

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

I. CALL TO ORDER

Dr. Rodgers

Dr. Griffin Rodgers, Director, NIDDK, called to order the 219th meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council at 10:00 a.m. on May 11, 2022, via Zoom videoconference. This meeting was conducted using a two-tiered webinar format. The panelist tier consisted of NIDDK’s Advisory Council members and NIDDK staff members who presented during the meeting. The audience tier was available to members of the public and allowed them to view and listen to the meeting.

ATTENDANCE – COUNCIL MEMBERS PRESENT

Dr. John Carethers
Ms. Dawn P. Edwards
Dr. Penny Gordon-Larsen
Dr. Debra Haire-Joshu
Ms. Davida Kruger
Dr. Jacquelyn Maher
Dr. Mark Nelson
Dr. Keith C. Norris

Dr. David Penson
Ms. Ricky Safer
Dr. Kathleen Sakamoto
Dr. Philipp E. Scherer
Dr. Elizabeth Seaquist
Dr. Michael Snyder
Dr. Gary Wu

Subject Matter Experts:

Ms. L. Neicey Johnson
Dr. Christian Faul

Ex-officio members:

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

Also Present:

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

I. ANNOUNCEMENTS

Dr. Rodgers

Dr. Rodgers noted that this is NIDDK's seventh consecutive virtual Council meeting. NIH has announced that meetings in September/October 2022 will be held in a hybrid format, accommodating both virtual and in-person attendance. The NIDDK meeting is scheduled as a hybrid meeting, with the in-person attendance taking place on the 6th floor of the C-Wing of Building 31. The Advisory Council website will have further details.

Council Member News

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

- **Dr. John Carethers** is Professor and Chair of the Department of Internal Medicine, Professor of Human Genetics, and is the John G. Searle Professor of Internal Medicine at the University of Michigan Medical School.
- **Ms. Davida Kruger** is a Certified Nurse Practitioner at the Henry Ford Health System in Detroit, MI.
- **Dr. Jacquelyn Maher** is a Professor at the University of California, San Francisco School of Medicine. She is Chief of the Division of Gastroenterology at San Francisco General Hospital and Director of the UCSF Liver Center.
- **Dr. Elizabeth Seaquist** is Director of the Division of Diabetes, Endocrinology and Metabolism and holds the Pennock Family Chair in Diabetes Research at the University of Minnesota Medical School.

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

Dr. Rodgers also recognized two subject matter experts at the meeting:

- **Dr. Christian Faul** is Associate Professor in the Division of Nephrology within the Department of Medicine and the Department of Cell, Developmental, and Integrative Biology at the University of Alabama at Birmingham.
- **Ms. L. Neicey Johnson** is a Senior Director of Programs at the Association of Black Cardiologists, Inc, and chairperson of the Georgia Clinical & Translational Science Alliance (CTSA) Community Steering Board.

Dr. Faul will participate in the Kidney, Urologic, and Hematologic (KUH) subcommittee. Ms. Johnson will participate in the DEM subcommittee.

Dr. Rodgers noted that former NIDDK Council Member **Dr. Ronald J. Sokol** has been named inaugural Chief Scientific Officer in Child Health at the University of Colorado's Anschutz Medical Campus. According to an announcement from the University, Dr. Sokol will help formalize a joint research enterprise to promote discovery and increase understanding of childhood disease, while also advancing clinical care to improve health across the lifespan. Dr. Sokol is an accomplished clinician, researcher, mentor, administrator, advocate, leader, and longtime friend of

NIDDK.

NIDDK Staffing News

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

- **Dr. Behdad Afzali**, Stadtman Tenure-Track Investigator and section chief in the Kidney Diseases Branch, received the American Society for Clinical Investigation's 2022 Young Physician-Scientist Award for his research achievements on the basic mechanisms of tissue inflammation and its resolution and healing.
- **Dr. Rebecca Brown**, Lasker Tenure-Track Investigator and an acting section chief in NIDDK's Diabetes, Endocrinology, and Obesity Branch, was elected to the American Society for Clinical Investigation. Dr. Brown has made important contributions to advancing research on rare disorders of extreme insulin resistance, such as lipodystrophy, and on use of the hormone leptin to treat these disorders.
- **Dr. Nicolas Gurdosh**, Stadtman Tenure-Track Investigator and acting section chief in NIDDK's Laboratory of Biochemistry and Genetics, was awarded the 2022 RNA Society Early-Career Research Award for making several key advances in RNA research.
- **Dr. John Hanover**, chief of NIDDK's Laboratory of Cell and Molecular Biology and director of NIDDK's Genomics Core, received the Society for Glycobiology's 2021 Karl Meyer Lectureship Award for his significant contributions to the field of glycobiology. Dr. Hanover's advocacy of glycobiology and research on O-GlcNAc-modified nucleoporins has had significant impact on multiple fields including diabetes, aging, and neurodegeneration.
- **Dr. Barbara Rehmann**, section chief in NIDDK's Liver Diseases Branch, was elected to the American Academy of Microbiology based on her scientific achievements and contributions to advancing microbiology.

Dr. Rodgers announced several new staff members who have joined NIDDK's Intramural Research Program as Stadtman Tenure-Track Investigators:

- **Dr. Ashley Frakes** will serve as acting section chief of the new Glial Biology Section in the Genetics and Biochemistry Branch.
- **Dr. Andrew Lutas** will serve as acting section chief of the Neuromodulation and Motivation Section in the Diabetes, Endocrinology, and Obesity Branch.
- **Dr. Quan Wang** will serve as acting section chief of the Nanoscale Single-Molecule Dynamics Section in NIDDK's Laboratory of Chemical Physics.

Dr. Rodgers also announced the hiring of new extramural staff members. Four new program staff have joined NIDDK's Division of Digestive Diseases and Nutrition (DDN):

- **Dr. Diana Cummings** will oversee DDN's program focusing on gut-brain-microbiome-nutrition interactions related to digestive disorders and obesity. Dr. Cummings received her PhD in neuroscience from the University of Virginia. Following post-doctoral work on olfactory system organization and plasticity, she joined the National Institute of Neurological Diseases and Stroke, where most

recently she served as a Scientific Review Officer.

- **Dr. Jan-Michael Klapproth** will oversee a DDN program focusing on pre-clinical and clinical research on diseases of the alimentary GI tract. Dr. Klapproth received his MD degree from the Albert Ludwigs University of Freiburg in Germany. He then completed post-doctoral laboratory research training and Internal Medicine and Gastroenterology subspecialty training at the University of Maryland in Baltimore before joining the faculty of Emory University. Subsequently, he moved on to the University of Pennsylvania where he progressed to the rank of Professor.
- **Dr. Robert (Dwayne) Lunsford** will be overseeing a DDN portfolio focusing on host-microbial interactions, pathogenesis, and microbiome-related projects. Dr. Lunsford earned his PhD degree from Virginia Commonwealth University. Following post-doctoral work that included a stint within the NIDDK intramural program, he spent ten years in the private sector investigating the preclinical development of new antibacterials. He then returned to NIH and was most recently deputy director of the Therapeutic Development Branch, within the Division of Preclinical Innovation, at the National Center for Advancing Translational Sciences.
- **Dr. Khoa Nguyen** will oversee a DDN program focusing on the biology of HIV persistence in the gut and the impact of HIV on GI health. He will also be representing NIDDK-wide interests on trans-NIH initiatives focused on HIV viral reservoirs and pathogenesis throughout the body. Dr. Nguyen received his PharmD from the University of Maryland Eastern Shore's School of Pharmacy. Over the past two years he has been working at NIDDK as a contractor where he has played a key role in managing and growing the Institute's HIV/AIDS research portfolio across Divisions.

Dr. Rodgers announced that one new extramural staff member has also joined NIDDK's Division of Diabetes, Endocrinology, and Metabolic Diseases Division (DEM). **Dr. Hanyu Liang** completed her medical training at Capital Medical University and her residency in Internal Medicine at the Sixth Hospital of Beijing, in Beijing, China. She then moved to Texas to pursue a PhD in Physiology at the University of Texas Health Science Center at San Antonio. Dr. Liang will join DEM as the Program Director for Translational Integrative Physiology.

Four new staff members have recently joined NIDDK's Division of Extramural Activities:

- **Dr. Sreenivasan Rajamoni Nadar** joined DEA as a Health Specialist in NIDDK's Office of Research Evaluation and Operations (OREO). Dr. Nadar recently served as a Scientific Review Officer at the National Institute of Aging. He earned a PhD in modeling and simulation of biophysical systems and then went on to obtain an MBA. Dr. Nadar has over two decades of research experience on neural signal/image processing, including systems applications to biology and medicine.
- **Ms. Shalanda Wellington** joined OREO as a participant in the NIH Pathways Recent Graduate Program. Ms. Wellington earned her Master of Science in Health Informatics Management from the University of Maryland University

College.

- **Ms. Tracie McGraw** and **Ms. Angela Walters** have joined DEA as Senior Grants Management Specialists to support DDN. Ms. McGraw has experience working at several NIH Institutes, including most recently at the National Cancer Institute (NCI). Ms. Walters will help manage awards that include complex clinical trials. She also comes to NIDDK from NCI.

