

**225th 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 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. Rodgers, Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), called to order the 225th meeting of the NIDDK Advisory Council at 8:30 a.m. EDT on May 8, 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. Ceciël Rooker
Ms. Davida Kruger	Dr. Kathleen Sakamoto
Dr. Jacquelyn Maher	Dr. Philipp Scherer
Dr. Mark Nelson	Dr. Elizabeth Seaquist
Dr. Keith Norris	

Subject Matter Experts:

Dr. Jamy Ard
Dr. Richard Blumberg
Ms. Neicey Johnson
Dr. Aylin Rodan
Dr. Claire Yang

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

Panelists and Speakers:

Dr. Talitha Washington

Dr. Atul Butte

Dr. Rodgers noted that NIDDK plans to hold hybrid Council meetings, which accommodate virtual and in-person participation, for the foreseeable future. Council members and staff were encouraged to attend Council meetings in-person whenever possible. The in-person experience fosters more engaging and productive conversations and facilitates more impactful discussions that can profoundly impact the Institute's future. The Council website will have further details in the future.

Recognition of Subject Matter Experts

Dr. Rodgers welcomed five 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. Ard will participate on the Division of Digestive Diseases and Nutrition (DDN) Subcommittee.
- **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. Blumberg will participate on the DDN 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 (DEM) Diseases Subcommittee.
- **Dr. Aylin Rodan** is an Associate Professor of Internal Medicine at the University of Utah School of Medicine. Dr. Rodan will participate on the Division of Kidney, Urology, and Hematologic (KUH) Diseases Subcommittee.
- **Dr. Claire Yang** is a Professor and Chief of Service at the University of Washington Medicine Department of Urology. Dr. Yang will participate on the KUH Subcommittee.

Council Member News

Dr. Rodgers recognized four Council members that agreed, once again, to extend their Council service and participate in the meeting: **Debra Haire-Joshu, Mark Nelson, Ceciel Rooker, and Kathleen Sakamoto. David Penson** also extended his membership and attended the January Council meeting but was not able to attend the May meeting. Dr. Rodgers thanked them for continuing their service on the Council because of the delayed processing of membership slates. Dr. Rodgers then presented certificates of appreciation to the retiring members.

In Memoriam

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

- **Dr. William Heinrich** was a former NIDDK Advisory Council Member and Professor of Medicine at the University of Texas Southwestern School of Medicine (UTSW) and was the inaugural holder of the John P. Howe, III, MD, Distinguished Chair in Health Policy. For the past 15 years Dr. Heinrich served as President of UTSW. During this period, he transformed the UT Health Science Center at San Antonio into a top-ranked academic health center with world-class programs in cancer, obesity and diabetes, dementia, and aging. Dr. Heinrich was a leader in nephrology and served as President of the American Society of Nephrology. Over his career, Dr. Heinrich authored over 300 original articles and chapters and was the founding editor of the popular dialysis textbook, “Henrich’s Principles and Practice of Dialysis.” Dr. Heinrich will be remembered for his creativity, good humor, wise council, and generous mentorship of students, residents, and young physicians.
- **Dr. Jerry Palmer** served for a decade on NIDDK Council as the Veteran’s Administration representative and was Professor Emeritus at the University of Washington in Seattle and his research was supported by NIDDK for many years. Dr. Palmer was professor within the Division of Metabolism, Endocrinology, and Nutrition at the University of Washington’s Department of Medicine for 45 years. He was also Chief of endocrinology at the VA Puget Sound Health Care System in Seattle for 35 years. Dr. Palmer’s many scientific achievements included significant contributions to NIDDK-supported clinical trials that revolutionized diabetes care. For example, he served on the Steering Committee for the Diabetes Control and Complications Trial from 1982 to 1993. He also played a central role in the Epidemiology of Diabetes Intervention and Complications Trial and was involved in both the Diabetes Prevention Trial of Type 1 Diabetes and TrialNet. Dr. Palmer also established the UW Diabetes Care Center, which he directed for 12 years.
- **Dr. Philip Cryer**, whose illustrious career at the Washington University School of Medicine in St. Louis spanned more than four decades. Dr. Cryer led the university’s General Clinical Research Center for more than 30 years. He also served as the longtime Director of the Division of Endocrinology, Metabolism & Lipid Research as well as a Professor of Endocrinology and Metabolism. Dr. Cryer received research support from NIH and NIDDK for more than three decades, including an NIH Merit Award, which provides extended grant support to investigators with outstanding records of scientific achievement. Dr. Cryer was internationally known for his research on hypoglycemia, including the physiology behind glucose counter-regulation, which are the mechanisms that prevent or correct hypoglycemia. This research led to the development of approaches to identify, prevent, and treat hypoglycemia in people with diabetes.
- **Dr. Gary Felsenfeld**, an intramural distinguished scientist, who was with NIDDK for more than 60 years and was a founding member of NIDDK’s Laboratory of Molecular Biology, serving as the lab’s Chief from the late 1990s until he retired in 2023. He studied physical chemistry with world-renowned chemist Linus Pauling before joining the Public Health Service in 1956 to work at the National Institute of Mental Health on polynucleotides. There, he played a role in discovering the first triple-stranded nucleic acid molecule. From 1961, when Dr. Felsenfeld joined NIDDK, he shared in the discovery of the first

erythroid-specific transcription factor and began investigating chromatin boundary regions, eventually identifying the protein CTCF as a major genomic boundary protein. This discovery led to research on long-range interactions in the nucleus that affect insulin regulation in human pancreatic cells. Dr. Felsenfeld's legacy encompasses the many trainees he mentored, including 25 currently active leaders of research groups worldwide. He published more than 250 primary research papers and garnered many awards. Dr. Felsenfeld was not just a great scientist, mentor, and leader, he was also a beloved colleague and friend with a great sense of humor and a warm, generous nature.

NIDDK Staffing News

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

- **Dr. Jenny Hinshaw**, Senior Investigator in NIDDK's Laboratory of Cell & Molecular Biology, received the Biophysical Society's 2024 Sir Bernard Katz Award in recognition of her outstanding scientific career in understanding the role of dynamins in membrane fission and fusion.
- **Dr. Susan Buchanan**, Deputy Scientific Director in the Division of Intramural Research and Chief of the Laboratory of Molecular Biology, received the Biophysical Society's 2024 Anatrice Membrane Protein Award. The award recognizes her impactful contributions to the understanding of outer membrane protein folding and insertion, and for structural insights into small and large molecule active transport across the outer membrane.
- **Dr. Jurgen Wess**, Chief of Molecular Signaling in NIDDK's Laboratory of Bioorganic Chemistry, was elected as a 2023 AAAS Fellow for his distinguished contributions to molecular and translational pharmacology.

Dr. Rodgers announced new extramural staff:

- **Dr. Minnjuan W. Flourney Floyd** joined DEM as a program officer in January 2024. In her position, she will provide oversight to DEM's growing program in Health Disparities and Health Equity and specifically will oversee programs addressing health equity research in adults with type 2 diabetes (T2D) at the individual level. Dr. Floyd received her Ph.D. in Health Services, Policy, and Management at the Norman J. Arnold School of Public Health, University of South Carolina, and a Master of Business Administration (MBA) in Healthcare Administration from William Howard Taft University, Denver, CO. Prior to joining NIDDK, she served as a Social and Behavioral Sciences Administrator at the National Institutes of Drug Abuse.
- **Dr. Jia Nie** also joined DEM in December 2023 as a Data and Technology Advancement (DATA) National Service Scholar, through a program run by the NIH Office of Data Science Strategy (ODSS). Dr. Nie is working on developing a dynamic, searchable metadata and meta-standards catalogue of NIDDK data science resources, including both basic science data types and clinical and observational data types. Dr. Nie will also organize a NIDDK data science workshop to gather community input.

Dr. Rodgers announced a retiring NIDDK staff member and congratulated her on her public service and remarkable career.

- *Ms. Van Nguyen* retired after 30 years of federal service at NIH, including 14 years at NIDDK. As NIDDK’s Budget Officer, Ms. Nguyen served as senior advisor to Institute leadership for all NIDDK’s financial activities. These activities included grants, research and development contracts, research management and support activities, Cooperative Research and Development Agreements (CRADAs), gift funds, and royalties. Prior to her time at NIDDK, Ms. Nguyen worked at the National Institute of Mental Health and the National Institute on Aging.

