

**222nd Meeting of the
National Diabetes and Digestive and Kidney Diseases Advisory Council**

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

Hybrid Meeting

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

I. CALL TO ORDER

Dr. Griffin Rodgers

Dr. Griffin Rodgers, Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), called to order the 222nd meeting of the NIDDK Advisory Council at 8:30 on May 17, 2023, via a hybrid meeting (in-person and Zoom video conference). The meeting was conducted using a two-tiered webinar format. The panelist tier included NIDDK Advisory Council members and NIDDK staff members who presented during the meeting. The audience tier was available via a live stream to the public and allowed them to view and listen to the meeting.

ATTENDANCE – COUNCIL MEMBERS PRESENT

| | |
|-------------------------|------------------------|
| Dr. John Carethers | Dr. David Penson |
| Dr. Iain Drummond | Ms. Ceciel Rooker |
| Ms. Dawn Edwards | Ms. Ricky Safer |
| Dr. Penny Gordon-Larsen | Dr. Kathleen Sakamoto |
| Dr. Debra Haire-Joshu | Dr. Philipp E. Scherer |
| Ms. Davida Kruger | Dr. Elizabeth Seaquist |
| Dr. Jacquelyn Maher | Dr. Michael Snyder |
| Dr. Mark Nelson | Dr. Gary Wu |
| Dr. Keith Norris | |

Subject Matter Experts:

Dr. Carmella Evans-Molina
Ms. Karen Jordan

Ex-officio Members:

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. 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. Dana K. Andersen
Dr. Julie Barthold
Dr. Eric Brunskill
Dr. Shavon Artis Dickerson
Dr. Mary Evans
Dr. Katrina Loh
Dr. Peter Perrin
Dr. Robert Rivers
Dr. Cindy Roy
Dr. Neha Shah
Dr. Corinne Silva
Dr. Xujing Wang

ANNOUNCEMENTS

Dr. Griffin Rodgers

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

Recognition of Subject Matter Experts

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

- **Dr. Carmella Evans-Molina** is the J.O. Ritchey Professor of Medicine at the Indiana University School of Medicine and Director, Indiana Diabetes Research Center.
- **Ms. Karen Jordan** chairs the JDRF Research Committee and serves on the JDRF's International Board of Directors.
- Dr. Evans-Molina and Ms. Jordan will participate on the Division of Diabetes, Endocrinology, & Metabolic Diseases (DEM) Subcommittee.

Council Member News

Dr. Rodgers recognized four Council members that agreed, once again, to extend their Council service and participate in the meeting: **Iain Drummond, Penny Gordon-Larsen, Mike Snyder, and Gary Wu.** He thanked them for continuing their service on the Council because of the delayed processing of membership slates.

In Memoriam

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

- **Dr. Robert Sherwin**, C.N.H. Professor of Medicine in the Section of Endocrinology, Yale School of Medicine. In addition to being an outstanding physician, scientist, and administrator, he was a dedicated mentor who inspired the careers of many outstanding researchers. A leader in diabetes research for several decades, Dr. Sherwin had strong ties to NIH and NIDDK. Early in his career he was a research fellow in metabolism and diabetes at NIH. He was Director of the Yale Center for Clinical Investigation, which was supported by the NIH Clinical and Translational Awards program. He was also the Director of an NIDDK supported Diabetes Research Center at Yale. Aside from his role as a Center Director, Dr. Sherwin's research earned substantial support from NIH, including NIDDK. Dr. Sherwin used this support well, establishing a remarkable publication track record in peer-reviewed journals. Dr. Sherwin also had a strong service record. For example, he served as President of the American Diabetes Association and on editorial boards for several journals. He also served on several NIDDK peer review panels and on an FDA Advisory Committee. As one of NIDDK's staff members noted upon learning of Dr. Sherwin's death—the entire diabetes field owes him a debt of gratitude.
- **Dr. Shaul Massry**, Professor Emeritus of Medicine and Physiology & Biophysics at the Keck School of Medicine, University of Southern California. Dr. Massry served as Chief of the Division of Nephrology from 1974 to 2000. Dr. Massry was a longtime NIDDK grantee, who received funding from 1972 to 2006. He was awarded honorary degrees from universities around the world and received several prestigious awards, including the National Kidney Foundation's (NKF's) David Hume Memorial Award. He also served as President of the NKF. Dr. Massry had been a frequent guest speaker at national and international meetings and a visiting professor at many universities across the globe. He published over 600 scientific papers, 111 book chapters, and edited 32 books. Dr. Massry will be remembered for his many clinical papers on calcium and phosphate metabolism in patients with kidney disease, and for his explorations of parathyroid hormone as a putative uremic toxin.
- **Dr. Beverly Torok-Storb**, an expert in hematopoietic stem cell biology and bone marrow transplantation, was an NIDDK Advisory Council member from 2016-2019. Dr. Torok-Storb's celebrated career has been intertwined with NIDDK going back several decades. Her first NIH award was an F32, supported by the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD)—a forebearer Institute in NIDDK's evolution. In addition to her independent research program, Dr. Torok-Storb also led the NIDDK-funded Center for Excellence in Molecular Hematology at the Fred Hutchinson Cancer Center since 1999. Dr. Torok-Storb was a force of nature when it came to her devotion to supporting and sponsoring the next generation of hematology scientists. She was especially committed to mentoring women and trainees from underrepresented backgrounds. She was extremely proud of developing the Summer High School Internship Program (SHIP) at Fred Hutchinson Institute, an internship for students from underrepresented backgrounds to intern and learn in biomedical

labs at the medical school. The program has grown steadily from its inception in 2011 to over 400 applications to the program last year. Dr. Torok-Storb's energy, zeal, and devotion will be sorely missed.

Dr. Rodgers also noted the passing of two retired NIDDK staff members.

- **Dr. Enrico Cabib**, retired NIDDK Principal Investigator, died on February 24, 2023. Dr. Cabib's scientific acumen and humorous outlook enriched NIDDK since he joined in 1967. As a post-doc in Buenos Aires, Argentina, in the early 1950s, Dr. Cabib discovered the second and third sugar nucleotides, the sugar donor function of sugar nucleotides, and the first sugar transfer reaction. With these discoveries, he helped his professor, Dr. Luis Leloir, win the Nobel Prize in Chemistry in 1970 for discovering sugar nucleotides that synthesize carbohydrates in mammals. In his first experiment at NIH, Dr. Cabib discovered chitin synthetase, a crucial component of the yeast cell wall. In 1988, he pointed out that some of the yeast cell wall components are not found in people, but are common among fungi, making them apt targets for anti-fungal agents. Dr. Cabib remained a leader in his field and discovered most of what is known about the biochemistry and genetics of the yeast cell wall. He trained many of the best scientists in his field and demonstrated a passion for the bench throughout his career. Despite his incredible achievements, he remained humble. He retired from NIH in 2012 at 87 years of age.
- **Dr. Sarah Kalser**, a retired NIDDK Program Director, died on March 4, 2023. Dr. Kalser was a pioneer for women in her field, as the first female grants administrator and the first female program director at NIDDK. Dr. Kalser was recognized for her contributions to the foundational research on atropine metabolism and drug metabolism by the liver in response to hypothermia and chronic cold exposure. She played a key role in leading research programs that developed oral bile acid therapy for gallstones and helped establish liver transplantation as a viable clinical therapy for end-stage liver disease. Her notable achievements earned her various honors, including the Distinguished Service Award from the American Association for the Study of Liver Diseases and the American Gastroenterological Association, along with several NIH awards.

NIDDK Staffing News

Dr. Rodgers welcomed new staff members to the NIDDK Intramural Program:

- **Dr. Angel de la Cruz Landrau** joined NIDDK as the Director of the Fellowship Office. Dr. de la Cruz Landrau previously worked within the National Institute of Neurological Disorders and Stroke's Intramural Training Office as a scientific Program Manager overseeing training and career development for trainees. He also served as a Program Manager for the High School Scientific Training and Enrichment Program within the NIH Office of Intramural Training and Education.
- **Dr. Margaret Rodgers** joined NIDDK as a Stadtman Tenure-Track Investigator and acting section chief of the Ribonucleoprotein Assembly Section in NIDDK's

Laboratory of Biochemistry and Genetics. Prior to joining NIDDK, Dr. Rodgers was a postdoctoral fellow at Johns Hopkins University.

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

- **Dr. Behdad (Ben) Afzali**, Stadtman Tenure-Track Investigator and section chief in NIDDK's Kidney Diseases Branch, was elected to the American Society for Clinical Investigation for his work on basic mechanisms of tissue inflammation.
- **Dr. Joanna Klubo-Gwiezdzinska**, Lasker Tenure-Track Investigator and acting section chief in NIDDK's Metabolic Diseases Branch, was elected to the American Society for Clinical Investigation for her work on thyroid cancer.
- **Dr. Anne Sumner**, section chief in NIDDK's Diabetes, Endocrinology, and Obesity Branch, received the Arteriosclerosis, Thrombosis, and Vascular Biology Diversity and Inclusion Leadership Recognition Award from the American Heart Association. She was honored for her dedication to mentoring early-career scientists from underrepresented groups and promoting opportunities for people with disabilities, while conducting research on the detection and prevention of diabetes and its complications in people of African descent.
- **Dr. Lee Weinstein**, chief of NIDDK's Metabolic Diseases Branch, was elected as a fellow to the American Association for the Advancement of Science for his distinguished contributions to the fields of endocrinology and metabolism.
- **Dr. Jinwei Zhang**, Senior Investigator in NIDDK's Laboratory of Molecular Biology, received the RNA Society's Early-Career Award for his outstanding achievements in the field of RNA research, which may lead to potential development of novel antibacterial and antiviral drugs against drug-resistant bacteria and HIV.

