

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 218th meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council at 10:00 a.m. on January 26, 2022, 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. Iain Drummond
Ms. Dawn P. Edwards
Dr. Penny Gordon-Larsen
Dr. Debra Haire-Joshu
Dr. Mark Nelson
Dr. Keith C. Norris

Dr. David F. Penson
Ms. Ceciel Rooker
Dr. Kathleen Sakamoto
Dr. Philipp E. Scherer
Dr. Michael Snyder
Dr. Gary Wu

Ad hoc members:

Dr. John Carethers
Ms. Davida Kruger
Dr. Jacquelyn Maher
Dr. Elizabeth Seaquist

Ex-officio members:

Dr. David A. D’Alessio
Dr. Cindy Davis
Dr. Ian Stewart

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 E. Portnoy, Deputy Director, Division of Extramural Activities, NIDDK
Dr. Gregory G. Germino, Deputy Director, NIDDK
Dr. William Cefalu, Director, Division of Diabetes, Endocrinology and Metabolic Diseases, 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

NIH and NIDDK Panelists and Speakers:

Dr. Lawrence Tabak

Dr. Gary Gibbons
Dr. Karen Teff
Dr. Olivier Blondel
Dr. Ashley Xia
Dr. Pamela Thornton

B. ANNOUNCEMENTS

Dr. Rodgers

Dr. Rodgers noted that this is NIDDK's sixth consecutive virtual Council meeting. While he had expected the May 2022 meeting would be held in person, he noted that NIH just announced that May Advisory Council meetings will be virtual. He urged members to check the NIDDK Advisory Council website for updates.

Council Member News

Dr. Rodgers recognized five new members of the Advisory Council:

- **Dawn Edwards** is a Wellness Ambassador for the Rogosin Institute in New York, who works with patients and helps guide them in managing their kidney disease.
- **Debra Haire-Joshu, MD**, is the Joyce Wood Professor and holds joint appointments in the Washington University School of Medicine and the Brown School of Public Health at Washington University in St. Louis, Missouri.
- **Keith Norris, MD, PhD**, is the Executive Vice-Chair for Equity, Diversity, and Inclusion and Professor of General Medicine at UCLA.
- **Ricky Safer** is the Founder and CEO of PSC Partners Seeking a Cure, a non-profit that provides education and support to patients with Primary Sclerosing Cholangitis (PSC) and their families; and raises funds to research causes, treatments, and cures for PSC, which damages bile ducts inside and outside the liver. (Note: Although Ms. Safer officially joined the Council at this meeting, she was unable to attend because of a family emergency.)
- **Philipp Scherer, PhD**, is Professor and Director of the Touchstone Diabetes Center at the University of Texas Southwestern Medical Center in Dallas, Texas.

Ms. Edwards and Dr. Norris will participate in discussions within the Kidney, Urology, and Hematology (KUH) subcommittee. Ms. Safer will participate in discussions within the Digestive Diseases and Nutrition (DDN) subcommittee. Drs. Haire-Joshu and Scherer will participate in discussions within the Diabetes, Endocrinology and Metabolic Diseases (DEM) subcommittee.

Dr. Rodgers also recognized four individuals serving as ad hoc members during this Council meeting:

- **John Carethers, MD**, is the C. Richard Boland Distinguished University Professor and John G. Searle Professor and Chair at the University of Michigan Health System.
- **David Kruger, MSN**, is a Certified Nurse Practitioner in Diabetes and Manager of Clinical Research at the Henry Ford Health System in Detroit, MI.

- **Jacquelyn Maher, MD**, is a Professor of Medicine in the Division of Gastroenterology at the University of California, San Francisco School of Medicine.
- **Elizabeth Seaquist, MD**, is the Pennock Family Chair and Vice Chair, Clinical Affairs, and Director of the Division of Endocrinology and Diabetes at the University of Minnesota Medical School.

Drs. Carethers and Maher will participate in discussions within the DDN subcommittee. Ms. Kruger and Dr. Seaquist will participate in discussions within the Diabetes, Endocrinology, and Metabolic Diseases (DEM) subcommittee.

In Memoriam

Dr. Rodgers reported the recent passing of several NIDDK grantees and staff members:

- **Dr. Hal E. Broxmeyer**, distinguished hematologist and longtime NIDDK grantee, died peacefully on December 8, 2021. He was 77 years old. Dr. Broxmeyer was an inspired mentor and researcher in the field of umbilical cord blood transplantation. His contributions to the NIDDK Hematology research portfolio included spearheading the Indiana University hematology T32 research grant program for 32 years and running the large Cooperative Center of Excellence in Hematology for more than 20 years. He published more than 838 peer-reviewed scientific papers and received many awards and distinctions, including the Gold Medal of the City of Paris (where the first cord blood transplant was performed), the E. Donnall Tomas Prize of the American Society of Hematology, the Donald Metcalf Award of the International Society of Hematology and Stem Cell Research, the President's Medal of Honor from Indiana University, the Lifetime Achievement Award from the Cord Blood Association. He was the first person holding a Ph.D. to be elected President of the American Society of Hematology.

NIDDK Staffing News

Dr. Rodgers also announced several awards to staff members of NIDDK's Intramural Program:

- **Dr. William Eaton**, NIH Distinguished Investigator in the Laboratory of Chemical Physics, won the 2022 Peter Debye Award in Physical Chemistry from the American Chemical Society for his outstanding research contributions to the physical chemistry of proteins. Dr. Eaton will be recognized at the Society's awards ceremony in March 2022.
- **Dr. Kenneth Jacobson**, section chief in the Laboratory of Bioorganic Chemistry, was named a Fellow of the American Society for Pharmacology and Experimental Therapeutics for his vast contributions to pharmacology, including his role in making more than 35 novel compounds commercially available as pharmacological research tools.
- **Dr. Carole Bewley**, chief of the Laboratory of Bioorganic Chemistry, was named a Fellow of the American Society of Pharmacognosy for her high-level contributions in the field of natural products.

Dr. Rodgers announced several new staff members who have joined NIDDK:

- **Dr. Raquel Greer** recently joined the NIDDK's Division of Kidney, Urologic and Hematologic Diseases (KUH) as a new Program Director focusing on health disparities research, especially associated with kidney disease. Prior to joining NIDDK, Dr. Greer served as an Associate Professor of Medicine and Epidemiology at Johns Hopkins University, where she also received her Medical Degree and completed her Internal Medicine Residency Training. Dr. Greer's research focused on improving health care quality and promoting health equity for patients with chronic kidney disease (CKD) and CKD risk factors.
- **Dr. Maureen Monaghan Center** is a behavioral scientist and clinical psychologist, with a specialization in pediatric psychology. Dr. Monaghan Center earned her Ph.D. in Clinical Psychology at the University of Virginia and completed fellowship training in pediatric psychology at Children's National Hospital from 2006-2008. She also earned her M.S. in Clinical and Translational Science from the George Washington University School of Medicine and Health Sciences in 2013 and is a Certified Diabetes Care and Education Specialist. Prior to joining NIH/NIDDK, Dr. Monaghan Center was a tenured Associate Professor of Psychiatry and Behavioral Sciences at Children's National Hospital and George Washington University School of Medicine in Washington, DC. Within DEM, she will serve as Program Director for Diabetes Behavioral Science.
- **Dr. Albert Hwa**, also joining DEM, is a graduate of Cornell University, where he earned a degree in Chemical Engineering. Dr. Hwa received his Ph.D. in Biological Engineering at Massachusetts Institute of Technology. Prior to joining NIDDK, he was the Operations Director for Center for Cell-Based Therapy for Diabetes at Joslin Diabetes Center and a Lecturer in Medicine at Harvard Medical School. His research focused on stem cell derivation, the manufacturing of autologous islet cells, and transplantation methods. At NIDDK, Dr. Hwa's grant portfolio will include studies that focus on the development and regeneration of the pancreatic endocrine compartment, as well as the application of this knowledge in stem cell differentiation and regenerative medicine.
- **Dr. Shavon Artis Dickerson** is a new DEM Program Director for Health Equity and Implementation Science. Dr. Artis Dickerson has over 17 years of federal experience. Among her previous roles, she served as the Senior Advisor for Health Equity Research and Analysis in the Office of Health Equity at the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD). She led research programs and evaluation projects addressing violence against women and women's and girls' mental health at the U.S. Department of Health and Human Services, Office on Women's Health. She also directed NICHD's Safe to Sleep® national public health campaign to reduce sleep-related causes of infant mortality and led community-based and culturally tailored maternal child health initiatives. Dr. Artis Dickerson earned a doctorate in public health in health policy from the George Washington University and a master's in public health in health behavior health education from the University of North Carolina at Chapel Hill.
- **Dr. Saira A. Mehmood** joins DEM as an AAAS Policy Fellow. Dr. Mehmood earned her Ph.D. in medical anthropology from Southern Methodist University,

