

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 215th meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council at 10:00 a.m. on January 27, 2021, 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

Ms. Tracey Brown
Dr. Iain Drummond
Dr. Penny Gordon-Larsen
Dr. Lisa Guay-Woodford
Dr. Barbara Kahn
Mr. Richard Knight

Dr. Mark Nelson
Dr. David Penson
Dr. Jeffrey Pessin
Dr. Michael Snyder
Dr. Ronald Sokol
Dr. Gary Wu

Subject Matter Experts:

Dr. Debra Haire-Joshu
Dr. Philipp E. Scherer

Also Present:

Dr. Griffin Rodgers, Director, NIDDK and Chair of the NIDDK Advisory Council
Dr. Karl F. Malik, Executive Secretary, NIDDK Advisory Council
Dr. Matthew E. Portnoy, Deputy Director, Division of Extramural Activities
Dr. Gregory G. Germino, Deputy Director, NIDDK
Dr. William Cefalu, Director, Division of Diabetes, Endocrinology and Metabolic Diseases, 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

B. NIDDK PANELISTS/SPEAKERS

Dr. Pamela Thornton
Dr. Mary Evans
Dr. Paul Kimmel
Dr. Robert Rivers
Dr. Katrina Serrano
Dr. Lisa Spain
Dr. Guillermo Arreaza-Rubin
Dr. Peter Perrin
Dr. Tracy Rankin

C. ANNOUNCEMENTS

Dr. Rodgers

Dr. Rodgers began by noting this is NIDDK's third consecutive virtual Council meeting. NIH has decided that all advisory council meetings will be held virtually at least through May 2021, so the next NIDDK Advisory Council meeting will again take place in a virtual format.

Council Member News

Dr. Rodgers recognized four members of the NIDDK Advisory Council who are "graduating" from Council service after today's meeting: Dr. Lisa Guay-Woodford, Mr. Richard Knight, Mr. Thomas Nealon, and Dr. Jeffrey Pessin. These members had fulfilled their terms in 2020 but agreed to extend their terms through this meeting until new members were ready to come on board. He thanked the members for their support, advice, and dedication.

Dr. Rodgers then introduced two subject matter experts serving at today's meeting:

- Dr. Debra Haire-Joshu is the Joyce Wood Professor of Health and Medicine, Director at the Center for Obesity Prevention and Policy Research, Scholar at the Institute for Health, and Director of the Center for Diabetes Translation Research at the Washington University in St. Louis, and
- Dr. Philipp Scherer is a professor in the Department of Internal Medicine, the Gifford O. Touchstone and Randolph G. Touchstone Distinguished Chair in Diabetes Research, and Director of the Touchstone Diabetes Center at the University of Texas Southwestern Medical Center.

Both Dr. Haire-Joshu and Dr. Scherer will participate in discussions within the Diabetes, Endocrinology, and Metabolic Diseases (DEM) subcommittee.

Turning to trans-NIH business in which NIDDK plays a key role, Dr. Rodgers explained that, in recognition of the important role of nutrition in health and disease, NIH has taken steps to bolster nutrition research. In 2015, NIDDK established the Office of Nutrition Research (ONR) to help coordinate and accelerate progress in this area. In May 2020, NIH announced the [2020-2030 Strategic Plan for NIH Nutrition Research](#), its first agency-wide strategic plan for nutrition research to further advance the science and address diet-related diseases across the lifespan. In light of ONR's key role in these strategic planning and implementation processes, NIH had been considering moving ONR into the NIH Office of the Director as part of the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI). On December 18, 2020, NIH sought public comment on the proposed transfer of ONR from NIDDK to DPCPSI via a Federal Register notice. The response from the public and nutrition research community was overwhelmingly supportive and, on January 8, 2021, Dr. Collins announced that NIH had begun the official transfer of ONR to DPCPSI. This reorganization positions ONR to enhance engagement of NIH Institutes and Centers in implementing the strategic plan, as well as to develop new collaborations and relationships focused on nutrition research, both within and outside NIH. It will also help to ensure coordination of and leadership for nutrition research across the agency.

NIDDK Staffing News:

Dr. Rodgers made the following staffing announcements:

- **Dr. Jean M. Lawrence** has joined NIDDK as a program officer in the Division of Diabetes, Endocrinology, and Metabolic Diseases (DEM), overseeing the diabetes epidemiology portfolio. Dr. Lawrence earned her Sc.D. in maternal and child health from the Johns Hopkins Bloomberg School of Public Health, a Master of Science in social administration from Case Western Reserve University, and a Master of Public Health from the University of Pittsburgh. Previously, she was a Senior Research Scientist in the Department of Research and Evaluation at Kaiser Permanente of Southern California.
- **Dr. Katrina Loh** has joined the Division of Digestive Diseases and Nutrition (DDN) at NIDDK. She will focus on gastrointestinal diseases of children, particularly involving liver disease and transplantation. Dr. Loh is a board-eligible pediatric gastroenterologist who earned her M.D. from Drexel University College of Medicine and completed her residency training in pediatrics at Connecticut Children's Medical Center and fellowship training in pediatric gastroenterology and hepatology at Children's National Hospital.
- **Dr. Julie Barthold** has joined the Division of Kidney, Urologic, and Hematologic Disease (KUH) as Program Director for clinical and translational research in women's urology, pediatric urology, and neurourology. Dr. Barthold earned her M.D. and completed a urology residency at Northwestern University. She completed her clinical fellowship in pediatric urology at Children's Hospital of Michigan/Wayne State University. She has extensive research experience and has been funded by NIH for nearly 20 years. She has also served on numerous NIH peer review panels and authored over 75 papers.
- KUH also welcomed **Mr. Jonathan Teinor** and **Ms. Neha Shah** as scientific program analysts.
- Dr. Rodgers welcomed **Dr. Jaron Lockett** as Director of the Office of Research Evaluation and Operations (OREO), within the Division of Extramural Activities (DEA). In addition to his science background, Jaron has experience in project management, evaluation, and communication. He comes to NIDDK from the National Institute on Aging where he served for several years as Scientific Program Analyst in the Office of Planning, Analysis, and Evaluation, Special Assistant to the Deputy Director, and Interim Director for the Office of Special Populations. Dr. Lockett is a graduate of the NIH Management Intern program. He earned his Ph.D. from Wayne State University.
- **Dr. Robert Karp** has retired after 19 years serving as a Program Director in DDN, overseeing a research portfolio on genomics and system biology studies of diseases within NIDDK's mission. Dr. Karp promoted studies of human diseases using genetically tractable model organisms, worked with staff in NIDDK's Center for Scientific Review to improve the quality of genomic research grant proposal reviews, played an important role in supporting NIDDK's Inflammatory Bowel Disease Genetics Consortium, served on the NIH Human Microbiome Project working group, and served as the first program director for DDN's microbiome research portfolio.

