226th 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 45, Natcher Conference Center and virtually using web-based collaboration/meeting tools.

I. CALL TO ORDER and ANNOUNCEMENTS

Dr. Griffin Rodgers

Dr. Griffin Rodgers, Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), called to order the 226th meeting of the NIDDK Advisory Council at 8:30 a.m on September 11, 2024, via a hybrid meeting (in-person and Zoom video conference). The meeting was conducted using a two-tiered webinar format. The panelist tier included NIDDK Advisory Council members and NIDDK staff members who presented during the meeting. The audience tier was available via a live stream to the public and allowed them to view and listen to the meeting.

ATTENDANCE – COUNCIL MEMBERS PRESENT

Dr. John Carethers
Dr. Jacquelyn Maher
Dr. Keith Norris
Dr. Phillip Scherer
Dr. Elizabeth Seaquist

Subject Matter Experts:

Dr. Jamy Ard
Ms. Patricia Birsic
Dr. Richard Blumberg
Dr. Arthur Burnett
Dr. Lilia Cervantes
Dr. Carmella Evans-Molina
Dr. Velia Fowler
Mr. Alfred Grasso
Dr. Aylin Rodan
Dr. Hunter Wessels

Ex-officio Members:

Dr. David D'Alessio
Dr. Cindy Davis
Dr. Ian Stewart

Also Present:

Dr. Griffin Rodgers, Director, NIDDK and Chair of the NIDDK Advisory Council

Dr. Karl Malik, Executive Secretary, NIDDK Advisory Council
Dr. Gregory Germino, Deputy Director, NIDDK
Dr. William Cefalu, Director, Division of Diabetes, Endocrinology and Metabolic Diseases, NIDDK
Dr. Stephen James, Director, Division of Digestive Diseases and Nutrition, NIDDK
Dr. Robert Star, Director, Division of Kidney, Urologic, and Hematologic Diseases, NIDDK

National Institute of Health (NIH) and NIDDK Panelists and Speakers:
Dr. Michael Chiang
Dr. Maren Laughlin
Dr. Tara Schwetz
Dr. Susan Yanovski

Dr. Rodgers noted that NIDDK plans to hold hybrid Council meetings, which accommodate virtual and in-person participation, for the near future. The Council website will have further details. Dr. Rodgers encouraged participants to attend in-person to facilitate rich discussions and interactions.

Recognition of Ad-Hoc Members and Subject Matter Experts

Dr. Rodgers welcomed eight ad-hoc members attending the meeting and thanked them for their time and participation in the Council process.

- **Dr. Jamy Ard** is a Professor of Epidemiology and Prevention at Wake Forest University. Dr. Ard will participate on the Division of Digestive Diseases and Nutrition Subcommittee.
- **Ms. Patricia Birsic** is a co-founder and on the Board of the National Pancreas Foundation. Ms. Birsic will participate on the Division of Digestive Diseases and Nutrition Subcommittee.
- **Dr. Richard Blumberg** is a Professor of Medicine at Harvard Medical School, 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. Arthur Burnett** is a Professor of Urology at Johns Hopkins University School of Medicine and on the Urology Care Foundation Board of Directors. Dr. Burnett will participate on the Division of Kidney, Urology, and Hematologic Diseases Subcommittee.
- **Dr. Lilia Cervantes** is a Professor in the Department of Medicine and the Director of Immigrant Health at the University of Colorado Anschutz Medical Campus. Dr. Cervantes will participate on the Division of Kidney, Urology, and Hematologic Diseases Subcommittee.
- **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. Dr. Evans-Molina will participate on the Division of Diabetes, Endocrinology, and Metabolic Diseases Subcommittee.

- **Dr. Aylin Rodan** is the Dialysis Research Foundation Presidential Endowed Chair, Associate Professor of Internal Medicine, Chief of the Division of Nephrology & Hypertension, and Investigator within the Molecular Medicine Program at the University of Utah School of Medicine. Dr. Rodan will participate on the Division of Kidney, Urology, and Hematologic Diseases Subcommittee.
- **Dr. Hunter Wessels** is a Professor and Nelson Chair of the Department of Urology at the University of Washington School of Medicine. Dr. Wessels will participate on the Division of Kidney, Urology, and Hematologic Diseases Subcommittee.

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

- **Dr. Velia Fowler** is a Professor and Chair, Department of Biological Sciences, University of Delaware. Dr. Fowler will participate on the Division of Kidney, Urology, and Hematologic Diseases Subcommittee.
- **Mr. Alfred Grasso** is the immediate past President and Chief Executive Officer of the MITRE Corporation, where he continues to serve as a Trustee and Consultant. Mr. Fowler will participate on the Division of Kidney, Urology, and Hematologic Diseases Subcommittee.

Council Member News

Dr. Rodgers recognized three Council members that fulfilled their term of service as the Council Member Class of 2024: **Ms. Dawn Edwards, Dr. Keith Norris,** and **Dr. Philipp Scherer**. He thanked them for continuing their service on the Council and presented those in attendance with certificates of appreciation.

In Memoriam

Dr. Rodgers noted a recent loss for the NIDDK research community:

- **David H. Wasserman**, Ph.D. was the Annie Mary Lyle Professor and professor of Molecular Physiology and Biophysics at Vanderbilt University School of Medicine, and a fellow of the American Association for the Advancement of Science. Dr. Wasserman earned bachelor's and master's degrees in kinesiology at UCLA, and a Ph.D. in physiology from the University of Toronto. He received several prestigious awards, including the Henry Pickering Bowditch Award and the Solomon A. Berson Distinguished Lectureship from the American Physiological Society, and a MERIT Award from NIDDK. Dr. Wasserman was a visionary physiologist who studied the regulation and disruption of glucose uptake and utilization in liver, skeletal muscle, fat, and the brain. He led groundbreaking research on the roles of physical exercise, insulin-stimulation and diet in metabolic health and disease. Dr. Wasserman is remembered by countless colleagues and students as a brilliant and generous scientist, friend, and mentor, with a commitment to excellence, high standards for honesty and scientific integrity, and an unquenchable sense of humor. He brought to the basic diabetes research community a deep understanding of the complex approaches used to study diabetes in animal models, and a passion for sharing technology widely to

improve the quality of metabolic research across the world. Dr. Wasserman's vision, high standards and generosity are embodied in an NIDDK-funded consortium that he spearheaded, the Mouse Metabolic Phenotyping Centers, a national resource for the study of the physiological, molecular, and behavioral characteristics of genetic mouse models of diabetes and obesity. Under his guidance, the MMPC at Vanderbilt has helped hundreds of investigators across the country by conducting high-quality experiments for them on living mice, and hundreds more by inviting them to Vanderbilt to learn how to do complex metabolic studies. He was instrumental in making the mouse into a physiologic as well as a genetic model, thereby improving its utility for sophisticated integrated diabetes and metabolic research.

