $44.622 billion for NIH, which is $2.837 billion less, or about a 6 percent decrease, than the 2023 enacted level. The bill provides the same amount of funding as FY23 for NIDDK. The Senate FY24 bill includes $47.724 billion for NIH, which is a $265 million, or 0.6 percent, increase over 2023. The bill provides NIDDK with $2.311 billion, which is a $10 million, or 0.43 percent, increase over the previous year.

Dr. Rodgers provided a brief comparison of the House and Senate's proposals for the NIH budget in FY24. The House bill decreases the total NIH budget by $2.8 billion, and it flat-funds or reduces funding for many NIH ICs. It includes provisions related to human fetal tissue research, foreign influence, and gain-of-function research. On

November 14 and 15, the House adopted several amendments that impose deeper cuts, including a $6.6 billion decrease for NIH below the FY23 funding level. The House will not resume consideration of the bill until early 2024, after House and Senate conferees resolve differences between their versions of all appropriations bills.

The Senate bill proposes to increase the total NIH budget by $265 million, with a $10 million increase to NIDDK to support diabetes-related research. It also supports targeted research initiatives on Alzheimer's disease, cancer, mental health, and opioids, among others. This bill has been approved by the full Appropriations Committee but has not yet passed the chamber.

Dr. Rodgers explained that to keep the government funded past November 17 when the first CR ended, Congress moved forward with a "laddered" approach for the second CR that extends funding for most programs and activities at current funding levels, through two separate dates. The first expiration date, January 19, applies to the programs and activities in four bills. Notably to NIDDK, this rung of the "ladder" contains the extended authorization for the Special Diabetes Program, providing just short of $26 million through January 19. The second expiration date, February 2, would apply to the programs covered by the remaining eight appropriations bills; this portion of the CR extends funding for NIH programs and activities. Just prior to the Council meeting, House and Senate leaders announced that they have reached an agreement on FY24 top line government spending levels. This bipartisan deal is the first step in the process for appropriators to negotiate and draft the twelve individual spending bills. Dr. Rodgers hopes that Congress can make much progress before the fast-approaching deadlines so that programs and activities can continue without any lapse in funding.

New NIH Director

Dr. Rodgers explained that NIH now has a new Director, Dr. Monica Bertagnolli. The Senate Health, Education, Labor, and Pension Committee held a confirmation hearing on October 18. During the Hearing, Dr. Bertagnolli emphasized the importance of supporting research that is accessible and equitable to all Americans, increasing patient access to innovation, and restoring public faith and trust. Of note to NIDDK, Senator Collins highlighted the Special Diabetes Program, and Senator Cassidy called for increased funding for obesity research. Dr. Bertagnolli was confirmed by a vote of 62 to 36 on November 7, and she officially began work as NIH Director on November 9. Dr. Bertagnolli's formal swearing-in ceremony took place on December 5. Dr. Larry Tabak will continue to serve as the Deputy Director of NIH, and Dr. W. Kimryn Rathmell, a renowned kidney cancer expert and influential leader in cancer research and patient care from Vanderbilt University, officially joined NIH last month as a new Director for the National Cancer Institute (NCI).

Congressional Activities

Next, Dr. Rodgers highlighted several meetings that NIDDK participated in with Congressional staff. In September, Dr. Rodgers attended the Reception to Celebrate Medical Research, organized by the American Association for Cancer Research. This reception was held on the Hill the evening before the 11th Annual Rally for Medical Research, where over 240 advocates met with members of Congress and their staff to

thank Congress for enacting eight consecutive years of robust funding increases for NIH, while urging members to support the highest possible appropriations increase for NIH in FY24. During the event, Dr. Rodgers spoke with Senator Durbin about NIDDK research.