Dr. Rodgers also welcomed **Dr. Sophia Jeon**, who joined NIDDK's Office of Scientific Program and Policy Analysis in March. She previously worked at the National Institute of Neurological Diseases and Stroke's Office of Science Policy and Planning, where she coordinated congressional and legislative activities and led working groups for several strategic plans. She earned her PhD in Immunology from the University of Pittsburgh School of Medicine and did her postdoctoral work at the National Eye Institute.

Dr. Rodgers then acknowledged recent awards received by extramural staff members:

- **Dr. Frank Hamilton**, Senior Scientific Officer and Program Officer in DDN, was honored by the American College of Gastroenterology in a cover story entitled "A Career in Medicine and Public Service" that recognized his more than 50 years of public service in advancing GI research and fostering diversity. Dr. Hamilton began his public service career as a commissioned officer in the US Public Health Service in 1970 where he worked on the landmark Department of Health and Human Services Task Force on Black and Minority Health. He joined NIDDK in 1987, where he has managed many different high-impact studies in GI conditions over the years and continued to promote diversity in the GI workforce and elimination of health disparities in people with GI diseases.
- **Dr. David Saslowsky**, Deputy Director of DDN, received the American Gastroenterological Association Research Service Award for contributions to the career development of countless digestive health and disease early career investigators, including a new program in response to hardships created by the COVID-19 pandemic.

Dr. Rodgers also gave some updates on the Special Statutory Funding Program for Type 1 Diabetes Research, or Special Diabetes Program, which provide funding for research on the prevention and cure for type 1 diabetes. NIDDK administers the program on behalf of the Secretary of the Department of Health and Human Services.

- On March 8, 2022, NIDDK convened a workshop with members of the research community to discuss research gaps and opportunities associated with type 1 diabetes. A summary of that workshop is available [here](#).
- On June 16, 2022, NIDDK will host a hybrid meeting of the Diabetes Mellitus Interagency Coordinating Council (DMICC). DMICC is an inter-agency committee made up mostly of HHS agencies and has a focus on diabetes. Members convene to identify emerging issues and opportunities and develop ways in which different governmental components can work together and build upon each other's expertise and resources. Dr. William Cefalu, Director of the Division of Diabetes, Endocrinology, & Metabolic Diseases at NIDDK, and Dr. Christopher Holliday, Director of the Division of Diabetes Translation at the CDC, will serve as Co-Chairs. At the June 16 meeting, members will review

recommendations from the 2021 National Clinical Care Commission Report to Congress on Leveraging Federal Programs to Prevent and Control Diabetes and its Complications. Representatives from federal agencies will provide their perspective on the report and work with other federal partners to identify next steps.

II. CONSIDERATION OF SUMMARY MINUTES OF THE 218th COUNCIL MEETING

Dr. Rodgers

The Council approved, by electronic poll, the Summary Minutes of the 218th Council meeting, which had been sent to them in advance for review.

III. FUTURE COUNCIL DATES

Dr. Rodgers

Dr. Rodgers noted that NIH has determined that the September 2022 Council meeting will be held in a hybrid format to accommodate both virtual and in-person attendance on the 6th floor of the C-Wing of Building 31. Although he expected the meeting to take place on one very full day on Wednesday, September 7, he asked Council members to keep open both September 7th and 8th in case a second day is needed. He also noted that Council meeting dates for 2024 have been added to the Council website. They are January 10-11, May 8-9, and September 11-12, 2024. Updated information will be posted on the Council website.

IV. ANNOUNCEMENTS

Dr. Malik

Confidentiality

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

Conflict of Interest

Dr. Malik reminded Council members that advisors and consultants serving as members of public advisory committees, such as the NIDDK Advisory Council, may not participate in situations in which any violation of conflict-of-interest laws and regulations may occur.

NIDDK staff shall assist Council members to help ensure that a member does not participate in, and is not present during, the review of applications or projects in which, to the member's knowledge, any of the following has a financial interest: the member, or his or her spouse, minor child, or partner (including close professional associates), or

an organization with which the member is connected. To ensure that a member does not participate in the discussion of, nor vote on, an application in which he/she is in conflict, a written certification is required. A statement is provided for the signature of the member, and this statement becomes a part of the meeting file. Dr. Malik directed each Council member to a statement in his or her meeting folder regarding the conflict of interest in review of applications. He asked each Council member to read it carefully, sign it, and return it to NIDDK before leaving the meeting.

Dr. Malik pointed out that when the Council reviews applications in groups without discussion—also called “en bloc” actions—all Council members may be present and may participate. The vote of an individual member in such instances does not apply to applications for which the member might be in conflict.

Regarding multi-campus institutions of higher education, Dr. Malik said that an employee at one campus may participate in any particular matter affecting another campus, if the employee’s financial interest is solely at one campus and the employee has no multi-campus responsibilities.

V. **REPORT FROM THE NIDDK DIRECTOR**

Dr. Rodgers

Budget Update

Dr. Rodgers updated the Council on the current budget and the NIH appropriations process for Fiscal Year 2022 (FY22). At the time of the January meeting, the federal government was operating under a continuing resolution enacted in December 2021. That resolution expired on February 18, 2022, and on that date, congress passed a third continuing resolution extending funding through March 11, 2022. On March 9, 2022, the House passed the FY22 Omnibus Appropriation Bill and a final four-day continuing resolution to give the bill time to pass through the Senate. The Senate approved the bill on March 15, 2022, and the President signed it into law. Just two weeks later, the President released his full discretionary budget request for FY23. The House Appropriations Labor HHS Subcommittee is currently holding its FY23 budget request hearing for NIH, and the Senate Appropriations and Labor HHS Subcommittee will do so soon as well.

Dr. Rodgers then reviewed the specifics of the FY22 budget. NIH received \$44.959 billion in FY22, a \$2.025 billion (4.7 percent) increase over FY21. NIDDK received \$2.204 billion, a \$72 million (3.4 percent) increase. Some ICs saw larger increases due to targeted funds for certain programs.

The President’s FY23 discretionary budget includes \$50.228 billion for NIH (a \$5.3 billion increase) and \$2.206 billion for NIDDK, which is a \$2 million increase. The President’s discretionary budget utilized the continuing resolution as the baseline for determining FY23 funding levels. This increased amount for NIH includes an additional \$5 billion for the Advanced Research Projects Agency for Health (ARPA-H) which would initially focus on cancer and other diseases, including diabetes and Alzheimer’s disease. The budget request also mentions other areas of interest to NIH, including ending the opioid crisis and the HIV-AIDS epidemic, addressing health inequities and

racial disparities, and transforming nutrition science.

Congressional Activities

On May 2, 2022, Dr. Rodgers and senior leaders from several other NIH institutes met virtually with clerks from the Senate Appropriations Labor HHS Subcommittee to discuss the coordination of autoimmune disease research at NIH. Dr. Rodgers spoke about NIDDK's research in this area including the Type 1 Diabetes TrialNet and The Environmental Determinants of Diabetes in the Young (TEDDY) study. Additionally, some of these activities are done in collaboration with the National Institute for Allergy and Infectious Diseases' (NIAID) Immune Tolerance Network.

Council Questions and Discussion

Comment from Council: *Why didn't NIDDK receive an increase in budget?*

Dr. Rodgers explained that the President's budget bases NIDDK's appropriation on the amounts included in the continuing resolution, which was based on FY21 and was lower than the amount NIDDK actually received in FY22. He also reminded Council that the President's Budget is a starting point and that appropriations often increase during the House and Senate appropriations processes. NIDDK will be closely following the House and Senate hearings.

VI. UPDATE: NIH TRIBAL HEALTH RESEARCH OFFICE

Dr. David Wilson

Dr. Rodgers introduced Dr. David Wilson, who was appointed as the first Director of NIH's Tribal Health Research Office (THRO) in the NIH Office of the Director in January 2017. Dr. Wilson works with representatives from NIH Institutes, Centers, and Offices to leverage trans-NIH resources and build collaborations throughout the research portfolio to address Tribal health concerns. He also fosters engagement and input from Tribal leaders and works to expand training opportunities for the American Indian and Alaska Native communities. He came to NIH from the HHS Office of Minority Health, where he served as Public Health Advisor and American Indian/Alaska Native Policy Lead. Dr. Rodgers also mentioned that he and Dr. Germino traveled to the NIDDK Phoenix Branch with Dr. Wilson to speak with Tribes in Arizona about NIDDK's ongoing efforts as they relate to the Institute's new Strategic Plan, as well as potential future activities.

Dr. Wilson began his presentation by showing a diagram that illustrated how THRO works with all the Institutes and Centers at NIH on programs and policies that promote research careers and health research in Tribal communities. He acknowledged that Tribal communities and underrepresented communities in general have had negative experiences with medical research and that the research community must first build trust within those communities before true collaboration can take place. Making sure that NIH values Tribal partnerships and contributions to research is an important part of that. The current Administration has been supportive of strengthening government-to-government relationships between the federal government and Tribal nations. In January 2021, the President released an executive memorandum that called for respect for Tribal sovereignty and regular, meaningful, and robust consultation with Tribal

nations.