Awards

Dr. Rodgers announced an award earned by a former NIDDK Council member:

- **Joseph V. Bonventre**, M.D., Ph.D., a longstanding NIDDK awardee and former NIDDK Council member, will receive the Homer Smith Award this fall. This award is presented annually to an individual who has made outstanding contributions that fundamentally affect the science of nephrology, broadly defined, but not limited to, the pathobiology, cellular and molecular mechanisms and genetic influences on the functions and diseases of the kidney. Established in 1964, this award recognizes one of the major intellectual forces in renal physiology.

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

- **Dr. Adriaan Bax**, Section Chief of Biophysical Nuclear Magnetic Resonance Spectroscopy in the Laboratory of Chemical Physics, was elected as a fellow to the Royal Society. He is recognized for developing numerous nuclear magnetic resonance methods to study molecular structure and motion, as well as his pioneering role in adapting these methods to investigate macromolecule structures and interactions.
- **Dr. Rebecca J. Brown**, Section Chief of Translational Diabetes and Metabolic Syndromes in the Diabetes, Endocrinology, and Obesity Branch, has been granted tenure. Dr. Brown studies human energy metabolism via rare diseases, such as lipodystrophy, and clinical therapeutics to address metabolic disturbances. By understanding the biology of rare conditions, she gains insight into pathophysiology and treatments for common metabolic diseases, including type 2 diabetes.
- **Dr. G. Marius Clore**, Section Chief of Molecular and Structural Biophysics in the Laboratory of Chemical Physics, was elected as a fellow of the U.K. Academy of Medical Sciences. He is recognized for his technical contributions to the foundations of modern biomolecular nuclear magnetic resonance, his creation of the standard method of annealing for nuclear magnetic resonance structure determination, and his discovery of transient rare states of proteins that play a key role in function and pathology.

- **Dr. Daniel Chauss**, Staff Scientist in the Immunoregulation Section of the Kidney Diseases Branch, was honored with a 2024 Distinguished Alumni Award from Florida Atlantic University's Schmidt College of Medicine. He is recognized for his pioneering work in immunoregulation that has pushed the boundaries of medical science.
- **Dr. Douglas Forrest**, Section Chief of the Nuclear Receptor Biology Section in the Laboratory of Endocrinology & Receptor Biology, and **Dr. Lily Ng**, staff scientist in NIDDK's Laboratory of Endocrinology & Receptor Biology, won the Endocrine Society's 2024 Endocrine Images Art Competition grand prize for their image of an astrocyte cell expressing type 2 (DIO2) deiodinase, an enzyme necessary for brain development that regulates the availability of thyroid hormone for neurons.
- **Dr. Meryl Waldman**, senior research physician in the Kidney Diseases Branch and Director of the Nephrology Consult and Dialysis Service, has been selected by the NIH Clinical Center as one of four 2024 Staff Clinicians of the Year. This award recognizes outstanding clinical excellence and compassion in the care of Clinical Center patients.

NIDDK Staffing News

Dr. Rodgers announced new extramural staff:

- **Dr. Stefania Senger** joined the Division of Digestive Diseases and Nutrition (DDN) as a Program Officer and will manage a portfolio focused on basic epithelial biology and translational studies related to immune and inflammatory alimentary diseases. Dr. Senger received her Ph.D. in genetics from the University Federico II in Italy and then came to NIH as a visiting research fellow where she studied the molecular mechanisms underlying maintenance and differentiation of the germline stem cells. Dr. Senger then went on to appointments at Massachusetts General Hospital/Brigham and Women's Hospital/Harvard Medical School, where she set-up a biorepository of organoids derived from patient intestinal biopsies to study how the intestinal microenvironment shapes epithelial responses and contributes to the pathology of intestinal diseases including celiac disease, necrotizing enterocolitis, and enteropathogen infection. Prior to joining NIDDK, Dr. Senger worked at the Center for Scientific Review, where she oversaw reviews associated with the cellular, molecular, and immune biology aspects of lung biology.
- **Dr. Kayla Hurd** joined the Division of Kidney, Urology and Hematologic Diseases (KUH) as a program analyst. Dr. Hurd received her Ph.D. from the Department of Anthropology at the University of Notre Dame in 2023.
- **Dr. Corinne Silva** was named the new Deputy Director of the Division of Diabetes, Endocrinology, & Metabolic Diseases based on her scientific expertise and contributions to the success of the mission of the Division and NIDDK. As Deputy Director, Dr. Silva will provide guidance and be responsible for facilitating research activities by working closely with the Division's scientific working groups and each of the program officers. Since joining NIDDK in 2009, Dr. Silva has managed portfolios on the role of signaling and nutrient sensing in metabolic disease, basic studies addressing the role of the intrauterine

environment in offspring metabolic disease, and the integration of circadian rhythms with metabolic disease. Dr. Silva also serves as the program official for NIDDK's Diabetes Research Centers Program.

- **Dr. Pamela Thornton** was asked to serve as the Acting Director of the Office of Minority Health Research Coordination following the departure of Dr. Rob Rivers for another position at NIH. In this role she will continue to address the burden of diseases and disorders that disproportionately impact the health of minority populations. Dr. Thornton is currently Senior Advisor for Workforce Diversity and Health Equity Research. She joined NIDDK as a Program Director in DEM in 2016.

Dr. Rodgers announced some retiring NIDDK staff members and thanked them for their years of service to NIDDK:

- **Dr. Maria Davila-Bloom,** who serves as a Scientific Review Officer (SRO) in the NIDDK Scientific Review Branch, will retire in December after 33 years to the Federal Government and NIDDK. Dr. Davila-Bloom received her degree in Nutritional Biochemistry from Columbia University followed by post-doctoral training in Physiology at Cornell University College of Veterinary Medicine in Ithaca, NY. Prior to joining NIDDK, she served as a nutrition reviewer at the Food and Drug Administration at the Center for Food Safety and Applied Nutrition from 1991 to 2001. Maria was recruited to the NIDDK in 2001. She has done outstanding work recruiting and managing panels developed to review grant and cooperative agreement applications. A large portion of these panels were focused on the science associated with DDN. For many years, she was also responsible for overseeing the very complex reviews of the Digestive Disease Research Centers. In addition, she was the SRO responsible for the DDK-C Standing Study Section that reviewed mentored career development (K) applications in DDN's mission from 2017 to 2022.
- **Dr. Jeffrey Kopp**, chief of the Kidney Disease Section in our Kidney Diseases Branch since 2013, retired after decades of service to NIDDK. Dr. Kopp joined NIH as a medical staff fellow in 1987 and came to NIDDK in 1995 as a Senior Investigator. He led important studies on focal segmental glomerulosclerosis and his research led to the discovery that chromosome 22 harbors a major risk locus for kidney disease in African Americans. Dr. Kopp has also been a dedicated clinician and educator, serving as a nephrologist at the NIH Clinical Center and as a professor at the Uniformed Services University of the Health Sciences. As a U.S. Public Health Service Officer, he deployed to three hurricanes – Katrina 2005, Wilma 2005, and Ike 2008 – providing care to special needs patients in emergency shelters. He continues to serve at NIDDK as a Special Volunteer in the Kidney Diseases Branch.

