223rd Meeting of the
National Diabetes and Digestive and Kidney Diseases Advisory Council

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

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

I. CALL TO ORDER
Dr. Griffin Rodgers

Dr. Griffin Rodgers, Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), called to order the 223rd meeting of the NIDDK Advisory Council at 8:32 a.m. on September 13, 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
Ms. Dawn Edwards
Dr. Debra Haire-Joshu
Ms. Davida Kruger
Dr. Jacquelyn Maher
Dr. Mark Nelson
Dr. Keith Norris
Dr. David Penson
Ms. Ceciel Rooker
Dr. Kathleen Sakamoto
Dr. Philipp Scherer
Dr. Elizabeth Seaquist

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

Ex-officio Members:
Dr. Cindy Davis
Dr. David D'Alessio

Also Present:
Dr. Griffin Rodgers, Director, NIDDK and Chair of the NIDDK Advisory Council
Dr. Karl Malik, Executive Secretary, NIDDK Advisory Council
Dr. Gregory Germino, Deputy Director, NIDDK
Dr. William Cefalu, Director, Division of Diabetes, Endocrinology and Metabolic

Diseases, NIDDK
Dr. Stephen James, Director, Division of Digestive Diseases and Nutrition, NIDDK
Dr. Robert Star, Director, Division of Kidney, Urologic, and Hematologic Diseases, NIDDK

Panelists and Speakers:
Dr. Todd Haim, Director, Office of Strategic Extramural Programs (OSEP), National Institute on Aging (NIA)
Dr. Shannon Zenk, Director, National Institute of Nursing Research (NINR)

II. ANNOUNCEMENTS

Dr. Griffin Rodgers

Dr. Rodgers announced that NIDDK will continue to hold hybrid Council meetings for the foreseeable future, although there might be an occasional fully virtual meeting as the need arises or circumstances change. Further details about the January 2024 Council meeting, as well as future meeting dates, will be posted on the Council website.

Recognition of Subject Matter Experts

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

- **Dr. Jamy Ard** is a Professor of Epidemiology and Prevention at Wake Forest University. Dr. Ard will participate on the Division of Digestive Diseases and Nutrition Subcommittee.
- **Dr. Richard Blumberg** is a Professor of Medicine at Harvard Medical School, and Chief of the Division of Gastroenterology, Hepatology and Endoscopy and Senior Physician in Medicine and Gastroenterology at Brigham and Women's Hospital. Dr. Blumberg will participate on the Division of Digestive Diseases and Nutrition Subcommittee.
- **Dr. Jose Florez** is a Professor of Medicine at Harvard Medical School and Chief of the Endocrine Division and the Diabetes Unit at the Massachusetts General Hospital. Dr. Florez will participate on the Division of Diabetes, Endocrinology and Metabolic Diseases Subcommittee.
- **Ms. Neicey Johnson** is the Senior Director for the Association of Black Cardiologists, Inc. Ms. Johnson will participate on the Division of Diabetes, Endocrinology and Metabolic Diseases Subcommittee.
- **Dr. Aylin Rodan** is an Associate Professor of Internal Medicine at the University of Utah School of Medicine. Dr. Rodan will participate on the Division of Kidney, Urology, and Hematologic Diseases Subcommittee.

Council Member News

Dr. Rodgers recognized five current Council members who will "graduate" from Council service after today's meeting**: Drs. Debra Haire-Joshu, Mark Nelson, David Penson, Kathleen Sakamoto, and Ms. Ceciel Rooker** have all fulfilled their term of service (as the Council member Class of 2023). Dr. Rodgers indicated that NIDDK may ask them to extend their Council service.

NIDDK Staffing News

Dr. Rodgers announced recent staffing news from NIDDK's Intramural Program:

- **Dr. Michael Eichner** joined NIDDK as Director of the Laboratory of Animal Sciences Section. Prior to joining NIDDK, Dr. Eichner was a facility veterinarian with NIH's Division of Veterinary Resources where he oversaw rodent and large animal colonies and ran the ICU service. Dr. Eichner is a Diplomate of the American College of Laboratory Animal Medicine, and his research interests include replacement, reduction, and refinement principles in animal models of human disease.
- **Dr. Ad Bax**, NIH Distinguished Investigator in NIDDK's Laboratory of Chemical Physics, received the 2023 International Society of Magnetic Resonance Prize for pioneering a series of novel nuclear magnetic resonance, or NMR, methods. Dr. Bax's work had a major impact on transforming NMR spectroscopy into a powerful, readily accessible, and well-established tool in structural biology, opening opportunities for important advances in the basic understanding of how biological systems work at the molecular level.
- **Dr. Astrid Haase**, Section Chief in NIDDK's Laboratory of Cell and Molecular Biology, was recently granted tenure. Dr. Haase's research aims to understand a class of molecules responsible for protecting germ cells, acquire valuable insights into how genome databases are maintained, and identify mechanisms that can be harnessed for diagnostics and therapy.
- **Dr. Mark Levine**, Section Chief in NIDDK's Digestive Disease Branch, was elected as a fellow to the American Society for Nutrition for his rigorous and extensive characterization of vitamin physiology, revealing unanticipated vitamin pathophysiology and opening new paths to prevent and treat disease.

Dr. Rodgers announced recent staffing news in NIDDK's Extramural Program:

- **Dr. Dhananjay (Jay) Gupta** is a new program officer in the Division of Diabetes, Endocrinology and Metabolic Diseases (DEM). Dr. Gupta received his Ph.D. from Jawaharlal Nehru University, New Delhi, India and did a postdoctoral fellowship in molecular signaling in the University of Saskatchewan, Canada. Dr. Gupta also completed a postdoctoral fellowship in transcriptional regulation of gene expression at the University of Vermont College of Medicine (UVM) and served on the faculty at UVM. He will oversee programs that include studies on the pathways that are involved in intermediary metabolism as they impact endocrine and metabolic diseases and basic studies in non-human animals related to the neural control of energy balance and weight gain, loss, and maintenance.
- **Dr. Jason Conage-Pough**, a Postdoctoral Associate at the Koch Institute for Integrative Cancer Research at MIT, has been selected by Kidney, Urology, and Hematological (KUH) to participate in the American Association for the Advancement of Science's (AAAS) Science and Technology Policy Fellowship Program. Dr. Conage-Pough graduated with his doctoral degree in cancer biology from Emory University and has received several awards, including the Peter

Karches Mentorship Prize, which recognizes the critical role of mentorship in engaging the future generations of cancer researchers.

