

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 212th meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council at 8:30 a.m. on January 30, 2020, at the Natcher Conference Center, Conference Room E1/E2, the NIH Campus, Bethesda, Maryland. As part of a pilot program, the open session of the full Council meeting was videocast live and available internally to NIH staff.

A. ATTENDANCE – COUNCIL MEMBERS PRESENT

Dr. David D'Alessio*
Dr. Toby Chai+
Dr. Iain Drummond
Dr. Penny Gordon-Larsen
Dr. Lisa Guay-Woodford
Dr. Barbara Kahn[§]
Dr. David Klurfeld*
Mr. Richard Knight
Mr. Thomas Nealon
Dr. Richard Peek

Dr. David Penson+
Dr. Jeffrey Pessin
Ms. Ceciel Rooker+
Dr. Kathleen Sakamoto+
Dr. Elizabeth Seaquist+
Dr. Michael Snyder
Dr. Ronald Sokol
Dr. Ian Stewart*
Ms. Lorraine Stiehl
Dr. Gary Wu

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

* *Ex Officio* member

+ *Ad hoc* member

[§] Joined through teleconference

NIDDK STAFF AND GUESTS

Abbott, Kevin – NIDDK
Abraham, Kristin – NIDDK
Agodoa, Lawrence – NIDDK
Andersen, Dana – NIDDK
Barnard, Michele – NIDDK
Barthold, Julia – CSR
Bavendam, Tamara – NIDDK
Berti-Mattera, Liliana – CSR
Boerboom, Lawrence – CSR
Begum, Najma – NIDDK
Bishop, Terry – NIDDK
Blondel, Olivier – NIDDK
Bourque, Sharon – NIDDK
Burch, Henry – NIDDK

Burgess-Beusse, Bonnie – NIDDK
Cappellacci, Ben – Palantir Tech
Camp, Dianne – NIDDK
Cash, Lisa – BETAH Associates
Castle, Arthur – NIDDK
Cerio, Rebecca – NIDDK
Connaughton, John – NIDDK
Copeland, Randy – NIDDK
Cowie, Catherine – NIDDK
Curling, Mitchell – NIDDK
Curtis, Leslie – NIDDK
Davila-Bloom, Maria – NIDDK
Dayal, Sandeep – NIDDK
Denny, Alexis – PKD Foundation

Densmore, Christine – NIDDK
Dirks, Dale – Digestive Disease National
Coalition
Doherty, Dee – NIDDK
Donohue, Patrick – NIDDK
Doo, Edward – NIDDK
Drew, Devon – NIDDK
Eggerman, Thomas – NIDDK
Evans, Mary – NIDDK
Fisher, Rachel – NIDDK
Gansheroff, Lisa – NIDDK
Girvin, Andrew – Palantir Tech
Gossett, Daniel – NIDDK
Greenwel, Patricia – NIDDK
Guo, Xiaodu – NIDDK
Haft, Carol – NIDDK
Hanlon-Tilghman, Mary – NIDDK
Hoff, Eleanor – NIDDK
Hoffert, Jason – NIDDK
Hoofnagle, Jay – NIDDK
Hoover, Elise – PKD Foundation
Hoshizaki, Deborah – NIDDK
Hyde, James – NIDDK
Jenkin, Connie – NIDDK
Jenkins, Ann – NIDDK
Karp, Robert – NIDDK
Ketchum, Christian – NIDDK
Kimmel, Paul – NIDDK
Kirkali, Ziya – NIDDK
Kozel, Peter – NIDDK
Kuczmarski, Robert – NIDDK
Laakso, Joseph – Endocrine Society
Larkin, Jennie – NIDDK
Lawlor, Sharon – NIDDK
Lee, Christine – NIDDK
Li, Yan – NIDDK
Linder, Barbara – NIDDK
Lynch, Christopher – NIDDK
Martin, Heather – NIDDK
Martinez, Winnie – NIDDK
Maruvada, Padma – NIDDK
Mendley, Susan – NIDDK
Morris, Ryan – NIDDK
Mullins, Christopher – NIDDK
Murray, Ryan – Am. Society of Nephrology
Nguyen, Van – NIDDK
Osganian, Voula – NIDDK
Otradovec, Heidi – NIDDK
Parsa, Afshin – NIDDK
Perrin, Peter – NIDDK
Perry-Jones, Aretina – NIDDK
Portnoy, Matthew – NIDDK
Rankin, Tracy – NIDDK
Regan, Karen – NIDDK
Repique, Charlene – NIDDK
Rieff, Heather – NIDDK
Rivers, Robert – NIDDK
Roberts, Tibor – NIDDK

Rosenberg, Mary Kay – NIDDK
Roy, Cindy – NIDDK
Rushing, Paul – NIDDK
Sadusky, Anna – NIDDK
Saslowsky, David – NIDDK
Sato, Sheryl – NIDDK
Schulman, Ivonne – NIDDK
Sechi, Salvatore – NIDDK
Serrano, Jose – NIDDK
Serrano, Katrina – NIDDK
Shelness, Greg – CSR
Shepherd, Aliecia – NIDDK
Sherker, Averell – NIDDK
Sierra-Rivera, Elaine – CSR
Silva, Corinne – NIDDK
Singh, Megan – NIDDK
Smith, Jaime – NIDDK
Smith, Philip – NIDDK
Smith, Theresa – NIDDK
Smith, Thomas – NIDDK
Spain, Lisa – NIDDK
Teff, Karen – NIDDK
Thornton, Pamela – NIDDK
Tian, Lan – NIDDK
Tilghman, Robert – NIDDK
Unalp-Arida, Aynur – NIDDK
Van Raaphorst, Rebekah – NIDDK
Vinson, Terra – NIDDK
Wallace, Julie – NIDDK
Wang, Xuqing – NIDDK
White, Vanessa – NIDDK
Wilkins, Kenneth – NIDDK
Wright, Elizabeth – NIDDK
Xia, Ashley – NIDDK
Yang, Jain – NIDDK
Yanovski, Susan – NIDDK
Zaghloul, Norann – NIDDK