and from 2019-2021, she was a Visiting Assistant Professor at Spelman College in the Department of Sociology and Anthropology. Dr. Mehmood is contributing to NIDDK's Health Disparities/Health Equity Research Implementation Plan by working to center the needs and priorities of the individuals and populations most affected by NIDDK related diseases into the core of this effort.

- **Dr. Cheryl K. Nordstrom** recently joined the NIDDK Scientific Review Branch as an experienced Scientific Review Officer (SRO) from the National Institute of Nursing Research (NINR). At NINR, Dr. Nordstrom was the SRO of the only NINR standing study section that reviews Fellowship and mentored career development applications, and she also managed the review of Clinical Trial Planning grants. Dr. Nordstrom earned her master's degree from the University of Michigan and doctorate at the University of Southern California Keck School of Medicine, where she studied the impact of potential stressors on early atherosclerosis.
- **Celena Snoddy** (Program Analyst) and **Britny Bock** (Program Specialist) have joined NIDDK's Division of Digestive Diseases and Nutrition.

Two staff members have recently been promoted within NIDDK, including:

- **Peter J. Kozel, Ph.D.** joined the NIDDK in June 2018 as a Scientific Review Officer (SRO) and was recently promoted as Chief of the Training and Mentored Research Section in the NIDDK Scientific Review Branch. The Section includes six SROs that manage the review of all institutional training grants, mentored career development awards, and fellowship applications submitted to the NIDDK. Dr. Kozel previously held SRO positions at NIDDK, the Center for Scientific Review (CSR), and the National Center for Complementary and Integrative Health (NCCIH). He was a Mirzayan Science and Technology Policy Fellow at the National Academies and earned his doctorate at the University of Cincinnati College of Medicine.
- **Karin Johnson** was recently promoted with the NIDDK Grants Management Branch (GMB) as Team Leader for Digestive Diseases and Nutrition grants. Prior to her promotion, Ms. Johnson worked in GMB as a Senior Grants Management Specialist who, for many years, managed several complex clinical trial grant projects.

In addition, several NIDDK staff members have announced their retirements:

- **Dr. Phillip Gorden**, NIDDK director emeritus and senior investigator, has retired after 55 years of service at NIH. Described as "*a legend at NIH*" by NIH Deputy Director for Intramural Research Dr. Michael Gottesman, Dr. Gorden touched nearly every facet of NIDDK. As a physician-scientist, Dr. Gorden contributed to seminal discoveries in endocrinology, including advances in insulin biology and diabetes. As NIDDK director from 1986 to 1999, he launched multiple practice-changing clinical trials. As a colleague and mentor, he leaves an immeasurable impact, not only because of his exceptional scientific acumen, but also because of his exceptional humanity.
- **Dr. Ellen Leschek**, a Program Director within DEM, will be retiring this month. Dr. Leschek has been at NIH her entire career and has been involved in many of the landmark studies of NIDDK. She served as the Project Scientist for the

Epidemiology of Diabetes Interventions and Complications (EDIC) and was program director for Type 1 Diabetes TrialNet, a large international clinical trial network that performs studies addressing the prevention of and early intervention in type 1 diabetes. She has also been the Program Director for the Rare and Atypical DIAbetes NeTwork (RADIANT), a large network of clinical sites that identify and study individuals with atypical forms of diabetes to better inform the study of type 2 diabetes. Her responsibilities also included leading the efforts on the NIH Interagency Coordinating Committee on Human Growth Hormone and Creutzfeldt-Jakob Disease.

- **Dr. Sheryl Sato**, a Program Director within NIDDK's DEM Division, will be retiring in March. Sheryl has been instrumental in leading NIDDK's basic science research programs in developmental biology, stem cell biology, and the regeneration of endocrine tissues and organs. She has coordinated research in the Human Islet Research Network (HIRN), a basic science research effort that is developing innovative strategies for the treatment, prevention, and monitoring of type 1 diabetes. Dr. Sato also founded and served as Program Director for the Beta Cell Biology Consortium, which, from 2001 to 2014, advanced our understanding of pancreatic islet cell development and function.
- **Sharon Bourque**, who had served as Grants Management Branch DDN Team Leader, retired at the end of December 2021. Ms. Bourque worked at NIH for 38 years, primarily in the NIDDK Grant Management Branch.

Dr. Rodgers extended thanks and congratulations to Drs. Gorden, Leschek, and Sato and Ms. Bourque for their dedicated and exceptional service to the Federal Government, the NIH, and the NIDDK.

Dr. Rodgers then shared the 2022 edition of the annual report "[NIDDK Recent Advances and Emerging Opportunities](#)," which is released each year at the winter Advisory Council meeting. The report highlights examples of NIDDK-supported research advances published in Fiscal Year 2021. The report also includes "Personal Perspectives" from people who have participated in NIDDK-sponsored clinical research as well as special features, such as one describing NIDDK's efforts to strengthen diversity in the scientific workforce. An executive summary of the report is available on the NIDDK website. Although the report is an Institute-wide effort, Dr. Rodgers particularly acknowledged the Office of Scientific Program and Policy Analysis for developing the content and managing the process, and the extramural divisions and Division of Intramural Research for their input and guidance. Dr. Rodgers welcomed comments from Council on this report.

Dr. Rodgers also mentioned two upcoming livestream events that will highlight NIDDK's research to improve health. The first event, scheduled at the end of March, will focus on current and emerging obesity research at NIDDK with Dr. Susan Yanovski, co-director of the Office of Obesity Research, and Dr. Marc Reitman, the chief of the intramural Diabetes, Endocrinology and Obesity Branch. The second event, scheduled at the end of April, will focus on implementation of the NIDDK Strategic Plan for Research, including improving health through diversity, equity, and opportunity. The second livestream event will feature Dr. Pamela Thornton, a program director in the Division of Diabetes, Endocrinology and Metabolic Diseases, and Dr. Katrina Serrano, a program director in the Office of Minority Health Research

Coordination. Event details will be available on Facebook.