Dr. Rodgers welcomed new staff members to the NIDDK Extramural Program:

- **Dr. Veerasamy "Ravi" Ravichandran** joined the NIDDK's Division of Digestive Diseases and Nutrition as a Program Officer in February. He holds an M.S. in Biochemistry, M.Phil. in Clinical Biochemistry, and Ph.D. in Biochemistry from the University of Madras, Chennai, India, as well as a Diploma in Computer Applications from George Washington University and an M.S. in Bioinformatics and Computational Biology from Johns Hopkins University. Before joining NIDDK, Dr. Ravichandran served for 10 years as a program official at National Institute of General Medical Sciences (NIGMS) and the National Library of Medicine (NLM), where he managed portfolios in bioinformatics, computational biology, systems biology, modeling, and data science. His interests are especially focused on data standards and data interoperability, and he is passionate about using data-driven approaches to solve complex problems in the biomedical field.
- **Dr. Martha C. Garcia** also joined the NIDDK Division of Digestive Diseases and Nutrition in February as director of the Drug-Induced Liver Injury and Fatty Liver Disease-Basic Science Programs. She earned her Ph.D. in Biochemistry at the University of Szeged in Hungary studying lipid biochemistry and completed postdoctoral research in lipid biochemistry and signaling at the Eastern Virginia

Medical School, Norfolk, VA, and the Osaka Bioscience Institute in Osaka, Japan. She also performed research on brain lipid remodeling at the National Institute of Alcohol Abuse and Alcoholism (NIAAA) and on drug metabolizing enzymes at the University of Pennsylvania. During her research career, she also conducted in vitro metabolism and toxicity studies at small biotechnology companies and on liver toxicology at the FDA. Subsequently, she served as a Scientific Review Officer at the NIH's Center for Scientific Review (CSR) for the Xenobiotic and Nutrient Disposition and Action Study Section. Prior to joining NIDDK, Dr. Garcia was a Program Officer at the NIGMS where she administered a portfolio of grants in the areas of drug metabolism and pharmacokinetics, delivery of molecules and biologics, and wound healing.

- **Dr. Nishadi Rajapakse** joined the Division of Diabetes, Endocrinology and Metabolic Diseases as the Program Director for Health Equity and Type 1 and Type 2 Diabetes. Dr. Rajapakse received her Ph.D. in Molecular Medicine & Translational Sciences from Wake Forest University in 2004 and an M.H.S. in Clinical Research from Duke University. Prior to joining NIDDK, Dr. Rajapakse was a Senior Program Director in the Health Inequities and Global Health Branch at the Center for Translation Research and Implementation Science at the National Heart, Lung, and Blood Institute (NHLBI). Prior to that, at the National Institute on Minority Health and Health Disparities (NIMHD), she directed the Transdisciplinary Collaborative Centers for and Health Disparities Research Focused on Precision Medicine (U54) initiative. Dr. Rajapakse's background spans basic research to implementation science where she has developed and managed a diverse research portfolio that included clinical trials and community-engaged research focused on Health Disparities, Precision Medicine, Environmental and Global Health.
- **Dr. Debbie Sue Gipson** joined the Division of Kidney, Urology, and Hematology (KUH) as the new Senior Scientific Officer for Precision Kidney Clinical Trials. Dr. Gipson joins NIDDK from the University of Michigan's Department of Pediatrics where she was a Professor of Pediatrics, specializing in pediatric nephrology. Dr. Gipson's research interests include clinical trials, translational, observational and health services research to improve the treatment options and health outcomes of children and adults with nephrotic syndrome and glomerular disease. She devised and initiated the TNF inhibition precision medicine trial alongside the Neptune MATCH study as the first precision medicine trial in glomerular disease. Dr. Gipson's work has been consistently funded by NIDDK. She is a leading researcher in pediatric nephrology with multiple high-impact publications.

Dr. Rodgers announced recent staffing news in NIDDK's Office of Clinical Research Support (OCRS):

- **Dr. Maria Heinicke** recently joined OCRS as a regulatory affairs specialist. Dr. Heinicke will assist NIDDK-sponsored study teams in complying with applicable regulatory requirements and Good Clinical Practice. Prior to joining the NIDDK, she served as a clinical coordinator within the Office of Clinical Trials Operations and Management at the National Institute of Dental and Craniofacial Research (NIDCR). She has a Doctor of Pharmacy degree from the Bernard J. Dunn School

of Pharmacy at Shenandoah University. Dr. Heinicke is a Board-Certified Geriatric Pharmacist and previously served as a clinical pharmacist helping to optimize pharmacotherapy for patients with multiple comorbidities.

- **Dr. Ian Bellayr** also recently joined OCRS as a regulatory specialist. Dr. Bellayr is interested in the development of drug products for the prevention and/or treatment of disease. Ian comes to NIDDK from the National Institute of Allergy and Infectious Diseases (NIAID) where he served as a regulatory specialist aiding intramural investigators in the development and regulation of their novel vaccine candidates. He also worked as a product regulator at the Food and Drug Administration (FDA) where he reviewed different regulatory applications related to drug products and devices. While at the FDA, Dr. Bellayr also engaged in research using high-throughput technology to better characterize cell-based therapies. He earned his doctorate degree in bioengineering from the University of Pittsburgh.

Dr. Rodgers provided an update on a proposed simplified review framework for NIH peer review criteria regarding the review of Ruth L. Kirschstein National Research Service Award (NRSA) Fellowships. Concerns have been expressed that some highly qualified fellowship applicants are disadvantaged in review.

- An analysis of 6,000 fellowship applications showed that a small number of institutions submit the majority of applications. The applications from these institutions do better in review and those with senior sponsors also do better.
- A Working Group of the Center for Scientific Review's Advisory Council concluded that the process is potentially leaving out highly promising scientists because it favors elite institutions, senior/well-known sponsors, and places an overly narrow emphasis on traditional markers of early academic success.

The major recommendations of the Working Group to address these issues are to:

- Revise the fellowship review criteria.
- Revise the fellowship application to align with the criteria.

NIH is now proposing to focus attention on three key assessments or core criteria:

- 1) Potential of the applicant
- 2) Strength of the science
- 3) Quality of the training plan

The idea is to structure these criteria to give less advantaged applicants a fair chance—without disadvantaging others. A focus is to reduce bias in review by reducing inappropriate consideration of sponsor and institutional reputation. NIH is also looking to incorporate changes to fellowship applications for alignment with the criteria.

NIH has a Request for Information open through June 23, 2023, where the community can review and comment on these proposed changes. Dr. Rodgers encouraged attendees to see the Request for Information ([NOT-OD-23-110](#)), consider the recommendations for improving fellowship review, and submit comments.

Dr. Gregory Germino provided an update on the release of the Health Disparities and Health Equity Working Group Report. The Working Group was formed in December

2021 and held 11 subgroup and steering committee meetings through December 2022. The Working Group presented the Draft Plan to the Advisory Council in January 2023. The Draft Plan was released for public comment from February 14 through March 31, 2023. There were around 20 responses submitted. Many commenters provided specific research or program suggestions that were disease specific, and these will help inform future planning efforts. Some commenters identified additional groups that may need specific focus to achieve equity, such as those with disabilities or with rare diseases. These comments highlight the importance of intersectionality in NIDDK's work—particularly how multiple identities may affect an individual's interactions with the health care system or engagement in research.

In response to these comments, the committee highlighted programs that were not well known, such as the imperative to include biological sex as a variable in biological research, and to appropriately engage and partner with sovereign Tribal communities on research efforts. The committee also clarified the need to consider Indigenous and other populations when conducting community-engaged research. This is a critical step towards achieving strength-based engagement and building interventions that are both effective and acceptable.

The final report will be entitled 'Pathways to Health for All: Health Disparities and Health Equity Research Recommendations and Opportunities.' The report is scheduled to be published on the NIDDK website during the week following this Council meeting.

NIDDK is already identifying next steps to support and expand health equity research by examining funding practices and flexibilities to facilitate support for health disparities and health equity proposals that may already be in the pipeline. Some of the concept clearances that were presented at Council related to new initiatives for health disparities and health equity. Several Working Group members expressed interest in continuing their involvement to assist NIDDK in pursuing a new framework for Health Equity Research. Since January, the Working Group has learned that NIH has several parallel efforts in this space, so the NIDDK-specific activities have been paused to avoid redundancy and use resources efficiently.

Dr. Germino thanked Working Group members for their enthusiasm and participation in the recommendations, staff for bringing the report to fruition, and the public commentors who provided thoughtful input.

II. CONSIDERATION OF SUMMARY MINUTES

Dr. Griffin Rodgers

The Council approved, by electronic poll, the Summary Minutes of the 221st Council meeting, which had been sent to members in advance for review.

III. FUTURE COUNCIL DATES

Dr. Griffin Rodgers

Dr. Rodgers noted that the NIDDK Advisory Council expects to hold meetings in a hybrid format for the foreseeable future. Although he expected the meeting to take place

on one full day on Wednesday, September 13, he asked Council members to keep open both September 13 and 14 in case a second day is needed. He also noted that Council meeting dates for 2025 have been added to the Council website. Updated information will be posted on the Council website.

IV. ANNOUNCEMENTS

Dr. Karl Malik

Confidentiality

Dr. 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. **REPORT FROM THE NIDDK DIRECTOR**

Dr. Griffin Rodgers

Budget Update

Dr. Rodgers updated the Council on recent budget events.

The FY 2024 budget process began March 9, 2023, with the President's Budget Request. On April 19, the House Appropriations Labor-HHS-Education Subcommittee held a budget oversight hearing focused on both COVID-19 and the budgets for public health agencies under HHS. The Senate Labor-HHS-Education Appropriations Subcommittee held a budget hearing for FY 2024 on May 4, 2023.

The 2023 NIH appropriations bill was signed into law in December 2022. The NIH received \$47.459 billion for 2023, which was a \$2.6 billion (5.6 percent) increase over fiscal year 2022. NIDDK received \$2.301 billion, which was a \$97 million (4.4 percent) increase over FY 2022. These increases included \$8.5 million to restore the mandatory Special Diabetes Program, which resulted from sequestration. The NIH budget also included \$5 billion for pain research at NIH.

Dr. Rodgers also reviewed details from the FY 2024 President's Budget Request. The request includes \$48.27 billion for NIH, which is \$811 million (1.7 percent) more than FY 2023. The budget also included \$2.30 billion for NIDDK, an increase of \$2 million (0.001 percent) that would maintain the Institute at FY 2023 levels.

