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

I. CALL TO ORDER
Dr. Rodgers

Dr. Griffin Rodgers, Director, NIDDK, called to order the 214th meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council at 10:30 a.m. on September 9, 2020, via Zoom videoconference. This meeting was conducted using a two-tiered webinar format. The panelist tier consisted of NIDDK's Advisory Council members and NIDDK staff members who presented during the meeting. The audience tier was available to members of the public and allowed them to view and listen to the meeting.

A. ATTENDANCE – COUNCIL MEMBERS PRESENT

Dr. David D'Alessio*
Dr. Iain Drummond
Dr. Penny Gordon-Larsen
Dr. Lisa Guay-Woodford
Dr. Barbara Kahn
Mr. Richard Knight
Dr. Rudolph Leibel +
Mr. Thomas Nealon
Dr. Mark Nelson
Dr. Richard Peek
Dr. David Penson
Dr. Jeffrey Pessin
Ms. Ceciel Rooker
Dr. Kathleen Sakamoto
Dr. Ronald Sokol
Dr. Gary Wu

Also Present:
Dr. Griffin Rodgers, Director, NIDDK and Chair of the NIDDK Advisory Council
Dr. Karl F. Malik, Executive Secretary, NIDDK Advisory Council
Dr. Matthew Portnoy, Deputy Director, Division of Extramural Activities
Dr. Gregory G. Germino, Deputy Director, NIDDK
Dr. Stephen P. James, Director, Division of Digestive Diseases and Nutrition, NIDDK
Dr. Robert A. Star, Director, Division of Kidney, Urologic, and Hematologic Diseases, NIDDK
Dr. William Cefalu, Director, Division of Diabetes, Endocrinology and Metabolic Diseases, NIDDK
* *Ex officio* member
+ *Ad hoc* member

B. NIDDK PANELISTS/SPEAKERS

Dr. Lawrence Agodoa
Dr. Dr. Mary Evans
Dr. Robert Karp
Dr. Christine Lee
Dr. Padma Maruvada
Dr. Robert Rivers
Dr. Sheryl Sato

Dr. Salvatore Sechi
Dr. Jose Serrano
Dr. Katrina Serrano

C. ANNOUNCEMENTS

Dr. Rodgers

Dr. Rodgers began by announcing that NIH has decided that all advisory council meetings will be held virtually at least through February 2021. The January 2021 NIDDK Advisory Council meeting will again take place in a virtual format.

Council Member News

Dr. Rodgers welcomed four new members of the NIDDK Advisory Council as the class of 2023:

- **Dr. Mark Nelson** is University Distinguished Professor and Chair of the Department of Pharmacology at the University of Vermont College of Medicine, where his research focuses on ion channel physiology and calcium signaling in the vasculature and neurovascular coupling. He will serve on the Kidney, Urologic, and Hematologic Diseases (KUH) subcommittee.
- **Dr. David Penson** is Hamilton and Howd Chair of Urologic Oncology; Chair of the Department of Urologic Surgery; Professor of Urologic Surgery, Medicine and Health Policy; and Director of the Center for Surgical Quality and Outcomes Research at Vanderbilt University. His research focuses on the comparative effectiveness of treatments for localized prostate cancer, and he is active in the field of health policy. He will serve on the KUH subcommittee.
- **Ms. Ceciel Rooker** is President and Executive Director of the International Foundation for Gastrointestinal Disorders. She has worked extensively with patients, families and health professionals to improve education and patient care for gastrointestinal and motility disorders. She will serve on the Digestive Diseases and Nutrition (DDN) subcommittee.
- **Dr. Kathleen Sakamoto** also joins the Council. Dr. Sakamoto is the Shelagh Galligan Professor in the Division of Hematology, Oncology, Stem Cell Transplantation and Cancer Biology at Stanford University School of Medicine. Her research focuses on signaling pathways and gene regulation in normal and aberrant hematopoiesis, including leukemia and bone marrow failure syndrome. She will serve on the KUH subcommittee.

Dr. Rodgers welcomed the new members and thanked them for their time and participation.

Dr. Rodgers also recognized **Dr. Rudolph Leibel** as an *ad hoc* member. Dr. Leibel is the Christopher J. Murphy Memorial Professor of Diabetes Research at Columbia University and a long-time friend to NIDDK. He joined the Diabetes, Endocrinology and Metabolic Diseases (DEM) subcommittee as a subject matter expert for this meeting.

Dr. Rodgers also gave a "shout out" to four current Council members who were scheduled to retire after this meeting as part of the Class of 2020 but have agreed to stay on to assist with the January 2021 Council meeting. These members are Lisa Guay-Woodford, Richard Knight, Thomas Nealon, and Jeffrey Pessin.

Dr. Rodgers announced several deaths in the NIDDK community. He relayed the sad news of the passing of Herbert Tabor, MD, a global authority on enzymatic pathways of polyamines and editor of the *Journal of Biological Chemistry* for more than 40 years—a position he held until his death at the age of 101. He was senior principal investigator in NIDDK's Laboratory of Biochemistry and Genetics and served as lab chief until 1999. Working with his wife, Celia, a physician scientist who died in 2012, Dr. Tabor revealed the multitude of functions served by polyamines, which are the organic compounds that interact with DNA, RNA, and proteins. Dr. Tabor died peacefully in his sleep on the NIH campus on August 20, 2020. Having arrived at NIH's recently created Bethesda campus in 1943, Dr. Tabor was the last living voice of NIH's formative years. A warm, humble, insightful and imaginative man as well as a consummate scientist to the very end, he leaves a profound scientific legacy.

Roger Unger, MD, also died in August at the age of 96. Dr. Unger had a long and extraordinary career at UT Southwestern. His work was pivotal in establishing the roles of glucagon and insulin in the control of blood glucose and his findings were central to our understanding of diabetes and endocrinology practice. Dr. Unger received many national and international awards and honors for his work illuminating blood glucose regulation and the causes of diabetes. He served as a member of the NIDDK Advisory Council from 1991 to 1995.

Dr. Rodgers also noted the passing of Dr. Paul Hyman, a pediatrician and an active member of the Data Safety Monitoring Board for the NIDDK Gastroparesis Consortium. Dr. Hyman passed away after complications from COVID-19. A former gastroenterology fellow in the NIDDK intramural program, Dr. Hyman's latest position was Chair of the Gastroenterology Department at New Orleans Children's Hospital. His pioneering research led to the development of the subspecialty, Pediatric Neuro-Gastroenterology. He trained many physicians in this specialty, which uses psychological and behavioral management therapies to address the brain/gut connection in children.

Dr. Rodgers also shared good news. Dr. Phillip Gorden, Director Emeritus of NIDDK, has received the Endocrine Society's highest honor, the Fred Conrad Koch Lifetime Achievement Award. In his distinguished 50-year career in clinical research, Dr. Gorden has contributed greatly to the treatment of diabetes, especially with his work on advancing insulin. A physician-scientist, his focus on patients has guided his biomedical research. During his tenure at NIDDK, he led initiatives, including the National Diabetes Education Program, that have shaped current practice.