Dr. Rodgers recalled Dr. Noni Byrnes’ presentation at the January Council meeting and mentioned the implementation of the Simplified Review Framework for most research project grants. As a reminder, NIH is implementing a simplified framework for the peer review of most competing research project grant applications, beginning with submissions with due dates of January 25, 2025. To keep up with the information and guidance he suggested that attendees visit the “Simplifying Review of Research Project Grant Applications” webpage. Either by navigating to [this website](#) or performing a web search on “NIH Simplified Review Framework.”

II. CONSIDERATION OF SUMMARY MINUTES

Dr. Griffin Rodgers

The Council approved, by electronic poll, the Summary Minutes of the 224th 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 September 11-12, 2024. Although the plan is to meet September 11, the Council was asked to hold both days open to maintain flexibility. Dr. Rodgers noted that the September Council meeting will be held in the Natcher Conference Center (Building 45). Updates about future meetings will be posted on the Council website.

IV. ANNOUNCEMENTS

Dr. Karl Malik

Confidentiality

Dr. Malik said 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 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 here in-person today have the statement in their table folder). Dr. Malik directed each Council member to a statement in their meeting folder regarding conflict-of-interest in review of applications. He asked each Council member to read it carefully, sign it, and return the signed hard copy or file before the end of the 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.

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.

V. COUNCIL FORUM: DATA SCIENCE & DATA MANAGEMENT

Dr. Gregory Germino, Dr. Talitha Washington, and Dr. Atul Butte

Dr. Germino reminded attendees that at the January meeting, Dr. Susan Gregurick provided an overview of the NIH Strategic Plan for Data Science. She reviewed progress made on the 2018-2022 plan and then introduced the updated 2023-2028 draft that was open for public comment at the time. In her presentation, Dr. Gregurick laid out the vision for how NIH will facilitate and support development of policy, programs, technologies, and infrastructure to continue to develop data-driven discovery across the agency. Dr. Germino introduced the Data Science Forum Series, intended to continue the discussion between Council members and two invited speakers with perspectives on how data sharing, data harmonization and integration, and emerging technologies, such as generative artificial intelligence (AI) and other machine learning models, will facilitate

knowledge generation and advance health across NIDDK science. Additionally, the forum was to include discussion of ways that researchers can ensure equity in the development and application of these novel methods, and ways that we can encourage equal participation and representation of all populations in such research and data.

Dr. Germino then introduced the two speakers. Dr. Talitha Washington is the Director of the Atlanta University Center Data Science Initiative; a tenured professor of mathematics at Clark Atlanta University; and an affiliate faculty at Morehouse College, Morehouse School of Medicine, and Spelman College. She is the lead Principal Investigator of the National Data Science Alliance, a national network of academic, industry, and government partnerships that will grow the capacity of Historically Black Colleges and Universities to transform data science discoveries into tangible societal benefits that advance equity for all. She is also the President of the Association for Women in Mathematics. Dr. Washington studied mathematics at Spelman College and earned her master's and Ph.D. from the University of Connecticut, where she also received an honorary Doctorate. She is a fellow of the African Scientific Institute, the American Mathematical Society, and the American Association for the Advancement of Science.

He then introduced the second speaker, Dr. Atul Butte, who is the Priscilla Chan and Mark Zuckerberg Distinguished Professor and inaugural Director of the Bakar Computational Health Sciences Institute at the University of California, San Francisco. He is also the Chief Data Scientist for the entire University of California Health System, the tenth largest by revenue in the United States. Dr. Butte trained in Computer Science at Brown University, worked as a software engineer at Apple and Microsoft, received his MD at Brown University, trained in Pediatrics and Pediatric Endocrinology at Children's Hospital Boston, then received his Ph.D. from Harvard Medical School and the Massachusetts Institute of Technology. Dr. Butte has been continually funded by NIH for 20 years, is an inventor on 24 patents, and has authored nearly 300 publications. He was elected to the National Academy of Medicine in 2015 and in 2013, he was recognized by the Obama Administration as a White House Champion of Change in Open Science, promoting science through publicly available data.

Dr. Washington discussed considerations for building data science networks that will address societal and health challenges. Dr. Washington presented data from Association for Women in Mathematics, noting that the percentage of women progressing from undergraduate members to full professors decreases with each step. Dr. Washington also stated that while African American individuals make up 12% of the US population, they make up only 3% of data and analytics professionals. The importance of having a data-skilled workforce is aligned with the NIH-Wide Strategic Plan, which calls for advances in data science, technology, and tools that will aid decision-making by patients and providers to improve disease prevention and health promotion. Dr. Washington provided the example of a health insurance company that maps electronic health records against models using AI and machine learning (ML) to determine treatment protocols, noting a lack of checks on these models to ensure their accuracy. Dr. Washington suggested that there are existing systems and protocols in place, like the IRB, that can help bring transparency to AI/ML processes.

Dr. Washington explained that data science serves as a measuring tool to identify and examine health disparities and lead to more questions and insights that spur additional

programming and improved outcomes. She then turned to the AUC Data Science Initiative, created by the Atlanta Universities Center (AUC), which is working to expand data science capacity across all Historically Black Colleges and Universities (HBCUs). Key highlights of the initiative include: building faculty expertise to create an ecosystem where students can thrive; emphasizing the importance of industry partnerships; introducing a data science minor with six learning outcomes that includes a course on data in the African diaspora community; and building up the 10 key technology areas included in the Chips and Science Act through workshops, courses, internships, research, symposia, and other opportunities.

Dr. Washington provided examples of the work carried out by the Data Science Initiative. She mentioned the AIM-AHEAD program at Morehouse School of Medicine that aims to build AI/ML capacity at minority serving institutions, increase underrepresented minority AI/ML scientists, and cultivate community trust to build diverse datasets. Additionally, a symposium on the Power of Data Behind Black Health held in June 2023 explored how to advance AI/ML approaches that improve health outcomes and address health disparities for Black communities. The resulting ideas from that symposium generated numerous project ideas that have been implemented. A generative AI faculty training session at Spelman College explored developing generative AI policies to minimize risk, how generative AI is advancing innovations in research, how generative AI will impact teaching and learning in undergraduate education, and how to prepare students to join the AI workforce.

Future programs include a Pre-Freshman Experience weeklong virtual program open to all HBCUs on data for social impact, scheduled for summer 2024. There is also a mini-grant program funded by Microsoft that is open to faculty and staff at HBCUs to support and strengthen HBCU faculty and staff researchers to enhance participation in and contributions to data science research and curriculum development. An upcoming symposium on Envisioning AI Education Across Disciplines will be held in June 2024 to develop strategies to infuse AI into courses from across disciplines. Dr. Washington also mentioned that there is a Seminar Series, also available on YouTube, which explored topics such as AI and Black health, mobilizing healthier communities through data, and why cultural competence matters.

The National Data Science Alliance (NDSA) is funded by the National Science Foundation (NSF) program to establish a national network of HBCUs to advocate for the building of institutional data science capacity. The vision is to increase the number of Black people who earn data science credentials by 20,000 and create equitable data science techniques and models. At this stage, the program is holding faculty workshops, curriculum development workgroups, and research affinity cohorts. Listening sessions held during the development of the NDSA program led to several themes including representation (need for demographic inclusivity, participation in decision making, addressing bias, and ensuring accurate representation in data), interdisciplinarity (highlighted the applicability of data science across disciplines), resources (encompassing issues such as insufficient support, financial limitations, software/hardware availability, buy in, and the need for professional development), and hands-on learning (role of data science in bridging classroom knowledge with real-world industry application). Workgroups were formed to develop curriculum for the creation of data science majors and minors. In June 2024, a research affinity cohort will meet for a two-week intensive

workshop to discuss and problem solve issues in data science such as algorithmic impacts on Black communities, credit card fraud, evaluating equitable energy access, machine learning approaches to exploring the relationship between adverse childhood experiences and adolescent opioid usage, and unveiling disparities in African-American health experiences.

