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 213th meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council at 11:30 a.m. on May 12, 2020, via Zoom videoconference. This meeting was conducted using a two-tiered webinar format. The panelist tier consisted of NIDDK's Advisory Council members and NIDDK staff members who presented during the meeting. The audience tier was available to members of the public and allowed them to view and listen to the meeting.

A. ATTENDANCE – COUNCIL MEMBERS PRESENT

Dr. David D'Alessio*
Ms. Tracey Brown +
Dr. Iain Drummond
Dr. Penny Gordon-Larsen
Dr. Lisa Guay-Woodford
Dr. Barbara Kahn
Dr. David Klurfeld*
Mr. Richard Knight
Dr. Kathleen Liu+
Dr. Mitchell Lazar
Mr. Thomas Nealon
Dr. Mark Nelson+
Dr. Aria Olumi+
Dr. Richard Peek
Dr. Jeffrey Pessin
Dr. Michael Snyder
Dr. Ronald Sokol
Ms. Lorraine Stiehl
Dr. Katherine Tuttle+
Dr. Gary Wu
Dr. Leonard Zon+

* *Ex officio* member
+ *Ad hoc* member

Also Present:
Dr. Griffin Rodgers, Director, NIDDK and Chair of the NIDDK Advisory Council
Dr. Karl F. Malik, Executive Secretary, NIDDK Advisory Council
Dr. Gregory G. Germino, Deputy Director, NIDDK
Dr. Stephen P. James, Director, Division of Digestive Diseases and Nutrition, NIDDK
Dr. Robert A. Star, Director, Division of Kidney, Urologic, and Hematologic Diseases, NIDDK
Dr. William Cefalu, Director, Division of Diabetes, Endocrinology and Metabolic Diseases, NIDDK

B. ADDITIONAL NIH STAFF AND GUESTS

NOTE: Due to the open webinar format of this meeting necessitated by the COVID-19 pandemic, only additional NIDDK staff who participated directly in the Council meeting are listed here. Other NIH staff and members of the public were able to view and listen to the open session of meeting in real time.

Burch, Henry – NIDDK
Castle, Arthur – NIDDK
Chowdhury, Bratati – NIDDK
Evans, Mary – NIDDK
Karp, Robert – NIDDK
Linder, Barbara – NIDDK
Perrin, Peter – NIDDK
Portnoy, Matthew – NIDDK
Rankin, Tracy – NIDDK
Saslowsky, David – NIDDK
Silva, Corinne – NIDDK
Teff, Karen – NIDDK
Wang, Xujing – NIDDK

C. ANNOUNCEMENTS

Dr. Rodgers

Dr. Rodgers began by thanking everyone for their flexibility and by giving special recognition to NIDDK's Computer Technology Branch, which planned, set up, tested, and managed the technology that allowed the Advisory Council meeting to be conducted virtually due to the COVID-19 pandemic.

Council Member News

Dr. Rodgers recognized six new *ad hoc* members at the meeting: **Dr. Mitchell Lazar** is the Willard and Rhoda Ware Professor of Diabetes and Metabolic Diseases, and the Director of the Institute of Diabetes, Obesity and Metabolism, and the Chief of the Division of Endocrinology, Diabetes and Metabolism at the University of Pennsylvania. **Dr. Kathleen Liu** is Professor in the Divisions of Nephrology and Critical Care Medicine in the Departments of Medicine and Anesthesia at the University of California, San Francisco. **Dr. Mark Nelson** is the University Distinguished Professor and Chair of the Department of Pharmacology at the University of Vermont College of Medicine.

Additionally, **Dr. Aria Olumi** is the Janet and William DeWolf endowed Professor of Surgery at Harvard Medical School and the Chief of Urologic Surgery at the Beth Israel Deaconess Medical Center. Dr. Olumi is also the Chair of Research at the American Urological Association. **Dr. Katherine Tuttle** is the Executive Director for Research at Providence Health Care in Spokane, Washington, and the Regional Co-Principal Investigator at the Institute of Translational Health Sciences and Clinical Professor of Medicine in the Nephrology Division at the University of Washington. **Dr. Leonard Zon** is the Grousbeck Professor of Pediatric Medicine at Harvard Medical School, an Investigator with the Howard Hughes Medical Institute, and Director of the Stem Cell Program at Children's Hospital in Boston.

Dr. Rodgers thanked them all for their time and participation.

NIDDK Staff News

Dr. Rodgers welcomed three new staff members who had recently joined NIDDK:

Dr. Holly Nicastro is a new program director within the Office of Nutrition Research. She will lead efforts within NIDDK and across NIH to implement the 2020-2030 Strategic Plan for NIH Nutrition Research and coordinate strategic planning of an NIH Common Fund effort in precision nutrition. **Dr. Norann Zaghloul** joined the Division of Diabetes, Endocrinology, and Metabolic Diseases as a program director overseeing portfolios in type 2 diabetes genetics and genomics and functional genomic modeling of diabetes and related metabolic conditions. **Ms. Shannon Givens-Bradley** recently joined NIDDK as a clinical trials specialist within the Division of Kidney, Urologic, and Hematologic Diseases.

Dr. Rodgers then highlighted recent honors received by two investigators within NIDDK's Intramural Research Program:

Dr. Robert Tycko, Deputy Chief in the NIDDK Laboratory of Chemical Physics, was recently elected to the National Academy of Sciences. Dr. Tycko was recognized for his invention of new methods in magnetic resonance spectroscopy of large protein assemblies and for structural characterization of protein fibers that develop in the pancreas and brain, contributing to diabetes and neurodegenerative diseases.

Dr. G. Marius Clore is an NIH Distinguished Investigator and Section Chief of the Protein Nuclear Magnetic Resonance Section in the NIDDK Laboratory of Chemical Physics. He was elected as a fellow in the Royal Society, an honor presented to scientists pioneering research in their field. Dr. Clore is known for his pivotal contribution to the development of nuclear magnetic resonance and for introducing three-dimensional structure determination of proteins, nucleic acids and their complexes.

Dr. Rodgers also reported that investigators within the NIDDK Intramural Research Program have had a strong scientific response to the COVID-19 pandemic. Twelve investigators have proposed a total of 17 COVID-19 related projects. Dr. Rodgers and the NIH Office of the Director have approved all 17 projects to move forward. Examples include:

- **Dr. Lothar Hennighausen** is engaged in a new research collaboration that uses RNA sequence analysis of COVID-19 patients to compare severe courses of infection to those with only mild or no symptoms.