NIDDK grantee Joel Habener, MD, Professor of Medicine at Harvard Medical School and associate physician at the Massachusetts General Hospital, has been awarded the 2020 Warren Alpert Award, along with colleagues Daniel Drucker at the University of Toronto and Jens Juul Holst of the University of Copenhagen. The award recognizes their work on incretins, hormones that affect insulin secretion and metabolic regulation. Their work has led to several treatments for type 2 diabetes, obesity, and short bowel syndrome. Dr. Habener has been an NIDDK grantee since 1979 and a recipient of a Method to Extend Research in Time (MERIT) award.

NIDDK Staff News

Dr. Rodgers welcomed four new staff members to NIDDK:

Dr. Brad Cooke, program officer in the Division of Diabetes, Endocrinology, and Metabolism (DEM), is overseeing the neurobiology portfolio that investigates the anatomy and function of the central and peripheral nervous systems. **Dr. Miranda Broadney** will also join DEM as program director to manage and grow a portfolio in clinical pediatric endocrinology. **Dr. Shilpa Hattangadi** is a hematology program director in the Division of Kidney, Urologic and Hematologic Diseases (KUH). **Dr. Eric Brunskill** also joined KUH as a new program director for developmental biology within the kidney and urology research programs.

Dr. Rodgers also announced some staff retirements:

Dr. James Hyde will be retiring from federal service in December. He joined NIDDK in 2000, serving as program director within DEM, where he oversaw research training and career development programs before moving to the Diabetes Research Centers program and the Neurobiology of Obesity research portfolio.

Dr. Catherine Cowie retired from NIDDK after 24 years of federal service and eight additional years as a contractor. She was program director for epidemiologic research in diabetes in DEM. Dr. Cowie oversaw the Diabetes Prevention Trial for Type 1 Diabetes, the Type 1 Diabetes TrialNet, and the Epidemiology of Diabetes Interventions and Complications (EDIC) study, which was the follow-up to the landmark Diabetes Control and Complications Trial (DCCT). Dr. Cowie was editor of two editions of *Diabetes in America* and received the Kelly West award from the American Diabetes Association for outstanding achievement in epidemiology.

Turning to trans-NIH news relevant to NIDDK, Dr. Rodgers announced that the NIH has released the first ever NIH-wide *Strategic Plan for NIH Nutrition Research*, led by the Nutrition Research Task Force that Dr. Rodgers co-chairs with the directors of the National Cancer Institute; National Heart, Lung, & Blood Institute; and National Institute of Child Health and Human Development. The plan sets a framework to answer important nutrition questions over the next 10 years to move closer to precision nutrition approaches to understanding what, when, why and how to eat. Dr. Rodgers and Dr. Francis Collins, Director of the NIH, published an op-ed in the *Journal of the American Medical Association* about this effort, and the full report can be found on the NIDDK website.

Dr. Rodgers also emphasized efforts to respond to the needs of the scientific workforce during the pandemic, a topic discussed during a Council Forum at the May 2020 meeting. Dr. Rodgers recorded a video that summarizes that discussion along with some of the steps undertaken by NIH and NIDDK to address the needs of the research community. The video, "COVID-19 Pandemic: Recovery Planning for NIDDK Research," is available on the NIDDK YouTube channel.

II. CONSIDERATION OF SUMMARY MINUTES OF THE 213th COUNCIL MEETING

Dr. Rodgers

The Council approved, by voice vote, the Summary Minutes of the 213th Council meeting, which had been sent to them in advance for review.

III. FUTURE COUNCIL DATES
Dr. Rodgers

In order to save time, Dr. Rodgers did not review all planned Advisory Council meeting dates. He noted again that the next NIDDK Advisory Council meeting on January 27-28, 2021, will again be virtual. Updates will be posted on the Council website.

IV. ANNOUNCEMENTS
Dr. Malik

Confidentiality

Dr. Karl Malik reminded Council members that material furnished for review purposes and discussion during the closed portion of the 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 the Council members that advisors and consultants serving as members of public advisory committees, such as the NIDDK Advisory 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 a member does not participate in, and is not present during, the 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, or 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. Dr. Malik directed each Council member to a statement in his or her 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.

Dr. Malik pointed out that when the Council reviews applications in groups without discussion --also called "*en bloc*" actions--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 at one campus may participate in any particular matter affecting another campus, if the employee's financial interest is solely at one campus and the employee has no multi-campus responsibilities.

V. REPORT FROM THE NIDDK DIRECTOR
Dr. Rodgers

Budget Update

Dr. Rodgers reported on the NIH appropriations for fiscal year (FY) 2021 and provided a brief overview of supplemental funding legislation to address COVID-19. In the December 2019 minibus appropriation bills passed by the House and Senate and signed by the president, the NIH received $41.5 billion, which is a $2.4 billion increase, or 6.1 percent, over FY 2019. NIDDK received an $84.5 million increase, or 4.2 percent, over the FY 2019 appropriation. It is important to note that these dollar values don't include funds for the Special Diabetes Program.

Turning to FY 2021, he explained that the appropriations cycle started with the release of the President's budget on February 10, 2020. The House held a hearing on that budget on March 4, 2020, but the Senate hearing has not been held because of the coronavirus pandemic. At the end of July, the House passed a minibus appropriations package that included the Departments of Labor, Health and Human Services and Education. He noted that the House and Senate would need to pass a continuing resolution prior to September 30 to avoid a government shutdown.

Dr. Rodgers reviewed the numbers in the President's budget request, which called for a $3.4 billion reduction in NIH's budget and a $190 million reduction in NIDDK compared to FY 2020. These numbers are typically the start of the annual appropriations process, although these are far from typical times for NIH and the biomedical research community.

The Consolidated Appropriations Act of 2021, which the House passed on July 30, 2020, included $47 billion for NIH, an increase of $5.5 billion over FY20. This amount includes a $500 million increase in NIH's annual appropriation as well as $5 billion in emergency spending, of which the ICs would get some portion. The bill includes $2.132 billion for NIDDK, which is a .85 percent increase over FY20. The Senate has not yet introduced any of its FY21 bills.

Supplemental Funding – COVID-19

Moving on to supplemental funding bills to address COVID-19, Dr. Rodgers reported that the three bills passed on March 6 (Package 1), March 27 (Package 3) and April 24 (Package 3.5) all included some funding for NIH. He noted that Package 3 also authorized the remaining FY20 funding for the Special Statutory funding Program for Type 1 Diabetes Research as well as partial funding for that program for FY21 (October 1-November 30, 2020).

The House passed their next COVID supplemental bill, the HEROES Act, in mid-May. The sweeping $3 trillion bill provided funding for a wide range of pandemic-related issues, including $4.7 billion for NIH. This includes $500 million to the National Institute of Allergy and Infectious Diseases and $200 million to the National Institute of Mental Health. The bill included $4 billion for the NIH Office of the Director to offset costs related to reductions in lab productivity during the pandemic and $1 billion to disperse to support new research.