The FY 2024 budget request specifically targets increases for specific areas such as the Cancer Moonshot, mental health initiatives, nutrition initiatives, and more. The overall budget excludes reauthorization of mandatory funding for the Special Diabetes Program, which was requested at \$250 million, a \$100 million increase over FY 2023. The President also requested increases for this program at \$260 million in FY 2025 and \$270 million in FY 2026. The FY 2024 budget request also includes \$2.5 billion for Advanced Research Projects Agency for Health (ARPA-H).

Congressional Activities

On April 19, 2023, the House Appropriations Labor-HHS Subcommittee conducted an oversight and budget hearing. The acting NIH director, Dr. Lawrence Tabak, and other senior leaders from the Centers for Disease Control (CDC) and the Administration for Scientific Preparedness and Response (ASPR) testified to the Subcommittee. Dr. Tabak discussed the COVID-19 response, pandemic preparedness, as well as the President's Budget Request and how it would affect the agency.

On May 4, 2023, the Senate Appropriations Subcommittee held a FY 2024 NIH budget hearing attended by Dr. Tabak and other senior NIH leadership. The Subcommittee expressed concern for the flat funding that would result in budget cuts for the NIH. Other topics included Alzheimer's disease, cellular therapies for diabetes, mental health, and substance use disorders.

On February 8, 2023, Drs. Rodgers, Cefalu, James, Star, Yanovski, and Serrano met with the Friends of NIDDK and provided an update on NIDDK activities. On February 14, 2023, Drs. Star and Thornton briefed Senator Ben Cardin’s staffers on NIDDK’s efforts to reduce health disparities in kidney diseases, as well as NIDDK’s Health Disparities and Health Equity Implementation Plan.

VI. ARPA-H

Dr. Renee Wegrzyn

Dr. Rodgers introduced Dr. Renee Wegrzyn, who became the inaugural Director of ARPA-H on October 11, 2022. Dr. Wegrzyn was previously the Vice President of Business Development at Ginkgo Bioworks and the Head of Innovation at Concentric by Ginkgo, where she focused on applying synthetic biology to outpace infectious diseases like COVID-19 with biomanufacturing and biosurveillance at scale. She comes to ARPA-H with experience working for two of the institutions that inspired the creation of ARPA-H, the Defense Advanced Research Project Agency (DARPA) and the Intelligence Advanced Research Project Agency (IARPA). While at DARPA, Dr. Wegrzyn was awarded the Superior Public Service Medal from the Department of the Army. Dr. Wegrzyn began her career as a postbaccalaureate fellow at an NIDDK intramural lab.

Dr. Wegrzyn thanked Dr. Rodgers for the introduction. Dr. Wegrzyn began by explaining President Biden’s vision for ARPA-H, which is to “...pursue ideas that break the mold on how we normally support fundamental research and commercial products in this country.” ARPA-H’s vision includes pursuing big ideas, for example, affordable custom cancer vaccines for all, 3D bio-printed replacements for damaged organs, and nanorobotic surgery delivered by a pill. A lot of these ideas will take 10 to 15 years to develop, and ARPA-H hopes to provide seed funding to show that such ideas are possible. ARPA-H expects to make its first program announcements in the weeks following Council.

ARPA-H is a Federal Research and Development Agency provided with a budget of \$2.5 billion. The ARPA-H Director reports directly to the HHS Secretary; ARPA-H was established within NIH, but it is a separate agency, allowing ARPA-H to work closely with NIH subject matter experts while operating via a different business model. There is a lean and nimble management structure that uses bottom-up Program Manager-driven ideas and decision-making. Program Managers need to have a clear and specific problem in health they want to help solve. Program Managers have a base term of 3 years, which is extendable. As a funding agency, ARPA-H has no intramural research labs and will fund extramural programs through Cooperative Agreements, Other Transaction Authorities (OTAs), or contracts rather than as grants.

The ARPA-H health ecosystem aims to move scientific concepts into first-in-human studies. For example, DARPA provided funding to mRNA vaccine research for developing yellow fever and Ebola vaccines, creating some of the fundamental research that allowed COVID-19 vaccines to move quickly to the market. The ARPA-H health ecosystem is made up of stakeholders (NIH, other federal partners, private investors, and non-governmental organizations), performers (academia and industry), and customers (health care providers and patient groups).

ARPA-H opened its first agency-wide open broad agency announcement (BAA), seeking funding proposals for research aiming to improve health outcomes across patient populations, communities, diseases, and health conditions. ARPA-H is also currently seeking to establish three geographic locations across the US through the pursuit of a hub-and-spoke strategy. One hub will be in the National Capitol Region, but there is an open solicitation for submissions to determine the other two geographic sites. The ARPA-H hub and spoke model will help to create a national health innovation network to achieve the goals within the ARPA-H initial mission focus areas. Along with the operations hub in the Washington D.C. region, there will be a customer experience hub and an investor catalyst hub. These hubs will form a network of people, institutions, and capabilities across the country which will allow for data sharing, faster launch of ARPA-H programs, and diversity among patient datasets.

A third strategy for gathering input on big problems in health, ARPA-H Dash to Accelerate Health Outcomes, has been launched to identify revolutionary evidence-based ideas to transform health. The ARPA-H Dash is a collaborative online competition open to bold thinkers across health and scientific communities and provides a simple, engaging, and impactful way to solicit the best ideas in the country to enhance the ARPA-H mission.

Dr. Wegrzyn explained the program and Program Manager system at ARPA-H. ARPA-H plans to hire 20 Program Managers in 2023, with growth to 80 Program Managers within 2 years. The ARPA-H portfolio will reflect the Program Managers' portfolios, be dynamic, and will—and should—change frequently. The Program Managers are the nucleus of the organization, and their energy and passion drive the mission. ARPA-H aims for radical change through investments that seek to address seemingly impossible barriers in demonstrating proof of concept for solutions to major challenges rather than making incremental advances. ARPA-H will not focus on a specific disease or technology; As such Program Managers have autonomy to select their own programs with input from ARPA-H and NIH staff. Program Managers will have 3 to 4 months to launch their first program, identifying milestones and selecting performing teams to solve the problem. They will work to deliver a solution using whatever resources necessary, manage competing teams through multi-step phasing, and oversee the transition of the project outside the agency.

Dr. Wegrzyn indicated that they will follow DAPRA's approach of asking Heilmeier questions about any candidate programs. Heilmeier questions, created by George Heilmeier, an early Director of DARPA—help to create a well-defined problem. The questions are:

1. What are you trying to do? What health problem are you trying to solve?
2. How does this get done at present? Who does it? What are the limitations of present approaches?
3. What is new about our approach? Why do we think we can be successful at this time?
4. Who cares? If we succeed, what difference will it make?
5. What are the risks? Identify any risks that may prevent you from reaching your objectives. Any risks the program itself may present?
6. How long will it take?

7. How much will it cost?
8. What are our mid-term and final exams to check for success?

Two additional questions have been added specifically for ARPA-H:

9. To ensure equitable access for all people, how will cost, accessibility, and user experience be addressed?
10. How might this program be misperceived or misused (and how can we prevent that from happening)?

Program Managers can be at any career stage. The program lifecycle includes designing a program, building a team, executing and measuring, learning and growing, and commercializing and transitioning. ARPA-H aims to develop programs that are unlikely to be funded through traditional funding and/or the commercial sector. ARPA-H has also created a Project Accelerator Transition Innovation Office to increase the probability at each step that solutions can “survive in the wild.” This office will engage the private sector so that projects can be transitioned and developed further outside ARPA-H. Engagement with the venture community will also aid in de-risking future investments by helping to identify key players to engage and learn gaps on the commercial side. ARPA-H also plans to collaborate with NIH and other partners throughout project lifecycles to help select concept ideas, identify partners, eliminate redundancy, and help with transitions.

There will be four initial mission focus areas. These are:

- Health science futures: expanding what is technically possible. Accelerate advances across research areas and remove limitations that stymie progress towards solutions. These tools and platforms apply to a broad range of diseases.
- Scalable solutions: reaching everyone quickly. Address health challenges that include geography, distribution, manufacturing, data and information, and economies of scale to create programs that result in impactful, timely, and equitable solutions.
- Proactive health: keeping people from becoming patients. Preventive programs will create new capabilities to detect and characterize disease risk and promote treatments and behaviors to anticipate threats to Americans’ health, whether those are viral, bacterial, chemical, physical, or psychological.
- Resilient systems: building integrated health care systems. Create capabilities, business models, and integrations to weather crises such as pandemics, social disruption, climate change, and economic instability. Systems are sustained between crises, from the molecular to the societal, to achieve better health outcomes.

Dr. Wegrzyn ended the talk by encouraging attendees to visit the ARPA-H website, <https://arpa-h.gov/>, to learn more.

Council Questions and Discussion

Comment from Council: The way projects are organized in ARPA-H seems confusing.

Dr. Wegrzyn explained that because ARPA-H is just a funding agency, the Program Managers structure projects independently. A program manager may choose a core facility that enables multiple indications or create multiple teams that will be assigned to work on the same problem. Teams and solutions are evaluated over the life of the project and may be reconfigured or assigned different tasks over time, all with the ultimate goal of reaching the endpoint.

***Comment from Council:** Will program managers define a broad area, receive solicitations, then reorganize from there?*

Dr. Wegrzyn agreed and stated that Program Managers will use a portfolio approach and will have explicit visions. More detailed examples will be provided in the coming weeks. BAAs will have clear expectations and goals. Teams are usually made up of many groups including both clinical and academic centers with commercial capacities to ensure solutions advance to the real world.

***Comment from Council:** How will proposals related to each of the mission areas be distributed through the three hubs?*

Dr. Wegrzyn replied that projects will be primarily funded in one of two ways. One is through a BAA and the second is directly through a Program Manager. Program Managers may allocate funding to any of the hubs that help achieve their goals. The hubs and spokes serve as tools, and the funding benefits the communities that are going to use those resources. The hub and spoke network has a consortium management firm that will help facilitate work between federal partners and other companies that may face barriers.