B. ANNOUNCEMENTS

Dr. Rodgers

Council Member News

Dr. Rodgers recognized new *ad hoc* members at the meeting: **Dr. Elizabeth Seaquist** is director of the Division of Diabetes, Endocrinology, and Diabetes and Pennock Family Chair in Diabetes Research at the University of Minnesota Medical School. Dr. Seaquist will serve on the Diabetes, Endocrinology and Metabolic Diseases (DEM) subcommittee. **Ms. Ceciel Rooker** is President and Executive Director of the International Foundation for Gastrointestinal Disorders (IFFGD) and will serve on the Digestive Diseases and Nutrition (DDN) subcommittee. **Dr. Toby Chai** is chief of Urology at Boston Medical Center and professor and chair of the Department of urology at Boston University School of Medicine. He will serve on the Kidney, Urologic, and Hematologic (KUH) subcommittee. Also joining the KUH subcommittee are **Dr. David Penson** and **Dr. Kathleen Sakamoto**. Dr. Penson is Paul V. Hamilton MD and Virginia E. Hold chair of Urologic Oncology and professor and chair of medicine and health policy at Vanderbilt University Medical Center. Dr. Sakamoto is Shelagh Galligan Professor in the School of Medicine at Stanford University. Dr. Rodgers thanked them all for their time and participation.

Dr. Rodgers continued with additional announcements.

Two NIDDK grantees and former NIDDK council members were among the 100 new members elected to the National Academy of Medicine in 2019. Election to the Academy is one of the highest honors in the field of health and medicine and recognizes those who have demonstrated outstanding professional achievement and commitment to service.

- **Dr. Anil Rustgi** is director of the Herbert Irving Comprehensive Cancer Center at New York Presbyterian/Columbia University Irving Medical Center and associate dean of oncology and Irving Professor of Medicine at Columbia University's Vagelos College of Physicians and Surgeons. He was elected for illuminating the importance of GI cancer genomics and genetics and demonstrating that p120-catenin (part of the adherens junctions) is a tumor suppressor in cancers and for linking p120-catenin to mesenchymal-epithelial transition (MET) in tumor metastasis, advancing therapeutic opportunities.
- **Dr. Ray DuBois** is dean of the college of medicine and professor of biochemistry and medicine at the Medical University of South Carolina in Charleston. Dr. DuBois was elected for discovering the critical and mechanistic role of prostaglandins (PGs)/cyclooxygenase in colon cancer and its malignant progression, elucidating the role of PGs in the tumor microenvironment, and spearheading the now-common use of drugs for human cancer prevention that target the PG pathway, like aspirin and other nonsteroidal anti-inflammatories.

On a more somber note, Dr. Rodgers recognized the passing of **Dr. Lloyd Aiello**, an

ophthalmologist and pioneer in the treatment of diabetic retinopathy during his long, distinguished career at Joslin Diabetes Center in Boston. In 1967, Dr. Aiello worked with his father-in-law (William P. Beetham, MD) to revolutionize the treatment of diabetic retinopathy with the use of laser photocoagulation, which remained the standard care for almost 50 years until the recent introduction of antibody therapies. Dr. Aiello also worked to develop a telemedicine system to detect abnormal blood vessel growth in the retina, facilitating early diagnosis of diabetic retinopathy for patients who live far from medical specialists. He was a compassionate, dedicated, and innovative physician scientist whose work saved the vision of people worldwide.

Dr. Rodgers noted that NIDDK celebrates its 70th anniversary in 2020, which will be marked with banners on the NIH campus, articles in NIH publications, and other observances.

He also mentioned that NIDDK is expanding its social media presence by piloting @niddk.gov on Instagram this month, in addition to existing Twitter, Facebook and YouTube channels.

NIDDK Staff News

Dr. Rodgers reported the following staffing news:

Dr. Rodgers welcomed **Dr. Terez Shea-Donohue** as program director in the Division of Digestive Diseases and Nutrition (DDN), where she will oversee projects relevant to integrative gastrointestinal physiology. Dr. Shea-Donohue earned her Ph.D. in physiology and biophysics from Georgetown University and completed her postdoctoral training at the Uniformed Services University for Health Sciences (USUHS). She continued her career there, attaining the rank of professor of medicine. In 2004, she joined the newly formed Mucosal Biology Research Center at the University of Maryland School of Medicine, where she became a tenured professor of medicine. Her most recent research centered on the impact of GI inflammation on neurocognitive behavior during recovery from brain injury and received the Jansen Award for Outstanding Basic Science Research from the American Gastroenterological Association Institute. Before joining NIDDK, she served as a scientific review officer at the NIH Center for Scientific Review.

He also welcomed **Dr. Ivonne Schulman** as program director for translational and clinical studies and acute kidney injury (AKI) within the Division of Kidney, Urology, and Hematology (KUH). Dr. Schulman earned her medical degree and completed her clinical nephrology fellowship at the University of Miami Miller School of Medicine. Before joining NIDDK, she held several positions at the University of Miami: professor of clinical medicine, fellowship director for the Interdisciplinary Stem Cell Institute, and medical director for the Davita Dialysis Unit. Dr. Schulman's research focused on identifying the mechanisms underlying the cardiovascular regenerative capacity of adult stem cells. Dr. Rodgers noted that her experience with young clinical trainees and PIs positions Dr. Schulman well for working with junior nephrology PIs.

Dr. Katrina Serrano has also joined NIDDK in the Office of Minority Health Research Coordination (OMHRC), where she oversees a portfolio aimed at advancing the science for the health of underrepresented populations and the training of underrepresented investigators. Dr. Serrano received her master's and doctoral degrees in health education from Texas A&M University and completed postdoctoral training in the Behavioral Research Program with the National Cancer Institute's Division of Cancer Control and Population Sciences. Previously, Dr. Serrano was a program officer for the NIH OD Office of Research on Women's Health.

Dr. Rodgers also announced several awards earned by staff members:

- **Dr. Peter Perrin** (Program Director for Gastrointestinal Host-Microbial Interactions, Basic Mucosal Immunology and Inflammation, within DDN) will receive the 2020 American Gastroenterological Association Research Service Award, which recognizes an individual whose dedicated efforts have significantly advanced gastroenterological science.
- **Dr. Paul Kimmel** (Program Director within KUH) received The Belding H. Scribner Award from the American Society of Nephrology. The award is presented to those who make outstanding contributions to the care of patients with kidney disorders or substantially influence the clinical practice of nephrology. Dr. Kimmel was recognized for his career-long contributions, including research studies of patient-centered issues, such as depression, anxiety, poverty and adaption to chronic illness in patients with kidney disease.