In late July, the Senate introduced their own COVID supplemental package, called the HEALS Act. This bill provided $1 trillion total, including $15.5 billion for NIH and $200 million for NIDDK. He also pointed out that $12.91 billion earmarked for the NIH Office of the Director included $10.1 billion to reopen NIH-funded research laboratories and reconstitute lost research and $1.24 billion for the ACTIV public-private partnership to

prioritize and speed development of COVID treatments and vaccines. The Senate has not yet voted on the HEALS Act.

Congressional Activity

Dr. Rodgers reported that on June 29 and 30, he and Dr. Chris Lynch, Director of the Office of Nutrition Research, met virtually with Senator Udall of New Mexico and Representatives McGovern of Massachusetts and Pingree of Maine to discuss the Strategic Plan for NIH Nutrition Research which was released in late May.

VI. COUNCIL FORUM UPDATE

COVID-19 Pandemic: Recovery Planning for NIDDK Research
Dr. Matthew Portnoy

Dr. Rodgers reminded Council members that during the May meeting, the group discussed the effects of the COVID-19 pandemic on NIDDK's research activities and made recommendations for how NIDDK and NIH can support researchers during this time. He then introduced Dr. Matthew Portnoy, Deputy Director of the Division of Extramural Activities, to give an update on the outcome of the forum and steps NIH and NIDDK have taken.

Dr. Portnoy started by reviewing some of the findings of the listening session during the May meeting. The discussion was led by Drs. Tracy Rankin, David Saslowsky, and Karen Teff, representing NIDDK's three programmatic divisions, and focused on four key areas: basic research, clinical research, training and career development, and the role of NIH and NIDDK in restarting the research enterprise. Dr. Portnoy referred the Council to the COVID Forum update document and reviewed the key recommendations that came out of the forum, several of which have already been implemented:

- NIDDK revised reviewer guidance on expectations for preliminary data in grant applications.
- NIH is temporarily accepting submissions of additional supporting preliminary data up to 3-4 weeks prior to review meetings. The latest guidance, NOT-OD-20-123 allows a one-page preliminary data update up to 30 days before review. This provision is currently in effect through the May 2021 Council meeting.
- NIH has allowed additional flexibility for grant submission deadlines for next 2-3 cycles and junior investigators have been given continuous submission privileges. The flexible stance on two-week late window will continue for the foreseeable future. Due dates from February to April 2020 were extended to May 1, 2020.

Two additional recommendations have not yet been acted on. These include the recommendation for more weighted consideration of bioRXiv publications in Principal Investigator bibliographies and directing reviewers to highlight the most promising aims to assist in partial funding decisions by ICs.

Dr. Portnoy also reported progress on the Council's recommendations in the area of award administration.

- NIH is extending maximal flexibility with grant start dates.
- NIH has extended flexibility for submission of Research Performance Progress Reports (RPPRs) on a case by case basis. NIDDK has accepted all late RPPRs.

- The NIH central COVID website now offers concise guidance on carryover policies in the form of FAQs.
- NIH has lowered administrative/paperwork hurdles to facilitate requests for carryover, award extensions, supplements, and reductions in scope. NIH will continue to review these on a case-by-case basis. ICs can use the Prior Approval Module in Commons to reduce paperwork and email communications
- To provide flexibility for payback of National Research Service Awards (NRSAs) for clinicians appointed to T32s, NIH has granted an additional year extension upon request for post doctorates who have payback obligations.

The Council also made recommendations about getting information out to researchers to explain COVID-19 interruption options and fiscal policies:

- Dr. Rodgers recorded a "Message to the Community" for NIDDK researchers, and NIDDK established a trans-DK COVID-19 Committee (chaired by Dr. Portnoy) to collate case studies and advice regarding grant issues that can't be answered by central NIH COVID-19 guidance.
- To help young investigators deal with productivity lapses, the NIH Office of Intramural Training and Education hosted an online workshop in April, "Supporting Yourself and Your Trainees During the Coronavirus Pandemic." The video of the workshop is publicly available on the Office of Intramural Training & Education YouTube Channel along with other videos targeted to fellows and trainees across the career spectrum.
- Dr. Portnoy also noted that the Council recommended developing a pamphlet on best practices for ramping up animal colonies.

The final category of recommendations concerned additional funding/resources. While waiting for news on the appropriations bills that include additional funding for NIH and NIDDK, NIDDK is using available discretionary funds to provide partial support, including R-56 bridge awards, to applications that fall outside the current paylines (16th percentile for established PIs, 25th percentile for Early Stage Investigators (ESIs).

Dr. Portnoy also reported that NIDDK has issued an agency-specific R01 RFA, entitled Mechanistic Studies of the Interaction Between SARS-CoV-2/COVID-19 and Diseases and Systems of Interest to NIDDK. NIDDK has also participated in and made awards to several notices of special interest for both administrative and competing supplement awards.

Council Questions and Discussion

Many K awardees have lost at least six months because laboratories and clinical research have been shut down. In addition, many (especially female K-awardees) have had additional family duties, with schools and daycares closed or on abbreviated hours, which may continue for some time. Many who were due to start interviewing for jobs have not been able to do so. Has there been any consideration about giving them an extra year of funding if their research or next opportunity has been halted due to the virus?

Dr. Portnoy said NIDDK will look into this.

How are you getting the word out about these programs to postdocs and other researchers? Are these mostly NIDDK-specific or NIH-wide initiatives?

Dr. Portnoy answered that most initiatives are NIH wide, and NIH issues regular guide notices. In addition, NIDDK training program directors are communicating regularly with applicants and awardees.

Dr. Rodgers thanked Dr. Portnoy for his presentation and assured the Council that NIH as a whole is working to address the challenges faced by young investigators, investigators with childcare needs, and investigators who rely on training and career awards. He indicated he will keep the Council updated on these efforts.

VII. CONCEPT CLEARANCE

Dr. Rodgers then turned to Concept Clearance, a step required before ICs can publish funding opportunity announcements, or FOAs. To streamline this process, summaries were supplied to Council members for their review before the meeting. The meeting included descriptions of eight concepts, four by the Division of Diabetes, Endocrinology and Metabolic Diseases and four by the Division of Digestive Disease and Nutrition. Because of time constraints, descriptions were brief to allow questions or comments. Cleared concepts will be made publicly available on the NIDDK website.

Division of Diabetes, Endocrinology and Metabolic Diseases Concepts

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

- **Integrated Islet Distribution Program (IIDP) Renewal:** Dr. Sheryl Sato, IIDP program director, explained the goal of this concept is to continue to provide the scientific community with access to high quality human islets for research. This includes human islet procurement and distribution to the research community, support for investigators new to the field of human islet biology (IIDP Islet Award Initiative Program), and program-wide human islet phenotyping to comply with NIH and community needs for enhanced rigor and reproducibility, resource reporting, and research utility. The current IIDP program provides human islet preps to 150 investigator-initiated projects resulting in 160 publications citing the resource. Each year, IIDP's Islet Award Initiative provides islet resources to 10-11 investigators embarking on new studies in the field of human islet biology. In addition, more than 900 fields of UNOS (United Network for Organ Sharing) data for each isolation have been made directly accessible to IIDP investigators. Current funding for the program ends in September 2021. Dr. Sato explained that, in addition, future directions for the program include releasing full IIDP datasets to the community-at-large to support secondary analyses, expanding standardized phenotyping of islet samples, improved quality control for Center assays and protocols, increased distribution of islets from diabetic donors, and exploration community needs for ancillary human tissues.