- **Dr. Dianne Camp** recently retired from her service as a Scientific Review Officer in NIDDK’s Grants Review Branch. Dr. Camp was responsible for managing several special emphasis panels, specifically those reviewing grant applications and cooperative agreements relevant to DEM. She also managed review of complex RC2 applications. Dr. Camp will remain on as a special volunteer at NIDDK.
- Dr. Rodgers also announced the retirement of **Dr. Philip Smith** from his position as Deputy Director for DEM. Dr. Smith has been with the NIH for over 30 years. Within NIDDK’s DEM, he has led the development of research priorities, maintained active involvement in basic science consortia, and been an integral part of administrative management. In 2019, he led the Division in an interim role. He also served as Co-Director of the NIDDK Office of Obesity Research and co-chaired the Accelerating Medicines Partnership on Type 2 Diabetes facilitated by the Foundation for the NIH. Dr. Smith has also made valuable contributions to collaborations across the NIH, including the NIH Obesity Research Task Force, NIH 4D Nucleome program, and NIH Metabolomics program.
- Dr. Rodgers extended thanks and congratulations to Drs. Karp, Camp, and Smith for their dedicated service.

Dr. Rodgers then turned to a regular feature of the winter Council meeting—release of the annual report titled “[NIDDK Recent Advances and Emerging Opportunities](#).” Now in its 21st year, this publication will also be posted on the strategic plans and reports section of NIDDK’s website and sent to Council members in hard copy. The report highlights examples of NIDDK-supported research advances published in fiscal year 2020. The cover of the report illustrates progress in research using single-cell technology to inform development of new therapies, as well as how NIDDK research is focused on reducing negative impacts of COVID-19, both in terms of health and reinvigorating research disrupted by the pandemic. Also included in the report are stories of discovery that trace research progress over many years, personal perspectives of people who have participated in NIDDK-sponsored clinical research, special features such as one describing the Institute’s efforts to achieve health equity, and a section on funding trends that illustrates NIDDK’s commitments to our guiding principles, including a link to the full funding trends data online. 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 extramural and intramural staff for providing input.

Dr. Rodgers also called Council members’ attention to several health information resources that NIH and NIDDK staff have developed. NIDDK’s COVID-19 research response [webpage](#) includes updates on new research opportunities and results. Dr. Rodgers joined Dr. Anthony Fauci on a series of spots on NIDDK’s [Healthy Moments](#) radio show. He also invited members to view a Facebook Live [interview](#) from December 14, 2020, with Dr. Cefalu about how NIDDK research is helping people with diabetes to improve their health and reduce complications, as well as interviews to be released in February 2021 with NIDDK’s Drs. Barbara Linder and Christine Lee. Dr. Rodgers encouraged members to follow NIDDK’s activities on Twitter, Facebook, and Instagram.

II. CONSIDERATION OF SUMMARY MINUTES OF THE 214th COUNCIL MEETING

Dr. Rodgers

The Council approved, by voice vote, the Summary Minutes of the 214th 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 next NIDDK Advisory Council meeting on May 12-13, 2021 will again be virtual. Updates will be posted on the Council website.

IV. ANNOUNCEMENTS

Dr. Malik

Confidentiality

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

Conflict of Interest

Dr. Malik reminded 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.

Dr. Malik explained that each year at the winter meeting the NIDDK Council approves its operating procedures, which were included for members' review with their premeeting materials. The procedures are unchanged from 2020, except for the active dates. There being no questions, a motion was made and approved to accept the updated council procedures for 2021.

V. REPORT FROM THE NIDDK DIRECTOR

Dr. Rodgers

Budget Update

Dr. Rodgers reviewed the fiscal year (FY) 2021 appropriations cycle, which started with the release of the President's budget request on February 10, 2020. The House held a hearing on the NIH budget on March 4, 2020, but the Senate hearing was not held due to the pandemic. At the end of July, the House passed a minibus appropriation bill that included the Departments of Labor, Health and Human Services, Education and Related Agencies appropriation that funds the NIH. The first of several continuing resolutions was passed by Congress and signed into law by the President on September 30, 2020, funding the government through December 11, 2020. On November 10, 2020, the Senate released their appropriations for the Departments of Labor, Health and Human Services, Education and Related Agencies, but the House and Senate could not reach an agreement. Three more continuing resolutions were passed to avoid a government shutdown as discussions continued. On December 21, 2020, Congress passed an omnibus appropriations package with COVID-19 supplemental funding. This was signed by the President on December 27, 2020.