Dr. Rodgers met with Mike Gentile, the Senate Appropriations Labor, Health and Human Services (LHHS) Subcommittee Clerk, to give an overview of NIDDK-supported research during his visit to the NIH campus on October 18. On October 23, Dr. Rieff, Director of NIDDK's Office of Scientific Program and Policy Analysis, met with staff from Representative Suzan DelBene's office. Dr. Rieff presented an overview of NIH and NIDDK, and discussed kidney transplant research, as Representative DelBene serves as a co-chair of the Congressional Kidney Caucus.

On October 27, Dr. Germino met with Senator Ben Cardin during his visit to the NIH Campus. Dr. Germino spoke on efforts related to social determinants of health, along with other participants from National Institute on Minority Health and Health Disparities (NIMHD) and National Heart, Lung, and Blood Institute (NHLBI). Senator Cardin also toured an NIDDK intramural lab to learn about and see first-hand some of the facilities improvements that are underway at NIH.

On November 11, staff from the Office of Representative Don Beyer met with Dr. Kevin Hall, one of NIDDK's intramural principal investigators to discuss Dr. Hall's research on ultra processed foods.

Upcoming Meetings

Dr. Rodgers mentioned that in early Spring, the annual Friends of NIDDK meeting will be held, where the Institute's latest accomplishments and upcoming goals will be discussed with the patient, physician, research, and disease advocacy organizations that will be represented.

Dr. Rodgers announced that NIDDK's 75th Anniversary is coming up, and there will be many opportunities in 2025 to highlight the anniversary, celebrate accomplishments, and look ahead to the future.

VII. UPDATE: CENTER FOR SCIENTIFIC REVIEW

Dr. Noni Byrnes

Dr. Rodgers explained that they regularly invite guests to visit the Council who can help provide updates about other components of the NIH. The goal in doing this is to provide context regarding NIH operations and how NIDDK is impacted by and impacts this milieu. He welcomed the Director of the CSR, Dr. Noni Byrnes. Dr. Byrnes became CSR Director in February 2019. Prior to being appointed Director, Dr. Byrnes served in a variety of roles at CSR in positions of increasing responsibility. She began as a Scientific Review Officer in 2000 in the Biological Chemistry and Macromolecular Biophysics Integrated Review Group (IRG). In 2006, she became Chief of the Cell Biology IRG and, in 2012, Director of the Division of Basic and Integrative Biological Sciences, where she oversaw more than 60 study sections in a range of different areas of basic science, including genomics; cell, developmental and structural biology; bioengineering; and

basic cancer biology. In January 2018, Dr. Byrnes was appointed Acting Deputy Director, and in May 2018, she assumed the role of Acting Director of CSR.

Dr. Byrnes thanked Dr. Rodgers for the invitation and the opportunity to present ideas on how to strengthen peer review for all of NIH. The mission of CSR is to ensure that NIH grant applications receive fair, independent, expert, and timely scientific reviews, free from inappropriate influences, so NIH can fund the most promising research. In FY23, CSR reviewed approximately 60,000 applications—more than three-quarters of those submitted to NIH. CSR has about 275 Scientific Review Officers (SROs) and the support of approximately 19,000 reviewers who conduct reviews in over 1,200 meetings.

Dr. Byrnes began by reviewing CSR's strategic framework for optimizing peer review. The goal is to optimize peer review in three domains: reviewers, study sections, and process. The basic operational principles are transparency; data-driven decisions; stakeholder engagement; and staff engagement, training, and development.

Next, Dr. Byrnes presented the ENQUIRE (Evaluating Panel Quality in Review) initiative for study section evaluation and restructuring. Launched in 2019, ENQUIRE is a systematic, data-driven, continuous process to evaluate study sections. About 20 percent of CSR study sections are assessed each year with the goal of assessing each study section every 5 years. This is a two-stage process. The first step is scientific evaluation, which uses a panel of external scientific experts to evaluate scientific currency of study sections to optimize identification of high impact research. The stage will help to identify emerging and declining areas and can result in recommendations to create, merge or sunset study section*s* using a variety of data and outcomes. In stage 2, process evaluation, study section function is evaluated and can result in additional recommend changes to optimize identification of highest impact research. Program officers provide feedback on the study section function. ENQUIRE takes about 12 to 18 months from initiation to implementation of new or restructured study sections.