Dr. Germino highlighted two awards received by Dr. Rodgers. First, the American Society of Hematology (ASH) honored Dr. Rodgers with the ASH Award for Leadership in Promoting Diversity at its annual meeting in December. In addition to serving as the director of NIDDK, Dr. Rodgers is the chief of the NIDDK Molecular and Clinical Hematology Branch and Molecular Hematology Section, where he has worked to achieve broad representation of diverse populations, both in the scientific workforce and among those who participate in clinical trials. The award recognizes his extraordinary commitment to diversity and inclusion in hematology. Second, Dr. Rodgers recently served as the John Morgan Visiting Professor at the University of Pennsylvania Perelman School of Medicine where he gave a Grand Rounds presentation on sickle cell anemia as part of this distinction. The professorship was established to honor Dr. John Morgan, who served as the first chair of the University of Pennsylvania Department of Medicine.

Dr. Rodgers drew Council members' attention to the 2020 edition of NIDDK's **Recent Advances and Emerging Opportunities** report, which is released annually at the Advisory Council's winter meeting. This is the 20th edition of the publication and coincides with the Institute's 70th anniversary. The report cover art includes images from NIDDK-supported efforts to develop 3-D chips that replicate the structure and function of human organs and tissues to model human health and disease states in the laboratory. These chips hold promise to advance knowledge of human biology, act as platforms for validating biological markers of disease, and play a central role in drug development and testing.

The report itself includes summaries of scientific presentations given at Council meetings in

2019 as well as stories about NIDDK-supported research and researchers as well as patients who live with or are at risk for diseases that are part of NIDDK's mission. This year's edition also includes a section on funding trends that illustrate NIDDK's commitment to its guiding principles, which were first presented at the May 2012 Council meeting. Dr. Rodgers acknowledged that production of the report is an institute-wide effort and particularly thanked the Office of Scientific Program and Policy Analysis for developing content and managing the project, and both extramural and intramural staff for providing input.

II. CONSIDERATION OF SUMMARY MINUTES OF THE 211th COUNCIL MEETING

Dr. Rodgers

The Council approved, by voice vote, the Summary Minutes of the 211th Council meeting, which had been sent to them in advance for review.

III. FUTURE COUNCIL DATES

2020

May 12-13 (Tuesday and Wednesday)

Natcher Conference Center (Building 45)

Rooms E1/E2, D, and F1/F2

September 9-10 (Wednesday and Thursday)

Building 31, C-Wing 6th Floor

Conference Center, Rooms 6, 7, and 10

2021

January 21-22 (Thursday and Friday)

Building 31, C-Wing 6th Floor

Conference Center, Rooms 6, 7, and 10

May 12-13 (Wednesday and Thursday)

Natcher Conference Center, (Building 45)

Rooms E1/E2, D, and F1/F2

September 1-2 (Wednesday and Thursday)

Natcher Conference Center, (Building 45)

Rooms E1/E2, D, and F1/F2

Most meetings are expected to be a single day. However, the NIDDK asks Council members to reserve two days for each meeting should a situation arise where a longer meeting is required.

Note: Dr. Rodgers informed the Council that the May 2020 meeting will move to Tuesday and Wednesday, May 12-13. Renovations on the Building 31 conference center have encountered further delays and may not be completed before the May meeting. This schedule is a departure from the typical Wednesday/Thursday meeting pattern made to accommodate the location change.

In addition, The January 2021 meeting has been moved to January 21-22 because January 19 is Inauguration Day and a federal holiday.

IV. ANNOUNCEMENTS

Dr. Karl Malik

Confidentiality

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

Conflict of Interest

Dr. Malik reminded 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 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.

Approval of 2020 Council Operating Procedures

Dr. Malik explained that at the winter meeting the NIDDK Council must approve operating procedures for the coming year. The proposed procedures for 2020—essentially unchanged from 2019—were sent to the Council with the premeeting materials. The only changes are the dates of the meetings. The motion was made and accepted.

V. REPORT FROM THE NIDDK DIRECTOR

Dr. Rodgers

Budget Update

Dr. Rodgers reported on the NIH appropriations for fiscal year (FY) 2020. The President's FY 2020 request was released in March 2019, and it proposed \$33.895 billion for NIH and \$1.747 billion for NIDDK. The House passed its Labor-HHS appropriations bill in June 2019, which provided \$41.084 billion for NIH and \$2.129 billion for NIDDK. Shortly after the last Council meeting in September, the Senate released language for their Labor-HHS appropriations bill, which provided a \$3 billion or 7.7 percent increase in NIH funding for a total of \$42.084 billion. The NIDDK portion of that was \$2.155 billion, a 6.2 percent increase over 2019.

Because an agreement could not be reached by the end of the fiscal year on September 30, 2019, Congress passed, and the President signed, continuing resolutions in late September and again in November to avert a government shutdown. The House and Senate reached an agreement in December, and the President signed two mini-bus appropriation packages on December 20, 2019, fully funding the government for FY 2020. The bill appropriated \$41.459 billion to NIH, which included \$2.114 billion for NIDDK, representing a 6.08 percent and 4.2 percent increase, respectively, for each. (Dr. Rodgers noted that these amounts do not include the Special Diabetes Fund that is allocated separately.)

With these increases, which are greater than the biomedical inflation index, NIDDK projects that it will be able to increase its payline for established and early stage investigators as well as for a group of investigators who recently received their first R01 grant from NIDDK and are in the process of submitting renewal applications.

Dr. Rodgers explained that, at any given time, NIDDK must juggle three different budget cycles simultaneously: closing down the previous fiscal year's cycle, operating in the existing fiscal year cycle, and preparing for the next appropriations cycle. The FY 2021 process will start with the President's budget, expected to be released on February 10th. Congress follows with their appropriations hearings in the spring. An update on the FY 2021 appropriations process will be included in the May Council meeting.