Dr. Washington concluded by encouraging governmental agencies to cooperate with other agencies to solve data sciences challenges. There may be too much partition between research funded by NSF and NIH, and the challenges of data science could be solved by working together.

Dr. Atul Butte discussed treating diabetes using health data to guide evaluation and treatment of patients. The United States spends billions on Electronic Health Records (EHR), but too few use this data in the practice of medicine. The University of California system has 10 campuses, 3 national labs, 227,000 employees, and 280,000 students per year; there are 6 medical schools and 14 other health professional schools. The system has a large operating budget and receives ample NIH funding. The University of California created a 10-year partnership with UnitedHealth Group to form a new accountable care organization and clinically integrated network. This involves combining healthcare data from across 6 University of California medical schools and systems. The same central database is used for operations and research. All six sites utilize Epic as their EHR. There are approximately 9.5 million patients in that database spanning approximately 13 years, as well as nearly half a billion encounters, 1.2 billion procedures, and 1.6 medication orders. Once the data are deidentified, ample demographic and census information is available.

Dr. Butte provided examples of how this database could be used to monitor and optimize population health for patients with diabetes. A data analysis using the University of California Health Systems database found extremely diverse treatment trajectories for patients with T2D. A dashboard allows for visualization of how all care is delivered across all five included academic medical centers. One model shows that the introduction of cardioprotective medications in eligible patients with diabetes showed significant improvements over 3 years. Data did not cause the change; rather, the visualization of data in the dashboard led to a discussion about sharing best practices. Type 2 diabetes treatment guidelines are very complicated, but by tracking only the first four medication changes for 97,231 patients, there were 12,134 different treatment trajectories with 8,988 unique to only one patient each. Using 10 years of UC Health Systems data, Dr. Butte's group made comparisons across treatment plans controlled with the propensity score of action to find that real world evidence can match the results of a trial like GRADE. Lastly, large language models can assess treatment plans developed by endocrinologists, and recent versions of Chat GPT can create care plans that match the recommendations of doctors for a given case. These tools might be useful to help standardize treatment outside of large academic medical centers.

Council Questions and Discussion

Dr. Germino, moderator

Dr. Germino asked a series of questions that were provided to the Council and Speakers ahead of time.

Given the rapid pace of advances in generative AI capabilities, what strategies can we employ to prepare future generations to utilize AI in addressing the research priorities of NIDDK?

Dr. Butte replied that more generative AI strategies will be used for clinical notes and physicians must prepare for the use of this technology with regards to physician notes and patient replies.

Dr. Washington agreed that generative AI is already widely accessible and will be increasingly used in new and interesting ways.

What skills, expertise, experiences, and training are needed in the workforce to keep up with emerging technologies and ensure ethical and inclusive research that will benefit all populations?

Dr. Butte said that quantitative science fundamentals, like skilled screening, will become increasingly important, and this is currently not taught in the traditional physician scientist training curriculum.

Dr. Washington added that undergraduates in the health sciences do not have a data science background and these programs should increase knowledge in digital literacy to prepare them for the jobs of the future. Dr. Washington sees training opportunities as an open-ended question and an opportunity to better understand and plan for ideas like digital literacy, incentivizing adoption, and more.

How are institutions integrating data management, harmonization, and sharing into your daily workflows? What incentives (carrots and sticks) will be needed to speed adoption of these values in the research community?

Dr. Butte envisioned future networks across the country of noncompeting institutions sharing data for businesses purposes, treatment, payment, operations, and research.

Dr. Washington mentioned that funding is often allocated to large well-resourced universities. Incentives for a variety of institutions to participate in data sharing need to be created and these incentives may be different from those used in the past for large institutions. She emphasized the need to consider the magnitude of different institutions to ensure varied needs are met.

What technologies do you see on the horizon, and what is needed to prepare for them now?

Dr. Washington said that technologies like cloud computing are important, but so are functional devices like laptops that enable appropriate access. She also highlighted the importance of ensuring equitable access and training. Technology development should take the end user into account.

The speakers also answered direct questions from Council members.

Comment from Council: *How can academia and industry interact in the interest of embracing change? Can you leverage expertise within industry to help train the next generation of leaders and ensure that there is diversity in thinking?*

Dr. Washington noted that curriculum development and training are happening in industry, and efforts are underway to bridge the divide between the education that industry and academia are offering. Providing opportunities for crosstalk through presentations and workshops allows for better discussion about and understanding of data science. Government leaders can also collaborate in building these relationships. A sustainable, collaborative relationship involved working together to develop technology, develop the talent pipeline, and make further connections.

Comment from Council: *What opportunities are there to encourage learning and engagement with students much earlier in life in order to increase the onramp for diversity in the workforce?*

Dr. Washington responded that the AUC has a K-12 working group that aims to bring programs to schools and support legislation in this area. There are also programs that train teachers in data science to give them the background they need to bring data science to their students. Morehouse School of Medicine provides health programming to K-12 students and has a data-driven summer program for high school. Other universities and AUC have resources for younger age groups as well. She also mentioned that, while expanding the pipeline in earlier years is important, bias still exists at all levels of academia, and a focus on removing barriers for researchers producing peer-reviewed science is important as well.

Dr. Butte added that diversity in data sets is still needed. Models should not be trained on small, regional data sets and need to reflect the populations that they will be used in.

Comment from Council: *What kinds of internships are available through the AUC? How can health systems connect with trainees that they could retain as part of the workforce?*

Dr. Washington answered that there is a disconnect between job ads and the skills that industry is seeking. More work is needed to ensure that the workforce is well-trained for industry needs, and that industry is representing those needs well. There are internships available at some HBCUs, but not all. The next step is developing internships at all HBCUs. There also need to be incentives for faculty to participate in these internships with industry.

Dr. Germino concluded that the NIDDK data science working group is currently developing a workshop on data and metadata standards for NIDDK mission diseases and conditions. Development and use of agreed upon data standards, standardized terminologies, and common data elements will be key to the success of data interoperability.

VI. REPORT FROM THE NIDDK DIRECTOR

Dr. Griffin Rodgers

Budget Update

Dr. Rodgers updated the Council on recent budget events.

Congress had to pass four short-term continuing resolutions (CRs) to keep the government funded at the fiscal year (FY) 2023 funding level while they worked to reach an agreement on the FY 2024 budget. The fourth CR used a laddered approach of two separate deadlines: March 8 for a package of six appropriations bills and March 22 for the remaining six appropriations bills, including the Labor, Health and Human Services, and Education bill. On March 8, the President signed the first package of six appropriations bills into law, providing full-year appropriations for FY 2024 for many departments across the federal government. This package also extended authorization for the Special Diabetes Program (SDP) through December 31, 2024, and included a new annual authorization level of \$160 million for the program, an increase of \$10 million and the first increase in that program since FY 2004. On March 23, hours after the expiration of the fourth CR, the President signed the second appropriations package into Law, funding all the agencies included in the remaining six bills, including NIH.

NIH received \$47.08 billion, a decrease of \$378 million over the FY 2023 enacted level. This overall decrease (0.8%) in total NIH funding is due to a decrease in this year's 21st Century Cures funding for All of Us and the BRAIN Initiative. Despite a tough budget climate this year, NIH received a number of targeted funding increases, including an increase of \$100 million for Alzheimer's and related dementias research and an increase of \$120 million for cancer research at the National Cancer Institute (NCI). NIDDK received \$2.31 billion, which is a \$10 million increase over FY23. This additional \$10 million was provided by Congress to support diabetes-related research.

On March 11, President Biden also released the FY 2025 President's Budget Request that proposed funding NIH at \$48.3 billion, which is a 2.7% increase over the 2024 enacted budget. It also requests \$2.31 billion for NIDDK, maintaining FY 2024 funding levels. The increases in the NIH budget request primarily target specific areas, such as the Cancer Moonshot, maternal and women's health, mental health initiatives, health disparities and health equity research, and more. The President's Budget also requests funding for the SDP through FY 2026 and includes \$1.5 billion for ARPA-H, the Advanced Research Projects Agency for Health.