NIDDK 75th Anniversary

Dr. Rodgers shared that NIDDK's 75th anniversary celebration begins in 2025. It will be an opportunity to engage the NIDDK community and to highlight how NIDDK has and will continue to work together with these partners to advance research and health for all. The anniversary banner and page are now live on the NIDDK website. Information about anniversary-related activities will be posted to this webpage as they finalize. More than a

dozen presentations, symposia, and panel discussions will occur at meetings throughout 2025. Additionally, NIDDK and members of the research community are authoring research perspectives and retrospective articles that will be published in a variety of journals. The articles will highlight how one discovery or approach can develop into future advances, as well as NIDDK's goals to enhance research to be more collaborative and inclusive.

II. CONSIDERATION OF SUMMARY MINUTES

Dr. Griffin Rodgers

The Council approved, by electronic poll, the Summary Minutes of the 225th Council meeting, which had been sent to members in advance for review.

III. FUTURE COUNCIL DATES

Dr. Griffin Rodgers

As noted previously, Dr. Rodgers told Council that future meetings will be held using a hybrid format to accommodate both virtual and in-person attendance. The next meeting of the NIDDK Advisory Council is scheduled for January 29-30, 2025. Although the plan is to meet January 29, the Council was asked to hold both days open to maintain flexibility. Updates about future meetings will be posted on the Council website.

IV. ANNOUNCEMEMNTS

Dr. Karl Malik

Confidentiality

Dr. Malik said that Council members are reminded 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

Advisors and consultants serving as members of public advisory committees, such as this Council, may not participate in situations in which any violation of conflict-of-interest laws and regulations may occur. Responsible NIDDK staff shall assist Council members to help ensure that the member does not participate in and is not present during review of applications or projects in which, to the member's knowledge, any of the following has a financial interest: the member, or his or her spouse, minor child, partner (including close professional associates), or an organization with which the member is connected.
To ensure that a member does not participate in the discussion of, nor vote on, an application in which he/she is in conflict, a written certification is required. A statement is provided for the signature of the member, and this statement becomes a part of the meeting file.

Prior to today's meeting, Council members were sent a statement regarding conflict of interest in their review of applications (members who here in-person today have the statement in their table folder). Each Council member should read the statement carefully, sign it, and then return the signed hard copy or file to Devon Drew (our Committee Management Officer) or to me before the end of the day.

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

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

V. REPORT from the NIDDK DIRECTOR

Dr. Griffin Rodgers

Dr. Rodgers updated the Council on recent budget events.

On March 8, the President signed the first package of six appropriations bills into law, providing full-year appropriations for fiscal year 2024 for many departments across the federal government. This package also extended authorization for the Special Diabetes Program through December 31, 2024, and included a new annual authorization level of $160 million for the program, an increase of $10 million and the first increase in that program since FY04. On March 23, the President signed the second appropriations package into law, funding all the agencies included in the remaining six bills, including NIH.

On March 11, President Biden released the FY25 President's Budget Request that began the budget process for FY25. On May 23, the Senate Appropriations Labor-Health and Human Services (HHS) Subcommittee held a hearing to discuss the budget proposal for NIH. On June 25, the House released their FY25 Labor-HHS appropriations bill, and the Senate released theirs on August 1. As part of the FY24 appropriations bill that included funding for HHS, NIH received $47.1 billion, a decrease of $378 million over the FY23 enacted level. The President's Budget request for FY25 proposes funding for NIH at $48.3 billion, a 2.7 percent increase over the 2024 enacted budget. It also requests $2.31 billion for NIDDK, maintaining the FY24 funding levels.

The House released the FY 2025 Labor-HHS appropriations bill on June 25. This proposal provides NIH and ARPA-H with flat funding at the current FY24 level of $48.581 billion. The bill also includes significant structural and policy changes for NIH by consolidating 27 existing NIH Institutes and Centers (ICs) into 15, including ARPA-H. NIDDK is proposed to be merged with the National Heart, Lung, and Blood Institute (NHLBI), and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) to create the National Institute on Body Systems Research. This new institute

would receive $7.1 billion, including an increase of $50 million specifically for diabetes research.

Dr. Rodgers mentioned that NIDDK is reviewing this and other proposals from Congress related to NIH reform and reauthorization. Two additional proposals were released by the House Energy and Commerce Committee Chair Cathy McMorris Rodgers and the Senate HELP Committee Ranking Member Bill Cassidy. NIH is open to working with Congress and other partners to identify ways to optimize NIH and bolster biomedical research efforts.

The Senate released their appropriations bill for FY25 last month. In this proposal, NIH would receive $48.851 billion, an increase of $1.77 billion over the FY23 enacted level. It also provides $2.361 billion for NIDDK, with a $50 million increase specifically for diabetes research. Dr. Rodgers noted that the Senate bill did not include the structural changes at NIH as the House proposed in their bill. However, the bill does include new authority for NIH to address loopholes in sexual harassment reporting. It also provides increases for several research areas, such as mental health, dementia, artificial intelligence, ALS, cancer, opioid use, maternal health, and diabetes.

In late May, the Senate Appropriations Labor-HHS Subcommittee held a hearing to discuss the President's Budget request for FY25, where NIH Director Monica Bertagnolli and other IC Directors, including the Directors of NHLBI, NCI, NIA, NIAID, and NIDA, testified. Members asked about a wide range of topics, including research on women's health, substance use disorder, mental health, cancer, health disparities, ARPA-H, and more. A few questions from Members focused on diabetes, including cellular therapies for type 1 diabetes, and concerns about how budget cuts may impact diabetes research.

Congressional and Constituency Activities

Dr. Rodgers highlighted several meetings that NIDDK participated in with Congressional staff and partner groups. On June 4, the Juvenile Diabetes Research Foundation hosted the "In It to End It" Congressional reception, where they launched their rebrand as Breakthrough T1D. Breakthrough T1D's CEO, Dr. Aaron Kowalski, as well as Senators Susan Collins and Jeanne Shaheen and Representative Gus Bilirakis, spoke on the importance of type 1 diabetes research.

Dr. Rodgers gave the opening remarks at "The Screen for Type 1 Summit" on the Hill, hosted by Sanofi on June 12. This event featured a panel, including celebrities Usher, Robin Arzón, and Adam Schefter, to share experiences with and encourage people to get screened for type 1 diabetes. Representative Kim Schrier, formerly a pediatrician, provided remarks as well.

On June 26, Drs. Will Cefalu and Saul Malozowski briefed staff from Representative Haley Stevens' office to discuss research on thyroid disease, with a focus on thyroid disease's disproportionate impact on women. In August, NIDDK leaders provided two briefings on diabetes. In early September, Drs. Will Cefalu and Griffin Rodgers met with staffers who work with Chairs and Ranking Members of the House and Senate Appropriations Labor-HHS Subcommittee to discuss new diabetes research initiatives.