Dr. Rodgers also reported on recent congressional activities. On September 17, 2019, he met with members of the House Labor-HHS Appropriations Subcommittee who visited NIH, including Chairwoman Rosa De Lauro (Connecticut), Representative Lucille Roybal-Allard (California), and Representative Lois Frankel (Florida). Also in September, Dr. Rodgers met with Representative Ed Case (Hawaii) and spoke with him about NIDDK's research activities, as well as training programs and early career opportunities for underrepresented minorities, including Native Hawaiians and Pacific Islanders.

Council Questions and Discussion

Dr. Pessin suggested that, if possible, part of the increase in funding for NIDDK could go to support equipment purchases for institutions. He noted that equipment purchases of \$50,000-\$100,000 are difficult to fund through the R01 mechanism yet are important to continuing research.

VI. COUNCIL FORUM: DATA SCIENCE AND DATA MANAGEMENT

Dr. Rodgers informed the Council of the launch of a year-long Council Forum on the Data Science Ecosystem. The rapid growth of massive and rich data sources, such as new imaging modalities, multi-omics methods, and clinical records, have changed how we use and store data. This new era requires better management of data, improved structures for supporting data sharing and integration, and new computational frameworks and analytical approaches to support innovative research. The Council Forum on the Data Science Ecosystem will consider how this space is evolving, how NIDDK is aligned in the context of this evolution, and opportunities for the future.

Dr. Rodgers then introduced Dr. Jennie Larkin to kick off the Council Forum. Dr. Larkin is Director of the Office of Research Evaluation and Operations (OREO) within NIDDK's Division of Extramural Activities.

Dr. Larkin began by explaining that this forum will explore the rapidly evolving landscape of data-related resources, policy, and research opportunities. It has two goals: to provide Council with an overview of key data science activities across biomedicine at NIH, and to inform Council discussions on possible opportunities and barriers and their impact on NIDDK-supported science. She shared the following topics, presenters and dates:

- **NIH Data Management and Data Science Activities** (January 2020) Dr. Susan Gregurick (NIH Associate Director of Data Science) will present the NIH Strategic Plan for Data Science.
- **How Data Management Strengthens Research and Discovery** (May 2020) Representatives from two Institutes and Centers (ICs) will provide perspectives on costs and benefits of integrating diverse data together into a managed data resource.
- **Artificial Intelligence Acceleration of Biomedical Research** (September 2020) Dr. Atul Butte of the University of California-San Francisco and Chief Data Scientist of the UC

Health System will address AI's impact on biomedical research, highlighting opportunities and limits of these approaches.

For the purposes of her presentation, Dr. Larkin defined data science as an interdisciplinary field that brings together the approaches of computational biology and statistics with biomedical knowledge to extract insights from structured and unstructured data. This includes data collection, data integration and visualization, and knowledge mining.

Dr. Larkin noted that the exponential growth and increasing complexity of available data about the natural world is both an opportunity and a huge problem, and data science can be the facilitator that helps researchers make sense of the data.

Good data science doesn't happen in a vacuum, Dr. Larkin said, singling out three key components of the data science ecosystem. These components include:

- Good data management
- Effective data sharing
- Data integration and re-use

These elements provide the optimal framework for achieving new discoveries, Dr. Larkin said.

Data Management

Dr. Larkin highlighted several initiatives supported by NIDDK that foster good data management, including the use of common data elements (CDEs) and their consolidation via the NIH CDE Repository. NIDDK has also supported [dkNET](#), the research portal that supports data and resource discovery among the NIDDK research community. dkNET provides important information about best practices in research data management, including links to high-quality data management planning tools like the University of California's California Digital Library, which features "DMPTool," a data management planning tool that helps PIs format data management plans.

dkNET also assists investigators with finding research resource identifiers (RRIDs) through their portals. These unambiguous identifiers can be used to differentiate antibodies, cell lines, and model organism strains. RRIDs permit investigators to unambiguously identify the resources that are part of their research, which in turn allows for increased reproducibility, thereby quickening the pace of scientific discovery.

Data Sharing

Next, Dr. Larkin discussed data sharing as a vital part of the data ecosystem, focusing on effective data sharing as being findable, accessible, interoperable and reusable (FAIR). She then used the FAIR framework to discuss how NIDDK can help investigators to share their data without expecting them to become expert data scientists.

She suggested NIDDK might want to consider how to help repositories host data effectively by identifying and publicizing repository best practices, as well as assisting with helping

repositories ensure that data can be reused. Data reuse is relevant to both rigor and reproducibility, ensuring that the data underlying publications are available to support the transparency of the research paradigm. Data reuse can also inform new scientific questions by the juxtaposition of multiple unrelated datasets. Finally, NIDDK can promote such practices by acknowledging both individual investigators and groups who are leaders in sharing and reusing high-quality data.

Scientists benefit from data sharing because doing so enables the validation of scientific results and allows analyses to be strengthened by combining data. Additionally, data sharing facilitates reuse of hard-to-generate data and accelerates future research. Data sharing also benefits the public by demonstrating proper stewardship of taxpayer funds, fostering transparency and accountability, and maximizing research participants' contributions.

Dr. Larkin shared data showing that NIH- and NIDDK-funded authors now routinely indicate how they share the data underlying their publications. The rate of data-sharing rose from about 30 percent of publications listed in PubMed Central in 2010 to almost 70 percent in 2019. Additionally, PubMed Central offers filters to let users identify which publications have data availability statements.

The Institute provides primary support for data sharing via the [NIDDK Central Repository](#), which curates, archives, and shares samples and data from >150 major multi-site clinical studies and trials. NIDDK has custodianship of all samples and data transferred to the Repository, and all data is quality-checked, curated, and de-identified. Additionally, no intellectual property protections are attached, and exclusive data access for study investigators is time-limited, ensuring that other investigators have access to data and samples following study completion.

NIH has spent the past several years updating its data management and sharing policy with a high level of engagement from the community. Following the recent end of the public comment period, NIH hopes to finalize the policy within the next several months. Additionally, the Office of Science Technology Policy (OSTP) has requested public comment on a trans-agency draft document identifying desirable characteristics for repositories for managing and sharing data. The goal is to establish a common understanding across all the NIH ICs of what constitutes a good data repository.