HHS Secretary Becerra testified at Senate and House Hearings in April to discuss the FY 2025 budget request. Members asked about a wide range of topics, including research on maternal health, opioid use disorder, youth mental health, cancer, and health disparities, as well as ARPA-H, and insulin pricing.

As the SDP received reauthorization and a funding increase, Dr. Rodgers provided an overview of the program's history. The SDP started in FY 1998 at a funding level of \$30 million per year, which increased to \$100 million per year starting in FY 2001 and increased again to \$150 million per year in FY 2004 and remained at that level through FY 2023. The recent reauthorization in the FY 2024 bill increased funding to \$160

million, which is the first funding increase for the Program since FY 2004. The increase will provide support for additional research to move faster towards more effective treatment and prevention of type 1 diabetes (T1D). The SDP is now authorized through December 2024.

Congressional and Constituency Activities

Dr. Rodgers highlighted the welcome reception hosted by American Cancer Society and Research!America at the end of January to celebrate the new NIH Director, Dr. Monica Bertagnolli. Dr. Germino attended on behalf of NIDDK and many Members of Congress also attended.

Dr. Rodgers then highlighted several meetings that NIDDK participated in with Congressional staff and partner groups. On January 22, staff from Senator Bernie Sanders' Office and the Senate HELP Committee met with Dr. Kevin Hall, one of NIDDK's intramural principal investigators to discuss Dr. Hall's research on ultraprocessed foods as part of the Committee's ongoing work to understand the relationship between food and health outcomes.

On February 22, NIDDK hosted the annual Friends of NIDDK meeting, during which discussions centered on the Institute's latest accomplishments and upcoming goals with the patient, physician, research, and disease advocacy organizations in attendance.

On March 5, Drs. Robert Star, Debbie Gipson, and Rodgers briefed Senator Debbie Stabenow of Michigan on recurrent focal segmental glomerulosclerosis and kidney disease research.

Upcoming Meetings

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

VII. CONCEPT CLEARANCE

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

Division of Digestive Diseases and Nutrition (DDN) Concepts

Various staff members presented concepts on behalf of the division.

The Role of Neuroimmune Interactions in Gastrointestinal Health and Disease

Dr. Terez Shea-Donohue

For gastrointestinal (GI) disorders such as inflammatory bowel disease (IBD), disorders of the gut-brain interactions (DGBI), metabolic diseases, and others, the correlation between disease pathology and symptoms is often imprecise, and there is a lack of disease or response biomarkers that assess treatment efficacy. In addition, current available therapies for these chronic debilitating GI diseases are limited, and traditionally have targeted either the nervous or immune system. A barrier to the development of new treatments is that these diseases are complex, multifactorial, exacerbated by stress, and may affect one gender more than another. In June 2023, NIDDK hosted a workshop highlighting neuroimmune crosstalk in the gut in health and disease as a focal point for research areas of interest to NIDDK including enteric neurodevelopment, neurogenesis, gut sensation, and gut-brain communication. The workshop recognized that dysfunctional neuroimmune communications contribute to the symptoms, severity, and chronicity of GI disorders. Moreover, remodeling of neuroimmune interactions may underlie the persistence of symptoms in disease remission in IBD or in the absence of overt disease pathology in DGBI. To advance research around neuroimmune interactions related to GI diseases, it is necessary to incentivize collaboration between siloed investigators in immunology and neurogastroenterology and facilitate sharing of state-of-the-art resources specific to each area.

Continuation of the Liver Cirrhosis Network

Dr. Jay Hoofnagle

The Liver Cirrhosis Network (LCN) was established in August 2021 by the NIDDK through Request for Applications (DK-20-003 and 004) with subsequent integrated support by the National Institute on Alcohol Abuse and Alcoholism (NIAAA), and the NCI. The LCN was charged to address several pressing clinical issues about cirrhosis that are encompassed in the development of two studies: a refined longitudinal natural history cohort (LCN Cohort Study) and a randomized, double-blind trial of statins for their effect in altering the natural history of liver cirrhosis (Rosuvastatin Efficacy and Safety for Cirrhosis in the United States (RESCU): A Double-Blind Randomized, Placebo-Controlled Phase 2 Study). Cirrhosis and chronic liver disease are listed as the 3rd most common disease-related cause of death in US adults below the age of 75 and its prevalence is rising. Cirrhosis of the liver is the outcome of many chronic liver diseases and once established, the irreversible nature places the patient at risk for significant clinical consequences such as portal hypertension, ascites, variceal hemorrhage, hepatic encephalopathy, severe hepatic dysfunction and, most ominously, liver cancer. Liver transplantation is the only viable avenue for reversing end-stage liver disease but is a medically and resource intensive intervention not available to many persons with cirrhosis. The LCN Cohort Study and RESCU were initiated within 1 and 2 years respectively from the establishment of the LCN and both are actively enrolling.

Continuation of the Nutrition Obesity Research Center (NORC) Program

Dr. Mary Evans

The NORC program has been an ongoing program for over 40 years with support for 11 NORCs across the US. The NORCs promote new discoveries and enhance scientific

progress through support of cutting-edge basic, clinical, and translational research related to nutrition science and/or obesity. The goal of the NORCs is to serve as a key component of the overall NIH/NIDDK plan to advance the fields of nutrition science and obesity and improve health of Americans across the lifespan. NORCs are intended to improve the quality and multidisciplinary nature of research on nutrition and obesity by providing shared access to specialized and technical resources and expertise. NORCs facilitate progress in research with the goal of developing new methods to evaluate, prevent, and treat obesity and to support basic and clinical nutrition science and dietary interventions. The NORCs are part of an integrated program of nutrition and obesity research at extramural research institutions that have established an existing base of high-quality, nutrition and obesity-related research. NORCs provide increased, cost-effective collaboration among multidisciplinary groups of investigators at institutions with an established, comprehensive research base in nutrition and obesity.

Silvio O. Conte Digestive Diseases Research Core Centers

Dr. Peter Perrin

The Silvio O. Conte Digestive Diseases Research Core Centers (DDRCC) program seeks to promote synergy between established investigators at domestic institutions who are engaged in digestive and/or liver diseases research. Each DDRCC supports a cohesive research base consisting of basic and clinical investigators actively conducting research related to an organizing theme that primarily aligns with NIDDK's mission as opposed to digestive and/or liver diseases research areas for which other NIH Institutes or Centers are considered the primary source of NIH funding. Both the theme and the structure should promote impactful multidisciplinary collaboration. This is facilitated by biomedical research cores that offer shared resources in a cost-effective manner, a pilot and feasibility program, and an enrichment program.

Dr. Rodgers then invited Council members to ask any questions related to the DDN concepts.

Council Questions and Comments

Comment from Council: Regarding both the NORCs and DDRCCs, is there an expectation that the number of centers receiving funding will change?

Dr. Evans responded that there are no opportunities to expand the number of centers.

Division of Division of Diabetes, Endocrinology, and Metabolic (DEM) Diseases Concepts

Members of the DEM staff presented concepts on behalf of the division.

Pilot/Opportunity Support for Generative Pretrained Transformers (GPT) to Accelerate Diabetes Research

Dr. Xujing Wang

One major challenge in T2D is the enormous heterogeneity associated with the disease. To address this challenge, the research field has generated a large amount of data and has accumulated a vast amount of prior knowledge about the disease. The data and prior

knowledge contain critical, but mostly hidden, information relevant to solving this challenge, however, cross-cutting gaps exist in integrating them and extracting predictive signals. One of the major problems is the lack of data science expertise in the T2D research field, and the lack of T2D-specific data science expert systems, models, and tools. This initiative proposes to address this problem by establishing a pilot funding program that leverages the emerging opportunities from recent data science advances. It will recruit multidisciplinary teams that include both T2D and data science experts to (1) develop AI foundation models for T2D; (2) validate the models with top research questions in T2D heterogeneity; (3) disseminate the models and engage the community for further development, validation and application; and (4) develop use cases that demonstrate the models' potential in accelerating the tempo of research. The expected outcomes will include new and diverse AI experts that have joined the T2D research workforce, new AI models that other T2D researchers can use, and informative use cases of the new models.