Currently there are 152 study sections in 13 different scientific clusters. In general, ENQUIRE results in substantive changes in study sections. This might mean the elimination or merging of smaller boutique panels, refreshing scientific guidelines, new study sections, or incorporation of growing and emerging scientific areas.

Dr. Byrnes also discussed an initiative to simplify review of NIH research project grant (RPG) applications. There are two main goals of the proposed changes. One is to refocus first-level peer review on its singular role of providing advice to the agency regarding the scientific and technical merit of grant applications, relieving reviewers of responsibility for administrative and policy compliance items, reducing burden, and incentivizing participation in review. The second goal is to mitigate reputational bias in the peer-review process; specifically, refocusing the evaluation of investigator and environment to the context of the proposed research project.

Dr. Byrnes provided an overview of some of the changes to the peer-review framework for RPGs. There are 5 current peer review criteria, which will be reorganized into three main factors: importance of research (scored) includes significance and innovation, rigor and feasibility (scored) includes strengths/weaknesses and approach, and expertise and resources (not scored) includes investigators and environment. Under the rigor and

feasibility factor, study timeline and inclusion plan for human participant research were added. There are additional criteria that are not scored but can affect the overall impact score. Most of these additional review considerations were removed from first-level peer review. Reviewers will only briefly comment on budget.

This process was carried out with community input. Initial input gathering occurred through blog posts. There were two CSR Advisory Council working groups convened with overlapping membership to consider non-clinical trials and clinical trial RPGs. Legal and regulatory guardrails were provided, and the working groups held 11 virtual meetings to develop framework and recommendations. The CSR Advisory Council approved the recommendations and publication of the working group report. An internal NIH review modified the framework, and it was approved by the ICs and NIH leadership. Public input was provided through Requests For Information and were mostly supportive of the changes. Implementation is planned to begin for applications received in January 2025, reviewed in summer 2025, with planned October 2025 funding.

The next steps between now and implementation include a one-stop centralized NIH site with information and FAQs. A number of changes and updates will be made to NIH systems, training resources will be developed, and updates made and published to funding opportunities. Dr. Byrnes thanked the participants of the CSR advisory council working groups.

Dr. Byrnes explained that CSR is also looking at the fairness of the criteria for National Research Service Award fellowship reviews. The goal is to optimize the identification and training of the most promising scientists of the next generation. There were concerns from the scientific community that NIH is potentially leaving out very promising research scientists of the future because of a process that favors elite institutions, and senior, well-known sponsors. Comments in response to an initial blog reinforced those concerns. Additionally, data analysis of more than 6,000 applications supported those concerns—that fellowship application submissions are concentrated in a small number of institutions, applications from institutions submitting a large number do better in review, and review outcomes for fellowships improve as the academic rank of the sponsor increases.

The Working Group on this topic made two recommendations. The first recommendation was to change the fellowship review criteria to focus on the potential of the applicant, strength of the science, and quality of the training plan. The second recommendation was to revise the fellowship application and the information provided to reviewers. The following sections are being revised: fellowship applicant section (eliminate grades); sponsors, collaborators, and consultants section (greater emphasis on training and mentorship approach and plan for any particular student), eliminate peer review of financial support (sponsor funding); and letters of support to address targeted, trainee-specific questions in structured fields (discourages boilerplate language, easier for reviewers to differentiate and evaluate). A proposal to have an optional statement of special circumstances is being considered for feasibility.