Data Integration and Reuse

Dr. Larkin emphasized that NIDDK has a strong history of supporting resources that permit both raw data and the knowledge derived from NIDDK-supported research to be both discoverable and reusable by the community. This includes provision of both a computing infrastructure to process data, as well as data integration and visualization tools to support knowledge mining by the community.

Dr. Larkin used a NIDDK-funded study to illustrate how artificial intelligence can solve bottlenecks and accelerate research. Pathologists usually classify diabetic nephropathy based on visual assessment of glomerular pathology. Although diagnostic guidelines are well

established, results may vary among pathologists. Modern machine learning has the potential to automate and improve accuracy in classifying diabetic nephropathy. Digital algorithms may also be able to extract novel features relevant to disease progression and prognosis. The authors used image analysis and machine learning algorithms to digitally classify biopsy samples from 54 patients with diabetic nephropathy and found substantial agreement between digital classifications and those by three different pathologists. This study demonstrates that digital processing of renal tissue may provide useful information that may augment traditional clinical diagnostics.

NIH's Strategic Vision for Data Science: Enabling a FAIR-Data Ecosystem

Dr. Susan Gregurick

Dr. Larkin introduced Susan Gregurick, Ph.D., Associate Director for Data Science and the Director of the NIH Office of Data Science Strategy. Dr. Gregurick brings substantial experience in computational biology, high performance computing, and bioinformatics to her roles. Most recently, she was Director of the Division of Biophysics, Biomedical Technology, and Computational Biosciences in the National Institute of General Medical Sciences (NIGMS). In this role, she oversaw programs that advance research in computational biology, biophysics and data sciences, mathematical and biostatistical methods, and biomedical technologies in support of the NIGMS mission to increase understanding of life processes. Previously, she worked for the Department of Energy overseeing the development and implementation of the agency's Systems Biology Knowledgebase and was professor of computational biology at the University of Maryland, Baltimore County, from 2000-2007.

Dr. Gregurick used four case studies to show how different types of research being conducted at NIH could benefit from applying a data science approach.

The first was a study of genetic and dietary effects on chronic obstructive pulmonary disease (COPD), a significant cause of disability and death in the United States. To date, separate studies have been done to collect genomic and dietary data for subjects with COPD, and researchers know that many of the same subjects participated in the two studies. Linking these datasets together would allow researchers to examine the combined effects of genetics and diet using the subjects present in both studies. However, different identifiers were used to identify the subjects in the different studies.

The situation presents researchers with several challenges: obtaining access to all the relevant datasets so they can be analyzed, understanding consent for each study to ensure that data usage limitations are respected, and connecting data from the same subject across different datasets so that the genetic and dietary data from the same subjects can be linked and studied, while avoiding any duplicated data.

In the second case study, hypothetical investigators might wish to utilize machine learning to mine large datasets to find features of mechanistic or diagnostic interest. Major challenges could include: accessing sufficiently high-quality datasets that are ready for machine learning; difficulties moving large datasets across networks to local computers or the cloud; access to

training and/or staff to develop new algorithms; and obtaining access to specialized hardware to run the analysis software.

The third case study focused on researcher confusion about what the concept of FAIR data (Findable, Accessible, Interoperable and Reusable) means in actual practice. These challenges include: how to prioritize time-consuming dataset annotation and curation that is perceived as an added burden; how to select metadata for annotation that is compatible with other datasets and tools in the ecosystem; and where to put the data for secure, long term storage while facilitating access for authorized users.

The fourth case focused on the need to broaden access to datasets, so citizen-scientists' can look for unrecognized patterns and relationships across datasets and beyond their research areas or disciplines. For example, computer scientists might like to compare two different biomedical datasets. Relevant challenges include: getting the word out so that more people can participate in citizen-science activities related to their expertise; obtaining data access for users who do not belong to traditional academic research organizations; and addressing siloed data organized by disease or body part in order to integrate diverse datasets.

Dr. Gregurick then discussed how data science can help solve these challenges in the next five years. She pointed out that the NIH Strategic Plan for Data Science would enable agencies to link data platforms from different ICs or agencies. Thus, researchers could take data from the Framingham Heart Study and link it with data from Alzheimer's, for example, in order to understand associations between cardiovascular health in aging and dementia.

The NIH Strategic Plan for Data Science would also assist with the problem of so-called dark data, in which published data remains unavailable for other researchers to use. Currently, a researcher would have to write to the PI of the study with the data of interest and then a member of the PI's team would have to make a copy of the data, annotate it, and then load the data into a system the outside researcher could use.

Implementation of the NIH Strategic Plan for Data Science would also allow for enhanced data security and data privacy, so that investigators would gain the ability to link electronic health care records with personal data and with clinical and basic research data.

Dr. Gregurick then discussed the goals of the NIH Strategic Plan for Data Science in five main areas:

- Data infrastructure
- Modernized data ecosystem
- Data analytics, management, and tools
- Workforce development
- Stewardship and sustainability

Data Infrastructure

Dr. Gregurick explained that the new plan is intended to build on NIH's longstanding

commitment to making research results and accomplishments available to the public. She outlined the current timeline for finalizing new data infrastructure requirements for NIH grantees, noting that the goal is for the final policy to be released this spring.

Dr. Gregurick stressed that both intramural and extramural researchers with NIH-funded or conducted research projects that result in the generation of scientific data will be required to submit a plan for data management. Each plan should explain how the scientific data generated by a research study will be managed. More detailed information will be forthcoming when the final policy is released, she said.

Modernized Data Ecosystem

The main goal in modernizing the data ecosystem is to support the storage and sharing of individual datasets via contribution to a public, open-source repository or a repository with authentication authorization for controlling privacy data. Part of this involves better integration of clinical and observational data into biomedical data science.