Established in 2015, THRO not only works with different ICs within NIH, but also different operating divisions within HHS (including the Indian Health Service) and other federal departments, such as the Department of Agriculture and the Department of Transportation. He outlined the functions of the Office as described in the NIH Strategic Plan for Tribal Health Research, FY 2019-2023:

- Acts as a central hub for coordinating tribal health research and American Indian/Alaska Native (AI/AN) capacity building across NIH, including serving as a contact for questions from tribal communities
- Supports ICO efforts to meet Strategic Plan Goals (such as the NIDDK Strategic Plan for Research, December 2021) by reaching out into Tribal communities to hear about their health and research priorities and identify ways to work together to address them
- Ensures adherence to the NIH Tribal Consultation Policy in government-to-government conversations
- Gathers meaningful input from Tribal communities about priorities, disparities, and other concerns
- Convenes NIH Tribal Advisory Committee of Tribal leaders who represent different regions of the U.S. and meet regularly to advise the work of THRO

He emphasized the importance of communicating the concept of Tribal sovereignty to research partners as well as the government-to-government relationship between Tribes and federal agencies, noting that this relationship is political and legal, not racial. He also stressed the diversity of Tribes, noting that there are 574 federally-recognized Tribes and another 66 state-recognized Tribes that are trying to get federal recognition. Each Tribe has their own history, language, culture, traditions, and experiences not only with the U.S. government but also with research. Engaging with as many Tribes as possible helps increase understanding of how biomedical research can become more inclusive.

When THRO was first established, the Office conducted a research portfolio analysis to better understand how NIH worked with Tribal communities and also to understand potential research gaps. That analysis was released in 2018. The Office will release a new analysis of 2019-2021 later this summer, which will show where NIH is investing funds and establishing partnerships both in terms of academic institutions and Tribal communities.

In 2019, the Office released its first NIH Strategic Plan for Tribal Health Research for 2019-2023. This trans-NIH effort was developed in consultation with the Tribes and their priorities for biomedical research in their communities. That report set out four key goals:

- Enhancing Communication and Collaboration
- Building Research Capacity for American Indian and Alaska Native Communities
- Expanding Research
- Enhancing Cultural Competency and Community Engagement

Dr. Wilson pointed out that cultural competency and community engagement are essential for the success of the first three goals.

By the end of 2022, THRO will report on their progress, which will set the stage for work on the next Strategic Plan, to be released in 2024.

Dr. Wilson then reviewed some of the partnerships that THRO has participated in recently, including helping the National Center for Advancing Translational Science (NCATS) with the National COVID-19 Cohort Collaborative (N3C), a large research program that gathers electronic health records from across the country to better understand how COVID is spreading in communities. THRO also worked with the National Institute on Minority Health and Health Disparities (NIMHD) and its Tribal Epidemiology Centers, which provide local surveillance and infrastructure support for communities to build capacity to respond to public health emergencies. The Office also worked with NIAID on COVID-19 vaccine trials. THRO has also worked closely with Dr. Rodgers, Dr. Germino, and others in the NIDDK Intramural Research Program.

Since THRO was established, NIH has increased its investment in Tribal health research, not only in the size of the budget, but also in synergistic efforts across Institutes and Centers. Looking at numbers from the 2018 analysis, NIH was investing roughly \$180 million annually in AI/AN research from fiscal year 2015 through fiscal year 2018. In fiscal year 2018, that \$180M supported 254 research-based projects specifically focused on AI/AN health or community resource needs. More than three-quarters of that investment came from 10 ICs and the Office of the Director. The investment was split among research (43 percent), infrastructure and community outreach (30 percent), and workforce development (28 percent). Since 2018, NIH's investment in AI/AN research has grown to over \$350 million annually.

THRO recognizes that data sharing and data management are priorities for Tribal communities and other underrepresented communities in the country, and the Office works with the NIH Office of Science Policy to identify upfront the protections needed to ensure that data will not be used unethically. Dr. Wilson pointed out that Tribal communities are not against participating in research, but they want to limit the amount of stigmatizing and unethical research that may come from their participation in research and the use of their data. An NIH-initiated Tribal Consultation aiming to solicit input from Tribal Nations on responsible data management and sharing resulted in a report recommending strengthening engagement built on trust, training researchers, and aligning research practices with Tribal laws, policies, and preferences. Additionally, a new NIH Tribal Consultation Policy was released on March 17, 2022, recognizing the unique concerns of AI/AN communities regarding data sharing and providing a road map for how to consistently engage Tribal communities.

As an example, Dr. Wilson described the N3C, a community-driven initiative that allows research teams nationwide to study clinically important questions about COVID-19. Webinars held with Tribal communities prior to the research project helped explain how N3C data would be used and led to beneficial feedback. A Tribal Consultation for the Helping to End Addiction Long-Term (HEAL) Initiative also identified Tribal research priorities as well as how to engage with AI/AN communities to speed

development of scientific and local solutions to the opioid crisis.

A challenge shared by many NIH ICs is how to ethically include urban AI/AN populations who do not live on Tribal lands. He explained that when people live on a land base that is a sovereign nation, researchers must abide by the laws and conventions of that nation. However, more than 70 percent of AI/ANs live in urban areas and it is not clear how Tribal laws and sovereignty apply to these communities. THRO is working with Native American academics and the NIH Tribal Advisory Committee to develop guidance that will provide more clarity about how to expand research projects into these communities.

A key element to addressing health in AI/AN communities is responding to the health concerns and interests in Tribal communities and supporting ICs that are attempting outreach. THRO has conducted and featured on their website interviews with NIH leaders on topics of interest to AI/AN communities, which serve as a platform for Tribes to better understand the work of Institutes across the NIH. A future interview will feature Dr. Rodgers.

Another THRO focus is training and career development opportunities that foster the next generation of AI/AN biomedical research scientists. The NIH summer internship program is a good example of this. Before the pandemic, this program included study on the NIH campus as well as a visit to Congress so interns could learn about the funding process and their role as advocates for research within their communities.

THRO has been encouraging other NIH programs to gather community input on research. For example, the NIH Common Fund held community listening sessions for Tribal communities and organizations to help identify solutions and inform about the development of interventions to address health disparities and advance health equity. The sessions identified barriers to Tribal participation in research, such as the issues related to internal review boards (IRBs), which are not funded and rely on volunteers, a model that is not sustainable in many communities.

Dr. Wilson stated that a big part of the THRO's Strategic Plan is focused on communication. THRO helped address misinformation during the pandemic with clear, culturally appropriate, and responsive communications developed for Tribal communities that had a positive impact on vaccine uptake. THRO uses both Facebook and LinkedIn to reach communities, especially with information about career opportunities in research. However, in many communities, internet access is not consistent, and radio is still the best way to reach people, especially elders. A radio media tour with Dr. Fauci reached more than 2 million people through Native American radio stations.

Dr. Wilson explained that part of cultural awareness and community engagement involves increasing awareness within the research community of traditional ways of healing and how cultural adaptation can benefit research. For example, last year as part of Native American Heritage Month, Dr. Don Warne of the University of North Dakota gave a presentation on the Interconnectedness of Culture and Science.

THRO was very involved in COVID-19 vaccine development, working with various

federal agencies to provide Tribes with information about protocols and other aspects so that they could make the decision whether to participate in the vaccine trials. Tribes also reviewed communication materials for the vaccine trials to ensure they would be received well by the communities. This process led to groundbreaking data-sharing and biological specimen-sharing agreements between pharmaceutical companies and Tribal communities that wanted to participate in the phase III clinical trials. This includes a Data, Material, and Biospecimen Sharing and Ownership Agreement template created by Tribal lawyers to give researchers a clearer idea of Tribal concerns about research participation.

The overarching goals of the THRO's efforts are to respect the sovereignty of tribal nations and to work together with transparency and clear communication as equal partners in biomedical research. Dr. Wilson referred the Council to the THRO website, Facebook, and LinkedIn pages for more information.

Council Questions and Discussion

Comment from Council: *What can we do to get the word out more to researchers about data sovereignty and how to respectfully handle data obtained in Tribal communities?*

Dr. Wilson hoped that educational sessions at the time of the release of the new Data Sharing and Data Management Policy in early 2023 will help address this gap.

Comments from Council: *There is controversy among researchers around engaging urban Native Americans in studies because they haven't gotten Tribal consent to share genomic information. There are also questions about how representative urban Native Americans are of their tribes. The challenges of recruiting urban Indians into research projects has led to great under-representation of Native people within clinical trials.*

Dr. Wilson recognized the work that Dr. Rodgers and Dr. Germino are doing with THRO to extend research opportunities for community members who receive health care through the Indian Health Service. However, he warned against expecting a quick fix.

Dr. Wilson said that engaging each of the individual Tribes is important. Some have had positive experiences and are open to their members participating in research. Others have not had positive experiences. Creating inclusive environments and protocols that support ethical research and result in benefits for the communities will help encourage other Tribes to participate.