- **Dr. Adriaan Bax** and **Dr. Philip Anfinrud** are extending their research report in the *New England Journal of Medicine* on speech droplets and measuring volumes and length of time that they remain airborne.

- **Dr. T. Jake Liang** is collaborating with intramural and extramural scientists on a project focused on the detection of SARS-CoV-2 in the stool of COVID-19 patients.

- **Dr. Carson Chow** is currently preparing a publication entitled "Global prediction of unreported SARS-CoV-2 infection from observed COVID-19 cases."

- **Dr. Daniel Appella** is performing work targeting the SARS-CoV-2 RNA pseudoknot with antiviral thyclotide molecules.

  Dr. Rodgers commended these NIDDK scientists on their creativity and scientific energy as they address new questions and challenges presented by the COVID-19 pandemic.

  Dr. Germino then announced that Dr. Rodgers was named a finalist for the Samuel J. Heyman Service to America Medals. The Sammies, as they are known, honor members of the federal government workforce, highlighting the work of employees making significant contributions to the governance of the United States. The awards are considered the Oscars of American government service. Dr. Rodgers was named alongside his colleague, Dr. John Tisdale, for pioneering innovative research on sickle cell disease. Among many other ongoing achievements in this field, Dr. Rodgers played a leading role in the

development of hydroxyurea, the first effective FDA-approved medicine for treatment of sickle cell disease. Dr. Germino congratulated Dr. Rodgers for his nomination on behalf of all NIDDK.

NIDDK Strategic Plan Update

Dr. Germino then updated Council members on recent steps taken to advance development of an NIDDK Strategic Plan, an overarching plan that will complement NIDDK's disease-specific planning efforts. Since the January Council meeting, NIDDK has released a public request for information, or RFI, to seek innovative ideas for research opportunities and strategies to advance NIDDK's mission.

Dr. Germino invited meeting attendees to submit their ideas through the RFI web form that can be found on the NIDDK website and in the NIH Guide through July 31st, a later deadline than originally discussed due to COVID-19 disruptions.

In reviewing progress to date, Dr. Germino noted the success of introductory calls with the members of the NIDDK Strategic Plan Working Group of Council in February. March saw the release of the RFI. Additional working group meetings have been postponed until July. Based on the COVID-19 crisis, NIDDK has added a new theme to the strategic plan: how NIDDK should respond to emergent research opportunities and challenges such as those currently posed by COVID-19 or other future emergencies.

Once NIDDK has a draft version of the plan, it will be posted on the NIDDK website for public comment. Overall, the planning process has been extended by about three months due to the pandemic.

II. CONSIDERATION OF SUMMARY MINUTES OF THE 212th COUNCIL MEETING
Dr. Rodgers

The Council approved, by voice vote, the Summary Minutes of the 212th Council meeting, which had been sent to them in advance for review.

III. FUTURE COUNCIL DATES
Dr. Rodgers

In order to save time, Dr. Rodgers did not review all planned Advisory Council meeting dates. He noted that the September 2020 NIDDK Advisory Council meeting is scheduled for September 9-10 and is still tentatively slated to be held in the Building 31 6th Floor Conference Center. However, the meeting could be moved if ongoing renovations are not completed in Building 31 or if pandemic conditions continue, necessitating another online meeting.

Additionally, Dr. Rodgers reminded Council members that the January 2021 Council meeting has been moved to Wednesday January 27 due to lack of hotel availability during the week of the Inauguration.

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 the 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. Responsible 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 noted that, prior to this meeting, Council members were sent a statement regarding conflict of interest in their review of applications. He asked each Council member to read it carefully, sign it electronically, or if providing a wet signature, sign and scan the document, and to return the image file or the file to NIDDK before the end of the day.

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

Regarding multi-campus institutions of higher education, Dr. Malik 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 reported on NIH appropriations. In December 2019 the House and Senate passed two minibus appropriation bills, which the President signed into law and that funded the government for FY 2020. The NIH received about $41.5 billion, which was a $2.4 billion increase, or 6.1 percent, over FY 2019. NIDDK received an $84.5 million increase, or 4.2 percent, over the FY 2019 appropriation. These figures do not include funds for the Special Statutory Funding Program for Type 1 Diabetes Research (Special Diabetes Program).

The FY 2020 appropriations process wrapped up just a couple of months before the FY 2021 appropriations cycle started with the release of the President's budget request on February 10, 2020. The FY 2021 President's budget request calls for a $3.4 billion reduction in NIH's budget and a $190 million reduction in NIDDK's budget compared to FY 2020. Typically, Congress holds appropriations hearings in the spring, and indeed, the House Labor, Health and Human Services, Education, and Related Agencies (L-HHS) Appropriations Subcommittee held a hearing on the NIH budget request on March 4, 2020. A Senate hearing on the NIH budget, however, has not been held due to the COVID-19 pandemic.

Council members can expect an update on the status of the FY 2021 appropriations process at the September Council meeting.

Supplemental Funding – COVID-19

Dr. Rodgers also provided a brief overview of the supplemental packages from Congress to address the COVID-19 pandemic, most of which include some funding for NIH.

- **Supplemental Package 1** - The first COVID-19 legislative package was signed into law on March 6, 2020, and included $8.3 billion of supplemental funding. Its purpose was to prepare for and respond to the pandemic, with an emphasis on important issues such as worker-based training to prevent and reduce the exposure of healthcare and other essential workers to the virus. The supplemental included $836 million for the National Institute of Allergy and Infectious Diseases (NIAID) with $10 million of those funds to be transferred to the National Institute for Environmental Health Sciences.
- **Supplemental Package 2** - Package 2, which was passed in mid-March, covered a range of critical issues such as paid sick leave, insurance coverage for coronavirus testing, nutrition assistance and unemployment benefits, but it was not directly related to NIH research funding.
- **Supplemental Package 3** – The Coronavirus Aid Relief and Economic Security Act (CARES) was signed into law on March 27, 2020. The total supplemental funding was approximately $2.1 trillion, which included almost $950 million for NIH. Of this, $706 million went to NIAID. Importantly for NIDDK, the CARES package also authorized the remaining $53.4 million for FY 2020 funding for the Special Diabetes Program and provided about $25 million in partial FY 2021 funding for the program.
- **Supplemental Package 3.5** – The fourth aid package, commonly known as "3.5", was signed into law on April 24, 2020, and largely focused on providing financial assistance for small businesses and healthcare providers. The law provided approximately $484 billion total, including $1.8 billion for the NIH, with a focus on coronavirus testing and development of new testing platforms and technologies.