Dr. Rodgers and Dr. Cefalu also met with Rep. Kim Schrier on September 10 to discuss diabetes initiatives at NIDDK as a follow up to the Sanofi event in June.

Council Questions and Discussion
Dr. Rodgers, moderator

Comment from Council: *Regarding the House proposal to create 15 new ICs with a flat budget, was there a shift in funding from within the three ICs that would make up the new Body Systems Institute?*

Dr. Rodgers said that those details were not made available. He added that the Senate did not have the creation of new ICs in their budget, but NIDDK will continue to monitor this pending legislation.

VI. THE NIDDK OFFICE of OBESITY RESEARCH
Drs. Susan Yanovski and Maren Laughlin

Dr. Yanovski provided an update on the NIDDK Office of Obesity Research (OOR). The medical complications of obesity range throughout the body from increased risk of cognitive dysfunction and stroke, coronary heart disease, many forms of cancer, and gout. The COVID-19 pandemic revealed the increased risk for serious disease and death in people with obesity highlighting the serious consequences of obesity on health.

The NIH Obesity Research Task Force was founded in 2003 to accelerate progress in trans-NIH obesity research, develop and implement an NIH strategic plan for obesity research, and serve as a point of contact for trans-NIH obesity initiatives, external requests, and meetings and seminars. More than 20 ICs and offices have representation on the Task Force, and it is cochaired by Drs. Rodgers, Gibbons, and Bianchi. Several medical complications of obesity relate to NIDDK's mission including type 2 diabetes, insulin resistance, disorders of gut-brain interaction, lower urinary tract symptoms, pancreatitis, metabolic dysfunction-associated steatotic liver disease, gallbladder disease, and chronic kidney disease. Obesity research received $1.2 billion in NIH funding in FY23 from over 2,600 projects. NIDDK is the largest funder, with 45 percent of all awards.

The OOR is organized in the NIDDK Office of the Director and is comprised of two Co-Directors and a program analyst. The OOR seeks to advance the understanding of obesity and its comorbidities with a goal of accelerating the development of effective prevention and treatment strategies. The Office oversees the Obesity Research Working Group, which provides a forum for sharing and coordination of trans-NIDDK and trans-NIH obesity research activities. OOR develops workshops, conferences, and webinars. They also develop research initiatives and assist in the preparation of obesity-related reports and inquiries. OOR assists the Director of NIDDK in identifying and prioritizing exciting and emerging areas of science in NIDDK disease-mission areas.

Dr. Yanovski explained that over the past few years the NIDDK OOR has identified several areas of scientific opportunity including reducing health disparities; mechanisms and optimal clinical use of highly effective medications; pathophysiology of chronic inflammation in obesity; neuroscience, basic behavioral and social sciences; genetics,

genomics, and epigenetics; and obesity complications. They have also identified several cross-cutting themes such as moving beyond BMI to understand the heterogeneity of obesity, developing precision medicine approaches to obesity prevention and treatment, optimizing clinical trial design through encouraging the use of modern research methodologies, developing enabling tools and data ecosystems, and enhancing training and workforce development.

Dr. Laughlin further described the Obesity Research Working Group, which has membership from multiple NIDDK Divisions and Offices. It is a forum to share and discuss NIDDK and NIH obesity research activities, portfolio analysis, and scientific advances. Additionally, the working group has three subgroups: the Neuroscience and Behavior Working Group, the Immunology Working Group, and the Health Equity Working Group. The subgroups facilitate communication between experts from across the NIH that do not always interact with each other.

The Neuroscience and Basic Behavioral Research Working Group focuses on human brain function associated with energy balance, eating, and other health behaviors; new brain regions, interoception, gut-brain interaction, and other tissue crosstalk; peripheral and autonomic nervous systems, damage or changes to nervous system caused by obesity, and mechanisms of incretin mimetic drugs. The Immunology of Obesity Working Group focuses on inflammation in obesity and its role in diseases within the NIDDK mission, the altered role of the adaptive immune system in obesity, and characterization of the human immune system in obesity. The Obesity and Health Disparities/Health Equity Working Group interacts with NIH-wide offices to assess the effects of policies or programs to address adverse social drivers on obesity-related health behaviors and outcomes, study the role of structural racism and adverse environments on biological and behavioral pathways underlying risk, and carry out dissemination and implementation research for prevention and treatment in diverse settings and populations.

Dr. Laughlin described several ongoing health equity research projects:

- Time-Sensitive Obesity Policy and Program Evaluation (R01 Clinical Trial Not Allowed, PAR-21-305).
- Bringing Resources to Increase Diversity, Growth, Equity, & Scholarship for Obesity, Nutrition, & Diabetes Research (BRIDGES) Consortium (RFA-DK-20-034)
- Dissemination & Implementation Research in Health (R01 Clinical Trial Optional, PAR-22-105).
- Notice of Special Interest (NOSI):): Analysis of Existing Linked Datasets to Understand the Relationship between Housing Program Participation and Risk for Chronic Diseases and Other Conditions (R01-Clinical Trial Not Allowed, NOT-DK-24-029l).

Other OOR research projects include:

- Obesity Discovery Science Research to Improve Understanding of Risk and Causal Mechanisms for Obesity in Early Life (R01 Clinical Trial Optional, RFA-DK-21-025).
- The Physiology of the Weight Reduced State Clinical Trial Consortium (UG3/UH3 Clinical Trial Required, RFA-DK-19-017/018).

OOR also offers a monthly speaker series with speakers nominated by NIDDK staff and widely advertised across NIH. Speakers include a range of senior and junior researchers from diverse backgrounds. Some of the topics ranged from transformational basic research (immunology, neuroscience, tissue crosstalk, and circadian medicine), impactful clinical research (clinical use of new therapies, obesity and kidney disease, health equity, and social determinants of health), and issues in obesity medicine training, medical guidelines, and health economics.

OOR has held several workshops over the past few years. Some of these include Neural Plasticity in Energy and Homeostasis and Obesity (April 13-14, 2023) and Interoceptive Contributions to Obesity and Disorders of Gut-Brain Interaction (April 30-May 1, 2024). There were also workshops specifically on anti-obesity medications including Medications to Treat Obesity: Past, Present, and Future (September 8, 2023) and Pharmacotherapy for Obesity in Children and Adolescents: State of the Science, Research Gaps, and Opportunities (November 28-29, 2023). An upcoming NIDDK workshop is planned for May 7-8, 2025, on the topic of Real-World Evidence to Optimize Use of GLP-1 Based Therapies. The purpose of the workshop is to identify gaps in our knowledge of the benefits and risks of GLP-1 based therapies and how they could be addressed using real word evidence to inform policy and clinical practice decisions.

Dr. Laughlin mentioned an upcoming Request for Information on Research Strategies for Addressing Obesity Heterogeneity to seek information on understanding interindividual variability in susceptibility to development of obesity, its complications, and response to treatment, with the goal of developing precision prevention and treatment strategies. Additionally, the office has a number of public-private partnerships including with the National Collaborative on Childhood Obesity Research, the National Academy of Science, Engineering, and Medicine (NASEM) Roundtable on Obesity Solutions, and the Foundation for the National Institutes of Health (FNIH) Obesity Biomarkers Working Group.