Comment from Council: *How large is the high school program that aims to encourage AI/AN investigators? What are you doing to encourage them to continue their studies and go into research?*

Dr. Wilson said several programs are in place. They are currently developing regional training hubs that provide opportunities for research institutions to partner with a community and give high school juniors and seniors a six-week experience in research in a variety of disciplines. Three regional hubs have been established, and THRO has requests for five more to be set up and is currently looking for IC partners. THRO is

also working with the National Institute of General Medical Science's Science Education Partnership Award (SEPA) program that focuses on K-12 students' science literacy and engagement.

THRO is also working with IC partners to provide opportunities for PhD students who want to become post-docs and pursue tenure-track positions at the NIH. While the pandemic has set back in-person opportunities, they are getting back on track now.

VII. UPDATE: HEALTH DISPARITIES AND HEALTH EQUITY WORKING GROUP *Dr. Gregory Germino and Dr. Pamela Thornton*

Dr. Rodgers introduced Dr. Germino and Dr. Thornton to give an update on the Health Disparities and Health Equity Working Group which was established after the Council Forum on Underrepresented Investigators and Underrepresented Science. Plans for the group's structure and process were announced at the January Council meeting.

Dr. Germino reviewed how the Working Group complements NIDDK's Strategic Plan published in December 2021, with an overarching theme to empower a multidisciplinary research community, engage diverse stakeholders and leverage discoveries of connections among diseases across NIDDK's mission to improve prevention, treatment, and health equity to pursue pathways to health for all. The Working Group, established in January 2022, complements the Strategic Plan with the goal to recommend specific research activities to address health disparities and health equity and incorporate the perspectives of community members and patients and identify ways to measure and track progress over time.

The Working Group is organized into five scientific themes and subgroups:

1. Engaging communities and building sustainable partnerships
2. Understanding social determinants of health (SDoH) effects on the biology of health and disease
3. Interventions to address SDoH effects, eliminate disparities, and improve health
4. Addressing upstream causes of SDoH and health disparities from an NIDDK perspective
5. Listening to community perspectives

Since the last presentation, the group has added a new component to the preliminary outline for the report that will come out of the Working Group. This section will articulate a series of values and guiding principles, definitions, and potential frameworks to guide NIDDK's health equity efforts. The full outline stands as follows:

- Introduction
- Background
- Guiding principles, frameworks, and definitions to guide NIDDK's health equity efforts
- High-impact, actionable research recommendations (by subgroup)

- Strategic research opportunities across mission areas
- Immediate, mid-, and long-term goals
- Implementation needs
- Metrics for progress and success, and accountability
- Conclusions
- Appendices
 - Planning process
 - Roster

The initial subgroup meetings have focused on high-impact, actionable research recommendations, including strategic research opportunities, and some groups have started to lay out immediate, mid-term, and long-term goals. Future meetings will work on the other aspects of the outline.

Dr. Thornton explained that each subgroup has at least one community member who also participates on the Steering Committee of the working group. Subgroup 1, which focuses on engaging communities and building sustainable partnerships, has three additional community members. She also mentioned that Subgroup 5 (community perspectives) is fully composed of individuals living with, at risk of developing, or caring for someone with diseases and conditions within NIDDK's mission.

She then reviewed Subgroup 1's goals, which include to:

- Identify effective engagement strategies to enhance participation in all phases of research by communities that experience disproportionately worse health outcomes
- Propose strategies to create and sustain partnerships for research by building trust
- Identify strategies for developing community-driven research priorities

Dr. Giselle Corbie, co-chair with Dr. Robert Rivers, then introduced the key questions and themes that this subgroup is considering. These include:

- What activities and values help create and sustain trusting collaborations between communities and researchers?
- What practices, strategies, and methods are effective in ensuring equitable and balanced partnerships with communities in research activities?
- What people, professions, or organizations hold trust with the community that NIDDK should include in its research efforts?

She then reviewed key themes emerging from these questions. To build trust in collaboration, the subgroup emphasized power-sharing and co-ownership, mutual respect, and equal voices in all stages of the research process. She emphasized bidirectional education, capacity building, and engagement that ensures the integration of community perspectives and values in the dissemination of results beyond scientific publication. She also urged practices, strategies, and methods (including alternate funding structures) that encourage investigators to build long-term community

relationships. A sequence of grants, rather than one-time grants, may allow for trust building, collaboration, and dissemination of results and replication of models.

To advance health equity, research teams should identify healing or health-related opportunities for individuals who may be disenfranchised or historically marginalized from healthcare settings, rather than focusing on narrowly defined research objectives. The subgroup also suggested that NIDDK engage trusted partners such as community health workers and patient advocates in both geographic and online communities, faith-based groups, and civic groups.

Next, Dr. John Carethers, co-chair of Subgroup 2 with Dr. Jenna Norton, introduced subgroup 2, focusing on understanding SDoH effects on the biology of health and disease. The group initially had seven external experts, but several had to resign because of competing demands. Dr. Keith Norris and Dr. Sherita Hill Golden have since joined the group. The group's goals include:

- Identify biological factors affected by SDoH
- Examine how these factors contribute to disease development, severity, and long-term outcomes
- Identify biological consequences of intergenerational stressors and their long-term impact on health and risk of disease
- Identify promising intervention targets for prevention and treatment

The group initially considered questions such as:

- What biological questions are ready for exploration at the intersection with health disparities? (e.g., chronic stress and metabolism studies)
- What are promising stress prevention and treatment studies to pursue?
- Are there reliable biological markers that are responsive to differences in SDoH? Are there methods to quantify differences in lived experience?
- How can we ensure biological specimens are available from diverse communities?

This spurred the group to pose several research questions, such as how biological behavior and social factors interact to affect the biology of disease and resilience by looking at geographical variations in outcomes and the relationships between race and metabolites as well as among structural racism, discrimination, and disease stigma. This may include looking at the biological processes of stress and metabolism and considering how this may influence the risk and treatment of diseases within NIDDK's mission. Because SDoH can lead to stress which raises the risk for certain diseases, can stress management interventions such as mindfulness and physical activity and time in nature affect NIDDK outcomes?

Addressing these research questions requires consideration of various infrastructure considerations. It requires diverse participation in terms of ancestry, race/ethnicity, sexual orientation, gender identity, socioeconomic status, and co-existing conditions, as well as broad collaboration among patients, community members, organizations,

governmental agencies, and transdisciplinary research approaches. Big data and machine learning will play a role, especially ensuring diverse inputs to ensure the applicability of the data across situations. Dr. Carethers also pointed out that, without a way to measure structural racism, it is difficult to show the impact of potential interventions.

Dr. Thornton then introduced Subgroup 3, adding that the subgroup's title has been slightly revised from "Interventions that lessen the effects of SDoH to improve health" to "Interventions to address SDoH effects, eliminate disparities, and improve health". This change has been made in response to feedback from the co-chairs of this group to reflect that SDoH can be beneficial or harmful. The goals of the group remain the same:

- Identify interventions that help people overcome adverse SDoH to improve health
- Meet individuals "where they live, work, play, learn, and pray" to understand strengths, resources, and challenges in their environments
- Examine healthcare- and community-based supports that will improve equitable access to health-promoting services and care

Dr. Debra Haire-Joshu, co-chair of the subgroup with Dr. Mary Evans, then reviewed the themes that have emerged from the group's consideration of the following questions:

- What are research opportunities regarding interventions that integrate screening for social needs into medical care, leveraging telemedicine opportunities, or embedding lifestyle or other interventions into existing local or national social services or community programs?
- What research is needed on intensifying and providing "between visit" care for NIDDK diseases or conditions in order to prevent, treat, or address their complications
- What research is needed to improve uptake and implementation of appropriate clinical practice guidelines?
- What approaches could better address structural racism or bias (implicit or explicit) in healthcare?

The group's discussions have considered screening for and addressing social needs such as food insecurity, transportation, childcare and whether these are best addressed together or one at a time. They also considered the differences between short-term crisis relief and long-term interventions.

Specifically, they considered care delivery systems, such as telehealth, which emerged as a short-term intervention during COVID-19 but appears to have some advantages as well as the potential to further contribute to disparities. What are other ways to deliver between-visit care, especially in under-resourced communities? They also addressed sustainability and developing trusted partnerships that do not put additional burdens on organizations.

Another topic centered on capturing and monitoring information. How do apps and

other technology-based tools work with diverse and under-resourced populations? How can we apply solutions equitably? This led to discussions of implementation science and context and methods that help increase understanding of what works in which situations and who it works for. Do we need to redefine success through a health equity lens? For example, the Diabetes Prevention Program has proven more effective in some groups than others. Looking at this through a health equity lens could lead to better understanding of why this is.

They also discussed approaches to addressing structural racism and bias in healthcare, including what constitutes an effective training and ways to evaluate curricula and outcomes.

Themes that have come out of these discussions include:

- **Implementation and resource needs**, including engaging stakeholders (including non-healthcare sectors and organizations) in research without overburdening them, and new multi-level approaches that apply implementation science methods that consider both individuals and communities
- **New tools or methods to advance the field**, including common measures and validated methods for looking at structural racism and SDoH, such as socioeconomic status and education level, and approaches to interrogating large datasets to build algorithms to predict disease risk and health outcomes
- **Infrastructure and training needs**, including disparities in access to technology and technology-driven interventions, and scalable training opportunities for investigators to better understand how delivery approaches can reverse systemic biases in healthcare and best practices for conducting science in a way that eliminates disparities.