***Comment from Council:** The cooperation model is interesting. It is always challenging to encourage cooperation instead of independent work. How would you manage efficiency in a large group and promote cooperation?*

Dr. Wegrzyn answered that there are a few different ways. One method is to incentivize cooperation with downstream funding for groups that work together in teams. Another method is to create specific ground rules from the beginning of a project and make sure data sharing agreements are in place. ARPA-H believes in transparency, and funding is optional to those that do not want to collaborate and share proprietary information. New tools like homomorphic encryption for data sharing can also potentially be used as a digital handshake prior to data sharing so that both parties agree to share before data transfer. Using these different practices with the funded teams will allow the agency to determine some of the best practices to promote collaboration.

***Comment from Council:** It is always a struggle in the university setting to capitalize on this kind of opportunity. Many universities are not set up for a rapid-cycle situation such as this and how to respond in a timely fashion.*

Dr. Wegrzyn stated that the rapid-cycle funding has been challenging for other agencies too. For example, departments at Historically Black Colleges and Universities (HBCUs) have typically managed smaller amounts of funding. In moving forward, methods to work with HBCUs need to be created, such as teaming them with other groups that have

successfully navigated the process or ensuring clear communication about how the projects will work. Another example is teaming with a commercial entity that has a project manager and assigning a project manager to work with university teams to prepare for this kind of engagement.

Comment from Council: *How will ARPA-H find Program Managers that understand the science?*

Dr. Wegrzyn explained that ARPA-H has created a series of videos that detail what it is like to be a Program Manager. They have a simple intake form for people that are interested, and the agency will walk potential applicants through the process.

Comment from Council: *Obesity is an underlying condition that may lead to a lot of chronic diseases that need to be addressed. How do we ensure that the projects that move forward are pathbreaking and able to address what is needed?*

Dr. Wegrzyn responded that for any potential project, the Program Managers need to spend the first few months talking to experts in the field. It is suggested that the number of experts should be around 100 people.

Comment from Council: *Is there a way for NIDDK to become a trusted authority?*

Dr. Wegrzyn explained that ARPA-H is always open to innovative ideas. One way to communicate with the agency is to provide a white paper discussing ideas that should be investigated further. A concrete project idea can be submitted through the open BAA and is another effective way to get an idea promoted to ARPA-H. Experts at places such as NIH will be contacted once an idea has been developed. For example, NIDDK could suggest obesity experts for Program Managers to contact.

Comment from Council: *There is a part of this that sounds like venture funding. How do you balance impact versus time to deliverable? There are things that could be impactful for health but that take a lot of time versus other things that are not as impactful but could have a deliverable within the next couple of years.*

Dr. Wegrzyn stated that the ARPA-H return on investment is focused on healthy outcomes rather than financials. They also try to account for the fact that the end product has to have value in the marketplace. Without a commercialization option, a project may not succeed. The long-term path for some projects may be federal, state or local funding if not attractive to venture. Sometimes projects can also provide a fundamental demonstration even if they may take a longer time to develop.

Comment from Council: *How, when, and where does ARPA-H plan to engage with the patient community? Patients should be engaged throughout the process.*

Dr. Wegrzyn commented that ARPA-H is actively engaging with patient groups to make sure that the agency is listening and working to understand the problems that patients and other advocates are seeking to address. As new Program Managers are brought on, insights provided by patient groups will be shared with the intention of connecting

Program Managers to the ideas about which that they are passionate. At the moment, programs do not exist for specific diseases, but ARPA-H plans to close the gap on identified, critical areas of research through the addition of staff. The customer experience hub will work directly with patients through the hub-and-spoke network, which will serve as a vital engagement resource for Program Managers. The public, including patients and parents of patients, can submit through ARPA-H Dash any ideas that they would like ARPA-H to work on.

Comment from Council: *The Program Managers are very critical to ARPA-H and will have a short timeframe to deliver results, so selection for Program Managers seems important. How is ARPA-H ensuring that there will be diversity of opinions and ideas within the Program Managers? Is there also a best-practice guide for how ideas are evaluated and presented for further development?*

Dr. Wegrzyn commented that ARPA-H has four pillars of diversity they consider as they are growing the Program Manager pipeline: demographic diversity, geographic diversity, topical diversity, and diversity in experience. The most challenging so far has been demographic diversity due to historic bias in the STEM fields. ARPA-H is building a Program Manager bootcamp that will last about a week in order to help new hires understand the basics and know how to move forward. The Heilmeyer Questions also help to standardize the evaluation process for new projects.

Comment from Council: *The success of these projects depends on commercialization. Can you better define the incentives for commercial entities with this program?*

Dr. Wegrzyn replied that this is an area of discussion within the agency. Right now, Program Managers are leaving the biotechnology sector because of economic factors and lending their perspective and experience in the industry to ARPA-H. ARPA-H also has a transition office that can help smaller companies with services they may not yet have in house. Additionally, ARPA-H investments are not equity, so smaller companies are not worried about losing part of the company.

ARPA-H is also able to reimburse the FDA, and they are brainstorming ideas to leverage this authority as an incentive for biotechnology companies to work with ARPA-H in non-competitive ways, such as data sharing or, for example, helping to ensure that negative data is shared as well as positive data.

Comment from Council: *Private foundations may provide channels for grantees to talk to venture funding groups. These groups tend to like rare diseases because they may be a window into more common diseases. This could be an example of how to bring projects forward.*

Dr. Wegrzyn agreed that ARPA-H is still looking for best practices that might improve their processes.

Comment from Council: *DARPA provides some funding in the health space. Are there plans for collaboration and cost-sharing to ensure no duplication of effort?*

Dr. Wegrzyn indicated that DARPA receives a lot of ideas that do not necessarily relate to defense or national security. ARPA-H is coordinating with other agencies on project ideas, particularly when an idea is not a good fit for that particular agency. This can even happen at the Program Manager level. There are also platforms that were developed at other agencies that might also be leveraged for a different indication that is more appropriate for ARPA-H. There is also active collaboration with other agencies on generative AI.

***Comment from Council:** Are the BAAs meant to be reviewed by Program Managers or are these used to help select Program Managers?*

Dr. Wegrzyn responded that Program Managers are reviewing the BAAs as well as administrative staff. They are not being used to recruit Program Managers.

***Comment from Council:** There are a lot of Ph.D. students interested in non-academic careers. An internship program could help to demystify the job of Program Manager for trainees.*

Dr. Wegrzyn commented that workforce development is not an area that ARPA-H will be directly participating in over the next few years. It is important to get the technical program launched at this time. The agency has discussed shorter learning opportunities, such as week-long engagements to learn the ARPA-H model. Another way to work with ARPA-H is through contracting. There will only be 210 ARPA-H federal employees. Each Program Manager will have a team of Ph.D.-trained scientists that work with them as technical advisors, as well as budget and finance managers. These additional team members will be employed through federal contractors. Technical advisor positions may also be appropriate for early-career scientists.

VII. CONCEPT CLEARANCE

Dr. Rodgers then turned to Concept Clearance by Council, a step required before ICs can publish notices of funding opportunities, or NOFOs. 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. He then introduced each speaker.

Division of Diabetes, Endocrinology, and Metabolic Diseases Concepts

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

Diabetes Centers Resource and Coordinating Center (DCRCC)

Dr. Corinne Silva

The DCRCC will serve the needs of the three DEM Diabetes Centers (P30s) by providing a hub for the Diabetes Centers program to address timely opportunities and challenges including urgent needs and areas of emphasis, and to support the evolving roles of the Diabetes Centers programs. The role of the DCRCC will be to 1) encourage and administratively support cross Diabetes Centers programs and 2) provide administrative support for new programs involving outreach to diabetes researchers across the nation

that are not supported by a funded Diabetes Center. The DCRCC will provide the resources to build the infrastructure for and establishment of specific collaborative activities across the diabetes community that could include, but are not limited to, meetings and conferences, pilot studies, access to emerging technologies, visiting scholar programs, and other collaborative efforts. The DCRCC is intended to leverage the substantial investments by NIDDK in the Diabetes Centers programs by fostering and sustaining the development of novel interdisciplinary efforts in diabetes and endocrinology from pre-clinical to clinical, translation to dissemination, as well as promoting health equity and enhancing diversity in the research workforce.

Reducing Diabetes Health Disparities Leveraging Social Network Analysis

Dr. Xujing Wang

Social factors are among the major root causes of diabetes epidemic and associated health disparities. At the level of individuals, social disadvantages affect biology and increase one's risk for developing diabetes. At population level, social structures impact the efficacy of diabetes prevention, care, and management, resulting in disparities in translation no matter how effective our medical and treatment protocols are for individuals. Reducing diabetes health disparities, given the complexities, is extremely challenging. This initiative aims to foster multi-disciplinary team science to accelerate innovation and incorporate Social Network Analysis (SNA) and Social Network Interventions (SNI), which have shown promise in tackling the social component of health, disease, and health disparities, but are currently underutilized in diabetes. It proposes to establish a new Diabetes Social Health Innovation Center that will be responsible for (1) setting up standards, methods, tools, and best ethical practices; and (2) disseminating pilot funds to existing diabetes clinical studies to collect data, investigate the role social networks in diabetes health disparities, and investigate new paradigms of social intervention. Its overall objective will be to identify SNI strategies that will be effective at reducing disparities by improving the reach, uptake, and sustainment of our current interventions in populations facing disparities.

Next, Dr. William Cefalu presented 6 DEM renewal concepts:

Renewal of the National Health and Nutrition Examination Survey (NHANES) - Diabetes Components

We are requesting renewal of Initiative #1307 "NHANES - Diabetes Components" for the purpose of continuing the diabetes-related questions, examinations, and laboratory measures related to diabetes and its complications to estimate the prevalence and risk factors for pre-diabetes and diabetes among this US nationally representative cohort that will be included in NHANES cycles 2024-2028. Scientists from NIDDK/DEM and CDC/DDT have jointly proposed modifications to the current diabetes-related content in NHANES to provide more robust data on neuropathy (diabetes-related complication) and insulin underusage as well as to harmonize the questions with those on the National Health Interview Survey. The NHANES data are public use and have been used extensively by researchers in the United States and beyond as well as by NIDDK and CDC scientific staff and other federal agencies to inform public health and policy decision related to diabetes.