Dr. Rodgers also announced the release of the new NIDDK Strategic Plan for Research in December 2021. This plan represents two years of extensive input from many sources, including Advisory Council members, researchers, and patient advocates on the Strategic Plan Working Group, and numerous organizations and individuals who responded to NIDDK's public requests for information.

Dr. Rodgers expressed appreciation for the Council's support and efforts on these projects.

II. CONSIDERATION OF SUMMARY MINUTES OF THE 217th COUNCIL MEETING

Dr. Rodgers

The Council approved, by electronic poll, the Summary Minutes of the 217th Council meeting, which had been sent to them in advance for review.

III. FUTURE COUNCIL DATES

Dr. Rodgers

Dr. Rodgers did not review the upcoming meeting dates but noted that NIH has determined that the May 2022 Council meetings will be virtual. Updated information 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 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.

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. ITEMS FOR CONSIDERATION

Dr. Malik

Dr. Malik introduced two items for consideration:

- During the winter meeting, the NIDDK Council is asked to approve its Council operating procedures. These are unchanged from 2021. The Council voted unanimously to approve the procedures.
- The Institute's Director and Advisory Council must review and concur with NIDDK annual data and summary for the NIH Triennial Report on Inclusion before the report is submitted to Congress. The Council voted unanimously to concur with the data.

VI. REPORT FROM THE NIDDK DIRECTOR

Dr. Rodgers

Budget Update

Dr. Rodgers updated the Council on the NIH appropriations process for Fiscal Year 2022. He reviewed the year thus far: President Biden released his FY 2022 discretionary request (“skinny budget”) in April and his full budget on May 28, 2021. On May 25 and 26, respectively, the House and Senate Appropriations Labor-HHS-Education Subcommittees held their FY 2022 hearings for the NIH. In July, the House released their Labor-HHS-Education appropriations bill, conducted subcommittee and full committee markups, and passed a minibus on July 29 that included the Labor-HHS appropriation.

The new fiscal year started shortly after the September Advisory Council meeting, and since the full appropriation package had not been passed, President Biden signed into law a Continuing Resolution to keep the government operating through December 3, 2021. Prior to its expiration, he passed a second resolution to keep the government funded through February

18, 2022.

The President's Budget Request called for a \$9 billion increase in the overall NIH budget (a 21 percent increase over FY 2021), including an \$87.4 million increase for NIDDK. The House minibus bill passed on July 29 included \$49.4 billion for NIH, a \$6.5 billion, or about 15 percent, increase over the 2021 appropriation. This includes a 5 percent increase for NIDDK, from \$2.132 to \$2.238 billion. On October 18, the Senate released its Labor-HHS appropriations bill, which included \$48 billion for NIH—an 11.6 percent increase over FY 2021). This bill included \$2.217 billion for NIDDK, which is an \$85 million, or 4 percent, increase over the previous fiscal year.

The Special Diabetes Program funding was most recently approved for three years, meaning that the funding is in place for fiscal years 2022 and 2023. However, the FY 2022 funding is subject to sequestration and has been reduced by 5.7 percent. A new appropriations cycle will start with the release of the President's FY 2023, the announcement date for which has not been released.

Dr. Rodgers then turned to changes in NIH leadership. Dr. Francis Collins retired as Director of NIH and his last day was December 19, 2021. Dr. Larry Tabak, who spoke to the Council later in the meeting, is now serving as Acting Director of NIH. Dr. Tara Schwetz is serving as Acting Principal Deputy Director.

Congressional Activities

Dr. Rodgers also updated the Council on Congressional activities:

- On September 22, 2021, Dr. Rodgers participated virtually in a Rally Hill Reception for Medical Research and provided updates on medical advances and reinforced NIDDK's commitment to reducing health disparities, such as through the APOL1 Long-term Kidney Transplantation Outcome Consortium, or APOLLO, study.
- On November 9, 2021, Dr. Cefalu participated in a briefing for the Congressional Diabetes Caucus on type 1 diabetes and provided an overview of the Special Statutory Funding Program for Type 1 Diabetes.
- On November 18, 2021, Drs. Rodgers, Cefalu, and Norann Zaghoul briefed Rep. David Schweikert of Arizona on the genetics of type 2 diabetes, including an overview of advances in drug development and information on the Accelerating Medicines Partnership® (AMP®).
- On November 19, Dr. Cefalu spoke at a briefing of the Congressional Diabetes Caucus, which was held in conjunction with National Diabetes Awareness Month and the Endocrine Society's celebration of the 100th anniversary of insulin. Dr. Rodgers, along with Rep. Diana DeGette of Colorado and Dr. Kim Schrier of Washington, provided opening remarks, and Rep. Tom Reed of New York provided closing remarks.

Council Questions and Discussion

Comment from Council: *When will the FY 2022 budget be finalized?*

Dr. Rodgers hoped that the budget would be finalized in mid-February, but he said that in the meantime, NIDDK and Program Directors must fund based on last year's

budget—yet another layer of uncertainty for researchers already reeling from the budgetary effects of COVID.

VII. UPDATE: ACTING DIRECTOR, NATIONAL INSTITUTE OF HEALTH Dr. Lawrence Tabak

Dr. Rodgers introduced Dr. Larry Tabak, who became Acting Director of NIH in December 2021. Dr. Tabak previously served as NIH's Principal Deputy Director since 2010. Prior to that, he was Director of the National Institute of Dental and Craniofacial Research (NIDCR) from 2000 to 2010. Before joining the NIH, Dr. Tabak was a Senior Associate Dean for Research and Professor of Dentistry, Biochemistry, and Biophysics at the School of Medicine and Dentistry at the University of Rochester in New York. Among his many honors, Dr. Tabak is an elected member of the National Academy of Medicine.

Dr. Tabak thanked Dr. Rodgers for the introduction, reminding staff that his intramural lab was located at NIDDK while he was Director of NIDCR and that NIDDK conducts his BSC reviews. He started his presentation with an overview of some of the leadership changes at NIH since Dr. Collins's departure. Dr. Tara Schwetz has assumed the role of Acting Principal Deputy Director. Dr. Schwetz was Associate Deputy Director—a position created to assume orderly succession during transition—and she was able to step into her role immediately. Similarly, Dr. Courtney Aklin is now Acting Associate Deputy Director, a role she previously filled while Dr. Schwetz was on detail to the White House leading the efforts to stand up the Advanced Research Projects Agency for Health (ARPA-H). Dr. Carrie Wolinetz, the longtime Director of the Office of Science Policy at NIH, is currently on detail to the White House Office of Science and Technology Policy. Her deputy, Dr. Lyric Jorgenson, is serving as the Acting Director of the NIH Office of Science Policy. Dr. Tabak noted that he is grateful for the deep bench of talented people at NIH to manage this leadership transition smoothly.

COVID-19 and NIH

Dr. Tabak next gave an update on matters related to the COVID-19 pandemic. NIH closely tracks the seven-day case averages, and Dr. Tabak noted cautious optimism about the downward trend in cases, as was seen in South Africa. Less encouragingly, hospitalizations were only beginning to level off, and deaths were still rising.

In response to the pandemic, NIH launched the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership, the mission of which is to develop a coordinated research response to speed COVID-19 treatment and vaccine options. Initiated by Dr. Collins, this consortium consisted of industry leaders, government agencies, and non-profit organizations, and Dr. Tabak assumed the role of co-chair when Dr. Collins stepped down as NIH Director.