Dr. Rodgers reviewed the FY 2021 funding levels included in the President's budget request and the appropriations bills from the House and Senate, including the one that was signed into law in late December of 2020. The President's proposed budget included a \$3.4 billion reduction in the NIH budget and a \$190 million reduction for NIDDK over FY 2020. The House bill provided a \$42 billion annual appropriation for NIH plus an extra \$5 billion in emergency funding for the agency. The House appropriation included \$2.132 billion for NIDDK, an increase of 0.8 percent over FY 2020. The Senate bill included \$43.45 billion for NIH, an increase of 4.8 percent over FY 2020, and \$2.169 billion for NIDDK, an increase of 2.6 percent over the previous year.

The FY 2021 omnibus appropriations bill that was eventually signed into law in December 2020 included \$42.7 billion for NIH, which was a \$1.25 billion, or 3 percent, increase over FY 2020 and included funding for targeted programs, such as the BRAIN initiative, Alzheimer's disease, and opioid research. NIDDK received \$2.132 billion, an increase of \$18 million, or 0.8 percent, over FY 2020. It is important to note that these dollar values do not include funds for the Special Statutory Funding Program for Type 1 Diabetes Research. NIDDK's increase was on the lower end among NIH Institutes and Centers that did not receive targeted funding. The bill was bundled with a \$900 billion supplemental COVID-19 package, which included \$1.15 billion for NIH to support long-term studies of COVID-19 and \$100 million for the Rapid Acceleration Diagnostic (RADx) initiative. The budget process for FY 2022 will start soon, but a release date for the President's FY 2022 budget had not been announced.

Dr. Rodgers then turned to changes in the Administration and Congress as a result of the November 2020 elections and the inauguration of President Biden and Vice President Harris.

The President nominated Mr. Xavier Becerra for Secretary of the Department of Health and Human Services, and, at the President's request, Dr. Francis Collins will stay on as NIH Director. As a result of the November election and runoffs held in Georgia in January 2021, the number of Democrats and Republicans in the Senate is even, with Vice President Harris casting the deciding vote on any tied votes. Senator Chuck Schumer is now the majority leader, and Senator Mitch McConnell is the minority leader. Democrats retained their majority in the House, and Representative Nancy Pelosi continues as Speaker of the House, with Representative Steny Hoyer as majority leader and Representative Kevin McCarthy as minority leader. These changes will result in some new leadership posts on appropriations and authorizing congressional committees relevant to NIDDK, which were being finalized in the House and Senate.

Dr. Rodgers also reported on congressional activities since the September Advisory Council meeting. Dr. Rodgers participated in three virtual congressional briefings on different aspects of NIDDK's research. On October 5, he discussed NIDDK research on health disparities at a briefing organized by the Friends of NIDDK with opening remarks from Representative Donald Payne of New Jersey. On October 26, he participated in a briefing organized by the Ad Hoc Group for Medical Research and the Coalition for Health Funding to discuss how some conditions within NIDDK's mission increase risk for severe illness from COVID-19 infection and how the pandemic has affected biomedical research. On October 27, Dr. Rodgers participated in a briefing to discuss advances in type 1 diabetes research supported by the Special Statutory Funding Program for Type 1 Diabetes Research, with opening remarks provided by Representatives Diana DeGette of Colorado and Tom Reed of New York.

Council Questions and Discussion

Comment from Council: Will there be additional money coming to NIDDK for research into diabetes or obesity and COVID-19? Or will all COVID-19-associated research have to come out of existing appropriations?

Dr. Rodgers answered that President Biden has indicated that he would like to pass another stimulus package that would include money for COVID-19-related research. The current appropriations are right now the only funds available to give specific relief to young investigators and other research groups affected by COVID-19. The 0.8 percent increase in funding for NIDDK is below the current biomedical research inflation rate, which makes funding decisions for both COVID-19 related and non-COVID-19 research difficult.

Comment from Council: Will the NIDDK paylines remain the same?

Dr. Rodgers reported that staff are going through what-if scenarios. The hope is to keep paylines where they are both for established investigators and early-stage investigators and even give a greater bump to new investigators coming in for their first competitive renewal on an NIDDK application. Boosting those paylines has a number of benefits, and the Institute has received positive feedback. However, NIDDK is juggling several priorities.

Comment from Council: Researchers doing bench or clinical research have experienced shutdowns, and new waves of COVID-19 have led to repeats of problems seen earlier in the pandemic. This lost year may impact investigators' ability to compete for ROIs in the future. Has there been discussion at the NIDDK or NIH level about giving them a no-cost extension of another year? Can you build flexibility into the awards to lower the percentage that must be dedicated to research?

NIH is considering language that would encourage prioritization of these investigators, but individual Institutes will decide on their own. NIDDK is considering this in financial discussions. However, any changes would have to be made in the context of the current budget. He also acknowledged the disproportionate effect on young investigators and female investigators. The Council's report highlighted the importance of flexibility for these investigators. Dr. Malik commented that NIH has some flexibility with operating procedures for awards but would check on the extent of that.

Comment from Council: In light of the pandemic and the role of diabetes and obesity in severe disease and death, what are your thoughts about getting "moon-shot"-type funding for research into these conditions within NIDDK's mission?