Dr. Thornton then introduced Subgroup 4, which focuses on addressing upstream causes of health disparities through an NIDDK lens. This group's goals include identifying ways of understanding/addressing systemic barriers to health equity, and also identifying partnership opportunities to test natural experiments or pilot programs to inform policy and healthcare practices.

Dr. Marshall Chin, co-chair of this subgroup with Dr. Shavon Artis Dickerson, then presented highlights of the group's discussions so far, connecting them with themes that have emerged from the other three subgroups. Subgroup 4 considered four questions:

- What foundational work is needed to prepare and advance this field of research? (*e.g.*, partnership development, metrics)
- What multi-sectoral research models have been effective? What were the key components?
- What major policies/programs have been tested with intended or unintended effects? What existing policies/programs should be evaluated?
- What activities or forums could NIH/NIDDK create or join to continue planning for and participating in upstream research?

From those questions, the group came up with 25 different issues, factors, and themes that clustered in seven areas. Dr. Chin acknowledged that some of these topics are also

under discussion by other subgroups, especially Subgroup 3, but that some overlap is both inevitable and potentially advantageous. Many of these issues require a multi-level approach that connects upstream social determinants with interventions that address them and their impact on individuals and populations.

The macro-themes identified by Subgroup 4 include:

- Cross-levels of influence, from individual to societal
- Inclusion of many populations experiencing inequities (e.g., race/ethnicity, gender, LGBTQ+, persons with disabilities, etc.) in research design and participation
- Intersectionality of systems of oppression (e.g., race/ethnicity, gender, socioeconomic status)
- Anti-racism/discrimination/bigotry lens capturing structural inequities
- Umbrella health determinants include economics and systems of oppression
- Community engagement/patient voice
- Building evidence requires mixed methods and diverse research designs tailored to context

He suggested that a contribution that NIDDK can make in this area is to explore the relationships and intersectionality between the different factors that contribute to diseases in the NIDDK domain as well as the populations that experience inequities by race/ethnicity, gender, sexual orientation, disability, or other minority status. He pointed out that looking at one system of oppression in isolation is too simplistic. For example, issues affecting poor Black women have both similarities and important differences from those affecting poor White women or poor Asian American immigrants. Subgroup 4 felt strongly that research programs should reflect the complexity of the real world.

He also emphasized the importance of community engagement and the patient voice in research. While many organizations include this theme in their mission statements, it is often the first thing cut due to budget or time limitations.

He also warned that traditional study designs—including the gold standard of the randomized controlled trial—may be too narrow and that combining quantitative and qualitative research in a mixed-methods approach or engaging in natural experiments, observational studies, and transdisciplinary approaches should be explored, especially when studying SDoH.

Dr. Thornton then introduced the new subgroup that focuses on community perspectives. Co-chairs of this group include community member Arthur Johns working with Drs. Katrina Serrano and Voula Osganian, and Dr. Saira Mehmood as lead facilitator. The goal of Subgroup 5 is to gather input from people living with or at risk of NIDDK diseases and conditions as well as caregivers. Members of this group have agreed to share their health and healthcare experiences, their perspectives on research needs and priorities, and details about their social and community contexts. To build this committee, NIDDK recruited 15 volunteers with diverse experiences with NIDDK diseases and conditions as well as diversity in age, sex, gender, race and ethnicity, lived experiences, and geography.

Dr. Thornton then reviewed the process for this group, including one-on-one calls before meetings to gather initial input and suggestions, preview of discussion questions and orientation kick-off built into the first meeting, and opportunities for members to give additional feedback after the meetings. The group will meet three times. The first meeting, which has already taken place, focused on welcome and orientation. The second will seek input on the preliminary themes, and at the final meeting, members will give feedback on the draft plan.

Mr. Johns explained that, at the first meeting, the subgroup broke into two smaller groups of six members with a facilitator and a notetaker. The breakout groups considered the following questions:

- What does living a healthy life look like? What resources (in your community or elsewhere) help you live a healthy life? What would help you manage the disease/condition you (or your family member) have been diagnosed with?
- What is your biggest barrier to living a healthy life? What kind of strategies, interventions, or resources would help you overcome this barrier?
- What policies or programs help you most with your health or well-being? What local, state, or federal programs do you or people in your community use a lot or are needed to help improve your health?
- What strengths exist in your community? What do your communities need help with? What trusted people or organizations should NIDDK be sure to partner with in research?

He explained that they were still processing the results of the discussion, so the below list of emerging themes may not be complete at this time.

Supports for healthy living: Mr. Johns emphasized that each person's experience is different but essential supports may include:

- Access to fresh fruit and vegetables, transportation, green spaces, and affordable health care, the last being particularly important for those with complex health conditions
- Education/health information on how to manage health conditions
- Technology (social media and smartphone apps including personal health records and ways to communicate with providers)
- Meeting basic needs, including safe and affordable housing and safety in general
- Having a balanced diet and ways to exercise as well as appropriate education on these topics
- Time management techniques
- Community unity and programs that promote health and healthy living, such as community walks and gardens at low or no cost

They also discussed **barriers to healthy living**, including:

- Unsafe communities/neighborhoods, which cause stress and limit opportunities for physical activities

- Under-resourced communities, including those with a lack of transportation options and nearby grocery stores
- Inconsistent access to employee healthcare benefits and leave policy/flexibility so that workers can access care without losing income or threatening their job retention
- Lack of health care, especially access to specialty care and “world class centers”, that does not require hours of travel time
- The need for self-management of disease/health and lack of support and strategies for people to manage their own conditions and manage medications
- Negative impact of “medical trauma,” including the stress of seeking care and negative healthcare experiences

The groups also discussed policies and programs that communities, professional organizations, and governments can offer to support healthy living, including community-driven health education and promotion programs with achievable health goals and helpful resources, and programs offered by organizations such as the American Diabetes Association as well as government programs such as WIC. He noted that eligibility and access to these programs varies based on where you live and other factors.

Dr. Germino thanked Mr. Johns and the other subgroup leaders for their work on this project so far. He then opened the floor to questions from Council members.

Council Questions and Discussion

***Comment from Council:** Is it possible to offer use-case scenarios or examples of NIDDK-funded projects that engaged communities in explorations of the biological inputs of social determinants of health on disease and also offered something back to the communities? This may help researchers structure proposals around complex, intersecting, and important concepts. Thinking about it now rather than later may give insights into the sensitive issues, opportunities for strategic planning, and how best to make an impact.*

Dr. Germino said that the Steering Committee will consider this.

***Comment from Council:** How can NIDDK address the need for affordable housing and resources in the community? Does that involve outreach to legislators who have more control and can make a difference in those areas?*

Dr. Germino explained that, as a research organization, NIDDK can look at the effects or intersection of policy and health but can’t directly contact legislators or negotiate on behalf of communities. Communities, however, can reach out to legislators and, as NIDDK looks at upstream causes, it can offer an evidence base of interventions that have been tested or are being tested to evaluate impact on communities and community health.

Dr. Star mentioned that meetings have taken place with leaders from the NIH, the Patient-Centered Outcomes Research Institute (PCORI), and the Department of

Housing and Urban Development (HUD) to more fully evaluate the medical outcomes of HUD's housing programs. HUD leaders are trying to address them. Although NIH and NIDDK cannot address housing issues directly, interventions at the intersection of housing and health can have an impact.

***Comment from Council:** We need to balance aspirations of what we hope to achieve with setting appropriate expectations for these initiatives. This is important to prevent communities and junior researchers from becoming disenchanted when these interventions do not have a specific impact they hoped for.*

Dr. Germino agreed that this is sound advice, considering NIDDK has a limited budget and limited authority in these areas. However, it is still important to identify the issues and look for solutions to test. These are substantial issues to tackle, but one has to start somewhere.

Dr. Germino then asked Council members to submit any other comments to the Steering Committee, which will funnel them to the subgroups for discussion, as appropriate.

He closed by thanking all the NIDDK members of the Health Disparities and Health Equity Working Group and reviewed the timeline for the project. The Steering Committee, subgroups and working groups are all scheduled to meet over the summer. The group will be writing the implementation plan over the summer and hopes to give the Council a brief update in the fall. The draft will be shared publicly in the late fall with a goal to present it to the Council in January before spring 2023 publication.

VIII. CONCEPT CLEARANCE

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

The meeting included descriptions of 30 concepts total from the Division of Kidney, Urologic, and Hematologic Diseases; the Office of Obesity Research; the Division of Digestive Diseases and Nutrition; and the Division of Diabetes, Endocrinology, and Metabolic Diseases, as well as concepts for the Special Diabetes Program and Trans-NIDDK concepts.

Division of Kidney, Urologic, and Hematologic Diseases Concepts

Various KUH staff members as indicated presented these concepts on behalf of the Division. (Presenter name is included after the concept title.)