Council Questions and Discussion
Dr. Rodgers, moderator

Comment from Council: *How does bariatric surgery fit within the current landscape of obesity treatments?*

Dr. Yanovski highlighted NIDDK's significant commitment to bariatric surgery research but noted that there are unanswered questions within the field, such as where bariatric surgery fits within the landscape of weight loss medications, including as part of combination treatment or for people not achieving weight loss after bariatric surgery. Another unknown is the optimal order of treatment, such as trying medication prior to bariatric surgery. There is a lot of room for research in this area.

Dr. Laughlin added that there are several R01 studies in their portfolio that are looking at the comparison of incretin drugs and bariatric surgery.

Comment from Council: *Can you provide more information on the FNIH Obesity Biomarkers Working Group?*

Dr. Laughlin replied that this is a new Working Group currently attempting to raise funding for a project that seeks to identify obesity biomarkers that can be standardized and employed across clinical trials within the industry to better predict outcomes and monitor response to therapy. FNIH brings pharmaceutical partners and other industry groups together to collaborate in the pre-competitive space and achieve these goals.

Comment from Council: *How is the microbiome being studied in this portfolio, and are you looking for input across the scientific community to advance this knowledge?*

Dr. Laughlin indicated that the microbiome is studied by the immunology group and one of the cochairs has a microbiology portfolio in DDN. She noted the recommendation to continue building relationships with the scientific community in this area.

Dr. Yanovski highlighted a series of NIH listening sessions at national meetings to seek input from the scientific community and from people with lived experience and groups representing them. OOR will continue to seek input from both the scientific community and people with lived experience to determine research priorities for obesity.

Comment from Council: *What is the relationship between research on the heterogeneity of obesity and the heterogeneity of diabetes, given that they work on the same mechanistic basis?*

Dr. Laughlin replied that the understanding heterogeneity in obesity lags the understanding of heterogeneity in diabetes. However, with the development of various new obesity treatments, there is an opportunity to explore precision medicine approaches. OOR is starting to create a landscape of these approaches, beginning with collecting input from the scientific community.

Comment from Council: *There was a suggestion to include some of the biomarker studies with clinical trials and leverage the existing infrastructure to advance research questions.*

Dr. Laughlin agreed that this is an interesting idea and OOR is already incorporating social determinants of health research into clinical trials and more opportunity for synergy is a good idea.

Comment from Council: *Are there other federal agencies or departments within HHS that address health culture and prevention strategies that could serve as potential partners?*

Dr. Yanovski commented that OOR has met with federal partners such as Centers for Medicare and Medicaid Services, (CMS) and Centers for Disease Control and Prevention (CDC) to coordinate research ideas. The NIH Office of Nutrition Research has also served as a catalyst for bringing together partners across the federal government to talk about working together on some of these issues.

VII. UPDATE: NIH DIVISION of PROGRAM COORDINATION, PLANNING, AND STRATEGIC INITIATIVES (DPCPSI)

Dr. Tara Schwetz

Dr. Rodgers introduced Dr. Tara Schwetz, NIH Deputy Director for Program Coordination, Planning, and Strategic Initiatives who serves as Director of DPCPSI. Since joining NIH in 2012, Tara has worn many hats across NIH, including as Acting NIH Principal Deputy Director from December 2021 to November 2023. Dr. Schwetz then provided an overview of DPCPSI, which includes 14 offices that coordinate many NIH-wide activities, including the NIH Common Fund.

Dr. Schwetz began by explaining that DPCPSI is part of the office of the NIH Director with a budget of approximately $2.2 billion for FY24. The goal of DPCPSI is to coordinate science across the NIH. DPCPSI is made up to 14 different offices and one program, and two additional offices (*All of Us* Research Program Office and Environmental Influences on Child Health Outcomes Program Office) have been proposed and will hopefully be finalized soon. The role of DPCPSI is to align and catalyze science, help develop resources, and facilitate strategic coordination of both science and innovation. The mission is to advance biomedical and behavioral science through cross-cutting, innovative strategies that foster collaboration and synergies across NIH. The vision of the office is coordinated and harmonized NIH research that enables scientific discovery and enhances the impact of NIH to improve health for all. Leading through synergistic coordination of its offices and through vital IC partnerships, DPCPSI identifies and catalyzes research to address scientific gaps and opportunities, fosters collaborations, develops methods to enable research goals, and serves as an experimental testbed for innovative NIH-wide activities to improve the health of the Nation.

Dr. Schwetz described the proposed DPCPSI values:

- Respect: foster a collegial, collaborative, and professional environment that welcomes and recognizes contributions from all.
- Equity: embrace all aspects of diversity and promote an inclusive and accessible workplace environment for all.
- Coordination: catalyze and facilitate cross-cutting initiatives and frameworks to enhance research at NIH.
- Innovation: inspire bold and novel approaches to scientific research, capacity, and operations to lead impactful change.
- Partnership: build relationships across sectors and communities and develop collective strategies to achieve shared outcome.
- Excellence: leverage collective expertise to promote the highest standards of rigor, reproducibility, cultural credibility, and transparency.

She also provided the DPCPSI goals and priorities, which are:

1. NIH Research Advancement: align resources and catalyze innovation to stimulate transformational science.
2. Internal Workforce, Resource, and Infrastructure Alignment: enable a successful workforce by streamlining and synchronizing DPCPSI progress.
3. External Engagement: amplify the collective NIH work to and with the community.

For goal 1—NIH Research Advancement—DPCPSI is working to create an experimental testbed to push the boundaries on scientific and funding approaches, increase coordination across NIH to stimulate transformational science, advance evidence-based decision making, and develop cross-disciplinary training and resources.

For goal 2—Internal Workforce, Resource, and Infrastructure Alignment—DPCPSI is working to promote diversity, equity, inclusion, and accessibility; create opportunities to share experiences and insights to facilitate holistic connections; support for workforce recruitment, retention, and development; and optimize and streamline processes.

For goal 3—External Engagement—DPCPSI is working to communicate impact to the public to promote public health, transparency, and trust; amplify the value of our work through partnerships with ICs and offices and across HHS; forge synergistic internal and external partnerships to capitalize on shared priorities; and include communities as partners in research.

Next, Dr. Schwetz provided updates on select DPCPSI programs. DPCPSI is expanding research opportunities to where people seek care, such as their primary care physician. NIH recently launched Communities Advancing Research Equity for Health (CARE for Health) to test the feasibility of integrating clinical research into a primary care setting. Initially, the focus is on rural communities, but if successful, researchers hope to develop a nationwide network. It is a priority to focus on issues that are important to diverse communities, particularly those that are historically underrepresented in biomedical research. Providers will be offered a set of study options that sites can select from based on their specific community needs. This approach will help achieve longitudinal collection of clinical data to address health across the lifespan and build the evidence base for efficient and effective care. IC have been asked to put forward existing studies that would be appropriate for CARE for Health, and sites have applied to participate through an FOA. To sustain the effort, CARE for Health is developing a network research hub. Twelve applications were reviewed, and negotiations with six potential participatory organizations are underway. They expect to issue between two and five awards in FY24. There are many potential synergistic partnerships, and DPCPSI hopes to expand the program in the coming years.