Dr. Rodgers said there is a lot of attention on COVID-19 and the long-term sequelae, including acceleration of chronic disease and increased susceptibility of people with diabetes and kidney disease to serious complications. Professional societies and patient advocacy groups are also concerned about this, and discussions continue with members of Congress. Ms. Brown offered that she has brought this up in her discussions with President Biden, and he is receptive to the idea.

VI. COUNCIL FORUM (PART 2)

Underrepresented Investigators and Underrepresented Science

Dr. Gregory Germino and NIDDK Staff

Dr. Rodgers pointed out that the COVID-19 pandemic and recent reckoning of racial injustice have shined a light on health disparities and health equity. Continuing on the theme of the Council Forum on underrepresented investigators and underrepresented science from the September 2020 meeting, the presentations in this second part of the forum will consider NIH's funding ecology and the way that NIDDK and NIH consider race and ethnicity and social determinants of health in the science they support. He explained that Dr. Germino would start by providing some context for the discussion, followed by brief presentations by individual panel members and prepared remarks by some Council members.

Dr. Germino acknowledged the individuals representing the DEM, KUH, and DDN Divisions of NIDDK, as well as the Office of Minority Health Research Coordination, who have been meeting since the fall to prepare this presentation.

He started by stating that the NIDDK is focused on looking at whether the Institute is doing enough to achieve racial and health equity. He pointed to a landmark paper published in 2011 in *Science* by Ginther and colleagues showing that black applicants were 10 percent less likely than whites to receive NIH funding. A decade later, data indicate that blacks or African Americans still constitute only 1 to 3 percent of NIDDK's Research Project Grant applicant pool and continue to have less success in securing funding. Hoppe et al. revisited this topic in an October 2019 article in *Science Advances* and found that African American and black investigators received R01 funding at half the rate of white scientists. African American and black applicants make up a smaller fraction of the applicant pool at the beginning of the review process and fall out at higher levels at each step, with lower rates of submission and discussion among reviewers and lower impact scores.

The study also showed that African American and black applicants were at earlier stages of their careers and came more often from lower-resourced institutions. Drilling down further, they uncovered that African American and black applicants tended to propose research topics that also had lower award rates, including health disparities, health care delivery, adolescent health, and impact of socioeconomic and lifestyle factors. This variable of topic choice alone appeared to account for a large portion of the funding gap, revolving around reviewer decisions. The authors concluded that one way to diversify the workforce is to direct some funding toward meritorious applications that relate to these underappreciated topic areas.

The NIH Center for Scientific Review (CSR) reports that topics chosen by African American and black applicants are more likely to be discussed during peer review meetings, but less likely to be funded—which is opposite of the usual congruent relationship between discussion time and awards. On re-examination of the data, CSR found that topic clusters with low award rates are often funded by ICs with overall lower funding rates. This led to the sobering conclusion that much of the disparity in funding rates for African American and black investigators can be explained by differences in Institute and Center (IC) funding behaviors. For example, African American and black applicants were more likely to propose topics of interest to ICs with lower R01 award rates, like the National Institute on Minority Health and Health Disparities and the National Institute of Nursing Research. This finding suggests that the focus should be on IC funding behavior rather than on peer review.

Looking at NIDDK specifically, Dr. Germino presented a slide that showed award rates and the proportion of applications on 17 topics that together account for more than 50 percent of applications from African American and black investigators. NIDDK came in at about 20 percent, on the lower side of the distribution compared with other ICs.

Dr. Germino pointed out that the events of 2020 have promoted much soul-searching across the nation and also at NIDDK, which has within its mission some of the most common conditions that disproportionately affect racial and ethnic minorities, such as diabetes, obesity, and chronic kidney disease. It is already widely understood that COVID-19 has only worsened health disparities among minority populations. The pandemic and public examples of racial injustice have focused a spotlight on essential problems that have been with us all along, like the fact that zip code is often a more important determinant of health than genetic code. In the quest to understand the biological mechanisms of disease, Dr. Germino asked whether we have paid too little attention to the social determinants of health, which are major contributors to health disparities. Structural racism is an important driver of the social determinants.

Last summer, Dr. Rodgers challenged staff working on the NIDDK strategic plan to integrate research on health equity as an essential priority and cross-sectional theme. Both the strategic plan working group and members of the wider research community have identified health equity—and its reverse image, health disparity—as important topics to pursue with focus and urgency. He added that President Biden has committed the federal government to address issues of systemic racism.

Dr. Germino urged NIDDK to use its resources, not only to uncover the biological basis of disease, but to study all factors that can enhance health, lengthen life, and reduce illness and disabilities within our mission area.

Definitions and Concepts

To kick off the discussion, **Dr. Pamela Thornton** reviewed basic definitions and concepts and explained why the science of health equity and health disparities is relevant to NIDDK. She started by pointing out the difference between equality and equity. Equality gives everyone the same thing, which would be ideal if we all started from the same place. Equity, on the other hand, distributes resources according to need, such that all have access to the same opportunities and, therefore, what they need to stay healthy. The science of equity is important for ensuring everyone has the potential to achieve their optimal health potential, and because of its relevance to population health, including critically important outcomes that reflect the nation's overall health status, such as infant mortality. Americans have shorter life expectancy and worse health outcomes than other rich nations that spend far less on health care. Income inequalities and health disparities in part explain the trend.