- **Comprehensive Assessment of Renal function (COAR), Dr. Afshin Parsa:** Modern medicine lacks reliable tools, methods, and procedures for comprehensive and dynamic assessment of renal function that is inadequately captured by the GFR estimation, is inclusive of all renal compartment-specific functions, and accurately measures diverse states, physiologic processes, and

disease pathologies. This lack has significantly limited our ability to adequately determine clinical phenotype in individuals with acute or chronic kidney disease. Consequently, we are mostly unable to match clinical measures of renal function to underlying disease processes, which is limiting progress in both research and clinical practice. Accordingly, the overarching goal of this initiative will be to establish a reliable and comprehensive set of renal function measurement approaches and tools that accurately assess the entirety of renal functional state, reserve, and trajectory, and is optimized to diverse clinical conditions.

- **Towards a Personalized Approach to BPH/LUTS: Connecting Molecular Pathology to Lower Urinary Tract Symptoms, Dr. Ziya Kirkali:** This initiative is to support an initial workshop to engage stakeholders from across the spectrum of Benign Prostatic Hyperplasia (BPH) research and its connection to Male Lower Urinary Tract Symptoms (LUTS). Patient perspectives will be included to focus the research agenda on outcomes central to BPH/LUTS patients and their partners. Ultimately, the workshop will inform the establishment of a multi-site cooperative agreement to recruit a selected cohort of men with BPH/Bladder Outlet Obstruction (BOO)-associated LUTS. Molecular interrogation of biopsy tissue will be coupled with deep clinical phenotyping to permit the identification of subtypes of men with BPH/LUTS to develop personalized approaches for management. Although there have been important advances in the management of BPH patients in the last two decades, we still do not know which patient characteristics will lead to a successful outcome after an intervention, and who will not benefit or meet their symptom resolution expectations following obstruction relief. The workshop and follow-up Funding Opportunity Announcement (FOA) will foster research efforts combining epidemiology and integrated biological assessments to identify clinically relevant BPH patient subgroups. A precision approach to identification of subgroups based on symptoms and pathophysiological features will allow for improved, patient-centric, clinical outcomes and targeted intervention in trial designs and ultimately in clinical practice.
- **Clinical Trials to Inform Management of Urologic Chronic Pelvic Pain Syndrome Study (COMPASS), Dr. Christopher Mullins:** Urologic Chronic Pelvic Pain Syndrome (UCPPS), characterized by pain in the pelvic region usually associated with diverse urologic symptoms, is widely prevalent and highly debilitating for both men and women. Despite numerous past clinical trial efforts, there are currently no broadly effective therapies and clinical management is often based on trial and error. COMPASS as proposed will leverage critical new insights into patient phenotypes and associated clinical and biological contributors from the NIDDK's MAPP Research Network and the broader field to conduct a series of novel clinical trials for UCPPS that overcome limitations of traditional trial designs. The COMPASS program founded in this evidence-driven approach is expected to provide critical progress in defining new and effective clinical management strategies for UCPPS.
- **Novel Software Tools to Identify New Pathways of Blood Disease Development using Existing Genomic Datasets, Dr. Cindy Roy:** This funding opportunity will combine access to existing patient datasets and developmental 'omic resources with innovative, more widely applicable, software tools for identification of novel disease pathways, especially in non-malignant hematologic

diseases. We expect that the development of new software tools for genotype-phenotype analyses and disease pathway identification will provide junior investigators without current preliminary data unique opportunities to develop independent research areas in novel pathways elucidated from these datasets. We propose an initial “biohackathon” to build some of these software tools the year before the grant opportunity, to introduce data scientists to the hematology community, and to foster a hematology data science community.

- **KUH Training Coordinating Center: Fostering the Advancement of an Inclusive Learning Community (KUH FAMILY), Dr. Victoria Spruance:** The overarching goal of the KUH FAMILY Training Coordinating Center is to provide a home for all KUH trainees and junior investigators. This initiative is intended to build on the momentum being generated by the U2C Institutional Network Awards, the R25 KUH Summer Undergraduate Research Experience Awards, and other KUH-sponsored scientific consortia and training mechanisms that are actively recruiting an increasing number of trainees into the KUH space. To better engage these new cohorts of trainees and retain them in the KUH community, the KUH FAMILY will provide opportunities for trainees to: 1) connect with other trainees across the nation via a national peer-to-peer network, 2) access the growing number of novel, modernized career development resources generated by the KUH FAMILY and U2C Institutional Network Awards, and 3) compete directly for funding to support their training and research projects via the KUH FAMILY opportunity pool. In addition, the KUH FAMILY will provide support to ongoing institutional training programs, such as the U2C and R25 awards, to coordinate annual meetings, large-scale program evaluations, and continuous improvement activities.

Next, **Dr. Robert Star** presented five KUH renewal concepts:

- **Renewal of Advancing Clinical Research in Primary Glomerular Disease (Cure GN):** This initiative supports observational and translational research to better understand the natural history of the primary glomerulopathies (GNs) in a range of adult and pediatric individuals; understand clinical and molecular factors associated with varied outcomes; and to provide a platform for further study of GNs via ancillary studies that harness data and biosample collections for discovery of underlying causes and treatment targets. Continued support will be essential for sufficient follow up of enrolled participants; to adequately observe and capture the slowly progressive remitting and relapsing nature of these rare diseases; to identify disease subgroups; and to capture enough events to understand divergent clinical outcomes.
- **Renewal of the United States Renal Data System:** This proposed initiative renewal is to continue to provide a data resource on incidence, prevalence, mortality, and cost of kidney disease in the United States, satisfying a Congressional legislative mandate (OBRA 1986). This resource provides an invaluable resource for renal epidemiologists and colleagues in other government agencies, as well as providing a ready access to data for young investigators.
- **Extension of LURN: Research Network in Symptomatic Lower Urinary Tract Dysfunction:** The NIDDK’s Symptoms of Lower Urinary Tract

Dysfunction Research Network (LURN) seeks to improve our understanding of urinary urgency and associated symptoms so that it can be better diagnosed and more effectively treated in the adult population. A 3-year extension of the LURN is proposed to fully meet the enrollment targets and participant follow-up for the LURN clinical protocol and to allow for resources for data analysis and dissemination of study findings. Successful completion of the LURN Urinary Urgency Phenotyping Study will provide key insights that are expected to directly inform improved clinical management strategies for these common urologic symptoms.

- **Renewal of UDA: Urologic Diseases in America (Epidemiology of Urologic Disease) UroEpi:** This renewal will provide a resource for the research, lay, and clinical community for the descriptive epidemiology of non-malignant (“benign”) urologic diseases and disorders. This resource will serve as a critical platform to understand the burden of these diseases and disorders and for young investigators to acquire investigational skills in urologic epidemiology.
- **KUH Summer Undergraduate Research Experience Program:** This mechanism to support early outreach to undergraduate students and bring these young, talented trainees into the KUH research community seeks renewal. Selected undergraduate students participate in a 10-week hands-on research experience, paired with appropriate didactic training in the areas of kidney, urologic, and hematologic sciences. These programs culminate in a national symposium, where all R25 program participants come together to share their research accomplishments. Early evaluation data demonstrate that a vast majority of participants go on to receive advanced STEM degrees or are otherwise retained in the STEM workforce, and several remain in the KUH research community.

Office of Obesity Research Concepts

Dr. Maren Laughlin presented a single concept for which the Office of Obesity Research Concepts is requesting an expansion.

- **Physiology of the Weight Reduced State (POWERS) Expansion to Assess Biospecimens:** The purpose of this initiative is to expand the POWERS clinical trial consortium funded via RFAs DK-19-017 and -018, to allow for molecular analysis of tissues (blood, muscle, adipose and stool) collected during the study. POWERS is focused on elucidation of the metabolic, behavioral, and molecular mechanisms underlying individual variability in maintenance of reduced weight over time.

Dr. Rodgers then invited Council members to ask any questions related to the KUH or Office of Obesity Research concepts.

Council Questions and Comments

***Comment from Council:** Regarding the POWERS study, will researchers collect data on participants’ starting diets? We know pre-weight loss diets influence whether someone can maintain weight loss.*

Dr. Loughlin responded that the goal is to measure the full spectrum of inputs into the weight-reduced state, including participants’ diets. The study will also consider other

inputs, such as dietary recalls, observed meals, sleep, physiology, exercise, and energy expenditure.

Comment from Council: *We heard about the clinical aspects of chronic pelvic pain in the COMPASS program, but what progress has been made on the basic science side?*

Dr. Mullins replied that, although his presentation was limited to clinical interests, the work of the MAPP Network and NIDDK's R01 portfolio have yielded many advances in understanding underlying mechanisms, as well as the involvement of neurobiology and the immune system. Additionally, the NIDDK Central Repository is collecting biological samples associated with complex clinical data to support new studies going forward.

Dr. Star added that there is currently controversy over which animal models are preferred in this research space. He suggested the possibility of organizing a targeted meeting that includes animal modelers to review the new clinical data and make recommendations regarding preferred animal models going forward.

Division of Digestive Diseases and Nutrition

Various staff members presented concepts on behalf of the Division. (Presenter name is included after the concept title.)