Dr. Rodgers noted that Congress may pass an additional supplemental package before its August recess. Accordingly, NIH leadership and the ICs are discussing possible research opportunities related to COVID-19.

Congressional Meetings

In February, Dr. Rodgers met with Representative Kim Schrier (D-WA). She is a pediatrician and also a person with type 1 diabetes. She and Dr. Rodgers discussed NIDDK's research efforts into type 1 diabetes supported by the Special Diabetes Program, including TEDDY and TrialNet.

Also in February, Dr. Rodgers met with Representative Tom Reed (R-NY), co-chair of the Congressional Diabetes Caucus and the father of a child with type 1 diabetes. They discussed how the Special Diabetes Program has helped support research spanning the course of type 1 diabetes, as well as the challenges faced by families affected by type 1 diabetes.

That same day Dr. Rodgers met with Representative Jim McGovern (D-MA), who has a longstanding interest in nutrition research and the potential for this research to reduce the burden of chronic disease. Dr. Rodgers shared some of the NIH's nutrition research efforts and discussed some of NIDDK's programs, including the Diabetes Prevention Program and the Diabetes Prevention Program Outcome Study, that have demonstrated the impact of lifestyle changes, including dietary changes.

At a congressional reception that evening honoring the efforts of the NIH Children's Inn, Dr. Rodgers, along many other Institute and Center directors and NIH Director Dr. Francis Collins, had the opportunity to interact with several Members of Congress who are champions of NIH and biomedical research.

In early March, Dr. Rodgers shared the podium with Representative Jamie Raskin (D-MD) at the Digestive Diseases and Nutrition Coalition Annual Public Policy Forum. Congressman Raskin shared his personal story as a colon cancer survivor, and Dr. Rodgers discussed NIDDK's advances in digestive disease research over the years.

VI. CONCEPT CLEARANCE

Presentation of Concepts

Dr. Malik reminded Council members and staff that concept clearance is a relatively new requirement for any funding opportunity published by Institutes and Centers of the NIH. To make this process easier, all concepts will be presented and made available to Council prior to meetings via the electronic Council book. A synopsis of each concept will be presented at Council meetings, with an opportunity for discussion.

Division of Digestive Diseases and Nutrition Concepts

Members of the DDN staff presented a total of six concepts, five of which are trans-NIDDK in nature.

Trans-NIDDK HIV/AIDS Research

Dr. Peter Perrin informed the Council that nearly every NIH Institute or Center has a research component that interrelates with HIV science in its portfolio. At NIDDK there are two such areas of work, both of which cross NIDDK divisions: (1) cure research and (2) comorbidities, coinfections and complications research. Both areas are also inherently multidisciplinary and thus tackling questions in-depth benefits from building partnerships between NIDDK mission area experts and HIV scientists. Two concepts to promote such research synergy are:

- **Multidisciplinary Research on HIV Pathogenesis within the Mission of the NIDDK** and **Multidisciplinary Research on HIV Cure within the Mission of the NIDDK:** The proposed concepts for two interrelated RFAs would fund multidisciplinary teams to focus on comorbidities, coinfections, and complications associated with HIV (diabetes, obesity, liver disease, renal disease and urological particulate solutions) and cure research focused on the GI tract, male genital tract, renal and adipose tissue reservoirs, respectively.

  For the development of these first two concepts, Dr. Perrin described a working model based on a previous RFA that was presented to Council in September 2019. It required multiple PI teams that included at least one expert in HIV and one expert in the relevant area of gastroenterology, physiology or pathobiology. In less than a year, DDN has funded three applications from this RFA, with additional applications pending. Because of this success in getting HIV researchers into the NIDDK portfolio and getting NIDDK researchers to turn their attention to HIV topics, Dr. Perrin believes this is a good model for future use. He then described two concepts meant to continue fostering investigator-initiated HIV/AIDS research relevant to NIDDK, as an important part of expanding the overall portfolio:

- **Priority HIV/AIDS Research within the Mission of the NIDDK:** This would be a renewal of the successful program announcement with a set-aside (PAS), "High Priority HIV/AIDS Research within the Mission of the NIDDK." The existing effort has attracted both established and new PIs to NIDDK, with impactful projects in fields spanning all three divisions. An advantage of the PAS is that it has multiple receipt dates, so investigators who are not initially successful can strengthen and resubmit an application. Under the proposed renewal, all research applications would still be required to be relevant to the NIDDK mission and align with NIH-wide HIV/AIDS priorities, focusing on either cure or comorbidities, coinfections, and complications; the research could be basic, translational, or clinical.

- **Exploratory and Developmental HIV/AIDS Research within the Mission of the NIDDK:** This would replace PA-18-615 with a Program Announcement with special receipt (PAR) and continue to help grow the portfolio by providing HIV scientists and NIDDK scientists with the opportunity to enter this arena through pilot projects. Proposed research would still be required

to be relevant to the NIDDK mission and align with NIH-wide HIV/AIDS priorities, focusing on either cure or comorbidities, coinfections, and complications; the research could be basic, translational, or clinical.

NIDDK IBD Genetics Consortium Renewal
Dr. Robert Karp noted that since the Consortium started work in 2002, members and their collaborators have identified more than 250 inflammatory bowel disease (IBD) risk loci and placed many of their genes into pathways. However, there is still a pressing need for translation of the genetic findings into understanding of the pathophysiological mechanisms, as this understanding must precede the development of much-needed new therapies. An expanded focus on systems biology and non-European populations could facilitate this translation.

Dr. Karp explained that if the Consortium receives a 5-year renewal, Consortium members intend to increase recruitment from non-European populations. They would analyze less well-studied disease phenotypes, such as peri-anal fistulizing disease, which is an unmet medical need. They would emphasize longitudinal studies of disease progression and treatment responses, and would create single-cell level atlases of transcripts, proteins, transcriptionally active genomic regions, and lymphocyte receptor repertoires to form a resource for the entire IBD research community. All of these efforts could lead to the translation of genetic findings to an increased understanding of pathophysiological mechanisms.