Another effort is directed towards data science, which focuses on extracting data from clinical environments to leverage research studies to better understand national health trends. One example is conducting post-market surveillance of U.S. Food and Drug Administration (FDA)-approve drugs, with NIH involvement to enhance product safety and efficacy assessments. NIH is leading its cross-agency initiative addressing an urgent need for high-quality, comprehensive data from the clinical care environment to generate evidence necessary to improve decision making and have downstream health implications This new data initiative will create a Learning Health Systems Initiative to drive development and implementation of data standards and data collection systems that enable data sharing and fit-for-purpose use by any HHS agency and office.

Dr. Schwetz reviewed an Executive Order to advance research on women’s health, which is a comprehensive set of executive actions designed to spur innovation, unleash transformative investments, close research gaps, and improve women's overall health. There are several NIH efforts aimed aligning with the Executive Order. There is a NIH-

wide Women's Health Research NOSI linking to NIH parent funding opportunities across ICs and offices. The Small Business Innovation Research Program and Small Business Technology Transfer Program are committing to further increasing women's health investments by 50 percent. There is a new effort to identify and develop new common data elements related to women's health. And lastly, a biomarker discovery and validation initiative to help improve ability to prevent, diagnose, and treat conditions that uniquely affect women. NIH also released the NIH-Wide Strategic Plan for Research on the Health of Women earlier in 2024.

Also in the area of women's health, the NIH Pathways to Prevention Program plans to hold a workshop on the management of menopausal symptoms in late 2025. The Office of Disease Prevention commissioned an evidence review and launched workshop planning meetings that will lead to research suggestions on the topic of management of menopausal symptoms. There is also a RADx Tech ACT ENDO Challenge with submission due by October 11, 2024, to advance diagnostics for endometriosis.

Dr. Schwetz highlighted the *All of Us* research program, which aims to build a cohort of over 1 million people, currently at 800,000+ participants nationwide. It aims to be one of the largest and most diverse cohorts, with over 87 percent of participants coming from historically underrepresented communities. There have been over 440 publications on this data set so far. Dr. Schwetz highlighted a finding from this cohort that the *apolipoprotein L1* (APOL1) p.N264K variant is associated with a lower risk of chronic kidney disease and end-stage kidney disease. There is an *All of Us* ancillary study called Nutrition for Precision Health that is run by the Office of Nutrition Research to inform tailored dietary interventions that improve health. The goals are to develop algorithms to predict individual responses to foods and dietary patterns and to create a discovery science resource for the nutrition research community.

DPCPSI has several, additional ongoing initiatives that Dr. Schwetz highlighted. The initiative on Disability Research Across NIH is bringing NIH disability experts to support NIH-wide discussions on disability research and develop an overarching plan for the vision and coordination of NIH disability research. The Indigenous Data Sovereignty Policy is addressing a critical need to create a consistent approach across the ICs and offices to data management and sharing grounded in Tribal Sovereignty and Tribal research laws, codes, and ordinances. DPCPSI is leading the implementation plan for the ACD New Approach Methods Working Groups's recommendations. Finally, upcoming non-human primate (NHP) coordination efforts include NHP Evaluation and Analysis Study, a second Interagency Workshop on NHP Resources and Needs, and strategic management planning.

Council Questions and Discussion
Dr. Rodgers, moderator

Comment from Council: *How do you envision balancing Indigenous data sovereignty rights with the requirement to make federally funded research publicly available?*

Dr. Schwetz replied that this policy is still in development and a workshop is being held later in September to describe the current work and seek feedback from the community to

help develop recommendations. The focus is on research related to Tribal communities and research occurring on Tribal land.

Comment from Council: *Is CARE for Health primarily focused on treatment trials or is it also considering prevention trials? For example, The USDA has created a number of nutrition hubs designed to address prevention through physician nutrition, which could be an area for future interaction.*

Dr. Schwetz explained that there will be a broad portfolio, and while she cannot discuss specifics yet, not all projects moving forward are clinical treatment trials.

Comment from Council: *Regarding CARE for Health, how will physicians be compensated for their time spent in research activities, and will insurance play a role?*

Dr. Schwetz commented that this issue was a concern during community listening sessions, and they are considering unique solutions. The physicians participating in the studies will be compensated through a separate mechanism from insurance, and a process is in place to compute costs and build out a funding approach. This is a pilot project, so this approach can be adapted in future years.

Comment from Council*: Concerning CARE for Health, the biggest challenge with clinical research for rural sites is a lack of staff with training to carry out these studies. Will there be some workforce training or some other type of staff support?*

Dr. Schwetz agreed that this is challenging, and building infrastructure is a goal of the program. Through their listening sessions, they have found some academic centers that have built strong infrastructure with rural clinics. The program aims to provide the necessary infrastructure for research. Additionally, they hope that the opportunity to do research will encourage more clinicians to select rural locations.

Comment from Council: *Mobile platforms and remote monitoring tools developed for CARE for Health could enhance participant engagement in clinical trials across various research initiatives, addressing post-pandemic recruitment challenges in medical research.*

Dr. Schwetz agreed that this is one of the goals of the program.

Comment from Council*: Rural clinics may not have adequate access to basic technology, such as electronic health records. Are there other anticipated challenges with technology?*

Dr. Schwetz is aware that many rural sites are technology-limited, and the program aims to be flexible and provide support to the needs of rural clinics. The Office of Data Science Strategy is enhancing data efforts across Clinical Translational Research Awards, aiming to plant seeds to facilitate broader improvements in the research infrastructure.

VIII. UPDATE from the DIRECTOR, NATIONAL EYE INSTITUTE
Dr. Michael Chiang

Dr. Rodgers welcomed the Director of the National Eye Institute (NEI), Dr. Michael Chiang. Dr. Chiang became NEI Director in November 2020. Prior to coming to NIH, Dr. Chiang was at Oregon Health & Science University, where he was Knowles Professor of Ophthalmology & Medical Informatics and Clinical Epidemiology, and Associate Director of the Casey Eye Institute. Dr. Chiang is a pediatric ophthalmologist and is also board-certified in clinical informatics with an MD from Harvard Medical School and the Harvard-MIT Division of Health Sciences and Technology, and an MA in Biomedical Informatics from Columbia University. His research focuses on the interface of biomedical informatics and clinical ophthalmology in areas such as retinopathy of prematurity (ROP), telehealth, artificial intelligence, electronic health records, data science, and genotype-phenotype correlation. He is an Adjunct Investigator at the National Library of Medicine, and his group has published over 250 peer-reviewed papers and developed an assistive artificial intelligence system for ROP that received Breakthrough Status from the FDA.