Renewal - Cystic Fibrosis Research and Translation Centers

The Cystic Fibrosis (CF) Research and Translation (CFRT) Centers began in 1982 in response to a Congressional mandate and have been instrumental in promoting research that has led to new and better therapies. CF research often requires the use of specialized technologies and resources to support a cohesive research effort. The goal of the CFRT Centers is to make state-of-the-art technologies and resources readily accessible to a broad spectrum of investigators working to promote better communication and collaboration between basic and clinical researchers. These Centers achieve these goals by supporting three primary research-related activities: 1) Research Core Services that provide shared resources to enhance the efficiency of research and foster collaborations within and among institutions with strong existing bases of research on CF; 2) A Pilot and Feasibility Program designed to foster the development of new investigators and to provide seed-support for innovative high-risk projects; and 3) An Enrichment Program to promote interdisciplinary interaction and educational updates for investigators. The CF Centers played an important part in both the basic science development as well in the conduct of the clinical trials for the 2019 approval of a triple drug therapy that can be used by 90 percent of CF patients. Much research is still needed to improve the health, lifestyles and longevity of CF patients and the CF Centers are needed to support this important research.

Renewal of Human Pancreas Analysis Program for Type 2 Diabetes (HPAP-T2D) **<https://hpap.pmacs.upenn.edu/>**

The plan is to build on the progress and success of the first cycle of funding and invite a single cooperative agreement application to continue HPAP-T2D's deep and multiplexed phenotyping of pancreatic tissues recovered from donors with T2D and related metabolic disorders. Specifically, the initiative will task the existing HPAP-T2D team to continue with: 1) identifying, collecting, and intensively characterizing primary pancreatic tissues from patients with T2D and related forms of islet dysfunction, as well as matched controls; and 2) analyzing, organizing, and sharing the data resulting from the study of these tissues through expansion of the existing PANC-DB open-access resource database.

Renewal of Administrative Supplements to Support Emerging Physician Scientists to Develop Research Expertise in Diabetes, Endocrinology and Metabolic Diseases

Physician-scientists are an essential part of the biomedical workforce. However, over the past decade, the number of M.D.s choosing research careers in Diabetes, Endocrinology and Metabolic Diseases has not kept pace with the need. One identified roadblock for emerging physician-scientists is that they often have significantly less research experience and documentable productivity compared to Ph.D.s at the same career stage, putting them at a disadvantage in successfully competing for career development grants. To address this challenge, we propose to renew a program to enable continuity of research experiences for licensed or board-eligible M.D.s or M.D.-equivalents engaged in clinical or basic research within the division's mission.

Renewal of Type 1 Diabetes TrialNet (TN)

This initiative will fund the TrialNet Coordinating Center (TNCC) and the Clinical Network Hub (Hub) for the ongoing TN network. The TNCC and the Hub together support the consortium in the design and conduct of intervention trials aimed at preservation of insulin-producing cells in people at pre-clinical stages and early after diagnosis of T1D. The renewal will build on promising results and continue to make progress towards the durable prevention of T1D. TN aims to continuously improve the efficiency and outcomes of its trials and therefore conducts and collaborates on studies that explore mechanisms of disease pathology and measurements of disease activity. In this competing renewal, the TNCC will: (1) support a wide range of clinical trials and studies in varying stages of development, implementation, and completion, and (2) provide data and sample management, including standardized acquisition, quality control, dissemination, and public accessibility. The TNCC will be responsible for the peer-reviewed selection and funding of Clinical Centers to conduct TN clinical studies. Clinical Center directors will form the majority of the voting members of the Steering Committee, and play a major role in trial selection, design, and implementation. The main objective of the Hub is to enhance screening, recruitment, and trial implementation through coordination among network investigators and the T1D community, and to increase operational efficiency and flexibility of the network.

Limited Competition: Continuation of the Human Pancreas Analysis Program for Type-1 Diabetes (HPAP-T1D)

This limited competition would support a single cooperative agreement application to continue the mission of the existing HPAP-T1D effort. The HPAP-T1D is a large data- and resource-generation program that performs deep phenotyping of the human endocrine pancreas and its interaction with the immune system to better understand the molecular events that precede and lead to the beta cell loss in type 1 diabetes (T1D). HPAP-T1D datasets are shared with the research community through a searchable database called PANC DB. HPAP is a component of the Human Islet Research Network or HIRN that was created in 2014 to support innovative and collaborative translational research to understand how human beta cells are lost in T1D, and to find innovative strategies to protect and replace functional human beta cell mass.

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

Council Questions and Comments

Comment from Council: *Is the DCRCC a stand-alone academic funded entity?*

Dr. Silva stated that the plan was for stand-alone academic center, but there could potentially be more than one.

Comment from Council: *Concern was expressed that sometimes these academic centers add administration burdens instead of helping the institution.*

Dr. Silva responded that there are examples of other successful centers across NIDDK that can be used as a model, and they will be cautious of this issue moving forward.

Comment from Council: *The DCRCC is an interesting concept, particularly considering that disease centers already try to do this informally. Will this be another P30 application, and how will this be rolled out?*

Dr. Silva replied that this will be collaborative with input from Program staff. Drs. Silva and Perrin have discussed the Digestive Diseases Center and those networks that form both with encouragement and organically. There has been success both ways, but the disease centers need to begin working together. For example, the National Institute of Aging (NIA) has a research network that brings together different centers throughout the ICs, and it may be something to aspire to in future.

Comment from Council: *There was an earlier presentation from the Digestive Disease Centers that was about coordination of data management. Will this be part of the effort?*

Dr. Silva stated that data management will be part of this network. The NIDDK information network can assist, and the team is aware of the roadblocks regarding data management.

Dr. Cefalu added that the genesis of this project stems from the collaboration between the Diabetes Research Centers (DRC) and Centers for Diabetes Translation Research (CDTR) when the investigators wanted to collaborate but there were internal roadblocks. This effort will facilitate funding and synergy for collaborative projects.

Comment from Council: *Will this grow out of an existing DRC, or will it be an entirely new coordinating group?*

Dr. Silva explained that there are examples of both models, but the DCRCC would be a new separate entity.

Comment from Council: *These can work well when they are part of data centers so that they do not add too much to the administrative burden.*

Dr. Silva agreed and mentioned that coordinating centers already exist for some consortia, and this knowledge can be leveraged for planning purposes.

Comment from Council: *The creation of one center that can help collaborate across groups could facilitate future collaborations.*

Dr. Silva mentioned that additional information and conversation will take place on this topic during a sub-Committee meeting.

Comment from Council: *How will this help HBCUs and other that do not already have Diabetes Centers? Advancements stemming from existing centers may perpetuate inequality.*

Dr. Silva noted that is one of the goals for the plan. Individual researchers at an institution without a Diabetes Center could more easily collaborate with Diabetes

Centers, or HBCUs and other institutions without Diabetes Centers can be structured into existing centers to foster collaboration.

***Comment from Council:** It is important to make sure that the coordinating centers have strict and clear guidance on their roles and responsibilities. Some coordinating centers are better at collaboration than others and some may want greater control and make the collaborators subservient. It is important to clarify scope and also get input from the Diabetes Centers in developing the DCRCC.*

Dr. Rodgers responded that they would keep that in mind as they move forward.

Division of Digestive Diseases and Nutrition (DDDN) Concepts

Various staff members presented concepts on behalf of the division.

Simulation Applications to Improve Clinical Skills and Outcomes of Practicing Clinicians (Not Trainees) Treating Conditions and Diseases within the Mission of DDDN

Dr. Dana K. Andersen

This FOA is to support research to improve clinical skills and clinical outcomes in the management of conditions and diseases within the mission of DDDN through the development and use of simulation applications by practicing clinicians (not trainees). Simulation methods have been widely adopted and shown to improve clinical skills and outcomes in the Graduate Medical Education domain, but few studies have examined their potential benefit to clinical outcomes achieved by practicing providers. Obstacles to simulation use and adoption by practicing providers include logistical, geographic, and methodologic issues. The greatest impediment is the lack of evidence showing a clinical benefit of simulation use by practicing clinicians. This FOA will support studies which explore the effects and benefits of simulation use on clinical safety (morbidity and mortality), outcomes (resolution of the condition or disease) and cost (length of hospital stay, period of disability) of the treatment of diseases and conditions within the mission of DDDN by practicing clinicians. As simulation has its greatest benefit on a reduction of errors, and as medical errors account for much of the cost and poor outcomes of care, the enhanced use of simulation by practicing providers may improve care through reduced medical error occurrence and/or severity.

Autoimmune Hepatitis Clinical Research Network

Dr. Katrina Loh

Autoimmune hepatitis is a poorly understood form of liver disease that affects a wide range of individuals across the lifespan and a significant cause of end-stage liver disease, liver transplantation and death. Few advances have been made in the pathogenesis of this disease since it was first described in the mid-1950s, and little progress made in its management and treatment. The overall objective of this initiative is to establish cohorts of patients to conduct epidemiological-, clinical- and laboratory-based research focusing upon translation of molecular findings into clinical benefit to patients with these diseases through the creation of a clinical research network. The proposed clinical research network has the potential to contribute significantly to a part of clinical practice where

progress has remained stagnant for decades by further investigating pathogenesis, treatment and perhaps prevention or cure for autoimmune hepatitis.

Nutrition Obesity Research Center (NORC) Program Coordinating Center

Dr. Mary Evans

This proposed initiative would add a Coordinating Center to the NORC program. The NORC program is designed to support and enhance the national research effort in nutrition and obesity at academic and medical centers with substantial existing Federally funded research bases. NORCs support three primary research-related activities: Research Core services, a Pilot and Feasibility program, and an Enrichment program. All activities pursued by NORCs are designed to enhance the efficiency, productivity, effectiveness, and multi-disciplinary nature of research in nutrition and obesity. A Coordinating Center would permit the NORC program to sustain existing trans-NORC collaborations and working groups; to coordinate and manage trans-NORC meetings, communication, and the NORC Central website; to develop new projects of value to the nutrition/obesity community; and to provide additional funds for a centralized pilot and feasibility program targeting investigators from underrepresented groups in scientific research, which could be made available to institutions outside of the NORC consortium to reach the broader research community.