<u>Council Questions and Discussion</u>

Many of the IBD Consortium's objectives seem to mirror those of private foundations like the Helmsley Charitable Trust, which published a request for applications to create a tissue atlas. Are there opportunities to partner with and pool resources with similarly aligned private foundations?

Dr. Karp responded that the Consortium has a history of working closely with the Crohns & Colitis Foundation. Many Consortium investigators are involved with privately supported initiatives. NIDDK has found that the investigators have done a good job organizing collaborations on their own so has not seen the need to take a more active role in this.

Do you get many applications from new-to-you investigators or does most of your funding go to renewing existing Consortium grants and programs?

Dr. Karp responded that the Consortium typically receives only a small number of requests from new applicants each funding cycle. Following peer review, those applications have not scored well enough to be funded. However, Dr. Karp stressed that this is an open competition, and NIDDK continues to encourage new applications.

However, the NIDDK has funded a number of proposals via RFAs to support ancillary studies to the Consortium, in which outside investigators form collaborations with the Consortium to get access to Consortium resources to do their own projects, some of which have been quite exciting. Although new talent has been brought in this way, Dr. Karp would like to see more such applications, too. The Consortium now advertises on its own to attract investigators who want to pursue collaborations.

Is there a way for investigators to pursue funding for microbiome projects under the Consortium's auspices?

Dr. Karp replied that there are currently some microbiome research projects within the Consortium and among their collaborators, including researchers who have been active in the Helmsley Charitable Trust's IBD microbiome effort. Given the number of privately funded IBD microbiome efforts, the NIDDK doesn't feel the need to augment that at this time, but applications for collaborative projects in this area with the Consortium are welcome.

Will the Consortium's focus be on increasing recruitment from non-European populations within the United States? Or could this recruitment also include an international focus on rapidly industrializing nations whose genetic-environmental interactions could also be relevant to U.S. populations?

Dr. Karp responded that the Consortium is placing the highest priority on populations within the United States, although they have also included French Canadians. Research proposals focusing on a non-U.S. population particularly affected by IBD or that could otherwise be highly informative would be welcome, he added.

Time-Sensitive Obesity Policy and Program Evaluation
Dr. Mary Evans presented this concept proposing to renew a trans-NIDDK program that involves DDN, DEM, and the Office of Obesity Research. It was originally released in August 2012, then renewed in 2015 and 2018. Partners to date have been the National Cancer Institute (NCI), the National Institute of Child Health and Human Development (NICHD), the National Institute of Aging (NIA), and the NIH Office of Behavioral and Social Sciences Research (OBSSR).

To date, numerous policies have been implemented, targeted at a variety of obesity-related behaviors and factors, including the food environment, the built environment (housing, sleep, and environmental components such as noise and crime, and minimum wage) and healthcare-related programs. However, many knowledge gaps remain regarding the effectiveness of large-scale policies and programs aimed at reducing obesity at the population or subpopulation level. This program also provides an opportunity to evaluate the role of social determinants of health in populations at particularly high risk for obesity and adverse health effects.

A Program Announcement with special receipt (PAR) has been issued in the past to support opportunities for evaluation that are only feasible through expedited review and funding. The goal is to fund meritorious applications within 4 months of receipt. There is also an expectation to have (independent of PAR renewal) a non-time-sensitive companion Notice of Special Interest (NOSI) on obesity policy evaluation research.

Dr. Evans noted the continued need for a PAR to allow this type of time-sensitive research because policy and program implementation typically occur in the absence of solid outcomes data on health effects and analysis of any unintended consequences of these programs and policies. DDN is proposing to reissue the FOA, and the new PAR would have a first receipt date in October 2021. Proposal review would continue within NIDDK's review branch and NCI, NICHD and OBSSR participation is expected to continue.

Council Questions and Discussion

Are there other examples of trans-NIH initiatives like the one you presented?

Dr. Evans replied that NCI has a comparable program that focuses on tobacco cessation programs, and National Institute on Drug Abuse (NIDA) may have had a similar program, too.

Please elaborate on the review process and timing for funding applications to the Time-Sensitive Obesity Program. Can the rapid funding decisions be applied to other NIDDK grants?

Dr. Evans clarified that all funding applications for this program are competitively peer reviewed, but the process is managed by NIDDK's review branch, rather than going to the Center for Scientific Review (CSR). The applications undergo an expedited but otherwise typical NIH review process, including Council review. The goal is to have NIDDK-managed review occur within 2 months and then fund proposals within 4 months.

Why can't review and funding of other NIH and NIDDK programs be similarly expedited?

Dr. Rodgers responded that applications submitted to this FOA are inherently time-sensitive in that the policy or program of interest will be implemented within a quick period of time that is outside of the investigative team's control. To enable baseline data collection before the policy or program goes into effect, applications must be funded in an expedited manner. He also explained that review timing is generally an issue of prioritization, workload, and inter-institute coordination.

Division of Diabetes, Endocrinology and Metabolic Diseases Concepts

DEM staff presented seven concepts, six for continuation of ongoing initiatives and one new initiative proposal.

Epidemiology of Diabetes Intervention and Complications (EDIC) Study Renewal
Dr. Ellen Leschek outlined a proposal to renew EDIC, the successor to the landmark Diabetes Control and Complications Trial (DCCT) in people with type 1 diabetes that led to adoption of intensive therapy for control of blood sugar levels as the standard of care. EDIC continues to follow 92 percent of the surviving DCCT cohort 26 years later. Its current focus is on morbidities associated with age and prolonged disease duration and includes studies of cognition, physical function and frailty, advanced microvascular complications, cardiovascular disease and mortality, and disease trajectories. If renewed, EDIC would continue to study the combined impacts of type 1 diabetes and aging on age-sensitive morbidities, including cognitive and physical dysfunction, which appear to be increasing with time. Studies of severe type 1 diabetes complications, heart failure, and cardiac dysfunction would be pursued. Forty percent of the EDIC cohort has obesity, and studies of related complications—such as non-alcoholic fatty liver disease and obstructive sleep apnea—would be performed, as would quality-of-life measures and studies of health-economic consequences. The proposed renewal would cover fiscal years 2022-2026 (EDIC study years 29 to 33).