Nutrient-Stimulated Hormones and Neural Plasticity

Dr. Bradley Cooke

Two primary unanswered questions underlie the current obesity epidemic. The first is how the modern western food environment provokes unhealthy overconsumption and fat deposition despite multiple homeostatic regulatory systems that evolved to maintain a stable body weight. The second concerns what appear to be non-genetic transmission of maternal obesity and overconsumption to offspring, supporting a sudden exponential rise of metabolic disease throughout the population. New incretin receptor agonists are poised to revolutionize diabetes and obesity care through their effects on eating behavior, and thereby also provide powerful tools that give us a new window on how the brain is hijacked by the food environment, and how it particularly affects the developing brain and leads to unhealthy behaviors and metabolic responses. Given that incretin analog drugs are highly effective for a growing number of chronic metabolic, psychiatric, addiction, and neurodegenerative diseases, it is very likely that a large segment of our population will soon be treated with them. This emphasizes both the importance for incretins, and the imperative to work now to ultimately uncover the mechanisms of their effects on human development and biology. As an important first step, we will solicit investigator-initiated R01 proposals that focus on molecular, cellular, network, and behavioral neuroscience to address the roles of incretin and related hormones on these two critically important questions.

Collaborative Awards to Support Microphysiological System Pilot Studies in Diabetes Research

Dr. Albert Hwa

Advances in biomaterials, microfluidics, and tissue engineering have resulted in microphysiological systems (MPSs) that allow for greater control of three-dimensional cell cultures containing multiple cell types and constituting more physiological tissue organization. The use of patient samples and human induced pluripotent stem cell-derived cells coupled with MPSs will enable patient-on-a-chip or clinical-trial-on-a-chip studies of T2D development and treatment that is currently not possible. The utility of these systems lends themselves to powerful in vitro modeling of metabolic tissue crosstalk, study of basic mechanisms of human T2D, and the testing of prevention and

treatment strategies. MPSs are especially useful for investigating the heterogeneity of human T2D biology and clinical responses. However, adoption of such systems as a complementary research tool by traditional basic biology laboratories requires additional MPS expertise and resources. Opportunities exist for NIDDK to incentivize collaborative studies to encourage pairings of engineering and biology labs. The current initiative will support small pilot studies to conceptualize aspects of T2D biology for modeling with MPSs, to support feasibility studies, and to generate preliminary data. It is anticipated that these pilot awards may pave the way to enhance the success of future R01 submissions and broaden the use of MPSs in human T2D research.

Advancing Research on the Application of Digital Health Technology to the Management of Type 2 Diabetes

Dr. Henry Burch

The application of digital health technology to the management of T2D is at an inflection point and comes at a time where a paradigm shift in the approach to T2D is urgently needed. The global diabetes epidemic is rapidly outpacing the ability of current health care systems to provide optimal care and ensure patients achieve basic standards of diabetes care. The increasing availability of US Food and Drug Administration (FDA)-cleared digital health technology (DHT) for T2D management holds great promise for addressing current barriers to acceptable care by ensuring improved patient access to the health care system, enhanced patient engagement and sense of empowerment, improved glycemia and other diabetes-related metabolic outcomes, reduced clinical inertial and provider dissatisfaction, and provision of favorable economics at the health care system (HCS) level. While integrated multimodality digital health approaches, referred to as virtual diabetes clinics (VDC) hold great promise and are actively marketed by industry to employers, insurers, and HCSs, the scientific rigor of studies supporting this approach lags behind their promotion, and industry has little motivation for funding large randomized controlled trials to examine the efficacy of the digital VDC approach. This initiative is intended to advance research on the application of currently available DHT in a multimodality VDC model to examine the clinical efficacy of an urgently needed paradigm shift in the population health approach to T2D.

Shared Decision Making to Improve Diabetes Prevention and Care

Dr. Maureen Monaghan Center

Shared decision making is a collaborative process that enables and encourages people to play a significant role in the decisions that impact their health. Shared decision making is central to facilitating personalized, person-centered diabetes care. However, despite inclusion of shared decision making in evidence-based standards of care, current clinical practice is not optimized for effective shared decision making. Additionally, there is a paucity of research to guide the conduct and implementation of shared decision making in diabetes care, particularly studies evaluating application of shared decision making in real-world settings, with diverse populations, and with rigorous evaluation of cost and cost effectiveness. This proposed initiative addresses the critical need to build the evidence base linking shared decision making and health outcomes in patients with diabetes, with particular attention to facilitators and barriers to shared decision making in populations of patients traditionally underserved and/or underrepresented in clinical trials and sustainability in clinical care settings.

Dr. Cefalu then invited Council members to ask any questions related to the DEM concepts.

Council Questions and Comments

Comment from Council: For the proposal on nutrient-stimulated hormones and neural plasticity, given that many diseases of the brain involve blood vessels, will there be any research looking at neural modulation of plasticity and the effects first on blood vessels in the brain, such as endothelial cells or capillaries?

Dr. Cooke agreed that this is a good suggestion, and that interesting work is underway examining the role of endothelial cells in transporting nutrient-stimulated hormones across blood vessels.

Next, Dr. William Cefalu presented four DEM renewal concepts:

Centers for Diabetes Translation Research (CDTR)

The CDTR program was established in 2011 to improve translation of research findings related to diabetes prevention, treatment, and health equity by supporting research across the translational research spectrum (i.e., bedside to clinical practice and community settings, dissemination and implementation research). CDTRs provide local, regional, and national research resources to advance the field of diabetes translation, address diabetes-related health disparities, and develop the scientific workforce. The goal of CDTRs (<http://www.diabetes-translation.org/>) is to improve prevention/treatment of diabetes by promoting research that supports rapid dissemination, implementation, and sustained use of effective interventions/approaches, particularly in high-risk populations. CDTRs have documented evidence of progress from their current project period, which is the second renewal with seven funded grantees. To date, their scientific research base consists of over 790 members, over 4,000 consultation services across 24 local, regional, and national research service cores, and awarded 94 P&F projects. The objective of this renewal is to ensure uninterrupted support to the CDTR program after the current project period ending 6/30/2026. This will be a competitive renewal open to existing and new Center applications.

Accelerating Medicines Partnership in Type 2 Diabetes (AMPT2D) - Renewal

The Accelerating Medicines Partnership (AMP), is a pre-competitive collaboration among government, academia, and industry to improve the ongoing efforts to develop new therapies for complex, heterogeneous diseases (<http://www.nih.gov/science/amp/>). The overarching goal of AMP-Common Metabolic Diseases (CMD) is to use human genetics as a powerful approach to obtain human-data derived disease understanding and biomarker/therapeutic opportunities. This is being accomplished through systematic aggregation of existing genotype-phenotype data for CMD, related traits, and its complications as well as the generation of a large amount of new -omic data which are being deposited in the portal. The goal of the NIDDK-funded component of the consortium will be to continue to build on the current capabilities of the Common Metabolic Diseases Knowledge Portal and harmonize with other NIDDK resources.

National Health Interview Survey (NHIS) - Diabetes Components

We are requesting renewal of Initiative #1065 “Renewal of the NHIS - Diabetes Components” for the purpose of continuing the diabetes-related questions among this US nationally representative cohort that will be included in NHIS from FY2026-2030. Scientists from NIDDK/DEM and Centers for Disease Control and Prevention (CDC)/Division of Diabetes Translation will jointly review the current diabetes-related content in NHIS to ensure that we are obtaining robust data related to diabetes. We have modified the questions in the National Health and Nutrition Examination Survey (NHANES), renewed for FY25-29 last year, to harmonize the questions with NHIS whenever possible to strengthen our diabetes content in these two national surveys. The NHIS data are public use and have been used extensively by researchers in the United States and beyond as well as by NIDDK and CDC scientific staff and other federal agencies to inform public health and policy decision related to diabetes.