Program for Short-term Research Experiences in Nutrition, Obesity, and Digestive Diseases for Early Stage, New, and At-risk Investigators from Diverse Backgrounds Including Underrepresented Groups

Dr. Peter Perrin

Fostering diversity in the scientific research workforce is a key component of the NIH strategy to identify, develop, support, and maintain the quality of our scientific human capital. Research opportunities at institutions that have not been major recipients of NIH support and/or minority-serving institutions are often limited. This initiative seeks to enhance diversity amongst the research workforce by supporting short-term research experiences in nutrition, obesity, and/or digestive diseases for scientists from diverse backgrounds, especially those with appointments at non-research-intensive academic institutions. Program participants (candidates) could be early career, new, or at-risk investigators.

Impact of Comorbidities and Co-Infections on HIV Reservoirs

Dr. Peter Perrin

Because of advances in HIV science, particularly the development of effective antiretroviral therapy, HIV has evolved into a chronic disease. As people age with HIV, they are developing various comorbidities and co-infections that significantly impact their health and quality of life. There is emerging appreciation that these various conditions and co-infections also impact HIV reservoir biology in ways that are likely to interact with potential cure strategies. However, most research on HIV reservoirs does not incorporate the impact of inflammation, metabolic perturbations, or other pathophysiological processes associated with prevalent comorbidities or co-infections. Rigorous research to address this problem will require synergistic, collaborative

interactions between experts in HIV science and researchers with primary expertise in the pathobiology of the comorbidities or co-infections being investigated. This initiative will therefore bring together multi-disciplinary teams to address how comorbidities and co-infections that are prevalent in people interact with viral reservoirs in ways that would confound cure strategies aimed at sustained viral suppression or elimination from the body.

Ex Vivo Studies of HIV Infection and Pathogenesis Within the Mission of NIDDK

Dr. Peter Perrin

HIV research involving human subjects or nonhuman primate models are often complicated by multiple factors that impact experimental design and interpretation of results. In vitro cell culture studies of biochemical, molecular biological, and cellular mechanisms can be somewhat reductionist and not fully recapitulate in vivo events. This is particularly important in conditions such as HIV, where interactions between different organ systems, inflammatory pathways, and immune processes contribute to viral reservoir dynamics and pathogenic processes. This initiative seeks to stimulate the use of *ex vivo* technologies such as organoids and micro-physiological systems for elucidating the complex biological processes occurring during HIV infection in tissues within NIDDK's mission. For example, these types of models could be derived from individual people with HIV with well-characterized medical histories.; they could interrogate mechanisms operative under varying conditions, such as long-term viral suppression, the presence of multiple comorbidities and co-infections, polypharmacy, interactions between different tissue compartments (ex: gut-distal organ axes and impact of adiposity), diet, and others. Moreover, *ex vivo* infection of organoids or micro-physiological systems from people without HIV could provide model systems that circumvent confounders such as medical history, diet, or other factors.

Syndemics Impacting the Health of People with HIV-related Comorbidities and Co-Infections within NIDDK's Mission

Dr. Peter Perrin

Intersectional stigma and discrimination based on multiple factors, like race/ethnicity, gender identity, and sexual orientation, can impact the management of comorbidities and co-infections in people with HIV across the lifespan. People with HIV may also belong to other communities that experience stigma or discrimination. These include sex workers, people involved with the justice system, young people experiencing homelessness without a guardian, older people, people with disabilities, rural residents, and people living alone or in isolation. Moreover, there may be stigma associated with noncommunicable comorbidities such as obesity, diabetes or kidney disease, and co-infections such as viral hepatitis as well as with HIV itself. Such intersecting marginalized identities place people with HIV at greater risk for adverse social determinants of health, or social risks. This initiative addresses the impact of syndemic racism, homophobia, transphobia, discrimination, and stigma and their inter-relationships with social risks on development, exacerbation, and effective management of HIV comorbidities and co-infections within NIDDK's mission. The initiative will support research projects that address the impact of social risks, such as housing insecurity, food

insecurity, and economic insecurity, on comorbidities and co-infections in racialized, marginalized, and stigmatized populations.

Next, Dr. Stephen P. James presented 4 DDDN renewal concepts:

**Continuation of the Type 1 Diabetes in Acute Pancreatitis Consortium (T1DAPC).
Special Diabetes Program Initiative Renewal**

Acute pancreatitis (AP) results from acute inflammatory injury of the pancreas, which can be complicated with acute glucose intolerance. Once thought to be a transient effect of the exocrine pancreas, recent clinical studies revealed that 30-40 percent of patients with AP developed diabetes or impaired glucose tolerance within 3-4 years of even a single, mild episode of AP. The conceptual origin of the T1DAPC, the combined efforts of NIDDK's Divisions of Diabetes, Endocrinology, and Metabolic Diseases and Digestive Diseases and Nutrition led to the issue of RFA-DK-19-022 to fund clinical sites, RFA-DK-19-023 to fund a coordinating center, and RFA-DK-21-501 to provide funding for MRI studies of pancreas architecture and function. The objectives were to form multi-disciplinary teams composed of pancreatologists, endocrinologists, immunologists, and radiologists to conduct a clinical study to investigate the incidence, etiology and pathophysiology of diabetes following AP with a particular emphasis on the autoimmune processes that result in Type 1 diabetes (T1D). As a result, the Diabetes Related to AP and its Mechanisms (DREAM) study was initiated in 2022. Given the Divisions' investments, and the investigators' commitment and significant progress, we propose a continuation of the consortium to allow completion of the DREAM Study to accomplish several of the goals stated in the original RFAs.

**Renewal of Consortium for the Study of Chronic Pancreatitis, Diabetes and
Pancreatic Cancer Clinical Centers (CSCPDPCC - CCs)**

Pancreatic disease leads to significant morbidity, mortality, and health care utilization in the United States. Research progress in diseases of the exocrine pancreas [chronic pancreatitis (CP), pancreatogenic diabetes mellitus, and pancreatic cancer] have been hampered by multiple limitations. To address research gaps in CP and its sequelae, the NIDDK and the National Cancer Institute (NCI), funded the Consortium for the Study of Chronic Pancreatitis, Diabetes and Pancreatic Cancer in September 2015. The Chronic Pancreatitis, Diabetes and Pancreatic Cancer Clinical Centers (CPDPCC) have initiated four major studies: the Prospective Evaluation of Chronic Pancreatitis for Epidemiologic and Translational Studies, the International Study Group of Pediatric Pancreatitis: In Search for a Cure, a New Onset Diabetes Cohort, and the diagnosis and characterization of Type 3c diabetes mellitus secondary to pancreatic cancer and CP. Continuation of the consortium will accomplish several goals: a) to define and characterize the risks and natural histories of pancreatic diseases (including their progression) and their relationship to diabetes; b) to develop enhanced methods and biomarkers for prediction, early diagnosis, and monitoring effects of interventions to prevent, delay and/or attenuate the pancreatic diseases; and c) to propose clinical trial designs for effective testing of therapeutic interventions.

Renewal of USDA National Food and Nutrient Analysis Program (NFNAP)

Assessment of dietary intake is a required activity for many NIDDK-funded grantees conducting research focused on obesity surveillance, prevention, and treatment as well as dietary management of chronic diseases (i.e., diabetes, NAFLD, and chronic kidney disease). Once dietary intake is captured by a variety of methods, analysis of the resultant data most often relies on the Food and Nutrient Database for Dietary Studies (FNDDS) to determine the composition of a person's diet. The NFNAP determines the foods and beverages and dietary components that should be included in the FNDDS. NFNAP is an ongoing collaborative research project led by the US Department of Agriculture (USDA) and executed with scientific support and funding from multiple Offices and Institutes of the NIH as well as the CDC and the FDA. This initiative will provide NIDDK co-funding to support the production of NFNAP data.

Advancing Methods for Integrated Analysis of 24-hour Behavioral Patterns: The Role of Diet, Physical Activity, and Sleep

Diet, physical activity/sedentary behavior, and sleep are modifiable risk factors that play a role in the etiology and prevention of many chronic diseases, including overweight/obesity, diabetes, cardiometabolic diseases, NAFLD, and cancer. Many NIH-supported studies have collected data on these behaviors in relation to a variety of health outcomes, however, our understanding of how these interconnected modifiable risk factors impact health in diverse populations is limited. An opportunity exists to use data science approaches to integrate these behaviors across the 24-hour day and to examine their relationship with health outcomes. This initiative would support a trans-NIH consortium of three research centers and a coordinating center using computational approaches to integrate existing temporally collected data on diet, physical activity, and sleep to evaluate their association with health outcomes. When available, contextual, and other data could also be incorporated into analytical algorithms. The ultimate goals of this initiative would be to produce guidance and best practices for the joint collection and analysis of diet, physical activity, and sleep data in future NIH-supported research studies and to provide training and workforce development activities to support future generations of researchers with knowledge and training necessary to analyze data from these linked behaviors.

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

Comment from Council: Regarding the simulations project, will this require an established simulation center on site or just a site that people can use to enhance their skills?

Dr. James answered that access to simulation centers is a barrier to clinicians embracing the use of this tool. Technology has evolved to the point where there are virtual coaches and web-based designs. The availability of simulation applications is much broader than in the past. These developments allow for the use of simulation by practicing clinicians that do not necessarily have access to a simulation center.

Comment from Council: Is the idea to have a local or regional place for training?

Dr. James explained that the frequency, type, and intensity of simulation use that is optimal is unknown at this time. The participation of practicing clinicians in scenarios where they have little to no experience can improve clinical outcomes and safety, as well as reduce mistakes. This may require on-site simulations or the use of web-based technologies and both would be possible.

***Comment from Council:** Regarding the NORC coordinating centers, there seems to be redundance in the system regarding how an individual NORC is defined. Why not fund an additional NORC site instead of funding a coordinating center that has an overlapping set of missions and tasks?*

Dr. Evans responded that there is an ongoing discussion on ‘right-sizing’ the number of centers. This is a unique opportunity to bring the NORCs together in support of activities that have already been discussed. A coordinating center could leverage the NORC program and provide opportunities that are not available otherwise to institutions outside of the NORCs. This could be a way to research nutrition and obesity beyond NIDDK. It would benefit the broader research community.