NIDDK Diabetes Research Centers (DRCs) Program Renewal
Dr. Corinne Silva explained that DRCs' mission is to support extramural research institutions that have an established base of high-quality diabetes-related research. The DRCs also increase cost-effective collaboration among multidisciplinary groups of investigators and shared access to specialized technical resources and expertise. There are currently 16 funded DRCs. Two were new in FY 2020, and seven have been ongoing for 40 years or more.

The DRCs are structured to include an administrative core, which provides coordination and integration of the DRC components; biomedical research cores, which provide shared specialized technical resources and expertise to enhance research by DRC members; and a pilot and feasibility (P&F) program, which provides seed support for additional optional opportunities that include expanded or national cores or P&F programs. In order to build upon the DRCs' success, DEM proposes three changes: Diabetes, endocrinology and metabolism-specific cores would take priority for funding, although institutional cores would still be allowed with compelling justification. Additionally, 25 percent of direct costs of the base DRC funding would be required to go to the P&F program. Third, the P&F program category of established PIs doing innovative or high-impact, high-risk research would be eliminated to allow for an emphasis on PIs who are new to diabetes research and those who are developing techniques for the cores.

Council Question and Discussion

Have you considered the possibility that creating a hierarchy between funding for institutional cores versus diabetes-specific kind of cores can hamper the research being done? What if this change in emphasis brings unintended consequences to the program?

Dr. Silva emphasized that the intent is not to make institutional cores low priority. They will still be eligible for funding but must be justified with a compelling rationale. Dr. William Cefalu emphasized that funding decisions will be made on a case-by-case basis, but the intent is to strengthen the centers, not to take away from them. Staff has done a good job thus far reviewing both types of cores and providing funding where needed, he said.

Diabetes Prevention Program Outcomes Study (DPPOS) Renewal
Dr. Barbara Linder presented a concept for the renewal of DPPOS, the follow-up study to the Diabetes Prevention Program (DPP). DPP established lifestyle and metformin as effective means of delaying or preventing type 2 diabetes in high-risk

individuals. DPPOS has looked at longer-term effects of the DPP interventions on the durability of prevention, on diabetes complications by treatment group, and on cost effectiveness.

DPPOS is currently in its third phase and funding ends in January 2021. The investigators would like to continue follow-up of the cohort and have proposed several potential future directions, including studying the heterogeneity of treatment response and the clinical course of diabetes when it does occur, including the evolution of diabetes-related complications. In addition, they want to study the intersection between diabetes and aging-related outcomes. In accordance with NIDDK policy, DEM will convene an external evaluation panel this summer to evaluate the investigators' proposal and provide input to NIDDK about its scientific merit.

NIDDK Diabetes Foot Consortium Extension
Dr. Henry Burch presented a concept for a one-year extension for FY 2022. The aim of the Diabetic Foot Consortium is to develop biomarkers that predict clinical outcomes in patients with diabetic foot ulcers (DFU), a common health complication that is clinically significant and costly. Clinical outcomes of interest include healing and recurrence rates, and response to therapy. Predictive biomarkers would also be used as validated quantitative measures in future clinical trials.

Between 2018 and 2019, NIDDK funded six clinical research units and a Data Coordinating Center to build the Consortium's clinical site infrastructure, setting the stage for the development and validation of DFU biomarkers. In parallel, NIDDK sponsored a workshop on DFU biomarkers. The Consortium subsequently developed two protocols for investigating potential biomarkers in people with DFUs. Both were due to start enrollment in May 2020, but this has been delayed due to COVID-19. This delay is the reason for the proposed 1-year renewal. This extension would allow completion of recruitment and follow-up for the two biomarker protocols. It would also provide an additional evaluation period to define both the need and scope for a potential 5-year renewal in 2023.

Environmental Determinants of Diabetes in the Young (TEDDY)
Dr. Arthur Castle explained that TEDDY's main goal is to identify environmental factors and gene-environment interactions that cause prediabetic autoimmunity and type 1 diabetes. TEDDY also seeks to create a repository of data and biological samples for hypothesis-driven research. TEDDY recruited high-risk individuals and is following participants to a first primary outcome of islet autoantibody positive; in 2012, a nested case control cohort study was created to follow these positive individuals to a secondary endpoint of a primary outcome of diabetes. All TEDDY participants will be followed until they reach 15 years of age or receive a diabetes diagnosis. Results to date include finding heterogeneity in autoantibody presentation and development of a genetic risk score; the nested case-control cohort study has identified some patterns and associations (or lack thereof) of islet autoantibodies with viruses, the microbiome, and nutritional factors and metabolites.

The objectives of the proposed continuation would be to provide support for the standard follow-up of TEDDY participants and to initiate a second case-control cohort that would include children up to 14 years of age at antibody presentation. This cohort would include more than 420 new antibody-positive participants and more than 200 participants with new cases of type 1 diabetes.

Human Pancreas Analysis Program of Type One Diabetes (HPAP-T1D) Renewal
Dr. Xujing Wang explained that HPAP-T1D, which was created in 2016, is a resource-generation program that conducts standardized deep-phenotyping of human pancreas at various type 1 diabetes disease stages and provides the datasets to the community. HPAP-T1D is needed because the immune-islet cell interactions and the mechanisms of beta-cell loss during type 1 diabetes disease progression are still not understood, and there is a lack of detailed cellular and molecular phenotyping of the pancreas from people with type 1 diabetes.

HPAP-T1D seeks to overcome the research challenges presented by the scarcity of human type 1 diabetes pancreatic tissue available to individual researchers. To date, HPAP-T1D has received and analyzed 45 pancreases. These organs have come from people with type 1 diabetes and those without the disease. All data have been shared freely through an integrated

database called PancDB. There are currently more than 1,200 users of PancDB, and 13 papers using HPAP-T1D data have been published to date. HPAP-T1D resources have helped promote promising new science and new hypotheses about type 1 diabetes. If renewed, HPAP-T1D would continue collecting and characterizing pancreatic tissues from people with type 1 diabetes, expanding to include more cell types in deep phenotyping. It would continue to release datasets through PancDB, which would include enhanced data visualization and analysis features.