Dr. Tabak then gave an overview of ACTIV's nine trial arms, which study various treatments and interventions at all stages of infection in diverse patient populations. Although several agents did not demonstrate efficacy, invaluable information has been derived from all trials, regardless of the outcomes. Many studies are still ongoing, with more results expected in the next few months and into late spring.

Dr. Tabak also gave a status update on COVID-19 on the NIH campus. Trends in viral caseloads among NIH staff mirror the rest of the country, and administrative staff who can work remotely have been doing so. The Clinical Center continued its operations, and many in the intramural programs have been working onsite because they cannot do their jobs remotely. The senior-most leadership of NIH recently returned to the physical workplace with a telework option. Given the current omicron surge, other return-to-work plans are on hold, but the hope is to resume the process in the not-too-distant future.

NIH has an extensive, voluntary COVID-19 testing program. More than 21,000 people have been tested through either the Clinical Center asymptomatic option or the symptomatic car line program. At the beginning of February, NIH will launch an in-home antigen testing program in an effort to ensure continued workplace safety.

NIH remains open to patients and visitors. Masking is required on campus to ensure the safety of all, especially patients, since many NIH patients are immunocompromised as a result of their conditions or treatment. Guidance on the implementation of HHS Workplace Safety Plans is forthcoming.

Peer-review meetings will continue to be held virtually through May 2022. January and February Council meetings, program advisory committees and Boards of Scientific Counselors (BSCs) will also be virtual. NIH leadership is working to decide how future rounds will be conducted. While he emphasized that everyone wants to return to physical workspaces as much as possible, decisions will be made based on the status of the pandemic.

Artificial Intelligence and Machine Learning

Dr. Tabak then turned to recent science activities at NIH involving artificial intelligence and machine learning, which are being integrated into many areas of biomedical and clinical research. He explained that artificial intelligence (AI) is a program that can sense, reason, act, and adapt to new information. Machine learning (ML), a subset of AI, uses algorithms that improve performance as they are exposed to additional data as a function of time. Deep learning is a further subset in which machine learning is multilayered to neural networks, which can accommodate and process enormous amounts of data.

These are active fields for biomedical research, examples of which include text mining from electronic medical and health records, image analyses, interpretation of genomic sequences, monitoring sleep and vitals, and risk assessment.

He pointed out that, despite the benefits, there are also myriad legal and ethical challenges that must be addressed. These include racial biases that can be ingrained into the algorithms if the training sets are not representative of the entire community; Dr. Tabak noted a number of examples where biases led to inappropriate outcomes. He reinforced NIH's obligation to use these tools in the most ethical manner possible.

NIH convened the Advisory Committee to the Director (ACD) Artificial Intelligence Working Group after a workshop on the topic was held in July 2018; Dr. Tabak served

as co-chair, along with David Glazer from Verily, a research division of Alphabet Inc. The group included experts in AI and ML from across the country, including Eric Lander, Director of the White House Office of Science and Technology Policy (OSTP). The ACD made several recommendations for this area of research including:

- Support flagship **data generation** efforts to propel progress by the scientific community
- Develop and publish criteria for **ML-friendly** datasets
- Design and apply “**datasheets**” and “**model cards**” for biomedical ML
- Develop and publish **consent and data access standards** for biomedical ML
- Publish **ethical principles** for the use of ML in biomedicine
- Develop **curricula** to attract and train ML-Biomed experts
- Expand the pilot for ML-focused **trainees and fellows**
- **Convene** cross-disciplinary collaborators

He then described some of NIH’s responses to these recommendations:

Bridge2AI: This NIH Common Fund program will use biomedical and behavioral research grant challenges to generate multimodal data sets that will be hypothesis-agnostic, emphasize ethical best practices for AI/ML, and promote the formation and support of diverse teams. This program is launching in Spring 2022.

Nutrition for Precision Health (NPH) & AI: Powered by the *All of Us* Research Program, NPH aims to advance how we think about nutrition and inform more personalized nutrition recommendations. It will employ AI to predict human responses to different foods and dietary patterns and create new ways of visualizing and interrogating multimodal datasets. This program will use a unique tool set including *in silico* human dietary response replicates—user-tailored models—to predict health trajectories. This is one of the first studies to leverage the *All of Us* platform, which is working to recruit a diverse cohort of a million Americans. The program will start by examining baseline diet and physiological responses to meal challenges with 10,000 *All of Us* participants. The second module will examine responses to three short-term intervention diets in free-living controlled feeding studies in 1,500 participants. The third module is a domicile-controlled feeding study in 500 participants. This study will include collections of microbiomic, physiologic, metabolic, behavioral, cognitive, and environmental data, and it will leverage the extant genomic EHR record and survey data included in the *All of Us* platform. This program is due to launch in early 2023.

AI/ML Consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD): The goals of this program are to enhance participation and representation of researchers and communities that are currently underrepresented in the development of AI and ML models, as well as to address health disparities and inequities within AI/ML. The program also aims to improve capabilities of EHRs merged with other diverse data sets. NIH has established the AIM-AHEAD Coordinating Center with 55 institutions that have essential expertise in AI/ML and health disparities research, data science training, and data and computing infrastructure. The Center is distributed over six regional hubs. Next steps for the program include developing and implementing a

fair, equitable, and transparent process for recruiting additional members. Updates will be posted on the project website: <https://aim-ahead.net/>

To give an idea of the breadth of the program and the diversity of involved institutions, Dr. Tabak gave an overview of the framework of the initiative. Leadership cores are housed at the University of North Texas Health Science Center (Fort Worth), Vanderbilt University Medical Center (Nashville, TN), University of Houston (TX), University of California Los Angeles, University of Colorado (Aurora), Meharry Medical College (Nashville, TN), Morehouse School of Medicine (Atlanta, GA) and Johns Hopkins University (Baltimore, MD). The Data Science Training Core is run at Howard University (Washington, DC) and the Infrastructure Core is the National Alliance Against Disparities in Patient Health (Woodbridge, VA), Harvard Medical School (Cambridge, MA) and Vanderbilt University. The Data and Research Core is led by OCHIN, a nonprofit in Portland, OR. Dr. Tabak said NIH is looking forward to building out this program to empower the next generation of AI/ML approaches to addressing health disparities and preventing the biases in algorithms and EHRs.

Diversity, Equity, Inclusion, and Accessibility at NIH

Dr. Tabak next noted that the government-wide strategic plan to advance DEIA efforts in the federal workplace was released in late November, and it provides a roadmap for implementing [Executive Order 14035](#), issued by the Biden Administration in June 2021. The plan lays out key steps agencies can take to strengthen DEIA in their workplace policies, practices, and culture, and it charges Agencies with developing their own Strategic Plans by March 23, 2022. In accordance with the plan, NIH has developed a Working Group and strategic long and short-term goals to address racial, ethnic, and gender disparities at NIH and identify and address barriers in access to NIH funding by investigators researching health disparities.

The Diversity at NIH Working Group is developing a Strategic Plan with three objectives:

- 1) Implement organizational practices to center and prioritize DEIA in the workforce
- 2) Grow and sustain DEIA through structural and cultural change
- 3) Advance research to promote workforce and health equity

NIH is currently developing a comprehensive inventory of DEIA-related activities within the Institutes, Centers, and Offices across NIH. This inventory will be used to identify Strategic Plan content, contribute to required reports, and track progress. The NIH UNITE Initiative, which has been presented to Council previously, is integral to this process. The U Committee is helping with data collection, supplemented by report data from the NIH Office of Equity, Diversity and Inclusion. The I committee of the UNITE program is focusing on improving NIH culture and structure for equity, inclusion, and excellence. Dr. Rodgers and Executive Officer Camille Hoover are at the forefront of these efforts. The I committee has prioritized the establishment of an NIH antiracism steering committee that will work collaboratively to develop racial and ethnic equity plans (REEPs) for each Institute and Center.