Dr. Chiang explained that vision work matters because it has a substantial impact on quality of life and influences daily living and how we experience the world. When Dr. Chiang started as Director of NEI, he updated the NEI mission statement. The mission of the NEI is to eliminate vision loss and improve quality of life through vision research. To achieve this mission NEI provides leadership to:

- Drive innovative research to understand the eye and visual system, prevent and treat vision diseases, and expand opportunities for people who are blind or require vision rehabilitation.
- Foster collaboration in vision research and clinical care to develop new ideas and share knowledge across other fields.
- Recruit, inspire, and train talented and diverse individuals to expand and strengthen the vision workforce.
- Educate health care providers, scientists, policymakers, and the public about advances in vision research and their impact on health and quality of life.

NEI also created a NEI Strategic Plan in 2021 that has seven cross-cutting areas of emphasis: genes to disease mechanisms, the biology and neuroscience of vision, the immune system and eye health, regenerative medicine, data science, individual quality of life, and public health and disparities research. The portfolio is organized by diseases to include retinal diseases; corneal diseases; lens and cataract diseases; glaucoma and optic neuropathies; strabismus, amblyopia, and visual processing; and low vision and blindness rehabilitation.

Dr. Chiang explained that regenerative medicine—regenerating or reengineering tissues to replace dead cells or tissues—is an area of synergy for NEI and NIDDK. The first FDA-approved gene therapy (ATSN 101) in any field of medicine for an inherited disease was for a gene cloned at NEI, RPE65-driven Leber congenital amaurosis. It took decades of basic and translational work to develop this gene therapy. One of the reasons the early gene therapies were developed for the eye is because it is easy to access and easy to deliver the vector locally. There is a trans-NIH program for gene therapy known as the Accelerated Medicines Partnership Bespoke Gene Therapy Consortium, formed in 2021. This is a NIH public-private partnership (FNIH, FDA, industry, and multiple NIH

ICs) to develop gene therapy platforms and standards for ultra-rare diseases. In terms of basic and translational sciences, the goal is to optimize creation of adeno-associated viruses (AAVs) and improve AAV gene expression. For gene therapy pilot trials, they aim to standardize vector generation, harmonize manufacturing practices, streamline regulatory pathways for FDA approval, and de-risk the commercial sector. NEI is interested in many rare genetic eye diseases.

The NIH Regenerative Medicine Innovation Project was part of the 21st Century Cure Act "innovation projects." There were 20 projects that were funded between 2017 and 2020 that are now complete. NIAMS and NEI formed a trans-NIH working group in regenerative medicine to examine the feasibility of future public-private partnerships in this area with a workshop and a NASEM forum. The result was the identification of future needs, such as Good Manufacturing Processes for cell replacement tissues in the areas of quality control, cell sourcing, automation, and bulk production; bioequivalence of cellular therapies (characterizing and growing cell types); and regulatory risk. Ongoing discussions with NIAMS, NEI, and FNIH have been exploring the potential for a public-private partnership for cell-based therapy to address some of the gaps in knowledge. The goal would be to accelerate patient access to regenerative cell-based therapies through development of a standardized playbook including preclinical testing, manufacturing, and regulatory approval. This potential partnership could also be of interest to NIDDK.

Next Dr. Chiang moved to discussing data science and advances in ophthalmic imaging. The first FDA-cleared autonomous artificial intelligence (AI) algorithm was for diabetic retinopathy screening. There is the potential for AI algorithms to diagnose diseases related to the eye quickly and is most useful for patients in rural areas. There has been growth in "oculomics", which is the diagnosis and prognosis of systemic disease. For example, researchers analyzed liquid biopsy samples from the eye to predict age, finding that young people with eye diseases showed protein profiles typical of older individuals, even after treatment, suggesting potential for improved diagnostics and therapies based on this proteomic data. Other applications could be the use of multiomics to predict other diseases such as Parkinson's disease based on a retinal scan.

Dr. Chiang also mentioned some challenges with AI and machine learning (ML). The real world is heterogeneous in terms of imaging devices, race, and population, and models trained on one group are not always applicable to other populations. Large, diverse multi-center datasets could help overcome some of these challenges. Bridge2AI, a program of the NIH Common Fund, was a phase 1, $130 million project over four years. As one of four groups funded by this program, a team of ophthalmologists at the University of Washington is working to build an AI-friendly, hypothesis-agnostic dataset of diverse, well curated, and well-balanced dataset based on a diverse, 4,000 participant population in various stages of type 2 diabetes progression and recovery. The first part of the dataset is now available for diabetes research use: aireadi.org. Another area of priority for NEI is to enhance *All of Us* with ocular imaging. The goal is to collect a sufficient cohort of high-quality imaging of participants from diverse backgrounds to address scientifically relevant hypotheses-based on the interface of ocular and systemic data.

Dr. Chiang cited the importance of data sharing efforts, which are disincentivized by the current academic model, but are a cornerstone for modern research. Dr. Chiang emphasized the importance of NIH and White House data sharing policies and suggested

an alternate incentive for data sharing: a new publication type that can provide academic credit, citations, and is findable. There needs to be a gradual culture shift to incentivize data sharing and team science. The NIH Data Sharing Index Challenge aims to advance the NIH mission by promoting data sharing and developing a robust metric to reward exemplary data sharers with a prize purse of $1 million. This project was recently announced with a registration deadline in March 2025.

Dr. Chiang addressed two opportunities for data harmonization; a centralized system or a federated data network. A centralized data repository allows a large and aggregated multisite data repository, and data can be accessed and analyzed through a single point. However, this requires extensive legal, privacy, and security agreements, can take extensive effort to setup, and it is frequently impractical to send large files over the internet. Federated data networks share analysis methods rather than the data itself, which is a scalable process that does not necessitate data use agreements. However, it's more difficult to harmonize data across sites when analysis occurs in parallel. Common Data Model can be used to map data to integrated data ecosystems with the ability to create standardized cohorts and phenotypes. The model known as Observational Medical Outcomes Partnership is used by *All of Us* and many ICs. A pilot network study run by the Observational Health Data Sciences and Informatics program and Dr. Cindy Cai used a federated analysis of 12 datasets with 485 million patients to look at whether the risk of kidney failure was associated with intravitreal anti-VEGF exposure in patients with blinding diseases and was different among patients who received ranibizumab versus aflibercept versus bevacizumab. The findings suggested no difference in risk of kidney failure.

There is also a need for ocular imaging standards to provide better clinical care (quality, accessibility, and equity), produce better research (data science and AI), and improve cost through data sharing. In radiology, the Digital Imaging and Communications in Medicine (DICOM) standard was universally adopted, but it remains optional and has low uptake in ophthalmology. The NEI has been working with FDA and the Office of the National Coordinator to recognize the DICOM standard for ocular imaging devices. The Association for Research in Vision (ARVO) and the American Academy for Ophthalmology (AA) released a position paper in 2022 that recommended the adoption of the DICOM standard for ophthalmic imaging devices. NEI has published a new guide notice about imaging standards, with DICOM as a preferred standard.