- **Ancillary Studies to Large Clinical Studies to Understand the Heterogeneity in Older Adults with Diabetes:** Dr. Christine Lee explained that one third of adults age 65 and older have diabetes, accounting for more than 60 percent of healthcare expenditures for diabetes. This heterogeneous group ranges from healthy, independent older adults with no functional impairments or co-morbidities to frail, older adults with comorbidities and diabetes complications that affect mobility, eyesight and the ability to live independently. The current ADA Standards of Care recommend individualizing glycemic goals and personalizing treatment to account of these differences; however, there is a lack of evidence from randomized controlled trials to guide providers in how best to individualize

care for older adults. Building the evidence for a more tailored approach to diabetes care in older adults first requires a deeper understanding of the population, including which groups are most at risk for poor outcomes and potential modifiable risk factors. This knowledge will help in the design of future clinical trials. Dr. Lee explained that existing studies and databases, including large, longitudinal studies with characterization of diabetes from NIDDK trials and NHLBI cohorts and administrative datasets from the Centers for Medicare and Medicaid Services or electronic health records, may offer an opportunity to increase our understanding of diverse older adults with diabetes. The approach could involve merging datasets or adding new measurements to existing studies to better understand the heterogeneity among older adults with diabetes.

- **Pilot and Feasibility Studies to Facilitate Use of Diabetes Self-Management Education and Support to Improve Diabetes Care:** Dr. Lee explained that diabetes self-management education and support (DSMES) is efficacious in improving self-care behaviors and quality of life and leads to better health outcomes and lower healthcare costs. Current guidelines recommend that all patients with diabetes receive DSMES; however, only 5 percent of Medicare beneficiaries and 6.8 percent of primary insured patients receive DSMES within the first year of diagnosis. Many barriers to DSMES utilization exist in health care systems, amongst providers, at the patient-level and within the social, cultural, economic and physical environment. Examples of such barriers include: a shortage of trained and certified diabetes educators, low referral rates (possibly due to provider bias or lack of time), low perceived value and competing life priorities for patients, and /or lack of transportation to DSMES. This concept includes launching pilot and feasibility studies to develop and test pragmatic strategies to overcome barriers and improve access to DSMES for improved diabetes care.

- **Characterizing the Heterogeneity of Drug Response in Type 2 Diabetes through Deep Phenotyping and Data Integration:** Dr. Salvatore Sechi explained that response to medications for type 2 diabetes can vary. For example, metformin fails to control glucose level in a significant subset of patients. Predictive markers for this lack of drug response have not been identified for the majority of patients. The first step of this initiative would be a workshop where experts in "omics" technologies, physiologists, computational biologists, and clinical experts are brought together to explore the use of data and samples from clinical studies, as well as the use of data from electronic health records (EHRs) to identify predictive markers for drug response. This would be followed by a Funding Opportunity Announcement. Ideally, the outcome of the whole initiative would be a panel of markers that can be practically used for predicting drug response and thus optimize the treatment of patients with T2D.

<u>Council Questions and Comments</u>
Big Data is a good way to explore heterogeneity, and understanding heterogeneity is key to improving individual response to care. Are there ways to add new data from state-of-the-art technologies, such as wearables that measure exercise or apps for continuous glucose monitoring?

Dr. Lee answered that the concept does support the addition of new measurements to existing studies to study the heterogeneity in older adults, so the addition of new measures from such state-of-the-art technologies to ongoing study visits would be possible, in addition to leveraging biosamples already on hand, or merging EHR or administrative healthcare data records with cohort data. There is a role for technology in increasing access to DSMES,

especially as we can see how remote healthcare delivery and telemedicine has been leveraged to mitigate barriers to healthcare during the COVID crisis. The pilot and feasibility studies could also leverage technology and devices to bridge barriers to DSMES, but other ways of providing care to populations who do not have or use technology may also be needed to build the evidence base.

In the RFA for DSMES, it's important to emphasize that education and support also benefits people with pre-diabetes and pediatric diabetic patients transitioning to adult management.

Dr. Lee said that the team has been discussing that various populations may need different strategies to help them engage in DSMES. In addition to pediatric patients transitioning to independence, older adults may also need to transition from self-management to having caregivers to support them in their care. She pointed out that, while there is a need for diabetes prevention, that may be a separate effort from the one outlined here since the populations, strategies and outcomes differ. CDC has ongoing efforts to disseminate the National Diabetes Prevention Programs across the country with certification of Lifestyle Behavior Change programs based on the Diabetes Prevention Program to meet rigorous standards that ensure effectiveness which is different from certification for DSMES. Both DSMES and diabetes prevention programs are important targets for NIDDK's efforts on the pragmatic dissemination and implementation research spectrum.

Will the DSMES pilot studies address racial disparities in care and complications that stem from those disparities?

Dr. Lee agreed that this is critically important to address because racial disparities and inequities pose barriers to DSMES and exist on multiple levels: amongst the social, cultural and physical environment; healthcare system; providers; and patients.

Division of Digestive Diseases and Nutrition Concepts

Members of the DDN staff presented four concepts on behalf of the division.

- **Program to Advance the Careers of Scientists from Underrepresented Groups Conducting Nutrition, Obesity, and Diabetes Research:** Dr. Mary Evans introduced this program aimed at addressing some of the hurdles that scientists from under-represented minority groups face in securing independent NIH research funding. Programs that enroll cohorts of researchers with similar backgrounds and promote professional development, research skill-building, and mentoring opportunities have shown some promise thanks to the "cohort effect." The proposed approach for this concept is to create a collaborative cohort-based program that leverages the resources of research institutions with an established base of funding in nutrition, obesity, and diabetes research to provide career development and mentor eligible candidates from under-represented groups. Collaborations with non-research-intensive and/or minority-serving institutions will be encouraged. Evaluation metrics would include publications, presentations, grant applications (submitted versus funded), and a comprehensive tracking system to follow participants.

- **Identification and Characterization of Bioactive Microbial Metabolites for Advancing Research on Microbe-Diet-Host Interactions:** Dr. Padma Maruvada presented this concept that builds on recent advances in human microbiome research and

our growing understanding of the critical role of gut microbiota in host physiology and pathophysiology. Poor characterization of metabolites remains a major impediment to understanding the inter-relationships of diet, microbiome and host interactions. Several experimental pipelines are in place for characterizing the metabolites. The approach would be to support projects starting with identification of novel gut microbial metabolites from clinical studies, then characterize micro-organisms involved in the synthesis of metabolites, and further characterize plausible biological function and translational relevance of these metabolites. This program would also include direct support for the creation of a publicly available database of the knowledge base that results from these efforts.