The incidence for many of the diseases within NIDDK's mission—obesity, type 2 diabetes, chronic kidney disease, and end-stage renal disease—is higher for many minorities, who also experience a higher burden of complications from these conditions compared to non-Hispanic whites. The COVID-19 pandemic has shown a bright light on these unequal impacts due to the long-standing health disparities. Science may offer the opportunity to understand patterns and drivers of health disparities through the development and elucidation of a multilevel, social-ecological model of disease causation. These include social determinants of health (SDOH), which the World Health Organization defines as the conditions in which people are born, grow, live, work, and age that it considers mostly responsible for health inequities and the avoidable differences in health status seen within and among countries. While SDOH are neutral in nature and thus impact everyone, adverse SDOH disproportionately result in poorer health outcomes for marginalized populations.

Healthy People 2030 includes a place-based framework for SDOH. This important health equity approach considers social and geographic patterning of disease and health disparities that impact people over their lifespans and across generations. For example, a county-level map of the country shows that higher incidence of diabetes, poverty, and community vulnerability often coincide with higher concentrations of African American communities, which trace back to social and political structures such as slavery and Jim Crow laws. Similar patterns exist for other conditions and groups such as American Indians, related to the impact of removal and relocation policies that separated indigenous peoples from lands, family, and ability to continue traditional healthy lifestyles.

COVID-19 has drastically increased unmet social needs for resources related to health, such as for food, utilities, and housing. She showed a portrait referenced in a recent talk on racism by Dr. David Williams to reflect that while we may all be in the same storm, we are in different boats—some much less equipped for the current challenges. COVID-19 and the social storms around the pandemic disproportionately impact the health of disadvantaged populations and minorities.

Dr. Thornton reviewed some key definitions used at NIH:

- **Minority Health Research:** studies focused on health determinants that lead to specific outcomes within a minority group and in comparison to other groups.
- **Health Disparities Research:** a multidisciplinary field of study that focuses on a health difference, based on one or more health outcomes, that adversely affects disadvantaged populations.

- **Health Inequality vs Health Disparity:** Health inequality is the preferred term by many as it implies that a difference is unfair or unethical.

Estimates for the direct medical care costs of health inequality are over \$230 billion, based on a 2016 analysis that does not account for costs associated with the COVID-19 pandemic. Those costs have probably increased in the last year.

The Director of the National Institute on Minority Health and Health Disparities, in consultation with the Director of the Agency for Healthcare Research and Quality (AHRQ), is authorized to determine health disparities populations. This currently includes racial/ethnic minorities defined by the Office of Management and Budget, those with less privileged socioeconomic status, underserved rural residents, and sexual gender minorities. While NIH is concerned about disparities affecting all groups, including gender disparities, Dr. Thornton explained that the focus of the discussion was on racial and ethnic disparities as an important illustration.

Dr. Thornton explained that race and ethnicity are social—not biological—concepts developed in the 17th through 19th centuries to describe groups based on phenotype or some combination of shared background, language, religion, culture, class, or other markers of social differences. Grouping people this way may be convenient for research and other purposes, but it is problematic. While certain minority groups are more susceptible to some diseases, race/ethnicity are poor proxies for ancestry and biological risk out of context. Racial science has led to many cases of inappropriate conclusions and clinical decision-making. Also, racial classifications do not always align with self-perception. At the same time, race and ethnicity, when presented in the proper context, can predict healthcare access, quality, and outcomes. As such, they may serve as markers of unequal social experiences that need to be understood to be addressed effectively. Medical mistrust within minority communities stems from a history of unethical medical experimentation that dates back to slavery, the infamous Tuskegee syphilis study, exclusion in research and medical training, segregation and redlining, and other discriminatory and unethical practices.

While the American Medical Association and other professional societies and organizations have made strategic investments in health equity, discriminatory ideologies and misinformation persist. For example, a 2016 study by Hoffman and colleagues showed that many white people—including white medical students and residents—continued to hold inaccurate beliefs about biological differences, such as black skin being thicker than white skin and the blood of black people coagulating faster than the blood of whites. These fallacies are thought to be associated with the underprescribing of pain-relieving medication for black patients.

The landmark publication, *Unequal Treatment*, released in 2003 by what was then called the Institute of Medicine, described health inequities rooted in differential treatment and access to care based on social class and race/ethnicity and sustained by systemic racism. One of the reasons zip code matters to health outcomes is that where people live is still influenced by the legacy impact of discriminatory practices such as redlining and segregation that have long been illegal. Zoning maps that segregated Washington, D.C. in the 1930s correspond to areas of poverty and lack of health care access in the District today. The stressors of discrimination and poverty can result in chronically elevated stress levels that affect health over time. Experiencing discrimination is associated with diabetes, cardiovascular disease, and cancer, as

well as preclinical indicators of disease, such as inflammation, telomere weathering (shortening), and obesity.

Dr. Thornton also pointed to two categories of research into SDOH aimed at treating the whole person and improving health equity, from the work of Dr. Haire-Joshu and Dr. Felicia Hill-Briggs:

- **Compensatory research** involves ways to assist people who already have a disease with overcoming social risks to improve their health status. This may include integrating medical and social care.
- **Next-generation research** focuses on understanding and mitigating root causes of health disparities, such as policy and multisectoral approaches that highlight community voices.

She pointed to a scientific review published by the American Diabetes Association on social determinants and diabetes. The review concluded with research recommendations that included establishing core definitions and metrics for SDOH and pursuing both compensatory and next-generation studies. The study also called out opportunities for dissemination and implementation science to embed SDOH considerations within diabetes research. It also called for nurturing a diverse workforce with expertise in scientific methods and partnership development.