Understanding and Targeting the Pathophysiology of Youth-onset Type 2 Diabetes
Dr. Linder introduced this proposed new initiative aimed at developing effective prevention and treatment strategies for type 2 diabetes in young people, which has a particularly grim outlook. Incidence in youth is increasing and, as in adults, racial/ethnic minority and low socioeconomic populations in the United States are disproportionately affected. Youth with type 2 diabetes have more comorbidities and complications than do youth with type 1 diabetes at comparable diabetes duration and HbA1c levels. In addition, compared with adults, youth are more insulin resistant at comparable body mass index levels; hyper-secrete insulin at comparable insulin sensitivity; and do not respond well to metformin, the mainstay of treatment in adults. Youth with type 2 diabetes also have poor glycemic control and more rapid evolution of complications, leading to the prospect that as young adults they may have devastating complications in what should be the prime of their lives.

Given this picture, NIDDK feels strongly about finding both better type 2 diabetes prevention strategies for youth and more effective treatments for those who develop the disease. In December 2019, NIDDK held a workshop on this topic that highlighted multiple knowledge gaps, including the need to understand the factors that drive conversion of physiologic pubertal insulin resistance to full-blown type 2 diabetes. There is also a critical need for better metrics to more precisely identify who is at risk so they can be targeted for prevention efforts, as most youth with risk factors will not develop type 2 diabetes during adolescence.

DEM proposes to create a new pediatric consortium to recruit a large cohort of obese, potentially at-risk youth. The consortium would follow these youth through puberty, conducting serial oral glucose tolerance testing and extensive sample bio-banking along with careful health and psychosocial phenotyping. In the future, nested cohorts could be created for further analysis once some members of the larger group have developed type 2 diabetes. The emphasis would be on considering other factors besides blood glucose that may contribute to the development of type 2 diabetes in youth, particularly ectopic fat distribution.

Division of Kidney, Urologic, and Hematologic Diseases Concepts

Dr. Robert Star and Dr. Tracy Rankin presented seven concepts for renewals and program continuations, two of which are trans-NIDDK:

Kidney Precision Medicine Project (KPMP) Renewal
Dr. Star described the current core goals and activities of KPMP—ethically and safely obtaining human research kidney biopsies from patients with common acute and chronic kidney diseases, who are also actively involved in all phases of the project; evaluating molecular determinants of cells, structures, pathways, and disease targets; and building a data resource for the extended community. KPMP is meant to serve multiple communities, ranging from patients, pathologists, and clinicians, to researchers with diverse expertise tackling kidney questions from various angles. The proposed competitive renewal would support phase 2 of KPMP, which would invite additional researchers into the project and seek to double the biopsy rate, increase the number of ways to interrogate the tissue, and improve the already good informatics infrastructure.

Council Question and Discussion

Who are the "normal" kidney controls for this study?

Dr. Star noted that this is a very difficult issue and acknowledged that there is no perfect reference sample, but that for KPMP it involves samples from transplanted kidneys before they are transplanted and some samples of tissue from kidneys being surgically removed due to cancer.

Will children be enrolled in this study?

Dr. Star responded that the study is only enrolling adults because it comes with more-than-minimal risk and so is not appropriate for children.

Dr. Star briefly described four remaining KUH competitive renewal concepts for existing programs and studies:

George M. O'Brien Kidney Research Centers and **Pediatric Centers of Excellence in Nephrology**
KUH proposes continuation of these two existing centers programs. Dr. Star mentioned that the Kidney Research Centers will host a workshop in the fall to review the centers' structure and formulate recommendations to present to the KUH sub-council at a future meeting.

APOLLO: APOL1 Variants in Patients Undergoing Kidney Transplantation
This ongoing observational study focuses on how variants in the *APOL1* gene, which are the main cause of higher kidney disease rates in African Americans than other U.S. racial groups, affect kidney transplantation outcomes, with the ultimate goal of improving these outcomes. APOLLO analyses will assess transplant outcomes in kidney recipients in relationship to *APOL1* genotype in both the donor and recipient, and compared to appropriate controls. APOLLO will also follow general and kidney specific health outcomes in donors. Dr. Star noted that APOLLO needs more than one project period to achieve its goals, hence the renewal request.

SHINE: Non-ablative immunotherapy to prepare bone marrow for transplant
The SHINE program stimulates new investigations in nonmalignant hematology. Dr. Star explained that KUH is not asking for more funding for the program, but rather announcing that the new topic for the coming year will be non-ablative immunotherapy to prepare bone marrow for transplant. Cancer immunotherapies affect the bone marrow, and with this topic SHINE would encourage research to understand that process better and to design immunotherapies that are not as harmful to bone marrow.

Dr. Tracy Rankin presented the final two concepts of the day, both of which are trans-NIDDK proposed initiatives for continuation of existing programs.

NIDDK Education Program Grants (R25)
These grants are for research and education programs that primarily support undergraduate summer research experiences in areas relevant to the NIDDK mission. Dr. Rankin noted that a few programs also provide specific courses for participants, targeted to NIDDK mission areas. This long-standing program supports NIDDK's core principle of recruiting the next generation of researchers.

Renewal of NIDDK Support of Multi-Center Clinical Studies (U34/U01)
Dr. Rankin explained that any proposed study that encompasses more than two centers must apply through the cooperative planning process (U34) prior to submitting a competitive application to support the study or trial (U01). The only proposed change in this next phase is to develop a risk-based approach rather than a strict site-number-based approach. I.e., some studies have low risks with respect to intervention in the study but need more than one center to accomplish recruitment goals due to the nature of the study population, whether it is a rare disease or a pediatric population. NIDDK proposes that these types of

studies should be processed through the regular R01 pipeline. NIDDK plans to reissue a notice along with the program announcements to provide guidance to the community on categories of studies and attributes of studies considered high risk and that would require a U34 pathway.

Council Question and Discussion

How will you determine which studies are high- and low-risk? That's critical information for investigators.

Dr. Rankin said that NIDDK will use a multi-tiered assessment of each study's risk that will include interventional, operational, and financial risk. The current program announcements encourage all investigators who propose a large, multi-center study to contact the appropriate program staff well in advance of developing an application to discuss their study.

VII. COUNCIL FORUM

COVID-19 Pandemic: Recovery Planning for NIDDK Research
Drs. Tracy Rankin, David Saslowsky, and Karen Teff

Dr. Rodgers introduced the Council Forum as an opportunity to discuss the impact of the COVID-19 pandemic on research efforts, especially those in NIDDK's portfolio. He explained that the public health responses to the pandemic have focused immediate attention on clinical treatment of patients with the virus as well as prevention of its spread to others. As a result of these activities, non-COVID-19-related biomedical research has slowed or ceased, affecting almost all NIDDK-supported research.