- **Endoscopic Therapy for Barrett's Esophagus with Low-grade Dysplasia: The SURVENT Trial:** Dr. Jose Serrano presented this concept, which addresses Barrett's esophagus (BE), a complication of gastroesophageal reflux disease and a major risk factor for esophageal cancer, a deadly form of cancer that is on the rise. BE affects 1.7 to 5.6 percent of Americans and 0.5 to 1 percent of BE cases progress to cancer each year. Patients with BE should receive regular endoscopy to identify signs of progressing cancer, including dysplasia. High-grade dysplasia is treated with endoscopic eradication therapies (EET), but there is currently insufficient evidence to support eradication for low-grade dysplasia because of the high cost, associated risk, and uncertain risk/benefit ratio. Following a clinical trial planning grant awarded to a group of investigators in the fields of BE and EET, the approach would be to hold a multicenter randomized controlled trial that compares surveillance vs. EET in BE patients with low-grade dysplasia. With 19 centers in community- and university-based practices, the study's pragmatic design will provide real-world evidence regarding the routine use of biomarkers in guiding clinical decision-making for patients with BE.

- **Functional Screen of Genes within IBD GWAS Loci:** Dr. Robert Karp explained that researchers have identified more than 250 genetic loci associated with inflammatory bowel disease (IBD GWAS loci) but so far have identified the precise gene involved for only 66. Fine-mapping and single-cell RNA sequencing have helped identify some of these genes. High-throughput functional screening may offer the opportunity to identify more. This concept uses zebrafish, in which intestinal lining and innate immune systems show some strong similarities with mammals, powerful gene editing tools are available, and larvae can be screened in large numbers and are transparent, allowing observation of cellular processes in real time. A pilot screen of human type 2 diabetes loci in zebrafish using beta-cell mass assay identified novel genes. For this concept, investigators would develop high-throughput assays of innate immune and epithelial barrier function relevant to IBD, first in a pilot phase, then in a full-scale screen of zebrafish genes similar to human genes associated with IBD. All work would be done in consultation with experts in human IBD pathophysiology and genetics to ensure relevancy to human disease and would be double checked with human phenome-wide association studies (Phe-WAS) and studies of human cells and intestinal organoids. Investigators would be required to develop plans for communicating their findings to the IBD research community to promote translation to bedside.

<u>Council Questions and Discussion</u>

Will you consider partnering with the National Cancer Institute on the study of low-grade dysplasia in Barrett's Esophagus patients?

Dr. Serrano explained that this proposal came from a group of gastroenterologists who are caring for patients with BE so there may not be a way to bring in NCI at this point. However, NIDDK is working with NCI colleagues in other ways.

Is there an opportunity to leverage interest from NIDDK in dietary markers, especially plant phytochemicals released by microbiota?

Dr. Maruvada answered that another program is addressing that and may have results later this year.

The Vermont Center for Behavior and Health has looked at drug addiction, smoking, and incentive systems to change health behaviors. Their approach may overlap with the ideas to increase participation in DSMES programs.

Dr. Rodgers thanked the Council member for this resource.

Concerning career development for underrepresented minorities, would you consider another concept trying to get younger people into science as undergraduates, which is where the bottleneck is? Perhaps a program that gives undergraduates opportunities to work in laboratories and become interested in science as a career?

Dr. Evans agreed that interventions are needed at every stage of education and career to increase the pipeline and ultimately produce successful, funded researchers from currently underrepresented groups. She pointed out that NIDDK already has programs for undergraduates and pre-doctoral candidates. Another Council member pointed out that the National Human Genome Research Institute has an extensive summer research program that gets students excited and prepared for applying to graduate school.

Dr. Rodgers thanked the Council members for their comments and noted that this conversation is a good segue to the Council Forum on underrepresented investigators and underrepresented in science.

VIII. COUNCIL FORUM

Underrepresented Investigators and Underrepresented Science
Drs. Gregory Germino, Katrina Serrano, Lawrence Agodoa, and Robert Rivers

Dr. Rodgers introduced the Council Forum as an opportunity to discuss different facets of how structural racism increases health disparities, including ways in which COVID-19 takes a disproportionate toll on people of color. He noted that this session, the first of a multipart forum, will focus on underrepresented investigators and underrepresented science with the understanding that other aspects of this complicated puzzle will be addressed at future Council meetings. He then turned over the meeting to Dr. Germino.

Intersection of Health Disparities and Workforce Diversity Gap

Dr. Germino began by noting that COVID-19 can affect the function of many organs within the NIDDK mission, leaving patients with uncertain long-term consequences. Additionally,

individuals with diabetes, obesity, or chronic kidney disease are at much higher risk of being severely affected by SARS-CoV-2. COVID-19 is not colorblind, causing more severe disease in Black, Latinx, and Native Americans. These groups have higher rates of infection, hospitalization, and death that are up to five times higher than in white patients.

Dr. Germino noted that these pronounced health disparities intersect with other major events of 2020, including the tragic deaths of Ahmaud Arbery, Breonna Taylor, and George Floyd. These deaths have triggered deep soul searching as America, once again, takes tentative steps forward in addressing its history of racism and the structures that continue to deny justice and equal opportunity for all. This is not just a civil rights issue for the streets of America. It is also a health and workforce problem with important implications for NIH and particularly for NIDDK.

Dr. Germino said that structural racism has also resulted in fewer educational and professional opportunities for people of color, perpetuating a system that shuts out diverse voices and perspectives, denying them individual success, and depriving our nation of huge untapped potential. The lack of diversity in our biomedical workforce and the health disparities that fall within our research interests are distinct but interdependent problems that share a common origin.

At Dr. Rodgers' request, Dr. Germino has developed a framework for addressing both the research questions linked to health disparities and the lack of diversity within NIDDK and the extramural workforce. He worked with NIDDK Executive Officer Ms. Camille Hoover to establish a steering committee to advise the Institute on ways to build a more diverse, respectful, and inclusive 21st century workforce. The committee members represent a broad cross-section of the workforce.

On the extramural side, Dr. Germino has challenged each of the NIDDK Working Group of Council subgroups relevant to the Strategic Plan to address health disparities and workforce diversity in the Plan. To date, NIDDK's focus has often been on biological mechanisms or establishing equal efficacy of interventions rather than understanding the root causes or researching strategies for reducing or eliminating them, adding that the central role structural racism may play in health disparities is often unaddressed.

Dr. Germino closed by noting that the January 2021 Council Forum will discuss the problem of health disparities and how addressing them might improve the health of minority communities while increasing the diversity of the scientific workforce.

NIH Funding of Underrepresented Minority Scientists

Dr. Katrina Serrano of the NIDDK Office of Minority Health Research Coordination then shared research that compared the association between an applicant's self-identified race or ethnicity and the probability of receiving an NIH R01 award. Compared to white applicants, members of other racial and ethnic groups have a lower probability of receiving an NIH R01 award. While white applicants' probability of receiving funding approached 30 percent, Black applicants hovered around 16 percent during a seven-year period.

Additionally, underrepresented minorities make up a small proportion of the NIH R01 application pool. Applications from Black applicants increased from 2013 to 2018, but they still only make up about 2 percent of applications. Similarly, the number of Hispanic or Latino

applicants has increased, but they still only make up about 5 percent of the NIH R01 applicant pool.