Dr. Gregurick noted that NIH strongly encourages open-access data sharing repositories as a first choice and shared the [link to Trans-NIH Biomedical Informatics Coordinating Committee \(BMIC\) page on data-sharing resources](#). In general, she said, NIH does not endorse or require sharing in any specific repository, but rather encourages researchers to select the repository that is most appropriate for their data type and discipline. (Some initiatives do specify a repository, however.) To help researchers locate an appropriate resource for sharing their data and promote awareness of resources where datasets can be located for reuse, BMIC maintains lists of several types of data-sharing resources:

- Open NIH-supported domain-specific repositories that house data of a specific type or related to a specific discipline;
- Other NIH-supported, domain-specific resources, including repositories and knowledgebases, that have limitations on submitting and/or accessing data; and
- Generalist repositories that house data regardless of type, format, content, or subject matter.

Dr. Gregurick also noted that PubMed now links datasets with Digital Object Identifiers (DOIs), in the supplemental materials of publications. Additionally, NIDDK, dkNET and NIH support Research Resource Identifier (RRID) use. NIDDK has taken the lead in supporting RRID use, and she predicts the rest of NIH will follow NIDDK's lead.

Data Analytics, Management, and Tools

Dr. Gregurick discussed the need to optimize funding for NIH data repositories and knowledgebases. She noted that data resources have historically been funded through NIH research grants and that R01 grants have been the leading source of funding. However, this may not be the optimal funding mechanism for this type of resource.

NIH has issued a new funding announcement for data repositories and knowledgebases so that they can be funded, reviewed, and managed as data resources and not as research grants. This new mechanism should aid in achieving the goal of increasing widespread researcher

confidence in data and information integrity from these repositories. A resource plan will be required as well as a sustainability plan. Additionally, there are four main critical elements required in order to receive funding: scientific impact, community engagement, quality of data, and governance.

Dr. Gregurick then discussed Figshare, a data-sharing resource available for use by all NIH-funded researchers. Figshare is primarily for data that has no logical place to be stored and shared because the data doesn't naturally align with a domain-specific repository. Additional examples include data underlying publication figures and tables or useful data not associated with a publication.

NIH is currently running a pilot project with Figshare to learn how NIH researchers are sharing data, she said. So far, examples include some researchers who are sharing physician workflows and others who are sharing small-angle scattering data. Notably, all data is assigned a DOI so as to be citable. Fortunately, metadata templates exist so researchers can quickly generate and deposit data, including grant information so that NIH can understand the association between data and a researcher's grant. All data is searchable and indexed for search engines like Google or Bing, but researchers can also restrict how their data can be reused. As part of the pilot project, NIH Figshare offers some exclusive features, including support for larger datasets, updated metadata to improve discoverability of research, and courtesy data validity checks and review of dataset title and associated text by the Figshare team.

At the end of the year-long pilot program, the NIH will determine how generalist repositories best fit into the biomedical data repository ecosystem. Regardless of the outcome, researchers will still be able to access their published data via the main Figshare platform.

Dr. Gregurick next reviewed the Science and Technology Research Infrastructure for Discovery, Experimentation and Sustainability Initiative, better known as the STRIDES program. The NIH has been placing data into the STRIDES cloud platform, which features significant computation, analytics and data-sharing capabilities.

STRIDES provides professional services, including:

- Discounts on STRIDES partner services—such as for computing, storage, and related cloud services—for NIH Institutes, Centers, and Offices and NIH-funded researchers through their institutions.
- Professional services, including consultations and technical support, from STRIDES Initiative partners.
- Training for researchers, data owners, and others to help ensure optimal use of available tools and technologies.
- Potential collaborative engagements—Opportunities to explore methods and approaches that may advance NIH's biomedical research objectives

To access STRIDES services, intramural researchers will work with CIT staff to establish STRIDES accounts, enroll intramural team members, and provide a payment mechanism.

Extramural researchers will work with their institutions to gain STRIDES access via Carahsoft (Google) or Four Points (Amazon). The researcher's institution will set up the agreements with STRIDES and manage the enrollment of NIH-funded investigators. This includes account establishment, billing arrangements, and provision of data metrics, which will be reported to the funding IC.

Currently, the STRIDES cloud contains 30 petabytes of NIH data, including NHLBI's Framingham Heart Study, the All of Us Research Program, NCI Genomic Data Commons, NHLBI Trans-Omics for Precision Medicine (TOPMed) Program, and 12 petabytes of NCBI data resources. Dr. Gregurick anticipates that this data total will increase to 50 petabytes within the next year and noted that it is searchable using advanced artificial intelligence algorithms.

Dr. Gregurick also discussed NIH's efforts to develop streamlined logins for authorization of controlled-access data, better known as single 'sign-on' across the NIH data resources. The agency is using web tokens (industry standard technology) and are ensuring that the results are flexible to meet different NIH needs, chief among them that no existing systems will be harmed. The end goal is to have a consistent, NIH-wide system for accessing data from a wide variety of sources.

The NIH Researcher Authentication Service has hit its first milestone: the successful integration of GLOBUS's login functionality with a new NIH Login capability that uses OpenID Connect (OIDC) for electronic Research Administration (eRA) Commons accounts. GLOBUS customers can now log in with eRA Commons; this integration represents a foundational part of the Authentication Service project. OIDC can be rapidly adopted and extended to support other integration partners (e.g., Google, Terra, and Login.gov), Dr. Gregurick said.

Additionally, she discussed Fast Health Care Interoperable Resources (FHIR), a platform created by nonprofit Health Level Seven International for exchanging electronic health record (EHR) data. Already widely used in hundreds of applications across the globe for the benefit of providers, patients, and payers, FHIR can be applied to mobile devices, web-based applications, and cloud services. FHIR works using small, logically discrete units of information and reusable elements that can be assembled into working systems.

NIH is currently running two pilot projects that explore how FHIR technology can be applied to basic research:

- *Advancing Sharing of Phenotypic Information through FHIR* will increase the availability of high-quality, standardized phenotypic information for genomic research and genomic medicine by extracting relevant data from EHR systems using FHIR.
- *Development and Testing of FHIR Tools for Researchers* will fund development and testing of tools and resources that enable clinical researchers to extract clinical data from an EHR system for research and map their research data to the FHIR standard to be deposited in FHIR servers.