Dr. Tabak emphasized the leadership that NIDDK has shown in this area, serving as a model for other Institutes and Centers in their DEIA efforts. The NIDDK Inclusion, Diversity, Equity, Accessibility, and Civility (IDEA-C) Steering Committee has

instituted a number of efforts, including an anti-harassment program, listening circles, town halls, and an LGBTQ+ Community Support Working Group. Dr. Rodgers made one of the first statements from NIH on the need to end structural racism at NIH, and other Directors have followed suit.

Advanced Research Projects Agency for Health (ARPA-H)

Lastly, Dr. Tabak discussed the Advanced Research Projects Agency for Health (ARPA-H), which was proposed in the President’s budget for FY2022. The mission of this new agency will be “to benefit the health of all Americans by catalyzing health breakthroughs that cannot be readily accomplished through traditional research or commercial activity.” The idea is to leverage the approach pioneered by DARPA, BARDA, ARPA-E, and IARPA to create a pioneering agency within NIH.

The guiding principles of this initiative are designed to create a unique culture and organization linked to—but distinct from—NIH, by drawing on its vast knowledge, expertise, and infrastructure. ARPA-H will seek innovation through broad collaboration; leverage diverse individuals to be nimble, urgent, transparent, and time-bound; and engage stakeholders. It will be driven by principles of failing early, accepting risks, and be highly accountable to milestones.

Dr. Tabak reminded the Council that the President requested \$6.5 billion in the FY 2022 budget to establish ARPA-H. The House included \$3 billion for ARPA-H in their draft FY 2022 appropriations bill and included a section that outlined the characteristics of the new Agency. The Senate released similar appropriations language with a budget of \$2.4 billion. There are several potential authorization pathways for the agency, and NIH is optimistic about Congressional support for this concept and its success for FY 2022.

In the meantime, the White House OSTP has convened multiple listening sessions in collaboration with the NIH. Dr. Schwetz led this effort while on detail to OSTP. Over 16 listening sessions, OSTP engaged over 5,100 participants representing more than 250 organizations, resulting in many outstanding ideas.

Drs. Tabak and Rodgers then opened the floor for questions from the Council.

Council Questions and Discussion

Comment from Council: *There is enormous concern about how the social isolation of children during COVID-19 has affected cognitive and behavioral development. Is NIH collecting datasets for AI modalities to try to understand the root causes and impact of COVID-19 on childhood development?*

Dr. Tabak acknowledged the importance of this question and said that both the National Institute on Mental Health and the National Institute of Child Health and Human Development have efforts in this area. He said he would bring this important question back to the AI team for consideration.

Comment from Council: *What other AI initiatives are upcoming?*

Dr. Tabak said that many Institutes and Centers have efforts underway in this area,

including the Office of Data Science, the National Cancer Institute, and the National Institute of General Medical Sciences. In his presentation, Dr. Tabak chose to highlight those that bolster access and engagement among individuals and communities that have not been adequately represented in the past.

Comment from Council: *Given the tricky relationships between academic, industry, government, and nonprofit organizations in the United States, any data set pulled in aggregate may have conflict. How could NIH embrace relationships between academia, government, and industry, as was done during the pandemic to accelerate vaccine development? There is usually a tendency to put walls up rather than partner between industries.*

Dr. Tabak pointed out that he is the Deputy Ethics Counselor for NIH, and he plays a significant role in conflict management. He agreed that conflict has to be managed, not avoided. The key is to capture what each group brings to the table, and the partnerships forged during the pandemic can serve as a model for success in the future.

Comment from Council: *Is there a community advisory group helping with the AI Working Group? Is there a way to build in community input in a systematic way that can inform the process?*

Dr. Tabak said that he believes the AIM-AHEAD program is seeking community input because much of what it hopes to accomplish is at the community level. He paraphrased Dr. Gibbons from NHLBI, who has said that efforts in the community have to proceed at the speed of trust, and the only way to do that is by working with and listening to the community. He said he would bring the idea back to the working group to get their thoughts on how additional benefit can be gained from community input.

Comment from Council: *One of the challenges of AI and data mining is getting enough records in and representation of diverse phenotypes, especially as we try to solve more complex genetic problems and look for modifiers of disease that might emerge from EHRs. Sharing databases across boards can be a challenge, even though humankind could benefit from global sharing. What role does NIH play in driving coherence of EHRs to overcome this problem?*

Under Dr. Collins's leadership, NIH has long participated in the Heads of International Research Organizations (HIROs), a role that Dr. Tabak will assume during transition. This participation presents an opportunity to meet with international funders of medical research and discuss issues such as navigating barriers to collaboration, and there is great value to the diversity of viewpoints among members of the group. Engaging experts in AI/ML from the beginning of a project will vastly improve the availability and utility of data sets.

Comment from Council: *AI is a complicated field, even for someone who works in this area science. What are you doing to articulate it for the public? Is there a role for social and behavioral sciences in ensuring the breadth of population data and the representation of underrepresented populations? This may also tie in with gaps in science communication and trust in science that we've seen during COVID.*

Dr. Tabak agreed that this is an important component. One approach is to reach out to marginalized and underserved communities to engage them directly in dialogue and partnership, because that is when the studies take on more meaning to those communities. Dr. Rodgers and other NIH leaders have been instrumental in reaching out to better engage with communities. Dr. Tabak expressed hope that NIH can provide meaningful opportunities to organizations that serve these populations for more success in the future.

Comment from Council: *In addition to working transnationally, what collaborations exist or are planned between U.S. government agencies?*

Dr. Tabak said that the pandemic has underscored the crucial importance of partnerships with the FDA, CDC, and CMS during the pandemic. As part of the ARPA-H factfinding and feedback process, there was a trans-governmental committee co-chaired by Drs. Tabak and Schwetz with representatives from approximately 30 different departments across government; Dr. Tabak noted a strong interest in cross-collaboration. Ideally, the funding and authorization of ARPA-H will catalyze more efforts across agencies and departments. Health disparities touch on elements addressed by other Departments, such as housing and transportation.

There being no more questions, Dr. Rodgers thanked Dr. Tabak for his time.

VIII. UPDATE: NATIONAL HEART, LUNG AND BLOOD INSTITUTE

Dr. Gary Gibbons

Dr. Rodgers introduced Dr. Gary Gibbons, Director of the National Heart, Lung, and Blood Institute (NHLBI). Before joining NHLBI, Dr. Gibbons served as a founding director of the Cardiovascular Research Institute and the Chairperson of the Department of Physiology and Professor of Physiology and Medicine at the Morehouse School of Medicine in Atlanta. Throughout his career, Dr. Gibbons has received numerous honors, including election to the National Academy of Medicine. He was one of the early members of the prestigious Robert Wood Johnson Foundation Minority Faculty Development Program and was selected as a Pew Foundation Biomedical Scholar. He also has earned recognition as an established investigator for the American Heart Association.

Dr. Gibbons began by noting the importance of exploring collaborative opportunities with a focus on closing the health equity gap, which is a shared passion and objective for NIDDK and NHLBI. He also emphasized the enduring principle of supporting and promoting investigator-initiated discovery to support the health of the nation. He congratulated NIDDK on the completion of its new Strategic Plan for Research, noting that he sees a lot of potential for shared interests, goals, and objectives, and alignment across the themes presented.