Dr. Chiang highlighted an example of efforts toward quality-of-life improvements in diabetic retinopathy (DR) research. The Diabetic Retinopathy Clinical Research Network (now DRCR Retina Network) was established in 2002. The DRCR Retina Network is co-funded by NIDDK and has supported multiple comparative anti-VEGF studies. There is also potential for collaboration regarding stimulating translation of preclinical studies to patients. Finally, he discussed ongoing challenges related to public health and disparities in this field. The rates of DR are higher in non-Hispanic Black populations, and the Hispanic population is much more likely to have vision loss from DR that non-Hispanic Whites. Treatments developed over the past 50 years have reduced the risk of vision loss due to DR by more than 95 percent, but many people lack access to care. There is research underway looking at home optical coherence tomography (OCT) retinal monitoring to improve access. He stressed the importance of ensuring that scientific advancements are accessible to the communities most in need of the interventions and

highlighted two examples—home retinal monitoring and the NIH Common Fund CARE for Health Program—as opportunities to advance access to care.

Council Questions and Discussion
Dr. Rodgers, moderator

Comment from Council: *The eye is a barrier surface, and mucosal immunology could be an area of synergy for NEI and NIDDK.*

Dr. Chiang said that mechanisms of inflammation is an area that would be of interest to NIDDK and NEI and further discussion is warranted.

Comment from Council: *There are also potential private-public partnerships with institutions such as California Institute for Regenerative Medicine (CIRM).*

Dr. Chiang highlighted NEI's work with the Bespoke Gene Therapy Consortium, through which three clinical trials related to the eye are ongoing. One of those trials is being carried out by CIRM. The NEI is open to ideas for further partnership with CIRM.

Comment from Council: *Home OCT monitoring is interesting, but are the costs too expensive to make it routine or provide improved access?*

Dr. Chiang answered that home OCT monitoring is quite expensive and may be too expensive for mainstream use. However, the devices currently in use were designed for clinical practice. If there is a large market for home use, device makers could be incentivized to make OCT monitoring devices that are lower cost and designed for that purpose. The reimbursement model for home-based care is not yet well defined, and this is an outstanding question that could also add incentives for home monitoring.

Comment from Council: *Should we be using the AI/ML technology described to look for biomarkers related to a wide range of diseases, not necessarily limited to diseases specific to the eye?*

Dr. Chiang commented that there is feasibility to AI/ML aiding in diagnostics and prediction. Future research should explore study designs that span the spectrum from diagnosis to prediction, potentially involving biomarkers and gene-environment interactions.

Comment from Council: *Has the data harmonization described in eye research occurred in other areas of brain/body imaging?*

Dr. Chiang noted that, while he cannot compare the eye community to others, but that NEI is working with the American Academy of Ophthalmology to advance efforts toward harmonization from the top down.

IX. CONCEPT CLEARANCE

Dr. Rodgers then turned to Concept Clearance by Council, a step required before ICs can publish notices of funding opportunities. To streamline this process, summaries of the

concept were supplied to Council members for their review prior to the meeting. One renewal concept was presented. Cleared concepts will be made publicly available on the NIDDK website.

KUH Research Training Network (KUHR-TN)
Dr. Tracy Rankin

The KUH Division of the NIDDK has worked to strengthen institutional training by creating highly connected cohorts of trainees with enhanced resources to provide them a solid foundation upon which to progress to their next career stage. As such, the Division launched the KUH Research Training Network (KUHR-TN, formerly Institutional Network Award (U2C/TL1)) in FY20. Each award couples a National Research Service Award (NRSA) support mechanism (TL1) with a multi-component resource mechanism (U2C) to provide each trainee access to an array of improved mentoring, professional development, and networking opportunities. By limiting each institution to a single award and encouraging engagement of trainees across the breadth of KUH science (where applicable and feasible), we expect to cultivate a vibrant and dynamic network of people and resources across an entire institution to engage, recruit, prepare, and sustain the next generation of KUH researchers. Each institution may apply for a single award that will have at least five highly competitive trainee slots to support protected research and career development activities. Institutions are also encouraged to engage with additional external institutional partners to both enhance the research experience of the trainees and provide access to diverse pools of prospective trainees.

Council Questions and Discussion
Dr. Rodgers, moderator

Comment from Council: *What mechanisms are used to track trainees during and after the program?*

Dr. Rankin answered that there is a collaborative effort within the network to establish a program-wide evaluation group. This group aims to develop consensus on success metrics, create common standards and reporting requirements, and ensure consistency in data capture. The working group is also focusing on improving methods to track trainees after their appointments, acknowledging that this as a challenging task.

Comment from Council: *Is this network combining nephrology, urology, and hematology, or they are all separate?*

Dr. Rankin replied that the current funding opportunity does not require representation from all disciplines; rather, the aim is to encourage collaboration across different mission interests. This approach is designed to meet common trainee needs, foster networking, and promote diverse perspectives in problem-solving. It also allows only one program per institution to break down silos and build cohorts of trainees across interests.

Comment from Council: *To what extent are these challenges unique to KUH, and would it make sense to expand this across NIDDK?*

Dr. Rankin said that she can only comment for KUH, and that each division chooses how to spend their workforce training budgets. However, these challenges are not unique to KUH nor NIDDK, and even impact all of NIH more broadly.

Comment from Council: *Is this program mature enough to have any data showing that participation in this program increases success when applying for other awards?*

Dr. Rankin said that the program is not yet mature enough to have that kind of data. It was launched in 2021.

Comment from Council: *There is a need for broader efforts to address challenges in developing the scientific workforce. For example, changing the culture of research, influencing how academic institutions allocate resources, and partnering with loan repayment programs with training initiatives to offset high education costs. Workforce development issues are much broader than just this program and NIH should invest more resources to this issue.*

Dr. Rankin stated that as the program matures, they are trying to address trainee needs and the needs of the institution.

Comment from Council: *Is the grant mechanism still a T32?*

Dr. Rankin explained that this training program combines two funding mechanisms: a TL1 award, which is like a T32 award, providing direct support to trainees; and a U component, which funds additional resources for professional development and networking. This structure was adopted because the T32 mechanism alone couldn't support the desired professional development activities. The approach is modeled after the Clinical and Translational Science Awards program, linking an institutional NRSA mechanism with additional resources.

X. OPEN SESSION OF SUBCOMMITTEE MEETINGS

See Minutes posted on the NIDDK Council Minutes Website.

XI. 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.

XII. 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 849 grant applications (282 primary and 567 dual), requesting support of $370,130,239 were reviewed for consideration at the September 11, 2024, meeting. An additional 28 Common Fund applications requesting $13,998,503 were presented to Council. Funding for these applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, 1,252 applications requesting $490,157,884 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 September 11, 2024, meeting.

XIII. 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 226th meeting of the NIDDK Advisory Council was adjourned at 4:30 p.m. on September 11, 2024.

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

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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