Workforce Development

In summer 2019, 21 undergraduate and masters-level Civic Digital Fellows worked with NIH investigators on projects that included developing innovative machine learning algorithms for image analysis and grant portfolio analysis; and automating NIH's cloud computing environment. (Nine of the fellows were sponsored by the non-profit Coding It Forward and the rest by NIH fellowships.) The program was highly successful, and Dr. Gregurick reported that another group of Civic Digital Fellows will be coming to the NIH this summer.

Shortly before the Council meeting, Dr. Gregurick received word that the NIH Data and Technology Advancement National Service Scholar Program was funded. As a result, five or more data science and technology experts are expected to arrive at NIH in the late summer to spend 1- or 2-year service sabbaticals working on projects like: advancing interoperability for environmental health; analyzing Alzheimer's sequencing data; expanding our theories of brain circuitry as part of the BRAIN Initiative; or developing a platform for sharing medical images to accelerate validation of machine learning approaches to diagnosis and widen their clinical adoption.

Council Questions and Discussion

Given the difficulties in keeping up with data curation from their own labs, has NIH or NIDDK considered the use of electronic lab notebooks?

Dr. Gregurick noted that developing the metadata templates for sharing data is a critical first step and working with a data repository early in the research project will help. Her office has not yet evaluated electronic notebooks for labs, although she knows of some that have been funded through SBIR, and that the DOE is looking at working with a specific vendor to implement them as a widespread solution.

What can we do to promote consistent, true open access to data and not the partial open access we currently have?

Dr. Gregurick said that part of the intent of the NIH data management sharing plan is to ensure that researchers put links to shared data in their progress reports so NIH can track how the sharing occurs. Program staff will review data management plans before funding decisions are made, which will help encourage researchers to make their plan as robust as possible.

What are the patient privacy implications of FHIR and how do they overcome the fact that clinical trial patients currently consent to participate in specific trials, not to have their data reside in large repositories?

Dr. Gregurick said that NIH observes all patient consents as received. One benefit of using a web-token based system is that researchers can attribute to each piece of data how and with whom it may be shared. NIH can also ensure that data access is preserved as intended. But realistically, it is likely not possible to go back to patients in previous research and obtain their consent for broader uses of their data, suggesting that we should revise the consent paradigm

going forward.

If investigators must comply with the new data management requirements to receive NIH funds, and journals are mandating increased scrutiny of how data are reported, both together provide a strong incentive to get investigators to become consistent with data reporting.

Dr. Gregurick agreed, noting that this “back-end” compliance with journals is one of the tenets for NIH’s new FOA. Getting widespread agreement on a subset of common data elements that can be employed across all studies is a goal of NIH. Progress is slow but steady.

How much education will NIH be doing to help individual IRBs understand the security measures that must be taken to provide safe storage of cloud-based data?

Dr. Gregurick responded that her office has begun contacting major institutions to educate them on this issue. Again, progress is slow but steady.

What parallels are there with what the pharmaceuticals industry has been doing with their huge datasets?

Dr. Gregurick responded that steps are being taken to bring together pharma data with other types of data in ways that preserve both privacy and the intellectual property. Currently, the national laboratories have such systems. The NIH may adopt an approach based on their model within the next couple of years.

VII. SPECIAL ANNOUNCEMENT/UPDATE ON NIDDK STRATEGIC PLAN

Dr. Rodgers turned the floor over to Dr. Germino for an update on the news trans-NIDDK strategic planning effort that was originally announced at the May meeting.

Dr. Germino commented that the new year, the new decade, and NIDDK’s 70th anniversary seem like good timing to kick off the “2020 vision” for the NIDDK Strategic Plan.

The 21st Century Cures Act, passed in 2016, mandated that all NIH institutes must develop strategic plans. In the past, NIDDK’s strategic planning has been disease specific. The NIDDK strategic plan will take an overarching approach that encompasses the full breadth of the Institute’s mission. The plan that will be developed over the next year and a half will map out directions for NIDDK for the next five years and will demonstrate the value of our research to the broad community. The process of developing this plan will include input from Council members and the extramural community, including advocacy groups, professional societies, and others.

After the last council meeting, a Working Group of Council was assembled and arranged into subgroups; these include individuals from outside NIH as well as some NIDDK staff. Each subgroup will be co-chaired by a Council member and an NIDDK staff member. The recommendations of these groups will be brought before the full council in an iterative way for

input and comment.

In addition, we will be issuing public requests for information (RFIs). The first will be issued in the springtime to ask the broad community to weigh in on the topics in the framework for the strategic plan. We will go back to the community at the end of the process to gather comments on the draft plan.

Dr. Germino showed a timeline of the process that started with the kickoff in September 2019, followed by the assembly of the Working Group. In the next few weeks, the Working Group will have its first calls, and the RFI will be developed and released for 60 days of public comment. During that time, we will also hold calls of each of the Working Group subgroups. After an update to the Council in May 2020, the subgroups will review the input received from the RFI. Another update to the Council will take place in September 2020, after which we will start to draft the plan.

The plan will be written for a nonscientific audience and will be about 40 to 50 pages, focusing on the Institute's overarching priorities. The Working Group members and all Council members will have a chance to review and comment on the draft plan. As mentioned above, Council members will receive updates at each stage of the process. A final draft will be posted for public comment, then sent back to the Working Group to review, and then finalized and released in September of 2021.

Dr. Germino provided an overview of the framework for the plan, which includes topics and themes outlined in the NIH Strategic Plan template, including Scientific Goals; and Serving as an Efficient and Effective Steward of Public Resources, which addresses a variety of different themes, such as workforce and career development, including the physician-scientist workforce/pipeline and developing a workforce that represents the full diversity of the American people.

Another important theme that will be interwoven throughout the plan is participant engagement, in other words, thinking about participants and patients as partners in research planning and implementation. Several Council members presented on this topic in September, followed by a great discussion. The report will also highlight accomplishments that illustrate the value of NIDDK's work to the broader community. An additional component of the plan will be metrics, or ways to mark progress toward our goals. After the September Council meeting, a more complete version of the framework was shared with Council members, who responded with comments. Based on those comments, the framework has been updated, and Dr. Germino reported that the current draft would be sent to Council members soon after this meeting.