NIDDK also led a trans-NIH workshop on disparities in obesity and type 2 diabetes. A paper published by the workshop participants includes specific research recommendations around key equity themes, including taking a strengths-based perspective and engaging community partners throughout the research process. Dr. Thornton also pointed to an article by Dr. Rodgers and other NIDDK staff that discusses how structural racism interacts with social risks and exacerbates outcomes for black Americans with chronic kidney disease.

Dr. Mary Evans then presented examples of NIDDK-funded health equity research. She pointed out that this type of research clearly falls within NIDDK's mission, and the Institute has a history of supporting health disparities research. However, it is unclear whether NIDDK is supporting the right types or amounts of research to move the needle to address health equity, and there is a need to recognize and overcome barriers and challenges in this research area.

She shared some examples of related projects and programs funded by NIDDK. These include:

- **Centers for Diabetes Translational Research (CDTRs):** This program provides national research resources to translate efficacious interventions into real-world settings and promote rapid dissemination, implementation, and sustained use of interventions to prevent and treat diabetes. The most recent renewal of this funding opportunity required proposals to specifically address health equity with novel multidisciplinary and multisectorial partnership models.
- **Pragmatic Research in Healthcare Settings to Improve Diabetes and Obesity Prevention and Care:** For example, one project funded through this initiative—a trial called ASCEND involving 30 community health centers—focuses on developing and supporting implementation strategies and practice changes to screen patients for unmet social needs and improve diabetes outcomes.

- **Obesity Policy Evaluation Research:** NIDDK leads this trans-NIH obesity policy evaluation research program that invites observational studies that seek to evaluate new policies or programs implemented at the local, regional, or national level that are likely to influence obesity-related behaviors and weight outcomes. One example is a study to determine whether a Massachusetts program to provide funding to Medicaid Accountable Care Organizations to meet patients' food and housing needs affects dietary quality, psychological stress, health, and healthcare utilization.

NIDDK also funds a number of clinical trials. Examples include a cluster randomized clinical trial to test the efficacy of a multilevel, multi-setting early childhood obesity prevention program based at a Head Start program in South Texas that serves a primarily Latino population. Another example is a randomized comparative effectiveness trial that aims to mitigate race disparities in access to living donor kidney transplants.

Dr. Evans explained that NIDDK also has a history of leveraging trans-NIH programs and funding for NIDDK research. For example, the NIH Rapid Acceleration of Diagnostics for Underserved Populations (RADx-UP) program seeks to understand factors associated with disparities in COVID-19 morbidity and mortality and to reduce disparities for those populations disproportionately affected by the pandemic. As part of this program, one of NIDDK's Centers for Diabetes Translation Research uses mixed-methods data collection to adapt, optimize, and iteratively evaluate and refine a testing and education strategy for COVID-19 through a network of federally qualified health center (FQHC) partners. In another example, NIDDK grantees leveraged trans-NIH initiatives to provide training in the emerging field of implementation science and health equity to a diverse set of multidisciplinary scholars and mentors focusing on multiple chronic diseases, including diabetes.

Summarizing, Dr. Evans said that NIDDK has a track record of supporting health disparities and health equity research, but has not made enough progress toward eliminating health disparities for conditions within the NIDDK mission.

Next **Dr. Paul Kimmel** reported on opportunities to support health equity research at NIDDK by overcoming barriers. These include efforts to:

- Build capacity in the external health equity research community by increasing familiarity with research methods, increasing the number of investigator-initiated applications, and improving funding success rates.
- Expand NIDDK staff expertise to foster greater attention to health equity research, and generate new ideas to advance the field.
- Establish and communicate an NIDDK health equity research mission through scientific workshops, enhanced staff education and training, and review of application referral guidelines to ensure that research into SDOH in populations with obesity, diabetes, digestive diseases, and kidney, urologic, and hematologic diseases come appropriately to NIDDK.

Dr. Kimmel asked the Council to consider forming a working group to develop an NIDDK implementation plan for health equity research. Key issues to be addressed by this group include:

- NIDDK's current portfolio in this area

- The potential need to change how NIDDK supports health equity research
- Barriers, challenges, and opportunities to better support health equity research
- Decisions about which avenues to pursue
- Infrastructure and workforce necessary to support these efforts

Council Questions and Discussion

Dr. Kimmel then turned the discussion over to Council members, starting with a few members who had been asked in advance to speak on these issues.

Dr. Gordon-Larsen pointed out that NIDDK is one of two Institutes that has an R21 program designated to promote diversity. NIH needs more programs like this to address the unequal funding of minority students. She also saw a potential need for more discretionary or exception funds within NIDDK to make sure that diverse candidates are funded in line with NIDDK strategic priorities, especially health equity. While Institute and Center behavior in funding decisions is clearly important, it is also important to address structural factors that may reduce the number of black principal investigators who submit fundable proposals. This might include increasing the number of black investigators on study sections, identifying and reconsidering grants where bias may have played a role in decisions, and bringing in inclusive excellence reviews or study section intervention to identify and remedy cases of implicit or explicit bias. She pointed to an article in the journal *Cell* that suggested that \$32 million in additional funding across NIH could offset the racial funding disparity. Dr. Gordon-Larsen also spoke in support of the working group on health equity research and expressed a belief that there are many opportunities within NIDDK’s mission to address these issues.