Dr. Serrano informed the Council that during the last 10 years at NIDDK, Black investigators won 3 percent or less of the entire NIDDK research project grant pool, which translates to 16 or fewer awards per year. The numbers for NIDDK R01 grants are even lower, with fewer than 10 new NIDDK R01 awards going to Black investigators annually during the past decade.

Efforts to close these funding and application gaps have been framed as a pipeline issue and have centered on training more scientists. But Dr. Serrano shared research showing that the rate of Ph.D. production for scientists from underrepresented minority (URM) backgrounds has increased more than nine-fold between 1980 and 2013. In contrast, the rate at which these URM scientists are hired as assistant professors at medical school basic science departments has increased only about three-fold during that time. These data indicate that the URM scientific talent pool has enlarged over time and that the pipeline may not be the issue.

History of NIH and NIDDK's Workforce Diversity Efforts

Next, Dr. Lawrence Agodoa provided a historical perspective on NIH and NIDDK's efforts to diversify the biomedical research workforce. The United States Congress enacted the National Research Service Act in 1974 to ensure that adequate numbers of highly trained scientists would be available to conduct biomedical and behavioral research in support of the nation's scientific agenda. Under this authority, the NIH established several training mechanisms, including fellowships, research project grants, and F, K and T grants that the institutes and centers have adopted to train scientists to conduct research in their mission areas. NIDDK has used these mechanisms to train all scientists, not just those who are underrepresented minorities.

- During 1987 and 1988, the director of the NIH and the Advisory Committee to the Director held a series of regional meetings throughout the United States. Concerned individuals and organizations presented testimony regarding the underrepresentation of minorities in the biomedical and behavioral workforce. Recognizing these concerns, since 1989 the NIH has permitted institutes and centers to use administrative supplements to existing grants for the support of underrepresented minority scientists and students, a policy later formalized in the Diversity Supplement Program. To date, the NIDDK program has funded over 3,000 students and minority junior faculty.

- In 1995, the NIDDK began participating in the NIH-wide Diversity F31 program, which funds minority predoctoral students. To date, this program has helped more than 300 students obtain their terminal degrees. Also, in 1995 NIDDK partnered with what is now the National Institute of Minority Health and Health Disparities to create the Short-term Research Experience for Underrepresented Persons, or STEP-UP program, which provides high school students with intensive research experience each summer.

- In 1997, the NIDDK director and other senior members of the Institute met with the leadership of the National Medical Association, the largest and oldest national organization representing African American physicians, to establish a program to enhance the success of young NMA members who pursue careers in academic medicine. This program has funded 750 fellows to date.

- In 2000, Dr. Allen Spiegel, then director of NIDDK, sought to address minority health and health disparities in the Institute's mission areas. His first step was to establish the Office of Minority Health Research Coordination (OMHRC). This office was tasked with coordinating the development of the Institute's strategic plan on minority health and health disparities and monitoring implementation of that plan. OMHRC also assumed responsibility for developing health education programs, research and training opportunities for students, research grant programs, research supplemental awards to promote diversity and re-entry, capacity-building programs, and annual reports to Congress on the Institute's race and ethnicity data.

NIDDK then began to develop programs to help increase and train the investigator pipeline.

- In 2001, NIDDK created the Diversity Summer Research Training Program for undergraduate students. This program provides 10 weeks of immersive research experience for undergraduate students in NIDDK research laboratories in Bethesda, Maryland, and Phoenix, Arizona, and has trained 190 students.

- In 2003, NIDDK established the Network of Minority Health Research Investigators, composed of minority junior faculty and established successful investigators. Its goal was to facilitate mentorship among senior and junior faculty members and encourage the mentees to consider working in fields of interest to NIDDK. To date, 800 minority investigators belong to the network.

- In 2007, NIDDK expanded the STEP-UP high school program to include undergraduates. Both arms have now trained more than 2,500 students. In 2008, the Institute created the Small Grants for Diversity program to support URM investigators to conduct research for three years and generate preliminary data for R01 applications. In 2012, the NIDDK created the Partnership with Professional Societies Program to recruit and train underrepresented minorities. This program is now in its second five-year cycle.

Dr. Agodoa closed by noting that NIDDK and OMHRC combined have supported and trained more than 7,000 individuals from diverse and underrepresented communities during the past 40 years. Institute spending in this area amounts to about $7.1 million per year. These efforts, however, have not yet made a significant difference in the proportion of underrepresented minorities who are successful in getting R01 awards.

Potential Paradigm: Bridges and Pathways to Academic Success

Dr. Robert Rivers discussed reasons for this limited impact and how NIDDK can foster genuine improvements in the workforce diversity realm.

He began by describing NIDDK's current biomedical research workforce pipeline as a series of different tiers connected by "ladders." These ladders exist to provide opportunities for individuals to make that transition from one tier to the next. However, these ladders may also inadvertently winnow out people as they attempt to move from tier to tier.

As Dr. Agodoa described, the first tier of NIDDK's pipeline begins with high schoolers in the STEP-UP Program. Dr. Rivers noted that this tier, which focuses on predoctoral development,

also contains training programs for undergraduates, graduate students, and postdoctoral researchers. The next tier is a transitional tier for junior faculty, followed by independent or mid-career faculty. After another ladder, one arrives at the top tier, that of established, late-career faculty. Based on the slow pace of growth in the diversity of the scientific workforce, Dr. Rivers posited that the ladder analogy does not work for all. Dr. Rivers suggested a more apt analogy may be bridges and pathways to academic success.

Dr. Rivers shared his belief that what is needed is greater investment at key transition points throughout researchers' careers—potential "choke points" along the way—not just the initial stages. He noted that discussions about the need to support careers of URM researchers date back to the 2011 Ginther Report, which reported a significant racial gap apparent in NIH R01 funding. According to the report, the funding rate for R01 applications from Black/African American scientists was 10 percentage points lower than for other groups after controlling for an applicant's educational background, country of origin, training, previous research awards, publication record, and institution characteristics. This led NIH to look closely at individual and systemwide potential contributors and solutions, which resulted in recommendations, which were implemented starting in 2014. To date, NIH has spent approximately $500 million on these changes with a primary focus on the undergraduate research training programs that were loosely targeted at diversity.

While much attention is paid to the early part of the career path, Dr. Rivers noted that NIDDK already invests quite heavily in both high school and undergraduate populations. These investments are both important and cost-effective, and they will continue.

OMHRC is currently evaluating its program funding, which makes up 0.4 percent of the NIDDK annual budget.

Council Discussion

Noting that meaningful change must come in partnership with the extramural research community, Dr. Rivers then reminded Council members of the questions they have been tasked with considering for discussion:

Hiring

- What are the primary barriers for recruiting Underrepresented Minority (URM) applicants for training and faculty positions to your institution?
- What steps do you take to identify suitable candidates?
- Do URM new hires receive the same start-up packages as other applicants?

Advancement

- What are the top three barriers for advancement and retention of URM trainees and faculty at your institution?

Mentoring

- What mentoring programs exist in your institution to support URM faculty?
- What measures are taken to support mentoring?
- How effective do you think they have been?
- How do you assess mentoring success?

- Does your institution provide "precision mentoring" with a culturally competent mentor?