Dr. Rodgers went on to explain that this Council Forum was developed to be a listening session to enhance understanding of the extensive consequences of the pandemic on the research enterprise and look for ways to minimize the long-term consequences for research progress as well as researchers' careers.

Dr. Rodgers introduced Drs. Tracy Rankin, David Saslowsky, and Karen Teff, representing NIDDK's three extramural programmatic divisions, to lead the discussion covering four key areas: basic research, clinical research, training and career development, and the role of NIH and NIDDK in restarting the research enterprise.

Dr. Rankin reviewed the format for the discussion. She directed Council members' attention to two documents included in their packets: one that outlined the topics for discussion and discussion questions for the first three topics, and another developed by Drs. Leonard Zon and Barbara Kahn to support the fourth discussion topic. With limited time, Dr. Rankin cautioned that discussion would be brief and encouraged Council members to use the chat function to contribute other ideas for the record.

Basic Research

Discussion of this topic was moderated by Drs. Gary Wu and Mark Nelson.

Dr. Wu posed three discussion questions related to basic, "wet-bench" research, and suggested focusing on the first two for initial discussion:

- Are there unique aspects of basic science that may pose a particular challenge or hurdle in restarting the research process?
- How would you prioritize these challenges and hurdles?
- How can NIDDK facilitate and implement solutions?

Dr. Wu started by pointing out that labs lost time and money if they were working with cell cultures or research animals. In some cases, labs were forced to cull animals from their vivarium. Dr. Nelson added that it can take a long time to get mouse colonies and cell cultures started, and this will prevent research projects from picking up where they left off.

Other points brought up by Council members included:

- Social/physical distancing in some laboratories is quite difficult. It will no longer be possible for three people to share a bench. It may be necessary for researchers and research assistants to work in shifts or to use previously unused space.
- Labs will require more personal protective equipment (PPE) and cleaning supplies and will go through them faster, leading to additional expenses. Some labs are using 3D printing capabilities to generate PPE, but that also costs money. Having ample PPE on hand may help ensure that people use it properly.
- New technology is being developed to let people know when they are too close to each other. However, most require cell phone and GPS readings, and privacy concerns have been raised. Determining which of these technologies is most reliable may be valuable to researchers.
- Researchers at all career stages are affected by the loss of progress on their investigations. Investigators and other laboratory personnel—particularly early-career researchers—who have young children or who are in a population particularly vulnerable to COVID-19 face additional challenges to returning to research.
- Junior investigators have smaller research budgets and may be particularly vulnerable to consequences of the shutdown, especially if they have had to cull their animal or cell colonies. They may be forced with a decision about whether to continue in research. Ideas for NIH and NIDDK responses included: offering researchers flexibility in their budgets or mini-grants to recover their colonies and more time/relaxed requirements to meet specific aims or compile preliminary findings before having to complete renewal requests.

Clinical and Translational Research

Discussion of this topic was moderated by Drs. Ron Sokol and Katherine Tuttle.

Dr. Sokol opened by noting that, given the geographical differences in the pandemic and the restrictions put in place in response, the effects on clinical and translational research at institutions vary. At most institutions, clinical research has halted to protect the healthcare teams, participants, and the availability of PPE. In addition, many clinical research staff, particularly those who are healthcare providers themselves, have been redeployed as part of the pandemic response. The extent to which institutions can restart clinical research depends on whether the virus has decreased in their geographic area. In addition, the financial impact of the virus and shutdown on hospitals has been considerable and many institutions are bracing for additional fallout. The discussion questions for the Council members include:

- How are we going to resume research activities?
- What are our priorities?

Dr. Tuttle remarked that researchers must align with their institution's priorities and become team players and to keep the research enterprise alive for all of the really important NIDDK-supported activities while also realizing that study participants with diseases and conditions that fall within the NIDDK mission are often very susceptible to COVID-19 and its complications. She added that her institution was hit hard early and she and other researchers were redeployed to patient care services. It was a privilege to serve, she said, but her research productivity suffered. All study visits were suspended. They innovated with remote visits and even remote biosample collection with courier services. Study sponsors, including NIDDK, were flexible in adjusting timing.

Council members brought up the following observations and concerns:

- Recruitment of participants is a challenge as many people do not want to risk exposure to the virus by going to university hospitals to enroll in a study. Enrollment numbers will go down. Patients are not coming in for needed care, let alone research visits. Patients from underserved racial/ethnic minority groups in the United States—who are at increased risk for COVID-19 and its complications—are especially reluctant, which will further challenge recruitment of these individuals for clinical trials. Study enrollment may be slow and may not reach targets within expected time frames. Large database studies will suffer from missing data if this continues for 6 or 12 months.

- Clinical researchers need best practices on clinical research studies in the current environment, including electronic platforms for informed consent; safety monitoring; and remote collection of biosamples—ultimately, figuring out when to bring study participants into the hospital setting and when to conduct study visits by remote technology. Also, many institutions have gone from 1 percent telehealth to 95 percent or more telehealth for patient visits. Using telemedicine for research visits may not be a top priority at these institutions.
- Hospitals are launching campaigns to let the public know that hospitals are safe, if not safer, than some outpatient facilities because everyone is screened and wears PPE and follows disinfection standards. The likelihood of exposure to SARS-CoV2 is higher in the community than in most hospitals, and there is an educational opportunity to let people know that there is not an undue risk to continue with clinical studies when they open again.
- Clinical research has continued where there is likely direct benefit to the participant, especially those with rare diseases, but for those without a direct participant benefit, all face-to-face contact has been suspended.
- Prioritizing participant outreach during the pandemic, keeping in touch with them, and answering their questions can help build and maintain relationships during this time and may help overcome fears and concerns. Some participants have reached out to research clinics to see if the work is continuing.
- Some researchers are working on IRB approval for remote enrollment, consenting and alternate means of data collection, on the idea that it's better to adjust and keep going than to lose these research opportunities. Extending enrollment deadlines may also be preferable than abandoning research because researchers couldn't enroll a large enough sample size.
- Studies can also boost recruitment by aligning with organizations that have built trust and access with potential patient participants, especially those from racial/ethnic minority groups. The use of technology and remote visits may require a different level of trust than many clinical trials have, especially with underserved minority populations, so strategies to develop that trust in the current environment will be especially important.
- Another consideration is how testing positive for COVID-19 or even the stress of the pandemic (as a result of fear of exposure, unemployment, poverty, balancing home schooling with work, etc.) in general affects study eligibility and study results. Most researchers are not planning to routinely test study participants for COVID-19 until testing becomes widely available, although it could be a consideration in studies in immune-deficient patients.