***Comment from Council:** Regarding the NORC coordinating centers, can you provide a little more on what is meant by harmonizing research methods? This topic is discussed in Digestive Disease Centers frequently. Does it mean that access to unique capabilities is being provided within the NORCs, or is it a more unified way of doing research to allow for larger clinical studies between the NORCs?*

Dr. Evans replied that this will allow harmonization to accommodate larger data sets and clinical studies. For example, harmonizing methods across centers, such as methods for metabolic chambers, would allow for data comparison across studies. There is also an initiative to harmonize MRI methods so that methods are the same for all clinical studies.

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

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

Technology Hub Incubator for the Kidney (THINK)

Dr. Eric Brunskill

This initiative proposes to establish a kidney bioengineering technology incubator, Technology Hub Incubator for the Kidney (THINK), to act as a catalyst for innovation and accelerate research discoveries in kidney bioengineering. Building upon recent advances in regenerative medicine in the kidney, but recognizing new challenges, THINK aims to address unmet needs in therapies for chronic kidney disease and end-stage renal disease through a systems approach to generate kidneys for transplantation, supporting research, innovation, and education, outreach, and community building.

PheNOtyping Women At-Risk for Lower Urinary Tract Symptoms (NO-LUTS)

Dr. Julie Barthold

LUTS are a heterogeneous symptom complex of unclear etiology with potential origins during transition periods in women's lives. Multiple forms of therapy are available, but effective clinical management is limited by underreporting, variable natural history and lack of standardized clinical phenotyping that could facilitate improved, individualized care. NIH-funded consortia have made significant progress in developing methodologies to assess and measure the intersecting biological, behavioral and social factors that may contribute to LUTS development and severity. The Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN) has established important phenotypic criteria for LUTS, particularly for urgency and urgency incontinence. The Prevention of Lower Urinary Tract Symptoms (PLUS) Consortium collects population-based data that will provide important information about bladder health in women across the lifespan. The Phenotyping Women At-Risk for Lower Urinary Tract Symptoms (NO-LUTS) initiative will extend the work of the PLUS consortium and employ updated, robust clinical phenotyping tools. NO-LUTS will provide a detailed assessment of bladder health during perimenopause, a key transitional period for bladder health. The NO-LUTS longitudinal cohort study will identify potential risk and protective factors for LUTS and provide a new evidence base for individualized prevention and treatment strategies.

Next, Dr. Robert A. Star presented 6 KUH renewal concepts:

Renewal of NHANES - KUH

The goal of this proposal is to provide support for the National Health and Nutritional Survey. Among other features, this survey has served as the key indicator of the prevalence of chronic kidney disease in the United States for more than 20 years. In 2024, the survey will introduce a newly revised kidney awareness question, and in 2025, will introduce measurement of Cystatin C (in cooperation with the CDC).

Renewal Polycystic Kidney Disease (PKD) Center Program

The purpose of this initiative is to continue to support the PKD Research Consortium. The consortium will develop new, validate, and share resources including but not limited to cell lines, animal models, biospecimens, imaging, and clinical phenotyping. In addition, the consortium will administer an opportunity pool that will support the Innovation Program which will support the development of new resources and spark novel research ideas that will move the PKD field forward.

Renewal of Kidney Technology Development Research Education Program

The purpose of this initiative is to engage students from engineering and other quantitative scientific and technical backgrounds in kidney technology development. The proposal is to solicit research education programs to support team-based research experiences in technology development and nephrology.

Renewal of Stimulating Urology Interdisciplinary Team Opportunity Research (SUITOR) (multi-receipt dates)

The SUITOR program supports increased funding of interdisciplinary R01 research focused on cycling topics of interest in urologic diseases and conditions. Since the initial launch of SUITOR in 2019, the program has already provided support for multiple interdisciplinary investigators working in urinary incontinence and since the beginning of 2022, neurourology in a broad sense. An NIH-supported workshop convened in August 2022 emphasized the importance of neural mechanisms in a range of urologic diseases and conditions, and the significant knowledge gaps that remain. Maintaining broad scientific areas of urologic research will continue to facilitate cross-collaboration, enhance submission of applications that address a wider range of diseases and conditions, and encourage engagement of additional investigators in the field.

Renewal of Stimulating Hematology Investigation: New Endeavors (SHINE)

The Stimulating Hematology Investigation: New Endeavors (SHINE) program is intended to promote innovative, high-quality nonmalignant hematology research relevant to the missions of the NIDDK, the National Institute of Aging (NIA), and the National Heart, Lung, and Blood Institute (NHLBI). Investigator-initiated research project grant applications (R01s) in specific areas of basic and early translational hematology research are invited to this program that supports growth in the nonmalignant hematology research domain. Specific emerging topics that are at the leading edge of the field will change over time and will be updated regularly through the NIH Guide to Grants and Contracts

Renewal of Cooperative Center of Excellence in Hematology (CCEH)

The CCEHs are a national network of cores that provide state-of-the-art resources and services, expertise, enrichment activities, and small pilot and feasibility (P&F) funding to support and enhance the nonmalignant hematology research community and the quality of its science. This is a request to renew the CCEH program, with enhanced strategies to improve the transparency, accountability, shareability, and overall excellence of the program.

Next, Dr. Cindy Roy presented one KUH renewal concept (Dr. Star in conflict):

Renewal of NIDDK Extramural Digital Pathology Repository

Several Extramural Kidney Program clinical research networks have put Digital Pathology Repositories (DPRs) into place with digital whole slide images (WSI) available to support standardization of classical diagnostic criteria across clinical sites. A developing line of investigation is the mining of these digital data sets for discovery of unique computer visualized (pathomic) features which correlate with disease. KUH has the opportunity to renew current NIDDK resources and utilization of NCI infrastructure to maintain a user-friendly archive of kidney tissue WSI that can be deployed in tool development and kidney research.

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

Comment from Council: Regarding the THINK program, is it better to rebuild a kidney with individual components or try to build the entire organ?

Dr. Brunskill answered that there is still a lot about the kidney that is not understood, such plumbing issues: vascularization and the connection between collecting duct and ureter. Those things would need to be understood first in order to build a kidney from scratch.

Dr. Star added that both approaches are probably needed.

Comment from Council: Regarding the THINK project, it is also important to consider M.D./Ph.D. cohorts, as there may be a lot of bioengineers in these kinds of programs and could be a good workforce development area.

Dr. Brunskill agreed and added that additional training cohorts are welcome.

Comment from Council: In terms of building a kidney, are all cell types known? There may be a minority of cells that play critical roles. Organoids have been useful to investigate these questions.

Dr. Brunskill mentioned that the Kidney Precision Medicine Project is investigating this question and has evaluated over 1 million cells in the kidney, giving a good indication of the cells present. There still could be unknown cell types.

Dr. Drummond added that the ReBuilding a Kidney consortium has created a catalogue of cell types for the kidney. Some of the major cell types are stroma and interstitial cells that play important signaling roles. To some extent there is still a reliance on self-assembly and developmental mechanisms that we still do not understand. They are key areas of investigation; methods for vascularization and urine connection that have yet to be identified.

Office of Obesity Research Concepts (OOR)

Dr. Mary Evans presented concepts on behalf of the office.

Leveraging Administrative Data Linkages Between Housing-insecurity Interventions, Social Needs, and Obesity

Historical and contemporary housing-related policies, including segregation, discrimination, and red-lining have had long-term adverse consequences on marginalized and minoritized populations including inequitable distribution of resources and disproportionate experiences of housing insecurity and instability. Households with housing insecurity are also more likely to live in lower-resourced, high poverty neighborhoods with higher exposure to environments with lower education quality, an inadequate supply of healthy and affordable food, transportation challenges, violence and crime, a lack of safe greenspace and resources for physical activity, and reduced access to health care. This initiative would provide support for projects seeking to evaluate whether and how participation in programs addressing housing insecurity influence obesity outcomes using advanced computational approaches to analyze existing housing and

health-related data available through data linkages made available by Federal, State or local governments, and/or other large organizations. Applicants would be encouraged to examine factors such as multi-level neighborhood variables and other underlying social determinants of health (e.g., food insecurity, transportation, health care access, etc.) as well as participation in social services/programs, as available. A focus on health outcomes across the lifespan and in populations experiencing or at-risk for obesity-related health disparities is expected.

Dr. Evans also presented 2 renewal concepts.

Time-sensitive Obesity Policy Evaluation PAR (R01)

Nationally, there is an imperative to take action to reduce obesity prevalence at local, state and federal levels, especially in populations experiencing health disparities. While helping people achieve and maintain a healthy weight is a critical public health goal, relatively little is known about the effectiveness of large-scale policies and programs that could help achieve this goal at the population level, or any differential effects on sub-populations. This initiative is intended to encourage and support research in which a unique and time-sensitive opportunity has arisen to collect baseline data and then prospectively assess effectiveness of an imminent policy or program that is likely to prevent or reduce obesity in a given population (e.g., reduce energy intake, increase activity, decrease sedentary behavior, or improve access to obesity-related health care). This initiative will encourage innovative scientific partnerships between researchers and public and private-sector partners (e.g., community-based organizations, local governments, school districts, employers). The funding opportunity would have monthly receipt dates with a goal of issuing awards for meritorious applications within four months of submission.

Continued NIDDK Participation in the National Collaborative on Childhood Obesity Research (NCCOR)

Obesity during childhood and adolescence is alarmingly prevalent in the US and contributes to adverse health impact during both youth and adulthood. The NCCOR, established in 2009, is a public-private partnership bringing together four major research funders: the Centers for Disease Control and Prevention (CDC), the NIH, the Robert Wood Johnson Foundation (RWJF), and the USDA to accelerate progress in reducing childhood obesity in America. Several NIH Institutes, Centers, and Offices participate in NCCOR, with NIH scientific staff serving in leadership positions for workgroups and projects. NCCOR identifies research gaps and opportunities, develops tools and resources for the research and public health communities, and brings together stakeholders to explore opportunities to work synergistically across agencies to enhance high-quality research.