Looking to the Future

- What ideas do you have for increasing representation in the NIDDK biomedical workforce?
- How can NIDDK better address this issue (beyond giving money to universities to fund additional hires--Notice of Intent to Publish the FIRST Initiative)?

Dr. Germino announced that initial commentary on these questions would be provided by three assigned discussants: Drs. Penny Gordon-Larsen, Rudolph Leibel, and Kathleen Sakamoto. He cautioned that discussion would be brief and encouraged Council members to use the chat function to contribute other ideas for the record.

Dr. Gordon-Larsen told the Council that she was asked to talk about her perspective on her own institution, the University of North Carolina at Chapel Hill. She noted that her institution has faced challenges related to its location in a former Confederate state: Should the Confederate flag and Confederate statues remain in honored places on campus? These discussions have been difficult for faculty members of color and have even made it challenging to recruit new faculty members.

Since 2018, an assistant dean for inclusive excellence has helped the institution develop an inclusive excellence plan. This dean has also addressed systemic and institutional racism by refining training and hiring practices and focusing on URM faculty recruitment and retention. The dean has focused on training colleagues to recognize the potential for unconscious bias in the review of applicants, research funding, and dossiers for faculty promotion.

Next, Dr. Leibel reiterated the important role national policies play in the economic, social and educational well-being of individuals. He also recognized the Summer Program for Underrepresented Students (SPURS) at his own institution, Columbia University, which brings URM undergraduates to Columbia for biomedical summer research and has a good track record of developing young scientists.

Columbia also runs the Summer Research Program for Science Teachers, a training program for New York-area high school science teachers. They learn about and assist with both basic and applied research and receive extra training in science communication and pedagogy. Second-year participants mentor first-year participants. Dr. Leibel also is involved in Columbia's Short-Term Training Grant (T35), which brings first-year medical students to campus for focused summer research projects.

Dr. Leibel advocates partnering with specific schools or high schools in order to increase the pipeline of young URM scientists and these efforts should begin when students are as young as possible.

Dr. Sakamoto presented her slides later in the day, during the closed KUH subcommittee session, so limited her remarks to endorsing the concept of the bridge metaphor as a way to visualize helping URM scientists advance in their careers via sustained mentorship.

Council Comments

A variety of Council members contributed comments to the discussion, either verbally or by using the chat function of the meeting software. These included:

Hiring/Institutional Climate

- Secure high-level support, up to and including the president of the institution, which is necessary to create an institutional climate that welcomes all, including URM scientists.
- Explore whether NIH can, should, or does track the number of qualified, fully trained URM scientists who can't get their first job in academia. How does that number compare with URM scientists who are ultimately successful in sustaining a long-term career that includes NIH funding?
- Look for opportunities to institute so-called bias interrupters—policies and actions that will bring to a person's attention that an instance of bias is occurring.
- Increase resources for and emphasis on offering and facilitating inclusive opportunities for the spouse and children of potential URM faculty hires.

Advancement

- Consider unintended consequences of the current structure of diversity supplements. Since the award goes to the PI, not to the candidate, that junior investigator loses the opportunity to get credit for a peer-reviewed grant in future funding reviews.
- Consider ways to recognize URM researchers who excel at each career level as a way to help build momentum.
- Include diversity requirements in RFPs.
- Examine ways in which younger URM scientists are harmed when their socioeconomic status requires them to work for pay rather than getting research experience.
- Halt the unpaid labor practice of expecting URM faculty to automatically be responsible for representing "the URM viewpoint" and mentoring URM students and junior faculty. At the very least, don't penalize URM faculty who then have less time to devote to research due to this unpaid labor when considering advancement and funding opportunities.
- Extend the duration of early-career funding mechanisms and offer training to help young investigators accumulate the skills, publications, and other eligibility requirements for faculty appointments.

Mentoring

- Use a cohort approach to mentoring, in which mentees are matched with a variety of mentors across the entire university and even the broader discipline.
- Use a committee-based approach to mentoring, in which URM faculty mentees are encircled by an entire committee, all of whom are devoted to supporting different aspects of life and career for each mentee.
- Consider developing a framework for compensating mentoring by senior investigators who particularly focus on helping the career development of mentees from underrepresented groups. The COBRE program at the University of Vermont offers compensation to mentors.
- Consider what level of seniority is desirable in a mentor: perhaps senior investigators are too far removed from early-career challenges.
- Explore and encourage the use of mentorship "contracts" between mentors and mentees to clarify expectations and commitments.

- Create peer-to-peer mentoring opportunities in the form of workshops, symposia or other events for investigators from underrepresented backgrounds.

Looking to the Future

- Increase equity in clinical trials by partnering with historically minority-serving institutions and by enrolling vulnerable populations. Many trials are awarded to large academic medical centers, who often have white and wealthy patients and participants.
- Examine the potential for study sections to specifically include a broader interpretation of which scientific topics are worth studying and funding. For example, emerging topics like epigenetics may be overlooked in favor of more familiar focus areas, yet both may be equally valid.
- Refer openly to issues like unconscious bias and systemic racism at Council meetings and elsewhere to bring these issues into the open so they can be addressed.

Dr. Germino thanked all the Council members for their input, especially those who led the discussion, as well as the Office of Minority Health Research Coordination staff who presented. He then turned the meeting back to Dr. Rodgers.

Dr. Rodgers echoed Dr. Germino's thanks to all participants and presenters, then noted his appreciation for the wide diversity of ideas Council members shared. He noted that many of them helped home in on specific niches for improvement. He also noted that, while NIDDK has many good pipeline programs, much more needs to be done on the systemic level so that those who benefit from the NIDDK pipeline programs are then able to go on and thrive in their careers.

Dr. Rodgers reiterated that NIDDK staff will be capturing Council suggestions and moving forward with ideas. He then handed the meeting back over to Dr. Germino for an update on the NIDDK strategic planning process.

IX. UPDATE: NIDDK STRATEGIC PLANNING PROCESS

Dr. Germino

Dr. Rodgers turned the meeting over to Dr. Germino to share an update on the NIDDK strategic planning process with the Council.

Dr. Germino reminded the Council that the strategic plan will be an overarching research plan to complement NIDDK's disease-specific planning efforts. Since the May Council meeting, the NIDDK has received public comments that address all aspects of the draft plan from about 80 respondents—including organizations, individual researchers, people living with diseases within the NIDDK mission, and others.

Since the May Council meeting, NIDDK has convened the subgroups of the external Working Group for a set of productive and enlightening discussions. Dr. Germino thanked the external working group members and the NIDDK staff involved, then invited the external subgroup co-chairs to highlight a few examples of major research opportunities they have identified.

Stakeholder Engagement Subgroup

Mr. Richard Knight and Dr. Ellen Leschek, co-chairs

Mr. Knight noted that all stakeholders should be involved in future research efforts, including patients, caregivers, family members, clinicians, advocacy groups, and community-based organizations. Additionally, the subgroup noted that these stakeholders should be genuinely engaged across the research continuum, from generating and reviewing ideas to research planning and execution, oversight, and dissemination of results. The subgroup commented that stakeholders should have leadership roles in research and suggested that stakeholder engagement should be a funding requirement monitored with measurable metrics and outcomes.