Renewal of the NIDDK Catalyst Award

NIH high-risk/high-reward grant programs supported by the NIH Office of the Director (NIH-OD), including the Pioneer and New Innovator programs, have been highly successful at diversifying and strengthening grant portfolios across NIH. The NIH-OD programs are designed to prioritize research that spans the interests of multiple NIH institutes, and as a result, HRHR proposals that focus on NIDDK's mission areas are underrepresented. The NIDDK Catalyst initiative is patterned after key elements of the OD Pioneer Award, including requirements for an essay-based proposal focused on goals that are bold and innovative. Accordingly, the DDN joined with the DEM to offer this Catalyst program for FY2021 that funded such high-risk/high-reward proposals within the missions of DDN/DEM. Another request for applications (RFA) for Catalyst applications was published in FY2023 and applications are currently awaiting review in early 2024. Based on the robust responses to these prior funding opportunities, there remains a need to continue to support this unique and important part of DDN's/DEM's grant portfolios and provide a consistent avenue to support high-risk/high-reward research to tackle intractable problems within NIDDK's mission.

Dr. Cefalu also presented two SDP renewal concepts:

Integrated Islet Distribution Program (IIDP)

This request is to continue support of the IIDP. IIDP facilitates the distribution of human islets and associated samples including plasma, serum, peripancreatic lymph nodes as well as acinar, ductal, and duodenal tissues to biomedical researchers by establishing partnerships with qualified islet isolation facilities to prepare and distribute these samples. It also solicits requests for samples from new principal investigators and researchers new to the field of human islet research. IIDP efforts in the last project period are now supporting nearly 200 investigator-initiated projects, resulting in 168 publications in the first four years of the previous cycle. Human islets and associated tissues are essential resources for diabetes research to advance our understanding of human islet cell biology, and to promote the development of new therapies for the prevention and treatment of diabetes.

The Environmental Determinants of Diabetes in the Young (TEDDY) Data Coordinating Center

T1D is a serious and burdensome chronic disease that usually affects children and young adults. The rate of T1D incidence is rising worldwide, especially in the very young. These findings suggest that environmental triggers are responsible for increased and accelerated rates of disease in genetically susceptible individuals. TEDDY was established to identify environmental triggers of T1D, such as infectious agents, dietary factors and/or psychosocial factors, in genetically susceptible individuals that trigger or protect against the development of islet autoimmunity and T1D. TEDDY's overarching goal is to elucidate the etiology and pathogenesis of T1D and to inform new strategies to prevent or delay the disease. To date, TEDDY has shed light on the heterogeneity of the disease process. TEDDY completed recruitment of the subjects in 2010; retention and data accrual rates are meeting study projections. The study was designed to follow subjects for 15 years to accrue approximately 800 subjects who develop autoantibodies and 400 subjects who develop diabetes. The NIDDK recommends renewal of the TEDDY program to continue to conduct data analysis and prepare manuscripts, manage and perform quality control of NCC2 datasets and to prepare data sets for deposit in the NIDDK repository and other specialized repositories and finally closeout the study.

Division of Kidney, Urologic, and Hematologic (KUH) Diseases Concepts

Various KUH staff members presented concepts on behalf of the division.

Post-Dialysis Fatigue and Patient Science

Dr. Kevin Chan

Most people on chronic dialysis develop debilitating fatigue after their dialysis treatment. The scientific literature of post-dialysis fatigue is sparse, and we lack basic diagnostic criteria, an outcome measure, and pathophysiological explanation for this disease. This cooperative research initiative proposes to engage people with post-dialysis fatigue with qualitative scientists to establish a robust case definition, a diagnostic instrument, an outcome measure, and quality metrics for post-dialysis fatigue. The epidemiology and biology of the disease will be defined. This foundational science will form an anchor for subsequent therapy development and clinical trials.

Matching for Kidney Precision Therapeutics (MAP-IT)

Dr. Debbie Gipson

Patients with kidney disease are frustrated by the generic standard of care management that includes a series of treatments with low likelihood of kidney preservation and significant risk for toxicity. The Kidney Precision Medicine Project was implemented to advance the characterization of kidney disease mechanistic subgroups, associated biomarkers, and treatment targets with a goal to improve the subsequent opportunities for precision therapies. This new initiative is being designed to prepare the next step in the translational pipeline and will be informed by a March 18-19, 2024, NIDDK workshop entitled Preparing for Kidney Precision Medicine Trials. Currently identified gaps include a need for broader expertise in translating mechanism discovery to interventional trials, the translational gap from biomarker discovery to high reliability assays with

defined cut-points for target population identification and trial endpoints, and efficient screening of kidney patient disease mechanisms to inform precision clinical trial enrollment. The creation of a national matching for kidney precision therapeutics program (MAP-IT) is designed to address these gaps. In this first phase, initial objectives will be accomplished by 1) establishing a transdisciplinary, multi-institutional consultative team to assess and advise on kidney precision medicine trial proposals, 2) refine and deploy assays fit for use in human trials, and 3) implement clinical trials platform demonstration projects.

Management of Asymptomatic Renal Stones (MARS)

Dr. Ziya Kirkali

An asymptomatic renal stone in the kidney is like a time bomb! Patients are anxious not knowing what will happen to them and when, as symptomatic stone events are unpredictable and can vary in intensity. Philosophically, all symptomatic stones were once asymptomatic; and clinically, a planned intervention is always better than an unplanned one. Since there are no definitive trials, management of asymptomatic stones is controversial. A patient-centered approach will be taken to identify what matters most to the person who harbors an incidental or a residual asymptomatic stone after surgery. First, a workshop is planned to get patient input, bring in the urologic community and flesh out the idea. Then a Notice of Funding Opportunity will be developed to support a Clinical Research Consortium. The study will ask to consent all patients with an asymptomatic renal stone who do not want to be randomized (patient choice) and collect data. Patients with incidental or residual asymptomatic stones smaller than 15 mm in largest diameter consenting to the study to be randomized to either active surveillance or intervention (ureteroscopy/Shock Wave Lithotripsy) (patient/surgeon choice). The primary outcome will be stone-related surgery or Emergency Department visit, with multiple secondary outcomes. Machine learning will be used to; a) identify best management options for individuals with different characteristics, and b) identify optimal follow-up strategies for active surveillance.

Revisiting Development at KUH: Initiating New Directions, Launching Early-stage Investigators (ESIs)

Dr. Eric Brunskill

The Revisiting Development at KUH: Initiating New Directions, Launching ESIs (ReKINDLE) is an opportunity to rejuvenate the developmental biology field, address core fundamental scientific questions critical to the mission of KUH, while also attracting new investigators to the NIDDK. ReKINDLE aims to invigorate developmental biology by supporting researchers and ESIs with the resources to pursue groundbreaking research. By highlighting the importance of development, this program not only enriches our comprehension of fundamental developmental mechanisms but continues to lay a foundation for ongoing advancements in developmental biology, but also continue to foster growth in regenerative medicine, stem cell research, and the study of congenital anomalies.

Next, Dr. Robert Star presented 9 KUH renewal concepts:

Understanding Chronic Kidney Diseases of Uncertain Etiology in Agricultural Communities

Chronic Kidney Disease of Uncertain Etiology (CKDu) is recognized to cause end-stage kidney failure in rural areas of many Low- and Middle-Income Countries, resulting in a large death toll among the relatively young working age population. Environmental factors and extreme heat exposure are suspected, but there is a lack of compelling evidence for any agent, while family and geographic clustering raise the possibility of an unrecognized genetic susceptibility. Since 2021 NIDDK and National Institute of Environmental and Health Sciences (NIEHS) have jointly funded a consortium to find causes and potential interventions for CKDu. The consortium comprises of a Scientific Data Coordinating Center, Field Epidemiology Sites, and a Renal Science Core. It benefits from the active collaboration of Human Health Exposure Analysis Resource laboratories (funded by NIEHS).

Interventions to Improve Outcomes After AKI (COPE-AKI)

Acute kidney injury (AKI) is associated with high morbidity, including increased risk of chronic kidney disease (CKD), end-stage kidney disease (ESKD), cardiovascular disease, and mortality. There is limited evidence to inform recommendations for processes of care interventions targeting progression of kidney disease and the associated morbidity and mortality in AKI survivors. Since 2021, NIDDK has funded the Caring for OutPatiEnts after Acute Kidney Injury (COPE-AKI) Consortium, composed of three Clinical Centers and a Scientific and Data Research Center, to develop and test a process of care intervention that aims to reduce rehospitalizations, morbidity, and patient reported outcomes compared with usual care in patients after hospitalization with Stage 2 and 3 AKI. A 5-year extension of the COPE-AKI clinical trial is proposed to fully meet the enrollment targets, ensure appropriate representation of underrepresented minorities, complete participant follow-up, and allow for resources for data analysis and dissemination of study findings. There is currently no standard of care for patients after hospitalization with AKI. Successful completion of the COPE-AKI study will provide key insights that are expected to directly inform improved clinical management strategies and the development of standard of care for Stage 2 and 3 AKI survivors.