This followed a similar process to the changes to RPGs. A CSR Advisory Council working group considered how to strengthen the process. The CSR Advisory Council approved the recommendations and publication of the working group report. Internal NIH

input and approval was provided by IC and NIH leadership. Public input was mostly supportive of the changes. Implementation is tentatively planned for applications received April 2025, reviewed in summer 2025, with October 2025 funding.

Dr. Byrnes also discussed how CSR is promoting fairness in review. CSR conducts annual Chair orientation sessions, as there are approximately 90 incoming study section chairs per year. CSR has bias awareness training for reviewers that has been ongoing since August 2021. This training is targeted toward mitigating the most common biases in the peer-review processes, which includes personal testimonials, interactive exercises, and narrated mock study sections. Over 25,000 reviewers have taken the 30-minute training, which is delivered around 4 weeks prior to scheduled review meetings. Survey results indicate an increased ability of reviewers to identify bias with increased comfort in intervening. CSR also updated their Review Integrity Training module in August 2022. This is an interactive, scenario-based training on the reviewer's role in protecting confidentiality, integrity of the NIH review process before, during, and after the meeting. Content is based on actual cases. CSR also has a direct bias reporting mechanism (reportbias@csr.nih.gov), which is included in the signature of all CSR staff on outgoing emails. Every allegation is carefully investigated by CSR senior management.

CSR also has a mechanism to broaden the pool of reviewers, to help SROs find "lesser-known" qualified reviewers. CSR emphasizes the critical need for NIH to hear diverse perspectives to fulfill peer review's mission of identifying disruptive, and novel science. The most effective, highest-quality review committees are broadly diverse in multiple dimensions. These dimensions include: 1) scientific background and perspective; 2) demographic/geographic; 3) career stage and 4) peer-review experience. CSR continues to increase the diversity of its reviewer pool.

Dr. Byrnes presented data on CSR application and reviewer demographics over time. For women principal investigators (PIs), the percentage has remained fairly flat at around 35% since October 2019. However, the percentage of women reviewers on chartered study sections has always been higher than the PI percentage, due to more oversight. There has been a noticeable increase in the percentage of women serving on Special Emphasis Panels (SEPs) because of efforts to raise awareness and provide tools.

For under-represented minorities PIs, the percentage has also been fairly flat at around 9% since October 2019. As with women, the under-represented minorities membership percentage on study sections has been higher historically. Prior to recent efforts, the percentage of under-represented minority SEP reviewers was lower than the benchmark percentage. However, through raising awareness and providing expertise on a broader level, there has been an increase in under-represented minority SEP reviewers. She also noted that good SEP reviewers can get nominated to chartered study sections, expanding the pool of potential members. So, increasing diverse SEP reviewers helps feed the pipeline of potential diverse chartered study section members over time.

Council Questions and Discussion

Comment from Council*: There was a comment that there may be too much emphasis placed on impact and significance that may bias against research that may not be*

immediately transformational. The effort to mitigate reputational bias for an investigator is also concerning, particularly during competitive renewals.

Dr. Byrnes responded that investigator productivity remains important. Application renewals also vary by field; behavioral and social science-based applications rarely submit renewals. The investigator evaluation is still part of the review. Additionally, impact is an extremely broad consideration, and reviewers should consider various factors to make a best judgement call.

Comment from Council*: Can you comment on the process of how the new criteria will be used for determining which grants will be discussed by reviewers? Additionally, how will potential applicants be educated in the new process?*

Dr. Byrnes replied that these changes will not affect the not-discussed list; these are determined by the preliminary overall impact score average. In that regard, the process remains the same. Dr. Byrnes addressed the application changes and said that the application form will not be changed, and very little will change from the applicant standpoint. The difference will be in how reviewers evaluate the applications.