Office of Minority Health Research Coordination Concepts (OMHRC)

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

NIDDK Diversity Transition Scholars (F99/K000)

The purpose of the NIDDK Diversity Predoctoral to Postdoctoral Fellow Transition Awards (F99/K00) is to recruit exceptional graduate students from underrepresented backgrounds to pursue postdoctoral training focused on NIDDK research mission areas. Talented graduate students from all disciplines, especially those not currently in NIDDK research areas, are encouraged to apply to this opportunity. This program is committed to promoting and supporting diversity and working in collaboration with existing NIDDK pathway programs designed to increase the diversity of the NIDDK biomedical research workforce.

Dr. Rivers also presented 3 renewal concepts.

Small Grants for New Investigators to Promote Diversity in Health-Related Research

The Small Grants for New Investigators to Promote Diversity in Health-Related Research is a longstanding funding opportunity within the NIDDK OMHRC that is designed to support new investigators from diverse backgrounds, including individuals who are from nationally underrepresented backgrounds in biomedical and behavioral research. The goal of the program is to provide funding to new investigators to enable them to conduct small research projects that will generate enough preliminary data for subsequent, substantive funding such as an NIH R01. Based on a portfolio analysis, the program has been successful in meeting its purpose and goals. A majority of awarded investigators identify as Black/African American and Hispanic. Unfortunately, other meritorious R21 grant applications from talented and diverse investigators have not been funded. The continuation of this program is warranted.

Administrative Supplements to Diversify the NIDDK Clinical Research Workforce

Study coordinators are central to the success of patient recruitment and retention in clinical research. The proposed supplement program will renew and expand the pilot that was designed to train, support, and recruit study coordinators from diverse backgrounds to work on clinical research within the NIDDK mission. This renewal and revision will expand eligibility to all human subject studies and clinical research within NIDDK to ensure that we have a diversified biomedical research workforce.

Addressing Health Disparities in NIDDK Diseases

There are many diseases and disorders that disproportionately affect the health of underserved populations in the United States. Several of these diseases are high priority research areas for the NIDDK. The NIDDK's Strategic Plan highlights the cross-cutting theme of achieving health equity by eliminating health disparities among racial and ethnic minority populations and others who are underserved. Thus, there is an opportunity to support more research that aims to reduce health disparities and achieve health equity in NIDDK mission areas. Currently, this initiative supports applications that fall in line with NIDDK's R01 funding policies. Although several meritorious applications have been supported, many more that have missed the payline have not been. A modest set-aside will be included to continue to grow NIDDK's investment in this space.

NIDDK-Wide Concepts

Various staff members presented concepts.

Research Opportunities to Promote Workforce Diversity

Ms. Neha Shah

The NIDDK recognizes the need to diversify the scientific workforce by enhancing the participation of individuals from diverse backgrounds, including those from groups identified as underrepresented in the biomedical, clinical, behavioral, and social sciences research workforce (NOT-OD-20-031). NIDDK program staff have identified two high risk career points where investigators, especially those underrepresented in the workforce, would benefit from greater support: 1) recruiting diverse new investigators and early-stage investigators (ESIs) into the NIDDK research community by supporting successful competition for a first R01, and 2) retaining diverse at-risk investigators by reducing gaps in funding that can put investigators and their trainees at-risk of leaving the research workforce. To address these high-risk career points, this initiative proposes to fully fund meritorious R01 applications from new investigators, ESIs and at-risk investigators from diverse backgrounds that score beyond the payline. This initiative will complement the Small Grants for New Investigators to Promote Diversity in Health-Related Research (PAR-21-313), which supports diverse ESIs and NIs by funding R21s to develop preliminary data that will equip them to compete for subsequent, substantive funding such as an R01.

Dissemination and Implementation Research to Advance Health Equity

Dr. Shavon Artis Dickerson

Dissemination and implementation (D&I) research is a growing field that seeks to improve how evidence-based/-informed interventions are successfully adopted, implemented, and maintained in health care delivery and clinic/community settings. Factors that contribute to advancing equity, effectiveness, scale-up and sustainability of preventive measures, programs, policies, and interventions must be addressed. Equitable implementation of D&I theories, frameworks, and methods is critical to developing sustainable solutions to eliminate NIDDK health disparities and health inequities. This NIDDK-wide initiative proposes to: 1) support and grow equity-focused D&I research focused on NIDDK diseases and conditions for diverse patient populations and diverse practice settings and 2) increase the number of NIDDK investigators conducting equitable D&I trials.

There were also three renewal concepts.

Renewal of RDCRN-wide Rare Diseases Research

Rare disease is defined by the Rare Diseases Act of 2002 (Public Law 107-280) as a condition affecting fewer than 200,000 individuals in the United States. Research in rare diseases encounters barriers in the small numbers of expert clinical investigators at great geographic distances from patients, the paucity of reproducible diagnostics, and the unique ethical concerns around patient privacy and engagement of for-profit partners.

The Rare Disease Clinical Research Network aims to address these barriers with the development of centers of excellence in the conduct of clinical research in multiple rare diseases; the formation of effective partnerships with patient advocacy groups; the development of novel diagnostics and treatments; and the training of the next generation of rare disease investigators.

NIDDK Funding for Multi-Center Clinical Studies through Cooperative Agreements

NIDDK currently supports the funding of high-risk multi-center clinical studies through a U34 planning grant followed by a separate application for the clinical trial or study (U01). High risk multi-center clinical study proposals cannot be submitted as regular investigator initiated R01s. The current FOAs supporting the U34/U01 are expiring and will be reissued.

Renewal of NIDDK Education Program Grants

A core principle of the NIDDK's vision is to promote the next generation of research investigators by fostering exceptional training and mentoring opportunities. The NIDDK promotes training programs across the career stages of a developing scientific investigator. Understanding that early recruitment into scientific investigation can often lead to long-term retention in research, we recognize the need to provide opportunities for undergraduates to engage in research experiences relevant to the mission of the NIDDK. These early experiences raise awareness of diseases within our portfolio among emerging investigators and can motivate young students to pursue further training in these areas. We also recognize the need to promote opportunities for continuing education in novel technologies and emerging scientific opportunities in NIDDK-relevant mission areas for individuals at all stages of their career through the support of courses to enhance skills development to enhance competitiveness of the NIDDK's research workforce.

Dr. Rodgers then invited Council members to ask any questions related to the OOR, Minority Health Research Coordination, or NIDDK-wide concepts.

Comment from Council: *Is there enough of the correct types of datasets to leverage administrative data linkages?*

Dr. Evans responded that a portfolio analysis was carried out in NHLBI, NIDDK, and NCI, and that those data does exist. There are around 25 medium-to-large size clinical cohorts already available. The project could also include international data. With the data management sharing policy, more studies should become available, including the Nutrition for Precision Health Study, and perhaps All of Us.

Comment from Council: *Do these data sets include pregnant women, children, and individuals from diverse racial and ethnic groups?*

Dr. Evans affirmed that these data sets include pregnant women and significant diversity.

Comment from Council: Regarding the NIDDK Diversity Transition Scholars, the higher salaries offered by biotech companies have shifted postdoctoral candidates away from traditional academic post-doctorate positions. Is there a way to offer fellowships that are more relevant to the marketplace, including higher salaries and more biotech-oriented training programs, in order to retain more trainees?

Dr. Rivers responded that further discussion on this topic is needed. The question of how to retain trainees in health should be explored.

Comment from Council: Regarding retention, people who have just completed Ph.D. programs are not choosing academic science. One of the many reasons is the low pay associated with postdoctoral positions, as many talented individuals are not pursuing academic positions in favor of higher salaries offered by industry. Many institutions are increasing postdoctoral salaries to be equivalent with industry in order to retain talent, but this is not sustainable because funding models and grants will not allow for rapid salary growth.

Dr. Rodgers commented that this issue is happening across all the intramural programs at NIH and is an ongoing discussion, and that this topic will be taken under advisement and needs more in-depth conversations going forward.

There being no further questions or comments from Council, Dr Rodgers proceeded to request a motion for concurrence with the concepts presented. The motion was made and seconded and the concepts approved by Council vote.

VIII. OPEN SESSION OF SUBCOMMITTEE MEETINGS

See Minutes posted on NIDDK Council Minutes Website.

IX. CLOSED SESSION OF THE SUBCOMMITTEE MEETINGS

A portion of the meeting was closed to the public in accordance with the determination that it concerned matters exempt from mandatory disclosures under Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and Section 10(d) of the Federal Advisory Committee Act as amended (5 U.S.C. Appendix 2).

Members absented themselves from the meeting during discussion of and voting on applications from their own institutions, or other applications in which there was a potential conflict of interest, real or apparent. Members were asked to sign a statement to this effect.

X. CLOSED SESSION OF THE FULL COUNCIL

This portion of the meeting was closed to the public, in accordance with the determination that it concerned matters exempt from mandatory disclosure under Sections 552(b)(c)(4) and 552(b)(c)(6), Title 5, U.S. Code and Section 10(d) of the 31 Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

Members absented themselves from the meeting during discussion of and voting on applications from their own institutions, or other applications in which there was a potential conflict of interest, real or apparent. Members were asked to sign a statement to this effect.

CONSIDERATION OF REVIEW OF GRANT APPLICATIONS

A total of 1292 grant applications (430 primary and 862 dual), requesting support of \$ 658,974,556 were reviewed for consideration at the May 17, 2023 meeting. An additional 972 Common Fund applications requesting \$ 970,349,967 were presented to Council. Funding for these applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, 1045 applications requesting \$ 423,466,035 received second-level review through expedited concurrence. All of the expedited concurrence applications were recommended for funding at the Scientific Review Group recommended level. The expedited concurrence actions were reported to the full Advisory Council at the May 17, 2023 meeting.

XI. ADJOURNMENT

Dr. Griffin 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 222nd meeting of the NIDDK Advisory Council was adjourned at 4:30 p.m. on May 17, 2023.

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

Date

Griffin P. Rodgers, M.D., M.A.C.P.
Director, National Institute of Diabetes and Digestive and Kidney Diseases, and
Chairman, National Diabetes and Digestive and Kidney Diseases Advisory Council