- **Ingestible Gastro-Intestinal Sampling, Monitoring and Delivery Tools/Devices for Advancing Microbiome Research, Dr. Dwayne Lunsford on behalf of Dr. Padma Maruvada:** Altered microbial composition and metabolism have been implicated in a variety of both communicable and non-communicable diseases including diabetes, obesity, inflammatory bowel disease (IBD), and cancer. However, translating knowledge of microbiome research to impact health in humans remains largely an unmet goal. The exact nature and overall biogeography of human GI mucosal and microbial interactions are not well defined, and analysis of feces as a proxy for microbial composition and function does not truly reflect the regional host-microbe community interactions. Development of non-invasive, ingestible devices/tools for collection of samples and data for mechanistic exploration of GI microbiota interactions in clinical cohorts is needed to advance the field. This initiative seeks to support the development of ingestible tools/devices that enable sampling of luminal and mucosal contents (both host and microbial components), detecting and/or monitoring site-specific microbiome-host interactions.
- **The Liver Tissue and Cell Resource Center (LTCRC), Dr. Jose Serrano:** To understand the pathophysiology of the diseases leading to end-stage liver disease, it is essential for researchers to have access to liver tissue and cells from a variety of liver pathologies as well as normal livers. Moreover, these specimens are limited and prohibitively expensive on the commercial market. To address the limitation imposed on liver research by the lack of suitable normal and pathologic human liver tissue and cells, NIDDK has supported the procurement and distribution of liver tissue since 1986 and this concept would continue this investment.
- **A Consortium for Gut-Brain Communication in Parkinson's Disease, Dr.**

Terez Shea-Donohue: Treatments for Parkinson’s disease (PD) target only symptoms as no therapies exist for the neurodegeneration seen in this disease. More than 50% of patients who develop PD have a history of bowel complaints, predominantly constipation, gastroesophageal reflux, and nausea, which often precede the onset of motor symptoms. These findings indicate that GI dysfunction may be an early manifestation of the disease and that the gut may be an unexplored diagnostic and/or therapeutic target. Progress in gut-brain axis requires an infrastructure to support a multidisciplinary approach between investigators in neurology and gastroenterology. In addition, research into the temporal relationship between GI symptoms and disease progression in PD needs larger and longitudinal collections of patient data and biospecimens. This new initiative’s goal is to accelerate research progress by promoting partnerships across siloed clinical disciplines to investigate the gut’s role in the etiology and progression of PD. Research in this area may also apply to other neurodegenerative disorders that involve GI tract dysfunction.

Next, **Dr. Steve James** listed four additional concepts that were to be presented in more detail at the DDN Subcommittee open session:

- **Renewal of the Nonalcoholic Steatohepatitis Clinical Research Network**
- **Renewal + Extra Contribution to the NCI’s ASA-24 Self-Administered Dietary Recall Tools**
- **Renewal of Childhood Liver Disease Research Network (ChiLDReN)**
- **Expansion of Liver Cirrhosis Network**

Next, Dr. James opened the floor for Council questions on the DDN concepts.

Council Questions and Comments

***Comment from Council:** Regarding the Liver Tissue and Cell Resource Center, can you get the patient’s open consent by including a checkbox on the donor form? This way their genomic data would be open access.*

Dr. Serrano responded that these are deceased donors, not living patients.

***Comment from Council:** Is the Consortium for Gut-Brain Communication in Parkinson’s disease solely a clinical opportunity, with no animal modeling involved?*

Dr. Shea-Donohue replied that the actual form of the initiative is yet to be fully decided since it is currently in the concept stage. Dr. James added that, in general, NIDDK focuses on identifying the most important gap in the science of any issue or topic. In this case, the biggest gap is the lack of collaborative interactions between gastrointestinal-oriented scientists who have access to human gastrointestinal tissue and the neuroscience community, so funds will be focused there. NIDDK will continue to encourage research of all types in this area, including research that uses animal models.

***Comment from Council:** How will the ingestible sampling device mentioned be designed?*

Dr. James explained that this is best considered an engineering exercise and NIDDK's first foray into taking advantage of micro technologies in development. Several companies are developing innovative micro-platforms that can focus on the microbiome and metabolomics in an attempt to successfully access the tissues of the small intestine under more normal physiological conditions than are accessible by current methods.

Division of Diabetes, Endocrinology, and Metabolic Diseases Concepts

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

(Presenter name is included after the concept title.)

- **Integration of Novel Measures for Improved Classification of Type 2 Diabetes, Dr. Norann Zaghoul:** Type 2 diabetes (T2D) represents a “catch-all” diagnosis in which patients are grouped according to relatively simple measures of glycemia, irrespective of the underlying pathophysiology driving elevated blood glucose. Given that hyperglycemia can result from dysfunction in a number of organs and/or tissues, defining patients based on their specific defects will greatly improve understanding and management of disease. To better define the heterogeneity of T2D and stratify patients based on underlying mechanisms, more comprehensive approaches are needed that would integrate markers of organ- or system-specific dysfunction with clinical and molecular phenotyping. This initiative proposes to bring together investigators that have identified reliable measures of organ- or system-specific dysfunction in T2D with patient cohorts that have extensive clinical and/or molecular data. Development of novel markers of organ function in T2D will also be incorporated.
- **Cystic Fibrosis Related Diabetes (CFRD): Advancing Pathophysiologic Understanding and Clinical Treatment, Dr. Tom Eggerman:** Cystic Fibrosis (CF) is one of the most common, life-limiting genetic diseases. Cystic Fibrosis Related Diabetes (CFRD) is a poorly understood and clinically significant complication that affects about half of adult CF patients. The CF Foundation and NIDDK sponsored a CFRD Scientific Workshop on June 23–25, 2021 with the goal of sharing basic and clinical research data regarding CFRD disease mechanisms and treatment and to identify key research questions and knowledge gaps that can be used to inform research priorities. Some of the major CFRD research questions/gaps raised included biologic basis, development of better model systems, ascertaining genetic risk factors, identifying biomarkers and clinical markers, and optimizing nutritional aspects. In addition, determining the effects of highly effective modulator treatment (HEMT), utilization of novel treatment approaches, and how best to optimize healthcare delivery and patient education were additional research questions. The goal of this initiative is to stimulate both clinical and basic CFRD research to address the key research questions and knowledge gaps identified during this workshop.
- **Post-Baccalaureate Research Education in Diabetes, Endocrinology and Metabolic Diseases, Dr. Barbara Linder:** Data indicate that individuals from NIH-defined underrepresented groups enter biomedical science in lower numbers, are less successful at obtaining NIH grant support and are less likely to be promoted into leadership positions. Sustained efforts are needed to increase the pipeline of individuals from underrepresented backgrounds entering graduate

programs. There are multiple complex reasons that underrepresented minorities may not pursue biomedical careers after graduation from college. One approach to addressing some of these barriers may be to establish a supportive post-baccalaureate research education program to provide interested individuals with hands-on research experience and mentoring specifically focused on preparing these individuals to apply to graduate programs and pursue research careers in science. This initiative will create a Post-Baccalaureate Research Program for Underrepresented Minority (URM) college graduates who are not competitive for admission to PhD programs due to lack of research experience during college. The long-term goal of the initiative is to develop a diverse pool of post-baccalaureate students who will transition to and complete post-doctoral degrees in biomedical areas associated with DEM and, ultimately, pursue scientific careers.

Next, Dr. Cefalu presented two renewals for the division.

- **Rare and Atypical Diabetes Network (RADIANT) Renewal:** This multidisciplinary group of investigators with expertise in diabetes, clinical phenotyping, genetics, metabolomics, and bioinformatics is active at nearly 20 sites. RADIANT is enrolling individuals and families with rare and atypical diabetes for in-depth, phenotypic and genetic analyses to help characterize new subtypes of diabetes and to provide insights on mechanisms underlying more common forms of type 2 diabetes. To date, 729 individuals have been screened and of these, 160 individuals have been found to have a new, atypical form of diabetes and were enrolled for deeper phenotyping measures and genetic analyses. Additionally, a data and biospecimen repository is being created to facilitate broader research efforts to understand heterogeneity in type 2 diabetes and to foster precision medicine efforts with more targeted diagnostics and therapeutics.
- **Human Islet Research Network Enhancement Center (HIRN-EC):** This major research initiative investigates basic and preclinical aspects of type 1 diabetes islet biology. The HIRN currently involves five consortia and, since 2014, has made 77 awards to 265 investigators with funding totaling over \$150 million dollars. Currently there are HIRN grants funded until June 2025. Planned HIRN consortia include HPAC Research Grants (2022), CTAR (2023) and CMAI/CHIB (2024). To maintain coordinating center support for current and future HIRN grants and activities, funding for the HIRN Enhancement Center is needed through at least 2028. The HIRN-EC enhances and extends the impact of research carried out by the network by providing needed coordinating, communication, and informatics support.

Dr. Cefalu then moderated questions from Council related to DEM concepts.

Council Questions and Comments

Comment from Council: Regarding the post-baccalaureate program, one year may not be long enough to sufficiently aid participants. Is this program also aimed at economically-disadvantaged students? Considerations when selecting participants could include whether a student received a Pell Grant or was the first to graduate in their family.

Dr. Linder agreed that it's important to take a broad view to increase diversity and overcome under-representation in science.

Comment from Council: Can the post-baccalaureate program done in one year instead of two?

Dr. Linder responded that sponsoring institutions would have the flexibility to do so, depending on a student's situation.