Training and Career Development

Discussion of this topic was moderated by Drs. Richard Peek and David D'Alessio.

Dr. Peek opened by noting key questions to help address this topic:

- How will work stoppages impact training and career development?
- Are academic institutions bridging support for junior investigators?
- How do institutions ensure that trainees and early-stage investigators are prioritized in the re-startup process?

Dr. Peek reported that with academic institutions short on resources and focused on other priorities, there is an opportunity for NIDDK to take the lead role in addressing the training and career development needs of early-stage investigators. Flexibility seems to be a common theme among recommendations, especially when it comes to timing of grants submissions and preliminary data. Another point to consider is how the suspension of research should affect T32 appointments, payback regulations, and research experience.

Dr. D'Alessio added that young investigators may not be able to collect data while labs are closed and that might affect the next grant cycle and job prospects. Ideas include adding an additional review cycle for next year to keep review workloads manageable for the study sections, ensuring robust review of new investigator/ESI applications; keeping in mind the delays when study sections look at this year's young investigators (as compared with previous years); and increasing or extending the number of grants or funding periods to make up for the additional time necessary to become job-ready. Dr. D'Alessio added that it would be a disaster to lose a generation of good investigators because they came on the job market at the wrong time.

Suggestions from Council members included:

- A 6-month funded extension on the various types of training grants and career development awards to give young investigators additional time to move forward. Many institutions are freezing new hires now and this would ensure young investigators continue to be supported during this time. Grant extensions may also help those who had job offers that were withdrawn because of financial decisions due to COVID-19.
- A survey of T32 directors and scholars may reveal what investigators really need right now. These surveys would have to be anonymous to obtain candid responses.
- Trainees who are parents—and particularly women trainees— have been disproportionately affected because of school closures, homeschooling, and childcare.
- Minimizing paperwork and application requirements will avoid creating more work for those NIDDK is trying to help.

Role of NIH/NIDDK in "Restarting" the Research Enterprise

Discussion of this topic was moderated by Drs. Leonard Zon and Barbara Kahn, who had proposed its addition to the Forum.

Keeping in mind limited funds available, prior to the Forum Drs. Zon and Kahn developed and shared with NIDDK and Council members a list of non-monetary solutions, resources, and small supplements. These include:

- Flexibility in study section considerations, such as evaluation of preliminary data, deadlines for submitting data, or consideration of bio-archive papers as publications for the purpose of grant application review. Adding another grant application review cycle may also help.
- Flexible start dates and other administrative aspects.
- Informational or advisory resources, such as a video about how young investigators are dealing with lack of productivity and some practical considerations.
- An external advisory committee on COVID-19 issues.
- Animal husbandry and facility ramp-ups (already noted under the previous topics).
- Providing guidance to PIs for grant management, addressing issues such as paying salaries, dealing with funding cycles.
- Funding more K awards to help prevent promising investigators from leaving research.
- Supplementing K awardees and extending salaries for K awardees; this might help because many will be delayed in submitting R01 grant applications.
- Matching funds might enable institutions to keep postdocs on while they wait for job offers that have been put on hold.
- An enhanced grant mechanism for junior investigators to obtain their first grant with less data.
- For investigators at all levels, awards to support the most robust aims of a grant application rather than no support at all.
- Considerations for equipment repair or service contracts on equipment that didn't get used.
- Enhanced bridge funding for PIs with only one R01.

Council members brought up the following points:

- Bridge funding may not make sense for people on a 5-year grant; may need some limitations to prevent a flood of interest.
- Trainees whose job offers are on hold may end up competing with those next in line. Extending fellowships seems like a good idea.
- Need to consider that this situation may continue for longer than 6 months and solutions must be sustainable.
- Trainees may also need personal outreach and support during this time.
- Trainees may want to take advantage of this time to do additional coursework or to obtain training in informatics or big data analysis—types of research and remote science that are more likely to continue. This may be an opportunity for quantitative scientists, computational scientists and bench researchers to work together.
- Partial funding can be a flexible way that reduces the budget on grants while keeping people active in research with good ideas.

After the discussion wrapped up, Dr. Saslowsky mentioned several COVID-19-specific research funding opportunities that NIDDK is leading or participating in. These include:

- NOT-DK-20-018 Notice of Special Interest (NOSI): Availability of Urgent Competitive Revision Supplements on Coronavirus Disease 2019 (COVID-19) within the Mission of NIDDK
- NOT-DK-20-020 NOSI: Availability of Urgent Competitive Revision Supplements on COVID-19 Related to HIV Comorbidities, Coinfections, and Complications within NIDDK's Mission
- NOT-OD-20-097 NOSI regarding the Availability of Administrative Supplements and Urgent Competitive Revisions for Research on the 2019 Novel Coronavirus and the Behavioral and Social Sciences
- NOT-RM-20-015 NOSI: Availability of Emergency Competitive Revisions for Research on Severe Acute Respiratory

Dr. Rodgers thanked the Council members for their participation in the forum, adding that staff will be summarizing the discussion and moving forward with ideas. He pointed out that NIDDK may be one of the first NIH ICs considering these contingencies and he plans to share these ideas within NIH and also with other HHS components, as the problems discussed relate not only to NIH but also to sister agencies such as FDA, CMS and CDC.

He then turned the meeting over to Dr. Malik for housekeeping details for the subcommittee and closed Council meetings scheduled for later in the day.

VIII CONSIDERATION OF REVIEW OF GRANT APPLICATIONS.

A total of 1479 grant applications (572 primary and 907 dual), requesting support of $643,142,108 were reviewed for consideration at the May 11, 2020, meeting. An additional 1291 Common Fund applications requesting $2,099,288,061 were presented to Council. Funding for these applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, 982 applications requesting $332,470,747 received second-level review through expedited concurrence. All of the expedited concurrence applications were recommended for funding at the Scientific Review Group recommended level.

IX 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 213th meeting of the NIDDK Advisory Council was adjourned at 3:45 p.m.

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

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