Dr. Germino also introduced the subgroup co-chairs and members, including both current and former Council members and other members of the external community who are topic experts with broad scientific vision, along with NIDDK staff members.

The Subgroups include:

- Biological pathways and environmental contributors to health and disease (Gary Wu, MD and Chris Mullins, Ph.D., co-chairs)
- Pivotal clinical studies and trials (Elizabeth Seaquist, MD, and Averell Sherker, MD, co-chairs)
- Dissemination and implementation research (Penny Gordon-Larsen, Ph.D., and Pamela Thornton, Ph.D., co-chairs)
- Stewardship (Barbara Kahn, MD, and Matt Portnoy, Ph.D., co-chairs)
- Participant engagement (Richard Knight, MBA, and Ellen Leschek, MD, co-chairs)

Dr. Germino reported that a [strategic planning webpage](#) has been established. All Council members, advocacy groups, professional societies, foundations, and extramural investigators are urged to submit comments in response to the RFI. Dr. Germino thanked Council members who have agreed to serve as co-chairs and others from our external community who are serving as subgroup members.

VIII. 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. Three concepts were presented at this meeting: one for R01 clinical trials and two focused on type 1 diabetes and cardiovascular disease.

Trans-NIDDK Concepts

Dr. Tracy Rankin presented a concept on behalf of all divisions within NIDDK.

- **Enabling Early Phase Clinical Trials:** An analysis of R21 grants showed that the current approach does not provide adequate resources and time to acquire pilot data necessary to support funding for a fully powered clinical trial. To address this, this concept proposes a shift in approach to allow more time and resources for pilot clinical trials, which would strengthen subsequent R01 clinical trial applications, accelerate the development and translation of effective interventions, and provide greater opportunity for young investigators to acquire pilot trial support.

Council Questions and Discussion

What is the proposed maximum amount of funds and time for this type of grant? Will these resources be available to individuals in research networks already funded by NIDDK?

Dr. Rankin reported that actual dollar amounts have not yet been determined, but there will be a limit. They don't intend to restrict eligibility, but they are hoping that young investigators particularly would be able to leverage the opportunity to gather the preliminary data they need to move forward with their research.

How much preliminary data would be required to get this funding?

Dr. Rankin said that researchers would have to have the basis of a good idea, but not a lot of preliminary data, since generating and gathering the data is the idea of the program.

Would this be a good opportunity to encourage researchers to consider the feasibility of the study earlier in the process, including common challenges like participant recruitment, multi-site studies, and allocation of resources?

Dr. Rankin agreed that determining operational feasibility for any subsequent trial is part of the idea behind this concept.

Type 1 Diabetes and Cardiovascular Disease Concepts

Dr. William Cefalu presented two related concepts concerning type 1 diabetes and cardiovascular disease (CVD). The first concept was titled “*Understanding and Reducing Cardiovascular Disease in Type 1 Diabetes,*” and the 2nd related concept was titled “*Cardiovascular Repository for Type 1 Diabetes.*”

The rationale for both concepts stems from the observation that despite marked reductions in mortality and incidence of cardiovascular complications among adults with type 1 or type 2 diabetes, residual risk remains, and differences in disease presentation, compared to controls, persist. For example, while women in general have lower rates of heart disease, women with type 1 diabetes do not have that same cardio-protection, leading to increased mortality. The purposes of these two concepts would include encouraging clinical studies to determine the natural history of CVD risk with type 1 diabetes and supporting epidemiological studies to further define that risk. These early stage trials would focus on determining subclinical cardiovascular measures—such as computed tomography (CT) angiography or cardiac artery calcium measurement—to inform future larger trials. Mechanistic (pathophysiologic) studies would also further understanding of the roles of factors, such as autoimmune response, inflammation, and hyperglycemia in the development of CVD. The Diabetes Mellitus Interagency Coordinating Committee has identified the lack of cardiovascular tissue as a research gap for the advancement of mechanistic research in this area, so the second of these concepts would be the establishment of a biorepository for cardiovascular tissue.

Council Questions and Discussion

CVD is also a risk in people with type 2 diabetes. Why does this concept focus on type 1 diabetes?

Dr. Cefalu replied that the CVD is increased in individuals with both Type 1 and Type 2 DM. However, at this time we do not know how different the pathophysiology is in the two types of diabetes, including the roles of inflammation and autoimmunity. These initiatives are being developed to address that question.

Dr. Cefalu also noted recent advances in understanding of type 2 diabetes and cardiovascular health, including the cardiovascular benefit and renoprotection of newer agents. The purpose of this concept is to facilitate similar progress for type 1 diabetes.

Ms. Stiehl pointed out that other funding sources have limited research dollars focused on this area. She expected the diabetes community will be excited and appreciative of this actionable effort. She also recognized the contributions of former NIDDK staff member Dr. Judith Fradkin for drawing critical attention to the differences in CVD risk and progression between type 1 and type 2 diabetes, and the need for research to address them.

Will the repository contain plasma and other tissue in addition to cardiovascular samples?

Dr. Cefalu explained that many types of biological tissues are under consideration at this point, including plasma, whole hearts, arteries, brains, and kidneys.

IX. SUBCOMMITTEE MEETINGS

Portions of these subcommittee meetings were closed to the public, in accordance with the determination that they 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 Federal Advisory Committee Act, as amended (5 U.S.C. Appendix).

X. CONSIDERATION of APPLICATIONS

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 Federal Advisory Committee Act, as amended (5 U.S.C. Appendix).

A total of 1074 grant applications (203 primary and 871 dual), requesting support of \$372,679,706 were reviewed for consideration at the January 30, 2020, meeting. An additional 13 Common Fund applications requesting \$2,453,054 were presented to Council. Funding for these applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, 1217 applications requesting \$407,718,751 received second-level review through expedited concurrence. All of the expedited concurrence applications were recommended for funding at the Scientific Review Group recommended level.

XI. ANNUAL NIDDK INTRAMURAL RESEARCH PROGRAM UPDATE

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 Federal Advisory Committee Act, as amended (5 U.S.C. Appendix).

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 212th meeting of the NIDDK Advisory Council was adjourned at 4:30 p.m.

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

A handwritten signature in cursive script that reads "Griffin Rodgers".

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