Diversity of the Biomedical Workforce

Dr. Gibbons emphasized the importance of a diverse NIH biomedical workforce. He noted that an exceptional feature of the United States is its inclusivity of global talent, including people of a variety of ancestries and backgrounds. The NIH biomedical

workforce should reflect the country's diversity, but there is still work to be done toward this goal.

Dr. Gibbons showed data regarding the racial and gender breakdown of NIH investigators. The overall R01 pool showed a lack of equity in gender among awardees, but he noted sex/gender diversity has increased in cohorts at earlier career stages. The same overall trend existed in the corresponding racial and ethnic data he shared. These trends indicate that the NIH research pipeline is relatively healthy, and that diversity should filter upward to the entire R01 population over time. Dr. Gibbons recognized the opportunity to collaborate in a manner that bolsters diversity through training and career opportunities.

Synergies Between NIDDK and NHLBI

NHLBI and NIDDK share many research interests and a strong collaborative history, with overlap in missions, goals, and strategic plans. Examples of collaborations include the landmark SPRINT hypertension trial, the new ENRICH program in maternal health, and various diabetes prevention trials and cohort studies.

The populations served by NIDDK and NHLBI share risk factors, comorbidities, and lifestyle issues that lead to racial disparities in both health and life expectancy, reflecting converging social determinants of health that are risk factors for diseases such as cardiovascular disease, stroke, diabetes, kidney disease, and obesity. In many parts of the country, a history of redlining, discrimination, and segregation has created a legacy of modulated biological systems that influence health and disease, even decades after those policies were enacted.

Dr. Gibbons cited support for a research agenda that takes a holistic approach to social and biological determinants of health, and he is encouraged by a recent proposal to create NIH chronic disease centers that can adopt a multifaceted approach to studying the comorbid chronic diseases that drive health disparities. With the leadership of the National Institute for Minority Health and Health Disparities (NIMHD) and the involvement of both NIDDK and NHLBI, this collaboration could take a multilevel approach of establishing community partnerships to promote solutions that are related to the social determinants of health; testing collaborative care strategies for healthy communities using a multidisciplinary approach; and leveraging technologies, data advances, and improvements in implementation science to promote equity. The NIH Community Engagement Alliance (CEAL) Against COVID-19 Disparities takes a community-based and collaborative approach to addressing the needs of communities hardest hit by COVID-19. These efforts include academic medical centers with longstanding community engagement partnerships connecting with local clinics, pharmacies, faith-based organizations, and state and local health departments to address misinformation and mistrust, integrate community-led projects, and facilitate inclusion in COVID-19 trials, all while tailoring efforts to community resources and perspectives. The success of CEAL has provided additional information about how to address other health disparities using a similar framework to recognize the roles of individuals, genetics, and biology in familial, community, and social and environmental contexts.

Addressing women's health is another area of overlap between the existing NIDDK

and NHLBI portfolios. In particular, there is a three- to four-times higher rate of maternal morbidity and mortality among women of color in the United States, which is far higher than in any other developed country. Many common risk factors for potentially lethal complications—such as gestational diabetes, hypertensive disorders, preeclampsia, cardiomyopathy, and hemorrhage—overlap, including hypertension, diabetes, sleep disorders, obesity, and weight management during pregnancy.

NHLBI has begun to roll out the Early Intervention to Promote Cardiovascular Health of Mothers and Children (ENRICH) program, which targets community-embedded, evidence-based interventions to address maternal health disparities during pregnancy. The goal is to test the effectiveness of implementation-ready interventions that enhance maternal and child health, particularly with a focus on communities with high maternal morbidity rates. The ENRICH program leverages the home-visit nursing care model that focuses on bringing high-quality care and health information to patients where they are most comfortable and most likely to be receptive.

NHLBI also supports the Maternal Health Community Implementation Project, which is a complementary initiative that is taking a community-driven, bottom-up approach of building a community engagement platform to improve maternal health. One area of interest is pre-pregnancy counseling, recognizing that factors contributing to many maternal outcomes begin before conception and the need to intervene beyond pregnancy and obstetric care.

NHLBI's Trans-Omics for Precision Medicine (TOPMed) data resource is intentional in its diversity and inclusion of a variety of ancestral groups, a major gap in genomic resources. The majority of the 160,000 whole genomes in the dataset represent non-European people. The data includes information about diseases within both NHLBI and NIDDK's missions and is designed to be interoperable.

Dr. Gibbons closed with a few comments about NHLBI's BioData Catalyst cloud-based ecosystem, which will store and enable computation on large-scale genomics, clinical, and imaging data generated by researchers. The hope is that BioData Catalyst will also capture environmental factors, social determinants factors, lifestyle/individual behavior factors, as well as the full genome, epigenome, microbiome, and metabolome. The goal is to understand holistically all the determinants of health in a resource that broadly democratizes the access to this data, both for analysis and implementation to ultimately narrow the health equity gap in conjunction with community partners.

Council Questions and Discussion

Comment from Council: *Can you comment on the current efforts to increase diversity of physician-scientists in the biomedical workforce, in addition to Ph.D.s?*

Dr. Gibbons responded that, while progress is occurring, more must be done, especially when it comes to African-American males in the medical school pipeline. He noted that many medical schools are very effective at recruiting underrepresented groups; perhaps they could do more to encourage those students to pursue a career in biomedical science. He would also like to pursue reducing barriers to NIH support, as has happened with the diversity K awards. NIH ICs should consider working

collaboratively to incentivize medical schools to promote joint programs that emphasize inclusive excellence, particularly during residency and other parts of the career evolution.

Comment from Council: *How will NHLBI address health inequities that have a root in both social issues and biology, given that it can take many years to see meaningful change?*

Investigators at NHLBI have conducted numerous studies that consider epidemiological data, including ZIP codes, that may have an impact on an individual's health trajectory. Dr. Gibbons said that one reason ENRICH is so important is that chronic diseases probably begin in utero and perhaps even before conception. Investigators in high-risk communities will have the opportunity to test interventions during pregnancy and then to follow both mother and child over time. For example, a mother who develops pre-eclampsia faces long-term health risks, as will her child; the idea is to create an environment around mothers and children in high-risk communities to promote access to healthy lifestyles and lead to long-term health improvement. He added that ENRICH takes a similar long-term mindset as NIDDK brought to the Diabetes Prevention Program.

Comment from Council: *It's exciting to see the F and K awards becoming more diverse, but NIH should not get complacent about progress. NIH must not just open doors, but also support individuals at all stages along the training pipeline.*

Dr. Gibbons wholeheartedly agreed with this comment.

Comment from Council: *One concern is the lingering effects of the pandemic on young investigators. What can we do to support the diverse new generation of young scientists?*

Dr. Gibbons said he shared this concern and noted that NHLBI added a supplement program to their F and K grants to assist investigators who were displaced from their labs during the pandemic. There also should be more flexibilities for childcare and other significant life events that could be built into programs.

Comment from Council: *CEAL is doing important work to eliminate disparities, but too often partnerships fade, and other support tends to disappear when funding for community-engaged research ends. How can NIH continue to support these partnerships so that the rigorous equity and disparities research can continue even during periods of funding uncertainty?*

Dr. Gibbons agrees that “parachuting,” or appearing to parachute, into vulnerable communities only to withdraw erodes trust and should be avoided. An effective strategy would reinforce CEAL's value as a trans-NIH community engagement research platform that could be used to study a wide range of health disparities that span many ICs and should be a collective enterprise within NIH.