Dr. Rodgers announced recent staffing news in NIDDK's Division of Extramural Activities (DEA) and Office of Scientific Program and Policy Analysis (OSPPA):

- **Ms. Nisrin Suterwala-Husain**: joined the Office of Research Evaluation and Operations (OREO) in DEA as a Program Analyst. She served at the NIH Clinical Center Office of Protocol Services where she managed intramural protocols. Prior to that, she was an extramural support assistant for 10 years at the Center for Scientific Review. She will be working on NIDDK's Notice of Funding Opportunity (NOFO) process and other OREO activities.
- **Ms. Meryll Castro** joined OREO as a Health Specialist and will serve as the Inclusion Monitoring Officer, lead various evaluation projects, provide expertise in grant coding, and assist in NOFO development. Prior to joining NIDDK, she was clinical research coordinator in the Division of Endocrinology and Diabetes at Children's National Hospital. Ms. Castro earned a M.S. in Biotechnology from Johns Hopkins University.
- **Dr. Stephanie Mutchler** joined as an AAAS Science Policy and Technology Fellow in OSPPA. Dr. Mutchler received her Ph.D. in Pharmacology from the University of Pittsburgh and did postdoctoral research in renal physiology. Dr. Mutchler will be working in several OSPPA areas including Planning and Reporting activities.

Dr. Rodgers announced retirements among NIDDK staff members and congratulated them on their public service and remarkable careers.

- **Dr. Julie Barthold**, Program Director for Clinical and Translational Research in Women's Urology, Pediatric Urology, and Neurology, will be retiring from KUH in September. Dr. Barthold supported KUH urologic research programs using her clinical practice experience as a pediatric urologist and her clinical and research knowledge on topics including obstructive uropathy, vesicoureteral reflux, incontinence and enuresis, and urinary tract conditions associated with spina bifida. Her very broad program management responsibilities included the Stimulating Urology Interdisciplinary Team Opportunity Research (SUITOR) program. She also served as Project Scientist for the Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium and the Urology Centers Program.
- **Dr. Frank Hamilton**, a Program Official within the Division of Digestive Diseases and Nutrition (DDN), will retire at the end of September. Early in his career, Dr. Hamilton worked within the Office of the Surgeon General and contributed to the landmark DHHS Task Force on Black and Minority Health. The resulting "*Heckler Report*," published in 1985, led to the creation of the HHS Office of Minority Health. Frank joined DDN as a program official in 1987, where he managed programs on diseases of the alimentary system. His contributions to NIDDK scientific achievements are too numerous to list, but include seminal work on *H. pylori* gastritis, celiac disease, functional and GI motility disorders, fecal incontinence, and gastroparesis and premalignant

conditions of the GI tract. Dr. Hamilton has worked to increase diversity within the NIDDK workforce throughout his career. He has been an active contributor to NIDDK's Network of Minority Health Research Investigators (NMRI) since its creation in 1999. He has also been an active participant in diversity programs of major medical associations. Dr. Hamilton's work has touched the lives of numerous investigators and mentees over the years. His outstanding achievements have resulted in numerous achievement awards from within NIH and from professional societies.

- **Dr. Gary Felsenfeld**, NIH Distinguished Investigator and Scientist Emeritus, retired in June after serving more than 60 years at NIDDK. Dr. Felsenfeld studied physical chemistry with world-renowned chemist, Linus Pauling, before joining the Public Health Service in 1956, where he worked at the National Institute of Mental Health studying polynucleotides. There, he played a role in discovering the first triple-stranded nucleic acid molecule. Dr. Felsenfeld then joined NIDDK's newly formed Laboratory of Molecular Biology which shared in the discovery of the first erythroid-specific transcription factor. In 1976, he was inducted into the National Academy of Sciences and became chief of the Laboratory of Molecular Biology in the late 1990s. Over the next decade, he began investigating chromatin boundary regions, which eventually resulted in the identification of the protein CTCF as a major genomic boundary protein. This discovery led to research on long-range interactions in the nucleus that affect insulin regulation in human pancreatic cells.
- **Dr. Marvin Gershengorn**, Chief of NIDDK's Laboratory of Endocrinology and Receptor Biology, retired in June after 25 years of exceptional research at NIDDK. Dr. Gershengorn was a leader in his field, studying the structure and function of cell receptors. He worked to better understand how hormones produced in the brain and pituitary gland interact to control cell function in the thyroid gland and nervous system. His work has helped guide further research on the development of drugs for the treatment of endocrine and neurologic diseases.

Follow Up: NIDDK Portfolio Overview FY2012-2021
Dr. Gregory Germino, Deputy Director, NIDDK

Dr. Germino provided updates to questions regarding a presentation that took place at the Advisory Council meeting in September 2022.

Is the funding success rate of females who submit an R01 application the same as for males?

Dr. Germino explained that around one third of R01 grants are held by someone that identifies as female. Over the 10-year period (FY 2012 - FY 2022) there was a 51% increase in the number of females compared with a 12% increase in the number of male grantees. For type 1 (*i.e.*, new) grant awards, the success rate is the same or slightly better for females compared with males over the past 10 years. For type 2 grants (*i.e.*, competitive renewals) the overall unique number has decreased for both sexes resulting in greater fluctuation in rates over the years. Overall, females are less successful for type 2 renewal awards, compared with males. One potential contributing factor is that males

have historically been in the pipeline longer and this may also affect competitive renewal rates.

The proportion of NIDDK single-principal investigator (PI) R01 applications and awards data showed that the percentage of female applications received and funded has increased from 28% (FY 2013) to 33% (FY 2022).