Additionally, the subgroup emphasized that researchers should involve diverse stakeholders with a focus on representation from minority, marginalized, and remote populations and take into consideration the feasibility and appeal of their involvement by ensuring adequate compensation and minimal upfront costs and addressing barriers like financial and time limitations, childcare and transportation. Finally, the subgroup pointed out that both researchers and stakeholders require education and mentoring.

Stewardship Subgroup
Drs. Barbara Kahn and Matthew Portnoy, co-chairs
Dr. Kahn noted that their subgroup emphasized the need to enhance support for physician/surgeon-scientists. One possibility would be to expand the Loan Repayment Program or sync it with K awards to facilitate the application process for physician/surgeon-scientists.

The subgroup also noted that many institutions discourage researchers from applying for K awards because grantees who also do clinical work receive only partial salary support. The subgroup would like to see NIH implement incentives or other strategies to make the K award more attractive to institutions so that they encourage their physician/surgeon-scientists to apply for the program. A third suggestion for enhancing support is for institutions to encourage researchers to build active partnerships with data scientists. This would enable researchers to leverage their observations clinically into important research findings more efficiently, perhaps helping establish their careers earlier.

This subgroup also looked at increasing the diversity of the scientific workforce. They suggested being proactive in identifying and recruiting diverse candidates instead of passively waiting for these candidates to apply. They suggested looking for ways to bring opportunities to people in less-resourced medical centers, so they could remain close to their support networks. The subgroup also suggested holding focus groups with diverse young scientists to hear how this next generation envisions their career development.

This subgroup emphasized the importance of data science and data scientists to the research enterprise. They advocate increasing training for data scientists and promoting the idea that data scientists should receive more professional credit for scientific publications, even when they're not the lead or senior authors. Importantly, the fact that data science does not require extensive local equipment or laboratory space means that the discipline may be well-suited to prosper in underserved communities, which NIH can encourage.

Finally, this subgroup discussed improving the rigor and reproducibility of scientific research and how NIDDK might continue to promote open data, the culture of data sharing, and early sharing of publications.

Biological Pathways and Environmental Contributors Subgroup
Drs. Gary Wu and Chris Mullins, co-chairs
Dr. Wu introduced the concept of the scientific "interactome," which promotes cross-disciplinary interactions among basic scientists, clinical scientists, and population scientists. Interactions among scientists in these disciplines may lead to development of better model systems and understanding of gene-environment interactions.

The subgroup discussed health equity and disparities through this lens and determined that researchers need to develop an understanding of populations in their environments. Research modalities currently being used by basic scientists and clinical scientists perhaps can be applied to population science to accelerate this process.

The subgroup identified opportunities to promote the interactome, including incentivizing and promoting cross-disciplinary research teams in certain key areas. Additionally, the interactome would benefit from enhancing data science, sharing large datasets, reusing existing datasets, breaking down disciplinary silos, and focusing efforts on quantitative biology, which is relevant to basic, clinical, and population scientists.

The subgroup also advocated for moving from single-cell systems back into more comprehensive model systems, which might lead to model systems that are more reflective of human biology. Other suggestions from the subgroup included large-scale efforts to look for disease surrogates from diverse populations using basic science and population science methodologies (e.g. iPSC technology), and collecting biospecimens at a broad population level, with blood spot technology and metabolomics as opportunities.

Pivotal Clinical Studies and Trials Subgroup
Drs. Elizabeth Seaquist and Averell Sherker, co-chairs
Dr. Seaquist noted that the clinical trials subgroup had some themes in common with other subgroups' suggestions. For example, the subgroup advocates building community engagement by increasing NIDDK's focus on patient-centered research.

This subgroup also spent considerable time discussing workforce training and recruitment. They suggest that NIDDK should require principal investigators for R01 grants to have a plan to disseminate proposed/ongoing work to students early in their careers to help generate interest in science as a career. The group also recommends that NIDDK consider a K01 program specifically for URM individuals.

The subgroup also discussed data science and the need to leverage electronic health records, artificial intelligence, and machine learning by creating a funding mechanism to ensure that clinical scientists, data scientists, epidemiologists, and psychologists all can work together. Additional suggestions include creating opportunities to provide health research training to data scientists from other fields and promoting comparative effectiveness studies using big data and claims data.

The subgroup addressed the need to build upon the successes of research networks by balancing them with investigator-initiated research. NIDDK should focus on getting maximum benefit from using the clinical trial networks' infrastructure while still welcoming promising new investigators into the clinical trials arena. They also suggest that NIDDK should require clinical grant applications to include a transition from initial observational studies to pragmatic studies based on the data collected. They advocate for the importance of observational studies

and suggest creation of a separate study section for the review of these studies and a greater emphasis on research into the social, as well as biological, determinants of health.

The subgroup's last major topic was research needs and opportunities related to the COVID-19 pandemic and other emerging challenges. They recognized the virus's disproportionate effect on people with diabetes and obesity and suggested a time-sensitive program announcement for responding to pandemics and other emerging challenges (citing another NIH time-sensitive program announcement as an example), given the urgent need to examine links between COVID outcomes and diseases/conditions within NIDDK's mission.

Dissemination and Implementation Research Subgroup
Drs. Penny Gordon-Larsen and Pamela Larson, co-chairs
In addressing the issue of novel research, Dr. Gordon-Larsen told the Council that this subgroup advocated continuing to support natural experiments and studies to address effects of "natural changes or events," particularly those affecting vulnerable populations, using rapid funding mechanisms.

Dr. Gordon-Larsen reported that the subgroup advocates early partnership with stakeholders affected by research and those involved in implementation and dissemination, especially in health systems, policies and payment decisions. Stakeholders should be engaged early and equitably, for example, as initiators of research, and could invite investigators with relevant expertise to join those initiatives. The subgroup considered possible examples, including the possibility of NIDDK partnering with Medicare and CMS on demonstration projects, or to collaborate with payers or technology vendors when developing interventions.

Additionally, the subgroup recommends that NIDDK engage multidisciplinary experts in science education and translation. These experts could help write FOAs and grants and improve interpretation and use of evidence-based science (basic and other research) by stakeholders. They could also empower stakeholders through education about research (via courses, orientations, and web-based resources).

The subgroup suggests that NIDDK reconceptualize its role in the ecosystem of research dissemination and implementation in diseases within NIDDK's mission. The agency should play a bigger role in the science of dissemination/implementation to speed translation of interventions into practice. The subgroup suggested that NIDDK should also promote partnerships between investigators and stakeholders and provide a repository of information/education regarding priority evidence-based treatments and interventions ready for dissemination and implementation questions formulated by stakeholders. To date, there has been little work done on research dissemination, and there is a continuing need to build competency and translational science and science education at scale.

Dr. Germino again thanked the NIDDK strategic planning subgroup members and co-chairs for their participation.

Dr. Rodgers then turned the meeting over to Dr. Malik for housekeeping details for the subcommittee and closed Council meetings scheduled for later in the day.

X. ADJOURNMENT
Dr. Rodgers

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 214th meeting of the NIDDK Advisory Council was adjourned at 3:45 p.m.

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

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