Comment from Council: *NHLBI has been a leader with its cardiovascular disease*

(CVD) cohorts with data that have spanned 30 years. Has Covid affected the fieldwork involved in deep phenotyping and behavioral data collection that set these cohorts apart?

Dr. Gibbons reinforced NHLBI's commitment to a broad array of cohort studies, including the Coronary Artery Risk Development in Young Adults Study (CARDIA). NHLBI is working to improve its environmental exposure data and increase its use of mobile technology to enrich the cohorts.

Dr. Rodgers thanked Dr. Gibbons for his presentation, adding that they co-chair the Trans-NIH Nutrition Research Task Force and the NIH Obesity Research Task Force. One of the most recent advances of the Trans-NIH Nutrition Research Task Force was the newly launched Nutrition for Precision Health Initiative that Dr. Tabak mentioned in his presentation.

IX. CONCEPT CLEARANCE

Dr. Rodgers then turned to Concept Clearance by Council, a step required before ICs can publish funding opportunity announcements, or FOAs. To streamline this process, summaries of the concepts were supplied to Council members for their review before the meeting. Cleared concepts will be made publicly available on the NIDDK website.

The meeting included descriptions of three concepts by the Division of Diabetes, Endocrinology, and Metabolic Diseases.

Division of Diabetes, Endocrinology, and Metabolic Diseases Concepts

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

- **Establishing a Cohort to Clarify Risk Factors for Neurocognitive Complications in Pediatric Type 1 Diabetes:** Dr. Karen Teff presented this concept, first noting that adults with childhood-onset Type 1 Diabetes (T1D) have significant cognitive impairment compared to comparably aged individuals without diabetes. Impaired cognition may exacerbate difficulties associated with long-term diabetes management. Early disease onset appears to be a major risk factor for cognitive impairment as the metabolic insult of hyperglycemia to the developing brain may delay brain growth, decrease brain volume and neurocognition. Diabetic ketoacidosis (DKA) at the time of diagnosis, sustained hyperglycemia or repeated episodes of severe hypoglycemia may be additional important risk factors for predicting impairments to brain structure and function in children with T1D. To date, studies have been limited by their small sample size, lack of control groups and short length of follow-up. This FOA will solicit applications for a clinical consortium to establish a prospective, longitudinal observational cohort study to identify risk factors contributing to diminished neurocognition and changes in brain structure and function in pediatric patients with T1D. The proposed study is expected to include clinically significant outcomes such as intelligence quotient, other measures of cognition related to daily functioning (memory, executive function), measures of brain structure and function and metrics associated with continuous glucose monitor (CGM) usage. Identifying those children at greatest risk for neurocognitive dysfunction is critical for optimizing clinical care.

- **Human Islet Research Network - Consortium on Targeting and Regeneration (HIRN-CTAR):** Dr. Olivier Blondel presented this renewal concept, which will solicit new applications to the Consortium on Targeting and Regeneration (CTAR) that will continue to support the development of innovative strategies to increase or protect functional human beta cell mass in patients with Type-1 Diabetes (T1D) through controlled manipulation of beta cell replication, islet cell plasticity, in vivo reprogramming of pancreatic non-beta cells into beta-like cells, and protection of the residual beta cell mass from the autoimmune environment. CTAR is part of the Human Islet Research Network (HIRN) and this initiative would represent the second renewal of the CTAR effort (CTAR 3.0). In the past six years, the consortium has made significant progress toward its long-term goals. Renewed support is needed to bring the islet targeting strategies and islet-specific therapeutic solutions that are currently being developed closer to clinical applications, and to encourage the development of additional strategies to increase or protect beta cell mass in patients with T1D.
- **NIDDK Information Network (dkNET) Renewal:** Dr. Ashley Xia presented this renewal concept for dkNET, which was originally conceived in 2011 in response to community needs in Big Data biomedical research, with an initial focus on sharing of data and resources within the NIDDK research community. Since then, the needs and challenges have only grown. The program was renewed in 2017, with an expanded and more specifically defined scope to assist the community with information discovery, hypothesis generation, Rigor and Reproducibility (R&R), adherence to the Findability, Accessibility, Interoperability, and Reusability (FAIR) guiding principles, and education and workforce development. At this time, despite the growth of the program, several areas of expansion have been considered. These areas include: support for NIDDK-specific data types, engaging more domain experts in both basic and clinical research, and building a diverse and equitable workforce. Thus, based on the progress and the continued need, renewal of dkNET is proposed to continue supporting the critical community needs, and to help the NIDDK community leverage the emerging opportunities from Big Data science.

Council Questions and Comments

***Comment from Council:** Regarding the pediatric T1D study, over what time period would you expect to see meaningful alterations in neurocognition tied to T1D? It seems challenging to adequately power such a study within a five-year grant period. Could this outcome be observed very rapidly?*

Dr. Teff responded that there is evidence for both acute effects and long-term effects. Whether the acute effects are sustained is not completely clear, but there is evidence that those effects are sustained over a period of five years.

***Comment from Council:** There are other initiatives at NIH that align with dkNET efforts to put identifiers on datasets that show up in publications. It seems like advances in bioinformatics stemming from dkNET should be embedded in trans-NIH activities, perhaps through integration as a Common Fund activity.*

Dr. Xia agreed that this would be a critical step for dkNET, adding that staff consistently hear from other researchers and the user community that dkNET needs to interact with NIH-wide bioinformatic efforts.

***Comment from Council:** The islet discussion brings to mind the recent success with T1D at Vertex Pharmaceuticals. How should those kinds of breakthroughs impact the general direction of funding and initiatives? Should resources be put behind efforts that work, or should the search for new and different approaches be continued?*

Dr. Blondel responded that CTAR is specifically looking for new, discovery-focused projects. Beta and other islet cells are extremely hard to target with specificity. There is still a need for basic research across a broad spectrum, such as identifying beta cell-specific molecules or targeting vectors. Since CTAR is an incubator far from clinical application, its role is to explore as many options as possible to develop new tools and new strategies.

***Comment from Council:** Building on that question of clinical focus versus discovery-based science, we still need to approach this on a very broad basis rather than zooming in on a few examples that have proven to be successful. Focusing on discovery in the human islet area is still worthwhile to maintain current momentum. The CTAR concept that Dr. Blondel presented is solid and well-based, with a very bright future in that area.*

Dr. Cefalu informed Council that both the open and closed DEM sessions would provide additional information and further updates on this topic.

Dr. Rodgers requested a motion of concurrence for the three presented concepts. The motion was made and seconded. The 12 voting members of Council voted unanimously in support of the presented concepts.

**X. UPDATE: HEALTH DISPARITIES AND HEALTH EQUITY WORKING GROUP
*Dr. Thornton and Dr. Germino***

As an outcome of the Council Forum on Underrepresented Investigators and Underrepresented Science, the Council recommended the formation of a working group on health disparities and health equity. As such, NIDDK's inaugural Health Disparities and Health Equity Research Implementation Working Group was established. It will complement NIDDK's Strategic Research Plan for research. Dr. Rodgers introduced Drs. Thornton and Germino to provide an update on the progress of the Working Group.

Dr. Germino explained that the primary charge to the Working Group was to develop actionable recommendations and an implementation plan to advance health disparities and health equity research at NIDDK. The plan will operationalize NIDDK's recently-published Strategic Plan for Research overarching theme, "empowering a multidisciplinary research community; engaging diverse stakeholders; and leveraging connections among diseases to eliminate health disparities and improve prevention, treatment, and health equity—pursuing pathways to health for all."