Are there data available on how successful early-stage investigator (ESI) recipients have been on their first competitive renewals?

Dr. Germino stated that ESI applicants were given a three-point advantage and that the subsequent R01-equivalent funding, both type 1 and type 2, was good overall with between 42-53% holding at least one award. The success rate for type 2 awards in this group ranged from 16% to 32% with more investigators holding type 1 awards than type 2.

How does NIDDK compare to other NIH Institutes and Centers (ICs) with regard to the increase in its number of R01 investigators?

Dr. Germino described PI counts and R01 awards for other ICs. In general, both have increased for all institutes, with NIA having a steeper curve due to increased congressional appropriations the past several years. The number of PIs has increased for NIDDK somewhat faster than the number of awards, a likely reflection of the fact that many awards are now multi-PI awards.

Are there data on how many investigators have an R01 as the sole PI and are also a co-PI on a multi-PI grant? Further, if someone is listed on a multi-PI application, are they less likely to be included in other applications?

Dr. Germino displayed data from FY 2012-2022 that showed that there were 1,922 single-PI only, 870 multi-PI only, and 1,797 individuals that had both single- and multi-PI awards.

What is known about the diversity of the training pool? Is NIDDK losing people from underrepresented groups compared with 10 years ago?

Dr. Germino provided data from the F30 program (M.D./Ph.D. Fellows). For this analysis, only White and Asian trainees were identified individually. All other groups were collapsed into one group, for privacy, as there were less than 11% of individuals forming that group. From FY 2012 to FY 2022, there was a 33% drop in White trainees attributed to changes in NIH policy. There was also a 17% increase in Asian trainees, and the overall level of other groups remained stable. Data for the F31 program (predoctoral Fellows) showed that the other groups and Asians increased for this program, but the rate of increase was greater for White trainees. Data for the F32 program (postdoctoral Fellows) showed an overall decrease in the number of awards with a 43% decrease in all other groups (from 19 to 11) and a 29% decrease in White trainees. For the T32 program, there have also been steady decreases in the number of awards, in part due to a switch to an alternative mechanism for the Division of Kidney, Urologic and Hematologic

Diseases, with a 42% decrease in the number of White trainees, 56% decrease in Asian trainees, and 23% decrease in all other groups.

The data was analyzed by sex of trainees. For F31, F32, and T32 awards, there was a larger number of female trainees. The F30 program had a greater number of males.

In terms of R01s from FY 2012 - 2021, there has been a 50% increase in both Asian and Black PIs, a 12% increase in White PIs, and a 72% increase in PIs identifying as more than one race. In conclusion, Dr. Germino stated that while there has been an increase in Black applicants and awardees, the numbers are still small.

Council Questions and Discussion
Dr. Germino, moderator

***Comment from Council**: How are those identifying as Latino classified and are they reflected in this data?*

Dr. Germino said that ethnicity was not analyzed in these data sets. In general, those that identify as Hispanic perform better than Black individuals and worse than White individuals.

III. CONSIDERATION OF SUMMARY MINUTES
Dr. Griffin Rodgers

The Council approved, by electronic poll, the Summary Minutes of the 222nd Council meeting, which had been sent to members in advance for review.

IV. FUTURE COUNCIL DATES
Dr. Griffin Rodgers

As noted previously, Dr. Rodgers told Council that future meetings will be held using a hybrid format to accommodate both virtual and in-person attendance. The next meeting of the NIDDK Advisory Council is scheduled for January 10-11, 2024. Although the plan is to meet January 10, Council was asked to hold both days open to maintain flexibility. Updates about future meetings will be posted on the Council website.

V. ANNOUNCEMENTS
Dr. Karl Malik

Confidentiality

Dr. Karl Malik reminded Council members that material furnished for review purposes and discussion during the closed portion of this meeting is considered confidential. The content of discussions taking place during the closed session may be disclosed only by the staff and only under appropriate circumstances. Any communication from investigators to Council members regarding actions on an application must be referred to the Institute. Any attempts by Council members to handle questions from applicants could create difficult or embarrassing situations for the members, the Institute, and/or the investigators.

Conflict of Interest

Dr. Malik reminded Council members that advisors and consultants serving as members of public advisory committees, such as this Council, may not participate in situations in which any violation of conflict-of-interest laws and regulations may occur. Responsible NIDDK staff shall assist Council members to help ensure that the member does not participate in and is not present during review of applications or projects in which, to the member's knowledge, any of the following has a financial interest: the member, or his or her spouse, minor child, partner (including close professional associates), or an organization with which the member is connected.

To ensure that a member does not participate in the discussion of, nor vote on, an application in which he/she is in conflict, a written certification is required. A statement is provided for the signature of the member, and this statement becomes a part of the meeting file. Prior to today's meeting, Council members were sent a statement regarding conflict of interest in their review of applications. He asked each Council member to read the statement carefully, sign it, and then return the signed hard copy to NIDDK before the end of the day.

Dr. Malik pointed out that when the Council reviews applications in groups without discussion, that is, by "en bloc" action, all Council members may be present and may participate. The vote of an individual member in such instances does not apply to applications for which the member might be in conflict.

Regarding multi-campus institutions of higher education, Dr. Malik stated that an employee may participate in any particular matter affecting one campus of a multi-campus institution of higher education, if the employee's financial interest is solely employment in a position at a separate campus of the same multi-campus institution, and the employee has no multi-campus responsibilities.

VI. REPORT FROM THE NIDDK DIRECTOR

Dr. Griffin Rodgers

Budget Update

Dr. Rodgers updated the Council on the NIH and NIDDK appropriations for Fiscal Year 2024 (FY 2024).

The FY 2024 budget cycle began with the release of the President's Budget Request on March 9, 2023. Since the last Council meeting, both the House and Senate released their FY 2024 Labor-HHS-Ed appropriations bills on July 13 and July 27, respectively.