Special Diabetes Program Concepts

Dr. Cefalu invited staff members to present Special Diabetes Program concepts. (Presenter name is included after the concept title.)

- **Human Islet Research Network-Consortium on Modeling of Autoimmune Diabetes (HIRN-CMAD) (HIRN-CMAI/CHIB Phase III), Dr. Albert Hwa:** Research from the HIRN-Consortium on Modeling Autoimmune Interactions (CMAI) and HIRN-Consortium on Human Islet Biomimetics (CHIB) has made tremendous progress in establishing reagents, tools, and models to study immune-mediated diabetes. The proposed new HIRN-Consortium on Modeling of Autoimmune Diabetes (CMAD) will build upon these technologies to further our understanding of how human type 1 diabetes develops. The consortium will develop and optimize models to study how the immune system develops and deviates toward autoimmunity in T1D. These models may also be used to study triggers that begin the changes in islet cells and how that leads to immune cell interactions and beta cell mass decline. These models will also serve as platforms to test and accelerate translational T1D interventions.
- **Human Islet Research Network (HIRN) T1D Knowledgebase Program, Dr. Xujing Wang:** The exact disease etiology of type 1 diabetes (T1D) is still not fully understood, including what triggers the disease initiation, how triggering events lead to perpetuating β -cell destruction, nor how the interactions of on-site cell types contribute. This initiative proposes to develop a T1D pancreas knowledgebase, powered by systems biology. It will contain a database that maintains core datasets of the T1D pancreas, deep curated with meta data, and relevant domain knowledge in actionable forms, and a library of analytics, workflows, and computational modeling pipelines. It will offer an open science platform for scientists from multiple disciplinary backgrounds to leverage existing data, knowledge, and tools toward innovation and discovery in solving this T1D grand challenge. It will be a program under the Human Islet Research Network (HIRN), to maximally leverage its PIs, community, and collaborative infrastructure. It will engage both the T1D and the broader scientific community to contribute and to participate in governance.
- **Clinical, Behavioral, and Physiological Studies of Open- and Closed-loop Platforms: Toward Personalized, Fully Automated, Accessible Systems, Dr. William Cefalu for Dr. Guillermo Arreaza-Rubín:** This proposal will address barriers that limit progress toward physiological pancreatic hormone replacement open- and closed-loop systems. The initiative would support research to: 1) test and improve the safety, reliability, and clinical efficacy of these technologies in humans; 2) address behavioral/psychosocial factors that play a role in the

usability and acceptance of these systems and validation of measures that may be used as outcomes for the demonstration of efficacy and benefit; 3) test these technologies in subpopulations of patients not usually included in clinical trials who may benefit the most from their use; 4) test these technologies in individuals who are underserved or in low income and/or racial and ethnic minority groups, and better understand disparities in the use and adoption of these systems; and 5) use the technologies as tools to advance understanding of glucose regulation and its pathophysiology in patients with type 1 diabetes, including counter-regulation and impaired awareness of hypoglycemia.

Dr. Cefalu then opened the floor again to Council comments and questions.

Council Questions and Comments

***Comment from Council:** The new and renewal concepts have a heavy emphasis on type 1 diabetes. How do you weigh the relative emphasis of these different programs, particularly with long COVID and the anticipated increased in classic type 2 diabetes?*

Dr. Cefalu responded that DEM has started programs for new-onset, post-COVID-related diabetes, and a funding opportunity for a large youth/adolescent type 2 diabetes program was recently released. He also noted that many type 2-focused proposals presented in prior sessions are active now. Additionally, the concepts presented today include those discussed at a recent workshop on potential research opportunities appropriate for funding through the Special Diabetes Program, which is focused on type 1 diabetes. Thus, due to timing, a larger-than-average number of type 1 diabetes concepts were presented. Dr. Cefalu reiterated that NIDDK places high priority on both type 1 and type 2 diabetes research.

***Comment from Council:** How will DEM address data safety and integrity in the type 1 diabetes knowledgebase?*

Dr. Wang responded that the knowledgebase's design will be modeled on other agencies' platforms, including those from the National Science Foundation, the National Human Genome Research Institute, and the Department of Energy, and project staff will continue to carefully consider data safety and security as the project develops.

***Comment from Council:** Data science platforms are evolving very quickly. It can be easy to take several years to build a platform that will be outdated at completion. DEM needs a to build a platform that can be launched quickly and be functional, adaptable, and transformable.*

Dr. Wang thanked Council for the comment.

Trans-NIDDK Concepts

Dr. Rodgers invited NIDDK staff members to present four Trans-NIDDK concepts. (Presenter name is included after the concept title.)

- **Integration of Social and Medical Care, Dr. Barbara Linder:** Adverse social determinants of health (SDoH) disproportionately affect economically disadvantaged and minority populations and contribute to avoidable health

inequities that characterize NIDDK diseases. The U.S. is currently experiencing a transition to value-based payment models that incentivize health settings to treat the “whole person,” including SDoH. This transition represents an opportunity to effectively address SDoH through novel healthcare delivery models that extend medical care beyond clinic walls into community contexts. However, evidence for how to address social risks in healthcare settings is lacking and current implementation strategies vary across healthcare delivery contexts. This initiative will 1) jump start novel research to systematically screen for and address patients’ social risks to improve health outcomes in NIDDK diseases; and 2) grow a community of NIDDK researchers who can share effective strategies to integrate medical and social care in the context of healthcare delivery. Pilot and feasibility trials funded through this initiative will study interventions that involve screening for and addressing SDoH, through efforts to appropriately refer/navigate patients to resources to address these issues. These pilots will lay the foundation for larger, fully powered clinical trials focused on integration of social and medical care for NIDDK diseases.

- **Small Grant Program for NIDDK K01/K08/K23/K25 Recipients, Dr. Tracy Rankin on behalf of Dr. David Saslowsky and Dr. Lisa Spain:** The goal of this renewal is to enhance capability of currently funded career development award recipients (“K” awardees) to conduct research as they complete their transition to fully independent investigator status. The opportunity would support limited-scope projects that could include pilot and feasibility studies; secondary analyses of existing data; small, self-contained research projects; development of research methodology; and development of new research technology. This opportunity will provide K awardees support for short-term, limited-scope projects that will strengthen their competitiveness for a subsequent R01, or equivalent, and may provide preliminary data to support subsequent applications.
- **Development and Application of New and Existing Digital Health Technologies Including Mobile, Wearable, and Continuous Monitoring Tools for Conditions and Diseases within the NIDDK Mission, Dr. Ivonne Schulman:** Digital Health Technology has the potential to revolutionize the approach to health conditions within the NIDDK mission. Wearable and smartphone technologies enable collection of health-related data such as physiological variables, physical activity, dietary intake, sleep quality, behavioral input, and data related to social determinants of health, including environmental conditions or geolocations associated with adverse health outcomes. In addition, tools that allow continuous monitoring of biological analytes inform on the progression of a disease, response to treatment and/or management of chronic conditions. The use of such digital health technology not only provides researchers with a wealth of information, but also provides patients with tools for education and self-management and a sense of ownership over their own health. Digital health applications extend the reach of care providers with secure exchange of patient-reported data and permitting the exchange of secure tailored text messaging and may have the capacity to interface with the electronic health record. This initiative is timely since the availability and acceptability of wearable tools and devices is rapidly increasing. The current initiative concept will support Investigator-Initiated Research Project (R01) applications to further develop and optimize these technologies and promote their application to the study the

diseases and conditions within the NIDDK's mission areas.

- **Specialized Centers of Research Excellence (SCORE), Dr. Christine Maric-Bilkan:** Led by the Office of Research on Women's Health, SCORE used P50 grants at its inception, but in its new iteration, will use a U54 cooperative mechanism. The goals of the program are to support interdisciplinary approaches to advanced translational research on sex differences and to provide leadership in the development and promotion of standards and policies for the consideration of sex differences in biomedical research. NIDDK has participated in this program for over 15 years and currently funds two SCORE awards. The program's goals are aligned with the recently issued notice by NIDDK encouraging research on sex and gender differences, sexual and gender minority-related research, and race-ethnic diversity in NIDDK mission areas. The initiative also aligns with the mission and vision of the NIDDK's Strategic Plan for Research, which highlights improving women's health as a cross-cutting topic.

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

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 OF REVIEW OF GRANT APPLICATIONS.

A total of 1,220 grant applications (345 primary and 875 dual), requesting support of \$487,441,775 were reviewed for consideration at the May 11 and 12, 2022, meeting. An additional 1,078 Common Fund applications requesting \$1,053,807,032 were presented to Council. Funding for these applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, 1,093 applications requesting \$418,886,257 received second-level review through expedited concurrence. All of the expedited concurrence applications were recommended for funding at the Scientific Review Group recommended level. The expedited concurrence actions were reported to the full Advisory Council at the May 11-12, 2022, meeting.

XII. ADJOURNMENT

Dr. Rodgers

Dr. Rodgers expressed appreciation on behalf of the NIDDK to the Council members, presenters, and other participants. He thanked the Council members for their valuable input. There being no other business, the 219th meeting of the NIDDK Advisory Council was adjourned at 3:15 p.m. on May 11, 2022.

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

Date

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