Next, **Dr. Debra Haire-Joshu** highlighted the existing health equity research portfolio, which has traditionally focused more on compensatory interventions, which may put too much responsibility on the individual to deal with the inequitable circumstances to prevent or manage their disease. She encouraged an examination of the portfolio to emphasize next-generation kinds of research and find a better balance between the two types. She also supported the working group and said the goal should be not to advance health equity but to *achieve* it. She proposed looking at methodologies for developing multisectorial studies while also building the capacity of investigators and increasing the diversity of the workforce, adding that researchers need to look like the country at large. She also pointed out the need for mentor-mentee programs to work with investigators to submit successful proposals. She emphasized the need for implementation science approaches to help figure out what works and who it works for and team science approaches to build innovative partnerships to help drive research. To achieve health equity, research must involve the people who are most impacted. She also advocated for putting health equity in the review criteria for grants and telling applicants to address how their study would impact health equity.

Mr. Knight applauded the analysis presented by the speakers as this will help identify strategies for going forward. He then shared a quote that sounded like it was written today, but was from an article written in 1996: “Medicine and health are viewed as vital social institutions that reflect the norms, values, and social stratification systems of the larger society. Institution or systematic patterns of racism are legitimized and promulgated through accepted standards, criteria, organizational processes within the medical health complex that have effect of discriminating against minority groups. It is maintained that racism is manifested, whether it be overtly or covertly, through history, ideology, community relations, research education, and the professions and different treatment.” To make true headway this time, he said we have

to look at what we value and how the system is set up. Reviewers may need some education on the issues in order to value health equity as part of a proposal.

He also asked NIDDK to look at barriers to entry for minority investigators who may come from underfunded schools and what can be done to set up an infrastructure by which they can get the support they need. He also shared personal healthcare experiences of black patients—including his mother and kidney patients like himself—that demonstrate unequal care. Mr. Knight applauded NIDDK as a progressive Institute that has made a tremendous start with this analysis and has a strong team and leadership.

Dr. Germino thanked Mr. Knight and asked if any other Council members had questions or comments.

Dr. Pessin asked about NIH or NIDDK outreach programs for high school students from underrepresented populations to encourage them to pursue a research career. Dr. Rodgers commented that these programs do exist now, and another program will be proposed during Concept Clearance later in the meeting.

Ms. Brown pointed out that an analysis of the data on the growth of diabetes in the U.S. quickly reveals the role of inequities. The American Diabetes Association has been pushing hard on this issue and is looking at how to dismantle inequities and drive better outcomes. Our racially structured society is the root cause of racial inequity. She pointed to the need to address those power structures with what she calls “groundwater solutions” that affect the health of the lake and its inhabitants. This includes unconscious bias. The first step towards these solutions is the analysis presented today.

Building on that point, Dr. Guay-Woodford agreed that health inequality is a multi-factorial problem that will take a long-term commitment and a multi-pronged approach to solve. In the short term, she advocated for training on health equity issues, especially for study sections. She also suggested looking at how we populate our study sections in terms of expertise and perspective. Longer-term approaches include the working group proposed by NIDDK.

Dr. Germino thanked everyone for their comments and acknowledged the importance of the discussion, which is intended to be a kick-off for a longer conversation. He acknowledged the support from the Council for the idea of a working group on this topic. External experts will be involved as part of this effort to develop an implementation plan and identify the important questions to be addressed and opportunities to move forward.

Dr. Rodgers asked for continued input from Council members on this topic, adding that NIDDK wants to be prepared with potential proposals for addressing social determinants that underly, contribute to, and accelerate multiple chronic diseases within NIDDK’s mission.

VII. CONCEPT CLEARANCE

Dr. Rodgers then turned to Concept Clearance by Council, a step required before ICs can publish funding opportunity announcements, or FOAs. To streamline this process, summaries of the concepts were supplied to Council members for their review before the meeting. The meeting included descriptions of nine concepts, three by the Office of Minority Health Research Coordination, two by the Division of Diabetes, Endocrinology, and Metabolic Diseases, three by the Division of Digestive Diseases and Nutrition, and one by the Division

of Kidney, Urologic, and Hematologic Diseases. Because of time constraints, descriptions were brief to allow time for questions or comments. Cleared concepts will be made publicly available on the NIDDK website.

Office of Minority Health Research Coordination Concepts

Members of the OMHRC staff presented three concepts on behalf of their Office.

- **Renewal of the Short-Term Research Experience for Underrepresented Persons (STEP-UP) Program:** Dr. Robert Rivers summarized the successes of STEP-UP, which is a hands-on, summer research opportunity for high school and undergraduate students who are historically underrepresented in biomedical research. Established in 2002 to sustain a biomedical, behavioral, clinical, and social science research pipeline, STEP-UP focuses on expanding opportunities for talent development throughout the nation. In an external evaluation, outcomes from the prior initiative cycle were impressive: approximately 72 percent of alumni indicated that they plan to pursue an advanced degree. Almost 70 percent of recent STEP-UP participants indicated that they made large or very large gains in each aspect of their “science identity” as a result of the STEP-UP program. This includes feeling more like a scientist, feeling like part of the scientific community, gaining the confidence to succeed as a science major, and ability to get into graduate school. A pilot providing year-round research opportunities for undergraduates showed that students who participated throughout the academic year had improved academic performance and were more likely to pursue graduate training in the sciences. The STEP-UP Renewal Revised Approach would expand this shift to year-round research based on the positive results of the pilot program. Additionally, the program renewal would strive for greater geographic diversity by increasing outreach to more regions throughout the country and provide increased mentoring support.
- **NIDDK Participation in the Maximizing Opportunities for Scientific and Academic Independent Careers (MOSAIC) Program:** Dr. Rivers presented on NIDDK’s proposed participation in MOSAIC—a program led by the NIH’s National Institute of General Medical Sciences, which is a diversity K99/R00 Pathway to Independence funding mechanism. Based on the current lack of underrepresented scientists in the NIDDK workforce, as discussed at the September Council meeting, the plan would be for NIDDK to join MOSAIC and use targeted outreach to expand the diversity of the biomedical research workforce through K99/R00 transitional programs support, which would ensure that individuals who complete their post-doctoral training have opportunities to advance their academic careers. This would include strategic leveraging of past investments in R01 and T32 diversity supplements, as well as investments in the R25 Professional Societies program. Candidates would be eligible to apply as early as their third year of their postdoctoral training and must submit a diversity statement as part of the scored criteria review. K99/R00 grantees would be fully supported through comprehensive and overlapping mentoring opportunities through NIDDK, including the K Awardees’ Workshop and the Network of Minority Health Research Investigators.
- **Renewal of the Small Grants for New Investigators to Promote Diversity in Health-Related Research (R21):** Dr. Katrina Serrano discussed this proposed renewal, which would support new investigators (NIs) from diverse backgrounds to