The President's Budget Request was released on March 9 and included $48.270 billion for the NIH, which was about $811 million over the FY 2023 enacted level. The budget also included a proposed $2.303 billion for NIDDK, maintaining FY 2023 funding levels. On July 13, the House released their FY 2024 Labor-HHS Appropriations bill. The bill proposed $44.622 billion for NIH, which was $2.837 billion less, or about a 6 percent decrease, than the 2023 enacted level. The bill provided the same amount of funding as

FY 2023 for NIDDK. The Senate FY 2024 bill, released on July 27, included $47.724 billion for NIH, which was a $265 million, or 0.6%, increase over 2023. The bill provided NIDDK with $2.311 billion, which was a $10 million, or 0.43%, increase over the previous year.

The House bill decreases the total NIH budget by $2.8 billion, and it flat-funds or reduces funding for many NIH ICs. It includes provisions related to human fetal tissue research, foreign influence, and gain-of-function research. This bill has been approved by the House Appropriations Labor-HHS Subcommittee, but not the full Appropriations Committee.

The Senate bill would increase the total NIH budget by $265 million, with a $10 million increase to NIDDK to support diabetes-related research. It also supports targeted research initiatives on Alzheimer's disease, cancer, mental health, and opioids, among others. The full Appropriations Committee has approved this bill.

There are only a couple of weeks left before the 2024 Fiscal Year starts on October 1 and the Appropriations Committees have not finished their work on the FY 2024 budget. This means a continuing resolution to fund the government beyond October 1 and to avoid a lapse in funding is needed.

Dr. Rodgers gave a brief update on the status of the NIH Director search and nomination. President Biden nominated Dr. Monica M. Bertagnolli to be the next NIH Director. Dr. Bertagnolli currently serves as Director of NIH's National Cancer Institute, joining on October 3, 2022. Until the NIH Director nomination is confirmed by the U.S. Senate, Dr. Larry Tabak, will continue to serve as the Acting Director of NIH. In the meantime, Dr. Bertagnolli will continue to serve as the NCI Director. Earlier in the week, the Senate Health, Education, Labor, and Pensions Committee announced plans to hold a confirmation hearing in October.

Congressional Activities

Next, Dr. Rodgers highlighted a recent Congressional hearing as well as several other meetings that NIDDK participated in with Congressional staff. Dr. Rodger's testified before the Senate Appropriations Committee at a hearing that took place during the JDRF Children's Congress. The JDRF Children's Congress is a special event where Delegates from all 50 states meet with Members of Congress to educate them about type 1 diabetes and about issues important to the type 1 diabetes community. At the hearing, Dr. Rodgers shared ways in which the Special Diabetes Program, as well as other NIDDK-funded research, is accelerating breakthroughs and creating hope for those living with type 1 diabetes.

On May 24, Dr. Chris Koh, NIDDK's Director of the Division of Clinical Research and Dr. Barbara Rehermann, Principal Investigator in Liver Diseases Branch within the NIDDK Intramural Research Program (IRP), participated in a briefing with a Senate HELP Committee staffer to highlight exciting research projects in the NIH IRP. Dr. Rehermann presented her research on a mouse model with the microbiota of wild mice, and Dr. Chris Koh discussed his research on delta hepatitis.

On June 1, Drs. Greg Germino and Pamela Thornton briefed staffers of the Congressional Black Caucus Health Braintrust taskforce, Congressional Hispanic Caucus, Congressional Asian Pacific American Caucus, and Congressional Native American Caucus on NIDDK's Health Disparities and Health Equity Research Working Group Report.

On July 13, Drs. Will Cefalu and Pamela Thornton met with staff from the Congressional Joint Economic Committee to brief them on economic impacts of diabetes, the disproportionate impact that diabetes has on Native American communities, and the broader health equity issues around this chronic disease—a couple weeks after this briefing, the Committee held a hearing on this same topic.

Additional Updates

Lastly, Dr. Rodgers gave an invitation to follow the new NIDDK LinkedIn account. NIDDK posts research updates, funding and career development opportunities, and information about upcoming meetings and workshops.

VII. NATIONAL INSTITUTE ON AGING'S RESEARCH AND ENTREPRENEURIAL DEVELOPMENT IMMERSION (REDI) PROGRAM

Dr. Todd Haim, Director, OSEP, NIA

Dr. Rodgers began by introducing Dr, Todd Haim and the NIA REDI program, which provides bio-entrepreneurship training to boost the number of university startups and facilitate diverse career opportunities for early-career scientists working in the fields of aging and aging-related diseases, including Alzheimer's disease. As NIH looks to expand parts of this program, the NIA REDI program may be of interest to NIDDK.

Dr. Haim reported that the number of postdoctoral fellows transitioning into tenure-track positions has dramatically decreased over the last 50 years to about 20% to 30%. Additionally, the nature of academic positions has changed over the last 20 to 30 years, and they often include collaborations or translational work. NIH is aware of these issues and the NIH Biomedical Research Workforce Working Group made several recommendations to address this. Some of these included aligning training with the current job market, creating programs to supplement training grants to provide additional training opportunities, and encouraging Small Business Innovation Research (SBIR)/ Small Business Technology Transfer (STTR) awardees to provide internships to trainees.

Several programs at the NIH and elsewhere were created to address some of the concerns. The NIA used these programs as a basis for the REDI program. Under the REDI umbrella, there are a variety of award types including K01, SBIR, STTR, and R25 awards.

The REDI K01 award provides protected time (3-5 years) for a supervised career development experience leading to research independence. This differs from a traditional K01 in the career development plan, focusing more on business and entrepreneurship mentorship, in additional to traditional research mentoring. The candidates integrate research and career development activities to align with their career goals, typically related to technology development and commercialization.

The REDI SBIR/STTR is a 2-to-5-year award program designed for postdoctoral fellows or PIs that may be new to the SBIR/STTR space and are looking to transition to industry or small business. There is also a strong mentoring component to this award to ensure that awardees are learning necessary business and entrepreneurship skills throughout the award.