Phosphate Binders in Children with CKD (FIT4KID)

CKD-mineral bone disorder (CKD-MBD) is closely linked to the progression of CKD and the development of cardiovascular disease in children and adults. Management of CKD-MBD is unquestionably suboptimal and the current investigators have proposed a novel treatment paradigm. They have undertaken a clinical trial to test the paradigm. This initiative is intended to permit successful completion of the FIT4KiD multisite clinical trial by providing extended funding to the Data Coordinating Center as the clinical enrolling sites continue to accrue patients.

A Trial of Transplanting Hepatitis C-viremic Kidneys into Hepatitis C-Negative Kidney Recipients (THINKER-NEXT)

THINKER-NEXT is an ongoing multi-center trial with an overarching goal to determine if kidneys from hepatitis C-viremic (HCV) donors can safely be transplanted into HCV

negative patients with end-stage renal disease. Enrollment of trial participants, kidney transplantation, and one year follow-up of the cohort is anticipated to occur at the end of the current funding period. This initiative proposes an additional one year of funding to complete analysis of the data from the THINKER-NEXT trial.

George M. O'Brien Urology Cooperative Research Centers and the Urology Centers Interactions Core

This concept seeks support for continuation of the NIDDK George M. O'Brien Urology Cooperative Research Centers (U54) and the Urology Centers Interactions Core (U24). The Urology Cooperative Research Centers foster impactful, multidisciplinary research through diverse collaborations within and outside the Centers and serve as a national resource for the urology research community. The Interactions Core supports these efforts through coordinating the Urology Cooperative Research Centers, the urology P20 Centers, and urology Institutional Career Development (K12) Programs, as well as the broader urology community, all under the umbrella of the Collaborating for the Advancement of Interdisciplinary Research in Benign Urology (CAIRIBU) effort. In addition, the Interactions Core will serve as the hub for a CAIRIBU Opportunity Pool Program and additional travel, and research awards designed to support emerging scientists, including NIH defined ESIs and investigators new to the field of urology. All efforts will address the overall goal of improving prevention and clinical management of benign (non-cancer) genitourinary disorders through research excellence, enhanced sharing of resources and access to core services, and establishment of a robust research community trained to address the Nation's biomedical research needs for urologic disorders within the NIDDK's mission.

Re-competition of Institutional Career Development for Epidemiology of Urologic Diseases (UroEpi)

The goal of this renewal proposal is to provide institutional support to mentor and develop a cohort of investigators proficient and self-sustaining who can conduct epidemiologic research in urologic diseases within our mission, serving as a parallel resource to existing projects for chronic and ESKD within KUH, and for diabetes and digestive diseases within NIDDK.

KUH Predoctoral to Postdoctoral Fellow Transition Award (F99/K00)

The purpose of the Kidney, Urology and Hematology Predoctoral to Postdoctoral Fellow Transition Awards (F99/K00) is to recruit exceptional graduate students from diverse research disciplines and backgrounds to pursue postdoctoral training focused on Kidney, Urology or Hematology research. Talented graduate students from disciplines including, but not limited to, engineering, statistics, data science, imaging, biochemistry, and genetics are invited to apply to this opportunity. This program is committed to promoting and supporting diversity (both scientific and demographic) through training the next generation of kidney, urology, and hematology researchers.

Coordinating Unit to Support the Kidney, Urology and Hematology Innovative Science Accelerator Program Coordinating Unit (ISAC-CU)

Truly innovative, breakthrough discoveries often come from disruptive, risky research. Such innovative research must be supported by an equally innovative and nimble funding program. In 2021, KUH established the Innovative Science Accelerator (ISAC) Program, administered through the ISAC-CU, with the goals to provide: 1) seed funding, through a highly flexible funding process, for projects targeting discovery (hypothesis-generating) and exceptionally innovative, disruptive high-risk/high-reward research relevant to KUH research communities; and 2) a platform for researchers funded through the program to exchange ideas and resources to enable collaboration and accelerate innovation. We propose to continue to enable cutting-edge research and accelerate true innovation through the ISAC program.

Development of Catalytic Tools and Technologies for Kidney, Urologic, and Hematologic Diseases

The purpose of this initiative is to promote the development of innovative, enabling tools and technologies in the areas of KUH diseases. The initiative supports technology development projects that will catalyze new scientific endeavors or full-scale development efforts. This is a renewal of a concept approved in 2021, which has been successful in attracting investigators from other fields to KUH research and funding meritorious projects.

Office of Minority Health Research Coordination Concept

Dr. Rob Rivers presented a concept on behalf of the office.

Expansion of the Short-Term Research Experience Program to Unlock Potential (STEP-UP)

Historically, opportunities in this country have been mired by lack of resources based on a person's zip code. To address the myriad of health problems facing the country and the world, it is imperative that the full diversity of the United States is engaged in the biomedical research workforce. Moreover, from research, we know that more diverse teams tend to be more innovative than homogenous groups. To ensure that the biomedical research workforce encompasses talent with no boundaries on opportunity for talent, the NIDDK Short-Term Research Experience to Unlock Potential (STEP-UP) program was launched to provide hands-on research experiences to both high school and undergraduate students. For more than 20 years, this program has engaged students from throughout the country and US territories to work with researchers on the cutting edge of discovery. In this renewal, we seek to expand the program in partnership with the National Heart, Lung, and Blood Institute to have more high school centers located throughout the country. No changes are sought in the undergraduate program as the modifications made in the last round.

Office of Obesity Research

Dr. Voula Osganian presented a concept on behalf of the office.

Optimal Treatment Strategies for use of Anti-Obesity Medications in Children and Adolescents

Obesity in youth remains prevalent and a major public health problem. Since 2020, three anti-obesity medications have been approved by the FDA in youth ages 12 years and older with non-syndromic obesity. Studies of anti-obesity medications (AOMs) demonstrate significant improvements in body mass index (BMI) and cardiometabolic risk factors. However, a strong evidence base is lacking to guide treatment decisions for youth, in which physical and psychosocial growth and development need to be considered, including optimal developmental stage for AOM initiation; drug class and dosage; behavioral, nutritional and physical activity interventions to support growth and development and preservation of lean body mass; type and intensity of lifestyle interventions needed to support optimal weight and psychosocial outcomes; and potential strategies to enable discontinuation of AOMs and avoid lifetime use while preserving health benefits. This initiative will support investigator-initiated research to test AOM treatment strategies for youth with obesity that could be implemented in clinical care settings to maximize benefits and minimize risks of AOM use. Given the rapidly changing landscape and knowledge gaps in treatment strategies and safety with AOM use, well-designed studies are needed to support the appropriate, effective, and safe use of AOMs in diverse populations of children and adolescents. Findings will inform optimal medical management of children and adolescents with obesity.

Health Equity Concepts

Dr. Germino introduced this new set of concepts, which stem from NIDDK's report *Pathways to Health for All*, developed via Working Group with input from some members of the Advisory Council. The Working Group has been meeting monthly to discuss ways to implement the five major recommendations in the Report. The concepts presented are a notable step in the implementation process. Various staff members presented concepts.

Planning Grants for NIDDK Community-Engaged Research

Dr. Miranda Broadney

Understanding the critical importance of including rigorous community engagement in health research, NIDDK seeks to deepen the use of robust community-engaged methods across the spectrum of the Institute's research. This initiative proposes to solicit planning grant applications to assemble & strengthen community partnerships, assess feasibility and determine best practices to conduct community-engaged research focused on NIDDK mission diseases and populations that experience health disparities. If successful, these planning grants would support, enable, and lay the groundwork for future clinical studies or trials which have been co-created with community investigators. This initiative will also establish research activities that include the priorities of communities who are affected by and could benefit from rigorous pragmatic planning around devising research questions, describing community assets, and developing intervention approaches to better understand and/or improve the prevention and treatment of NIDDK diseases and

conditions. Subsequently, these new multidisciplinary teams should be prepared and equipped to execute their co-created research study.