Comment from Council*: A Council member cited several personal, specific instances of encountering bias in the review process. How do researchers, especially junior investigators, when you are in a study section where the SRO is not paying attention to review bias by the reviewers?*

Dr. Byrnes stated that there have been huge changes in how peer review reporting integrity is managed throughout NIH, and a lot of these scenarios, and how to handle them, are included in the staff peer review integrity training. She noted that there are differences in issues of integrity and bias. In cases of research misconduct or fraud, it is standard procedure to remove reviewers who report integrity issues from the grant, and that the issue is brought forward to the Office of Research Integrity, which then conducts an investigation.

Comment from Council*: What is the evaluation mechanism to evaluate the diversity efforts? Will there be opportunities to hear directly from CSR at scientific meetings?*

Dr. Byrnes stated that there will be objective evaluations and survey-based feedback. They will also look at objective measures, such as priority scores. It will also be difficult to know which measure may affect change as there are many efforts underway. Anyone interested in a presentation from CSR can contact the Outreach Director.

Comment from Council*: Will CSR be looking at how these revised review criteria affect diversity among PIs receiving grants?*

Dr. Byrnes responded that this will be measured, but there is no way to know for certain if the review process changes are responsible for any changes in diversity. Many changes are happening at multiple levels throughout NIH simultaneously. A key consideration might be how the discussions in sections are impacting scores.

***Comment from Council**: Will adding greater diversity to study sections help increase applicant scores from those individuals?*

Dr. Byrnes commented that CSR believes that researchers who have participated in the review process tend to do better in the competitive grant process themselves. There is some data from early career reviewers that suggests this may be true. There are also two Working Groups, one of which is looking at reviewer evaluation (quality of reviewers), and the other group is looking at incentivizing review and specifically looking at whether people who serve on study sections do better in the grant application process.

***Comment from Council**: Can you comment on bringing cutting edge concepts such as health IT and social determinants of health into the review process, particularly for disease-focused study sections?*

Dr. Byrnes explained that this will be part of the evaluations and CSR is paying attention to integrating these concepts into the expertise selected for study sections.

VIII. CONCEPT CLEARANCE

Dr. Rodgers then turned to Concept Clearance by Council, a step required before 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. Dr. Rodgers introduced Dr. Parsa to present the concept.

Precision Medicine for T1D Nephropathy
Dr. Afshin Parsa

This purpose of this concept will be to study the clinical and molecular determinants of type 1 diabetes (T1D) nephropathy and associated clinical outcomes. By establishing new kidney biopsy recruitment centers and leveraging the extensive resources from the Kidney Precision Medicine Project, this study will advance our understanding of the varied pathophysiologic processes and related outcomes of diabetic kidney disease in people with T1D and identify needed novel therapeutic targets.

Dr. Rodgers invited Council members to ask any questions related to the presented concept.

Council Questions and Comments

***Comment from Council**: The clinical presentation of type one diabetic nephropathy has changed over the past 30 years, and the reasons for this change are not understood. Thus, this is a very important area for research.*

***Comment from Council**: How will kidney function assessment be handled in the study; will the assessments differ across sites, or will there be a standardized approach?*

Dr. Parsa replied that kidney function assessments will need to be standardized across all sites to avoid bias. The hope is to have assessments done at individual sites but with

central quality control and oversight. Some functional measures may be taken from all participants, and others just in certain subgroups where it is most relevant (e.g., renal reserve in those with early disease). The overall process and methods for kidney function assessment will be the same at all centers to standardize the data.

There being no further questions or comments from 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.

IX. SUBCOMMITTEE MEETINGS

Open Sessions of the Subcommittee Meeting

See Minutes posted on the NIDDK Council Minutes Website.

Closed Sessions 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 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.

X. 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 1585 grant applications (586 primary and 999 dual), requesting support of $582,739,566 were reviewed for consideration at the January 2024 meeting. An additional 24 Common Fund applications requesting $18,707,730 were presented to Council. Funding for these applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, 868 applications requesting $359,070,149 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 January 2024 meeting.

XI. 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 224th meeting of the NIDDK Advisory Council was adjourned at 4:30 p.m. on January 10, 2024.

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