The REDI R25 funds institutions, not individuals, to promote the development of entrepreneurial education programs to broaden the skillset of graduate students and postdoctoral fellows in fields relevant to the mission of NIA. The funding opportunity supports creative educational activities with a primary focus on research experiences, courses for skills development, mentoring activities, and curriculum or methods development. The award period can be up to 5 years and all applications must include diversity recruitment plans.

The next steps for the REDI program are to consider gaps in the existing REDI umbrella for expansion, explore expanding the REDI concept to other ICs, and additional coordination and potential workshops to bring the REDI community together.

Only 2% of venture capital funding is awarded to women founders and 1.4% went to Black founders in 2022. There is also an existing program to increase the diversity, equity, and inclusion (DEI) in NIH SBIR through the NIH Applicant Assistance Program. This is a 10-week program offering NIH SBIR Phase I application demystification through workshops and a one-on-one coach that aims to increase the number of applications submitted by underrepresented small businesses that are compliant and responsive to the review criteria. These tied into our desire to design and launch the Start-Up Challenge and Accelerator program.

The NIA Start-Up Challenge and Accelerator program was designed in parallel with REDI to develop first-time entrepreneurs with a promising innovation concept and to address the challenges of diverse innovators and those addressing health disparities. This is a prize competition to provide strategic resources to entrepreneurs with an innovative idea for research driven technology or a product that will address aging research and innovation. Data from 2022 showed initial success of the program and that the majority of mentors are maintaining relationships with the mentee; participants reported a unique value of the programming with a focus on aging, health care innovation, and DEI; and 92% reported scheduling meetings with potential investors and partners through the program.

Council Questions and Discussion
Dr. Rodgers, moderator

Comment from Council*: It is relatively straightforward to track the success of people who remain in academia by looking at K01 awards and subsequent R01 awards. How will these companies be followed, particularly those that are funded in the private sector and how will you follow the career development of people who are no longer funded by NIH?*

Dr. Haim agreed that this is difficult. However, there are a few mechanisms for tracking. One example is tracking the intellectual property that is publicly available. We also have the ability to track participants via social media and other online information. All of these programs also use surveys and focus groups to track participants.

Comment from Council*: Given that we spend almost all of our time with trainees with academic goals in mind, it is a little shocking how few trainees end up in academia. These programs are incredibly valuable. Will the NIDDK set up a similar program?*

Dr. Rodgers explained that this talk was to bring information to the Council and the potential for setting up a similar program at NIDDK could be discussed in subcommittee meetings. This is a great opportunity, and I have a Senior Advisor on Innovation in my office to also look at some of these issues. NIDDK would also like to be more proactive in looking into some of these topics.

Dr. Haim encouraged participants to share the Start-Up Challenge announcement for the next funding cycle when it is announced. Projects should have a focus on the health of older adults but are open to NIDDK researchers.

Comment from Council*: How is the K01 operationalized? Traditional K01 programs require commitment by the institution to provide the individual with a faculty-level position, or the equivalent, for the duration of the award. The REDI K01 seems to have some uncertainty about where the applicant will be using the funds, and how is this handled to allow the decision making to occur during the K01 period?*

Dr. Haim explained that this was considered during the creation of the program. In looking at current awardees, the participants have research positions that also allow them to explore other areas. The entrepreneurial aspect fits into the overall training.

Comment from Council*: Do the applicants need to have a well-formed plan to move out of academia if have they decided to pursue other careers? Or do applicants tend to want to stay in academia?*

Dr. Haim responded that there is a mix of both, but that many individuals in the K01 program indicate that they would like to pursue academic positions, but ones that allow for collaboration and partnership.

Comment from Council*: Some of the awardees have formed their own companies. What is the role of industry across all of the programs described?*

Dr. Haim said that the majority of mentors come from industry and have reported that the program has been valuable to them as industry partners. Overall, the hope is to take advantage of public-private partnerships.

Comment from Council*: In terms of the K01 awards, are there opportunities for individuals that want to work in industry and not academia?*

Dr. Haim said that there is a mixture of applicants. The SBIR award is a better choice for individuals that are certain that they want to work in industry. The K01 award may be better for those that are uncertain about the path they want to take.

Comment from Council: *How was the diversity among awardees achieved and the types of outreach employed?*

Dr. Haim cautioned that it takes a lot of time and resources to meet those goals. A key factor was identifying and forming partnerships with minority business organizations, both trade and non-profit groups. The outreach efforts centered on bringing underrepresented individuals into industry and entrepreneurship.

Comment from Council*: If an individual wants to move from academia to industry, how can the individual take their product with them?*

Dr. Haim responded that the individual collaborates with the technology transfer office at their institution to license the technology. Institutions understand that if a technology is licensed to the investigator, the chances of success are much greater, and are typically willing to help with this process.

Comment from Council*: Regarding the Application Assistance Program, is that available in other ICs or just NIA? Clinical fellows often struggle with applying for grants and other processes.*

Dr. Haim answered that a few other institutes participate in the program. The NIH has made it a priority to simplify and streamline these application processes in the future, and hopefully less application assistance will be required.

Comment from Council*: Has there been an increase in quality with these applications?*

Dr. Haim mentioned that the first round of applicants were very competitive, much more so than expected, particularly for the applicants that went through the Application Assistance Program.

VIII. UPDATE FROM THE DIRECTOR, NATIONAL INSTITUTE OF NURSING RESEARCH

Dr. Shannon Zenk, Director, National Institute of Nursing Research

Dr. Rodgers welcomed Dr. Shannon Zenk, the Director of the National Institute of Nursing Research (NINR). Dr. Zenk's research focuses on inequity and health with the goal of identifying effective multi-level approaches to improve health and eliminate racial, ethnic, and socioeconomic health disparities.

In May 2022, the NINR released a new strategic plan that shared a new vision for the future of nursing research and includes a mission focused on advancing health equity. The 2023 report from the NIDDK's Health Disparities and Health Equity Working Group "Pathways to Health for All" outlined priorities and made recommendations similar to the

NINR's strategic plan. Dr. Zenk underscores two priorities from the NIDDK report that are well-aligned with the NINR strategic plan:

- To advance research on the mechanisms by which biological, behavioral, environmental, and structural factors interact to affect health, disease, and resilience.
- To advance research on interventions and studies on racism, health-related social needs, and social determinants of health (SDOH).