Program for Implementation Science and Health Equity Scholars (PrISHES)

Dr. Pamela Thornton

The PrISHES will train a cadre of investigators with advanced research skills in dissemination and implementation science and health equity in NIDDK-related disease prevention and management. Speedy translation of efficacious and expensive medical research into practice is essential to improve the health of all people. However, lags in getting research into practice persist (roughly 17 years); and only 1 in 5 evidence-based interventions make it into routine clinical practice. As cited in NIDDK's strategic priorities, workforce development and growing the field of implementation science are key strategies to close the gap between research and practice. However, NIDDK investments in implementation science have thus far been mostly limited to diabetes programs. Yet, promising interventions for many NIDDK diseases and conditions are ripe for testing appropriate adaptation and evaluation methods to increase their potential benefit in diverse patient populations and various community and health care settings. PrISHES leverages lessons from NIDDK and NIH investments to provide intensive short courses in relevant methodologies followed by mentorship activities with cohorts of multidisciplinary scholars. Anticipated outcomes include a cadre of investigators with advanced implementation science and health equity research competencies, leading to publications, grants, and overall retention in fields that can advance NIDDK disease prevention and management for all.

Integration of Social and Medical Care (Renewal)

Adverse social determinants of health, also called social risks, drive obesity, diabetes, and kidney disease outcomes. Social risks disproportionately affect racial and ethnic minority groups, rural populations, sexual and gender minority groups, and socioeconomically disadvantaged communities, and contribute to health inequities in NIDDK diseases. RFA-DK-22-038 requested pilot trials to test approaches to integrate social and medical care in health care settings. The trials will determine: 1) feasibility and acceptability of screening for social risks, identifying social needs and implementing referral service linkages (e.g., addressing transportation, housing, or food needs, etc.) within the context of a healthcare visit; and 2) preliminary signals of the intervention's impact on both the social risk/need(s) and NIDDK disease outcomes. These pilots will lay the foundation for larger, fully powered clinical trials. This FY 2024 initiative was intended to 1) jump start novel research to systematically screen for and address patients' social risks to improve health outcomes in NIDDK diseases; and 2) grow a community of NIDDK researchers who can share effective strategies to integrate medical and social care in the context of healthcare delivery. A budget cut to the FY 2024 initiative decreased the number of awards and eliminated the proposed 2nd receipt date. Funds are requested to re-issue the RFA with an FY 2026 receipt date to better achieve the goals of this initiative.

Dr. Germino invited Council members to ask any questions related to the Health Equity concepts.

Comment from Council: Is the PrISHES program similar to the K awards program?

Dr. Thornton responded that PrISHES is a training program more like an R25 than a K award. The scholars would be funded for a short-term intensive training experience, and then the program would support the mentors for a 2-year mentoring program to involve the scholars in grant writing, publications, and more. At this stage, Dr. Thornton expects many of the scholars would also have K awards or be involved with other supportive programs.

HIV/AIDS Research

Next, Dr. Peter Perrin presented two renewal concepts.

Priority HIV/AIDS Research within the Mission of the NIDDK

This initiative seeks to stimulate basic, translational, and clinical HIV/AIDS-related research within the mission of NIDDK that is aligned with NIH HIV/AIDS research priorities. The most recent priorities are outlined in NOT-OD-20-018, UPDATE: NIH HIV/AIDS Research Priorities and Guidelines for Determining HIV/AIDS Funding. Areas of interest include pathophysiological research on NIDDK-relevant comorbidities, coinfections, and complications; research toward an HIV cure that focuses on viral reservoirs in anatomical sites relevant to the mission of NIDDK, behavioral and social mechanisms impacting the development and management of NIDDK-relevant HIV co-occurring conditions, and NIDDK-relevant topics that cut across more than one NIH HIV/AIDS research priority.

Exploratory and Developmental HIV/AIDS Research within the NIDDK's Mission

This initiative encourages innovative basic, translational, or clinical research on NIH HIV/AIDS priority research within NIDDK's mission by facilitating exploratory and developmental research that might lead to a larger, more encompassing project. Several important HIV comorbidities, coinfections, and complications affect organs, tissues, and processes within NIDDK's mission. Examples include obesity, diabetes, and metabolic and endocrine complications; kidney, urologic and hematologic diseases; enteropathy and its impact on the digestive system as well as other organs and tissues; noncommunicable liver disease; and viral hepatitis. Understanding disease mechanisms in the context of HIV or its treatment is essential for prevention and management of these conditions. In addition, the contributions of health-impeding social determinants of health must also be addressed. Elucidating mechanisms underlying HIV reservoirs in NIDDK-relevant tissues is essential toward development of strategies for long-term viral suppression or eradication of HIV from the body.

NIDDK-wide Initiatives

Various staff members presented concepts.

Novel Device Neurotechnologies for Probing Peripheral or Body-Brain Neural Processes within the Mission of NIDDK

Dr. Diana Cummings

Bidirectional brain-visceral organ communication plays a critical role in controlling physiological functions that promote health and survival (e.g., energy homeostasis, digestion, voiding, etc.), and disruptions to this communication cause or contribute to many diseases within NIDDK's mission (e.g., obesity, metabolic dysfunction, disorders of gut-brain interaction, neuro-urological disorders, etc.). Distinct challenges faced by neuroscientists who study cells, circuits, and body-brain interactions involving peripheral organ systems include the relative inaccessibility and unique anatomy and physiology of visceral organs, as well as technical difficulties inherent to simultaneous interrogation of the brain and a visceral organ. Three recent NIDDK-sponsored workshops, e.g., Neuroimmune Crosstalk in the Gut, Neural Plasticity of Energy Homeostasis and Obesity, and Neurourology: Bridging Basic and Clinical Science to Understand Urologic Disease, emphasized the need for better neurotechnologies for interrogating interactions between visceral organs and the associated peripheral and/or central nervous system. This initiative's purpose is to facilitate the development and translation of transformative technological approaches that will break through existing technical barriers and improve capabilities for basic, translational, and clinical research on the peripheral nervous system and/or body-brain axis that is relevant to diseases within NIDDK's mission.

NIDDK Innovation Fund: Capitalizing on Rapid Advances in Data Science

Dr. Daniel Gossett

The field of AI and other data science technology is rapidly advancing, presenting new and revolutionary opportunities. We lack nimble processes to harness emerging opportunities to catalyze NIDDK science. Furthermore, our workforce has gaps that impact our ability to effectively leverage new data science technology to advance the NIDDK mission. There is a need for a NIDDK program that can quickly integrate new expertise and capitalize on the latest advances. The proposed initiative is to establish an innovation fund that allows NIDDK to rapidly capitalize on emerging and transformative opportunities and implement innovative ideas leveraging data science. The innovation fund will take advantage of timely and time-sensitive opportunities, prioritizing cross-cutting research that has NIDDK-wide impact and short-term efforts that limit out-year commitments. The fund will 1) support NIDDK science within NIH-wide ODSS-led efforts and 2) support a funding opportunity for short-term grants for specific emerging topics that are at the leading edge of the field, which will change over time and will be updated annually through the NIH Guide to Grants and Contracts.

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.

VIII. OPEN SESSION OF SUBCOMMITTEE MEETINGS

See Minutes posted on the NIDDK Council Minutes Website.

IX. CLOSED SESSION OF THE SUBCOMMITTEE MEETINGS

A portion of the meeting was closed to the public in accordance with the determination that it concerned matters exempt from mandatory disclosures under Sections 552b(c)(4) and 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 1,583 grant applications (790 primary and 793 dual), requesting support of \$809,618,229 were reviewed for consideration at the May 8, 2024 Council meeting. An additional 1,224 Common Fund applications requesting \$786,989,248 were presented to Council. Funding for these applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, 1,047 applications requesting \$445,798,216 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 May 8, 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 225th meeting of the NIDDK Advisory Council was adjourned at 4:30 p.m. on May 8, 2024.

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