Dr. Germino extended thanks to the staff working on this effort, including Working Group co-lead Dr. Pamela Thornton, who has also taken on the role of Senior Advisor

for Workforce Diversity and Health Equity within the NIDDK Office of the Director. The Working Group includes a broad cross-section of staff from NIDDK extramural divisions, review branch, and offices.

Dr. Thornton reminded Council members that the Working Group was organized around four scientific themes, which were introduced at the September Council meeting. Subgroup 1 focuses on engaging communities and building sustainable partnerships. This group will determine methods for incorporating an understanding of community members' lived experiences into research priorities, building sustainable collaborations with diverse stakeholders, and ensuring NIDDK centers equity into the fabric of its work.

Subgroup 2 will focus on determining how structural racism and other social determinants of health intersect with biological processes to cause disease. Work in this area might examine how discrimination, stigma, economic distress, and other stressors result in chronic stress, inflammation, dysregulated cortisol release, metabolic disease, and disruption of other biological systems.

Subgroup 3 will focus on determining how to address the negative effects of certain social and living conditions on health in order to improve health and eliminate disparities. The systems and stressors associated with structural racism are longstanding and complex and will take time to address. Subgroup 3 will also try to identify interventions that help people compensate for or overcome barriers that prevent equitable access to health-promoting resources.

Subgroup 4 will focus on how NIDDK may address the upstream causes of social determinants of health and health disparities. Actions may include root-cause studies that focus on understanding and correcting fundamental conditions that give rise to NIDDK-related health disparities. Interventions in this area have the greatest potential impact on health disparities but are also the most complex to achieve.

Dr. Thornton pointed out that the order of the subgroups has changed since they were presented at September Council; the subgroup focusing on engaging communities and building partnerships is now Subgroup 1 instead of 4, as this position better communicates the goal of centering equity and the individuals—patients, families, communities—that NIDDK serves in this work.

NIDDK hosted the kickoff meeting for the Working Group on December 15, 2021; Dr. Thornton highlighted the enthusiasm and appreciation displayed by Working Group members in attendance.

Each subgroup comprises an external co-chair and an NIDDK co-chair. Members include at least one community expert as well as multidisciplinary experts from academia and diverse organizations. Additional NIDDK staff representing program, policy, and review will also participate. An exception to this format was made for subgroup 1, which will include three additional community members to better represent individuals living with or at risk for NIDDK diseases.

The co-chairs of the subgroups are as follows:

Subgroup 1: Dr. Giselle Corbie with Dr. Robert Rivers.

Subgroup 2: Dr. John Carethers and Dr. Jenna Norton. (Dr. Paul Kimmel served as co-chair for this group until this month.)

Subgroup 3: Dr. Debra Haire-Joshu (Council member) and Dr. Mary Evans

Subgroup 4: Dr. Marshall Chin and Dr. Shavon Artis Dickerson (Council member Dr. Keith Norris also serves as a member of Subgroup 4.)

A key principle of this effort will be to incorporate input from community members and patients to help shape research recommendations to eliminate health disparities and promote health equity. As such, the Working Group has established a fifth subgroup that will hold community engagement listening sessions to gather additional input from individuals, patients, families, and caregivers to inform the plan. This subgroup will be made up of community members and patients living with, at risk for, or caring for someone with diseases and conditions within the NIDDK mission. The workgroup is now in the process of identifying community volunteers.

The subgroup is envisioned to include 12 to 15 participants representing as many different lived experiences as possible. Subgroup 5 will meet 3 times virtually to share what they would like subgroups 1-4 to accomplish and consider. They will also provide input on each subgroup's high-level recommendations and draft plan, giving their real-world perspectives on the ethics and feasibility of proposed ideas.

Additionally, the subgroup chairs and one community expert from each subgroup have been asked to form a steering committee to help coordinate the subgroups' deliberations. Dr. Thornton explained that the steering committee—which will include yet-determined members of subgroup 5—will meet for the first time in early February.

She then reviewed the timeline for the workgroup. Initially, the plan was to present findings and recommendations to the Council in September 2022. However, given the time required to build relationships with communities, the elevation of listening sessions to full subgroup status, acknowledging the importance of natural discourse, and scheduling challenges, NIDDK has decided to extend the timeline. The working group will present their report at the January 2023 Advisory Council meeting.

Council Questions and Discussion

Dr. Thornton then asked members of the working group who are also Council members to share their perspectives on the process thus far.

Dr. Haire-Joshu expressed her enthusiasm for the working group and the efforts being made by NIDDK to develop a roadmap to identify and implement the science needed to understand and address health equity and eliminate health disparities. She commended the creation of subgroup 5 as an example of true partnership and effort to address lived experiences.

Dr. Norris echoed those sentiments, highlighting the critical value of a multi-prong approach that looks at the biology of social determinants of health and ways to address or lessen effects on organ systems that are downstream from social determinants of health. He also acknowledged that these types of changes take time and stressed the

importance of varied concurrent efforts.

Dr. Carethers emphasized the importance of health equity as a topic that crosses all aspects of NIDDK and expressed hope that the recommendations of the Working Group can also apply to other Institutes and partnerships.

Dr. Gordon-Larsen emphasized the effort to address high-impact research activities, such as developing markers and metrics to understand and measure the effects of social factors on health disparities seen in NIDDK diseases and other chronic conditions. She reinforced the importance of the work being done and commended the structure and leadership within the workgroups.

Dr. Rodgers then opened the floor to questions and comments from other Council members.

Comment from Council: In addition to educating the community and getting buy-in and feedback from community stakeholders, it's also important to educate the scientific community, which may not have the context or experience of working with community members. Is the community engagement subgroup going to address that type of education for the scientific community?

Dr. Germino noted that the working group has discussed this issue because of its great importance to the process of centering health equity in the NIDDK portfolio. In service of this goal, scientists and researchers of all backgrounds would benefit from this type of education and an effort has been made to recruit subgroup members with little to no experience in the health equity space to participate in discussions about disseminating information to broad audiences. Dr. Thornton added that subgroup 1 is developing core principles and community-engaged methodologies and strategies in this area. Dr. Norris said that he and Dr. Arlene Brown have worked together to bring community members into the lab to develop reciprocal relationships and consider institutional barriers. Dr. Germino added that one possible outcome of the process may be to raise awareness more broadly about how people of varied backgrounds can help serve the goals of our communities in many ways, including addressing diversity issues in the physician-scientist pool.

XI. OPEN SESSION OF SUBCOMMITTEE MEETINGS

See Minutes posted on NIDDK Council Minutes Website.

XII. 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.

XIII. 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).

CONSIDERATION OF REVIEW OF GRANT APPLICATIONS.

A total of 1,243 grant applications (214 primary and 1029 dual), requesting support of \$511,272,196 were reviewed for consideration at the January 26-27, 2022 meeting. An additional 119 Common Fund applications requesting \$94,398,807 were presented to Council. Funding for these applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, 1279 applications requesting \$444,218,447 received second-level review through expedited concurrence. All of the expedited concurrence applications were recommended for funding at the Scientific Review Group recommended level. The expedited concurrence actions were reported to the full Advisory Council at the January 26-27, 2022, meeting.

XIV. 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 218th meeting of the NIDDK Advisory Council was adjourned at 1:44 p.m on January 26, 2022.

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