NINR is working towards the goals in their strategic plan by funding innovative research to help address today's most pressing challenges and by engaging in partnerships across the NIH. The hope is that by sharing the NINR approach to research and the types of research funded, opportunities for collaboration can be identified to work together to advance the missions of both NINR and NIDDK.

Dr. Zenk explained that the NINR mission is leading nursing science to solve pressing health challenges and inform practice and policy – optimizing health and advancing health equity into the future. The strategic plan outlines 5 research lenses: health equity, SDOH, population and community health, systems and models of care, and prevention and health promotion. These lenses were identified because NINR believes that they will allow them to innovate, think bigger, and greatly increase the impact on the field. In addition to leveraging the strengths of nursing research, the lenses promote multi-level approaches, cross-disciplinary and cross-sectoral collaboration, and community engagement in research.

The SDOH lens is a priority for NINR and is essential to solving intractable health challenges and the most persistent health disparities. SDOH helps researchers to explore 'why' questions to help break through key issues. For example, why can some people modify risk factors whereas others struggle? To answer complex questions like this, the bigger picture needs to be examined.

Nurses excel at looking at the bigger picture because they are located in a variety of settings including workplaces, schools, and long-term care facilities where nurses participate in prevention, treatment, care, and decision making. Nurses excel in the bigger picture because of a holistic approach to care. Nurses have a breadth of knowledge that spans the life force, crosses diseases and conditions, and extends from improving the health of individuals to that of entire populations.

Inequities related to diabetes were given as an example of SDOH research. Research into structural racism through historic residential redlining and diabetes mortality suggests that these practices caused a 50% increase in diabetes-related mortality. NIDDK has also studied how racism is a root cause of disparities in diabetes. These studies provide a solid foundation for SDOH research to address why these factors influence health and seek to identify solutions that take these factors into account.

NINR's SDOH portfolio supports aspects of this model, specifically research that considers individual factors and social needs. This provides a foundation to move further upstream from current research focus. Specific examples include:

- Remote Patient Monitoring of Chronic Disease in Community Health Centers

- Medication Adherence and Cardio-Metabolic Control Indicators among Adult American Indians Receiving Tribal Health Services
- Home Food Delivery for Diabetes Management in Patients of Rural Clinics
- Rural Libraries Promoting Walking and Walkability in Their Rural Communities
- Relationship between Food Insecurity and a Gestational Diabetes Risk Reduction Intervention: Outcomes among American Indian and Alaska Native Adolescent and Young Adult Females

Dr. Zenk described three factors that move research on SDOH upstream:

- Developing a shared understanding and common language for SDOH research.
- Encouraging collaboration that reaches across sectors and leverages the boots on the ground tenants of community engagement.
- Exploring new and expanded methodologies.

In 2022, a new NIH-wide SDOH Research Coordinating Committee to accelerate SDOH research across the NIH was formed. This includes research across diseases and conditions, populations, stages of the life course, and domains of SDOH. It also focuses on effectively leveraging SDOH advancements and innovation across all NIH institutes, centers, and offices to advance discovery across this multi-disciplinary field. The Committee released a new conceptualization of SDOH, described in a blog post on the NINR website: https://www.ninr.nih.gov/newsandinformation/newsandnotes/sdoh-rcc-001. The NIH conceptualization underscores that SDOH are the conditions in which people are born, grow, learn, work, play, live, and age and the broader set of structural factors shaping the conditions of daily life. This emphasizes that addressing SDOH is critical to population, community, and individual health and to reduce health disparities and advance health equity. Structural factors include social, economic, and legal forces, systems, and policies that determine opportunities and access to high-quality jobs, education, housing, transportation, information and communication infrastructure, food and health care; the social environment; and other conditions of daily life. SDOH can improve, maintain, or hinder health through multiple direct, indirect, and interacting mechanistic pathways.

Dr. Zenk also described the NIH Common Fund Community Partnerships to Advance Science for Society (ComPASS). This program is innovative in that it directly funds community organizations to lead the research and encourages organizations to partner with researchers and different sectors to design and carry out structural interventions to improve health and reduce health disparities. The ComPASS program is paving the way to give opportunity to community-based organizations to design unique programs that are tailored to pinpoint the social and economic factors affecting the communities that they serve. The goals of ComPASS are to:

- Develop and evaluate community-led health equity structural interventions that leverage partnerships across sectors.
- Develop a new health equity research model for community-led, multisectoral structural intervention research.

The core of this program will be 25 Community-Led Health Equity Structural Intervention (CHESI) sites across the country. Those community-led interventions will

be supported by a Coordination Center. The third initiative has a funding opportunity for ComPASS Health Equity Research Hubs due on October 31, 2023 (RFA-RM-23-012). The Hubs will serve as centralized research resources, providing tailored scientific, technical, and collaborative support for community engagement, research capacity building, and training to support community-led health equity structural intervention projects in collaboration with the ComPASS Coordination Center.

Another NIH-wide program on SDOH is the Transformative Health Disparities Program. This initiative aims to help to reduce, prevent, and eliminate health disparities. The initiative encouraged a focus on SDOH, and a number of awards have been funded. This grew out of the UNITE initiative, which aims to end structural racism and end disparities perpetuated by SDOH and the biomedical research enterprise.

The NINR is also working to address SDOH throughout the HHS by serving on the SDOH Working Group. HHS has a three-pronged strategy to address SDOH: enhance data infrastructure, improve connections between health and social service providers, and engage in whole government collaborations to implement comprehensive solutions.

In an effort to explore new and expanded methodology, the NINR issued a Notice of Intent to Publish a Funding Opportunity Announcement in August 2023 (NOT-NR-23-015) to solicit applications for establishing short courses for nursing research on SDOH. This program will support the creation and implementation of short courses of up to one year to develop a cohort of nurse scientists and scientists in aligned fields equipped to understand, conduct, and evaluate research on SDOH.

Next, Dr. Zenk provided some examples of how NINR is applying the SDOH lens to their scientific priorities. In 2020, firearm injury prevention was the first strategic imperative under the strategic plan. Firearm injury prevention was chosen because nursing research offers an important perspective, given that prevention work and related health consequences must be situated in the settings where nurses practice. This is a pressing challenge for the U.S. as firearm deaths rose by 35% in 2020, reaching the highest level ever recorded in the U.S. Firearm injuries and death are also concerning from a health equity perspective. In 2020, counties with the highest poverty rate had firearm homicide rates 4.5 times higher compared with counties with the lowest poverty rate. More than half of all Black teens (aged 15-19) who died in 2020 were killed by firearms. To quickly address the complex nature of this challenge, NINR released a NOSI, a Notice of Special Interest, in March 2023 for administrative supplements to their T32 grants to increase capacity for research in this area. An administrative supplement allows for a relatively quick, nimble response in getting resources in the hands of researchers. Another funding opportunity for short courses in firearm injury prevention for nurse scientists and those in aligned fields will be announced soon, with funding awarded next year (NOT-NR-23-016). There is also a critical gap for research in community settings. A funding opportunity for firearm injury prevention research in community health care settings was recently posted (RFA-NR-41-001). Under this initiative, NINR is interested in creative approaches to firearm injury prevention that capitalize on community health care settings to identify risk factors; reduce exposure risk in individuals, families, and communities; and prevent injury and reoccurrence, and mitigate disparities.

Maternal health is another research priority for NINR. NINR has an initiative for advancing integrative models of care that focuses on identifying solutions. This initiative supports intervention research to develop, implement, and evaluate integrated models of supportive care that address structural inequities to prevent adverse maternal health outcomes and disparities. A number of studies have been funded under this initiative including studies like the impact of integrating community-based navigation and maternal care for Black women; the effects of Medicaid policy interventions on racial equity, and severe maternal morbidity; and the benefits of using a community care and strengths-based technology intervention to improve maternal wellness and reduce disparities. Building on the interest in maternal health, NINR is co-chairing IMPROVE, which is aimed at addressing high rates of maternal morbidity and mortality in the U.S. IMPROVE supports research to reduce preventable causes of maternal deaths and improve maternal health before, during, and after delivery. It includes a special emphasis on health disparities and populations disproportionately affected.

NIH has awarded $24 million in first-year funding to establish Maternal Health Research Centers of Excellence. These centers are working towards reducing maternal morbidity and mortality and promoting health equity. The centers include 10 research centers, a data innovation and coordinating hub, and an implementation science hub. An example of how structural and social factors are integrated into the funded centers of excellence, a central focus of the center funded in Wisconsin is housing instability and its effects on maternal physical and mental health, as well as pregnancy outcomes.

Dr. Zenk also highlighted an NINR initiative that focuses on food and housing as SDOH. There was a funding opportunity inviting researchers to examine the impact of COVID-19-related food and housing policies and programs on health and health disparities. One study funded through this RFA is examining whether COVID-19-related increases in SNAP benefits reduce mental illness and increased use of mental health services by improving food security.

There is also a NIH-wide initiative on Climate Change and Health. This urgent cross-cutting effort includes research on how SDOH are affected by climate change and best practices to navigate these challenges. NINR created a subcommittee consisting of 10 members with expertise in climate change and health research to better understand how nursing research can contribute to this area of science. There will also be a Request for Information for public comment on ways that NINR and nursing research can make a difference and provide a unique perspective and approach to this area of science. An example of research funded in this area is a study to explore the relationship of glucose metabolism and heat exposure on the development of acute kidney failure and renal function in farm workers. With studies that look at molecular factors, NINR hopes to identify risks that could inform workplace policies and provide a foundation for future structural work.

Dr. Zenk also noted opportunities for collaboration between NINR and NIDDK. The NINR signed onto NIDDK's funding announcement calling for interventions that address structural racism to reduce kidney health disparities, with the aim of supporting a consortium to foster community-engaged intervention research. The NINR is also co-founding a resulting cooperative agreement with Emory Healthcare that seeks to develop, implement, evaluate, and disseminate multi-component, multi-level interventions that

mitigate the impact of structural racism on health care delivery for African American patients with chronic kidney disease.

Food and nutrition insecurity is another potential area for shared interest and collaboration. Dr. Zenk co-authored an article in 2022 (Zenk SN, et al. JAMA. 2022;327(20):1953-1954) that outlined several research priorities related to food insecurity. Some of these ideas were incorporated into a NOSI: stimulating research to understand and address hunger, food, and nutrition insecurity. Both NINR and NIDDK signed onto this NOSI along with 9 other institutes and centers. This aims to encourage research on the efficacy of interventions that address nutrition security and the mechanisms of food insecurity on a variety of health outcomes, including diabetes.

Dr. Zenk shared another potential collaboration between NINR and NIDDK. The Bridge-to-Care Initiative recognizes that patient health should be viewed in the context of an individual's social circumstances. The funding opportunity sought intervention research studies to address unmet social needs of individuals and families, and to address community social conditions through health care community partnerships.

Dr. Zenk acknowledged two NINR program directors participating in planning committees for two upcoming NIDDK workshops, Biological Mechanisms Underlying the Health Consequences of Racism, Marginalization, and Discrimination; and the NIDDK Dissemination and Implementation Health Equity Workshop. In conclusion, NINR has begun funding initiatives to encourage risk-taking and innovation to address complex questions. These initiatives pose opportunities for future collaboration with NIDDK based on shared interests, including SDOH.

Council Questions and Discussion
Dr. Rodgers, moderator

Comment from Council*: It is nice to see the systematic approach to moving research upstream. There was also a mention of community capacity building with the R25 funding. Could you say more on how community partners could be built into the R25?*

Dr. Zenk responded that there is a need for researchers in the area of SDOH to complement programs that already exist as well as for individuals interested in solely focusing on that area. The ComPASS program will focus on capacity building among both academic researchers and community partners. The IMPROVE initiative also has initiatives focusing on community. One of the initiatives is placing a high emphasis on building capacity for communities to address the questions that are important to them. There is also a growing recognition of the importance of capacity building among all partners across the NIH. It is also important to build capacity, particularly among the next generation of researchers.

Comment from Council*: Community partners often want solutions to advance more quickly than is traditional in academic science. Have you thought about that in terms of research timelines and opportunities to keep partners interested and engaged?*

Dr. Zenk agreed that there are some programs that aim for quick responses and results. ComPASS takes a measured 10-year approach focused on relationship building,

planning, active research, and sustainability. The two-year partnering phase acknowledges that communities need time to develop research partnerships. The five-year active research phase allows for rigorous, in-depth work. Finally, the two-year dissemination phase plans for translating evidence into policy and sustainable programming.

There is a tension between responding quickly to community needs and taking the time to build meaningful relationships, gather quality evidence, and plan for lasting impact. By designing a diversity of approaches, we can balance urgency and thoughtful engagement.

Comment from Council*: Firearm injury prevention is a complicated problem. What are some of the proposed interventions that might make a difference in the health care setting?*

Dr. Zenk responded that firearm injury research has been historically underfunded despite the scope of the public health crisis. However, initiatives by the Office of Behavioral and Social Sciences Research and other groups at NIH have begun addressing this research gap. When examining the landscape, community-based settings like health centers emerge as having enormous potential for impact.

As an example, NINR hosted a workshop focusing on this topic highlighted screening for firearm injury risk in health centers as an area needing both discovery and implementation science. Effective screening methods are needed, as well as research on integrating those tools into routine care.

Comment from Council*: There is a disconnect between the evidence on SDOH interventions and translating this research into policy and implementation, which remains a challenge. Could NINR investigate why evidence does not translate into policy change and the possible psychological or societal research on these barriers. How do we move from facts, devoid of politics and preconceived prejudice, and then take action that within the scope of NINR?*

Dr. Zenk said that this is within the scope of NINR, particularly around dissemination and implementation science. Just funding amazing discoveries, and not being able to translate them into practice and policy, does not do a lot of good. The momentum around implementation science across NIH is exciting, and more attention should be brought to this topic. Implementation science is a legitimate area of science that can be a way to improve overall health.

Comment from Council*: Clinicians are crucial in pushing research into practice. Organizations like American Diabetes Association and JDRF can help move research into clinical practice changes. There is a need for partnerships between researchers, clinicians, and organizations to translate findings into real-world impact. There is also concern about potential decreased telehealth reimbursement that would limit its use despite evidence of benefits. There is a need for greater emphasis regarding researcher-clinician-organization partnerships and applying research in areas like diabetes regulation and gun violence.*

Dr. Zenk commented that dissemination and implementation science can only achieve a certain level of success. There is also a need for partnerships with communities, with professional organizations, and with clinicians to move evidence-based research forward.

Comment from Council*: A leading cause of death in children is firearm injury. The political determinants of health, particularly with regards to firearm injury, has not been mentioned. Is there a path forward so that intergovernmental agencies can work together and take advice from health care professionals?*

Dr. Zenk stated that firearms are an area of collaboration across agencies, including the Centers for Disease Control and Prevention (CDC). Political determinants are part of the structural determinants of health. The research enterprise can generate evidence and suggest ways it can be implemented into practice and policy, but the decision-making process is in the hands of policymakers.

Comment from Council*: There is a NIH Centers for Medicare and Medicaid Services (CMS) consultation service that allows clinicians to work with CMS colleagues at the design phase to ensure that an NIH-funded clinical study has the appropriate end points for CMS. This is also a formal pathway for sharing scientific data with CMS to inform the decision-making process.*

Dr. Rodgers commented that there is a need to get Medicare and CMS involved, because those decisions often trickle down to private insurers and others. This is an area of fruitful collaboration.

Comment from Council*: Junior faculty get discouraged because academic promotion standards do not align with the timelines/work needed for community-engaged research. Additionally, the funding mechanisms and review process do not match this type of work. In order to keep developing the pipeline, there is a need to encourage the next generation, particularly those from disadvantaged backgrounds. Is there a way for NIH to help facilitate translation of research impact?*

Dr. Zenk mentioned that one option is to have funding opportunities that encourage this type of research. NINR, NIDDK, and other organizations have called for community-engaged research. There are mechanisms to fund scientists who are committed to partnering and developing mutually beneficial relationships in terms of moving research forward. There is evidence that NIH recognizes the importance through initiatives like ComPASS, which the agency has not invested in before. Hopefully there will be more of these opportunities for community-engaged research efforts in the future.

Comment from Council*: The European Union has different health systems than the U.S., but is there something that can be learned from other countries to decrease disparities? For example, France has been successfully treating opioid addiction through centralized medicine and clinics located in areas of need.*

Dr. Zenk agreed that learning from others to inform our science and approaches is important. One option is to hold workshops that can highlight successful work elsewhere to inform conversations in the U.S. Another option is to collaborate with successful investigators in teams supported by NIH funds.

IX. OPEN SESSION OF SUBCOMMITTEE MEETINGS

See Minutes posted on NIDDK Council Minutes Website.

X. 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.

XI. 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 O-F REVIEW OF GRANT APPLICATIONS

A total of 979 grant applications (276 primary and 703 dual), requesting support of $392,634,937.00 were reviewed for consideration at the September 13, 2023, meeting. An additional 45 Common Fund applications requesting $48,027,288.00 were presented to Council. Funding for these applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, 1,216 applications requesting $471,206,936.00 received second-level review through expedited concurrence. All 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 September 13, 2023, meeting.

XII. ADJOURNMENT

Dr. Rodgers expressed appreciation on behalf of the NIDDK to the Council members, presenters, and other participants. He thanked the Council members for their valuable input. There being no other business, the 223rd meeting of the NIDDK Advisory Council was adjourned at 4:30 p.m. on September 13, 2023.

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

November 27, 2023
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