conduct small research projects in the scientific mission areas of NIDDK. Initially developed in consultation with the Council, the first funding opportunity announcement was published in 2009. The program is designed to support the transition of early career investigators to become NIs and generate preliminary data to support an R01 application. Staff recently conducted a portfolio analysis of awarded grants between fiscal years 2010 and 2020. They found that only a small number of applications were funded compared to applications submitted. Slightly more than half of the investigators were female. The majority of the investigators supported through this program were Black/African American, or Hispanic/Latinx, but the program was also able to support investigators who identified as American Indian, Alaskan Native, native Hawaiian, Pacific Islander, and disadvantaged. About 14 percent of the investigators have gone on to obtain an R01 grant, although 42 percent tried unsuccessfully. Staff concluded that this program has been meeting its purpose, but that many meritorious applications remain unfunded, indicating a great ongoing need for such opportunities.

Council Questions and Comments

Comment from Council: The STEP-UP program is now available year-round for undergraduate participants. Is that also true of high school participants? Assuming that labs allow participation beginning at age 16, students could gain up to three years of laboratory experience by the time they enter college, which could increase their odds of success later on. At least they could gain additional laboratory hours during school holidays as well as the summers.

Dr. Rivers responded that current plans calling for the high school STEP-UP program to be year-round would remain in the pilot phase. So far, it appears that many high school students cannot continue with the anticipated 10 hours of research per week during the school year due to conflicts between clubs, sports, work, and college applications. The current plan would set aside a smaller amount of funding for high school students to do year-round research while still ensuring that all undergraduate participants could participate in research year-round.

Comment from Council: Would it be possible to promote these programs more within NIH and the university community?

Dr. Rodgers said that Council members will receive a short description of all available programs in the near future. Additionally, he took the opportunity to point out the success of the STEP-UP program, which is available to students in all 50 states, as well as all U.S. territories including the U.S. Virgin Islands, Puerto Rico, American Samoa, and Guam.

Division of Diabetes, Endocrinology and Metabolic Diseases Concepts

Members of the DEM staff presented two concepts on behalf of the division.

- **Continuation of Initiative for the Standardization of Hemoglobin A1c (HbA1c) and C-peptide Assays:** Dr. Lisa Spain discussed how, given the importance of HbA1c and C-peptide assays for diabetes diagnosis and management, continued standardization is needed for the development of point-of-care diagnostic tools. C-peptide is also a critical endpoint for trials of therapy to delay or prevent type 1 diabetes progression. In the past, this program has demonstrated its success in showing how measurements by different assay methods and labs have improved in accuracy

over time. This funding request would continue to provide administrative support, maintain access to and improve reference standards, reduce between-laboratory variability, communicate with users, certify new methods, and publish findings. Additionally, investigations would continue into HbA1c assay interferences such as sickle cell trait and fetal hemoglobin, as well as focus on the lower C-peptide range under real-world assay conditions.

- **Continuation of the Collaborative Islet Transplantation Registry (CITR):** Dr. Guillermo Arreaza-Rubin discussed the proposed continuation of the CITR, which was established in 2001 to collect and analyze data on islet transplantation activities, including islet allograft and autograft procedures following pancreatectomy. Captured data include islet characteristics, information on recipients and donors, medication data including immunosuppressives, and clinical safety and efficacy results. Currently, CITR has 29 active transplantation sites, including 17 in North America, 8 in Europe, and 4 in Australia and Asia, which have collected data from around 3,400 islet preparations. The FDA will be meeting in the near future to evaluate and consider approval of the biological license applications of purified human islet products in the near future. When that happens and there is approval, payers will require robust outcomes data to authorize reimbursement. New islet beta cell sources are expected to enter clinical investigation soon and will require a benchmark for comparing safety and efficacy with established islet transplantation outcomes. Novel islet delivery technologies and implantation sites will be studied, and targeted immunotolerance may provide better results than conventional immunosuppression. Future CITR areas of emphasis would include increasing data completeness and adding relevant data elements, compiling and sharing safety data, providing and analyzing data for outcome comparisons, positioning CITR as a partner in assessing innovative cell therapies, and continuing to serve as a resource for patients and the diabetes care community.

Council Questions and Comments

None noted.

Division of Digestive Diseases and Nutrition Concepts

Members of the DDN staff presented three concepts on behalf of the division.

- **Advancing Early Stage Investigator-led Mechanistic Biological Research on HIV Comorbidities, Coinfections, and Complications (CCCs):** Dr. Peter Perrin presented a trans-NIDDK concept that would address HIV CCCs, which is one of five NIH priority research areas for HIV research. As the HIV epidemic has progressed, antiretroviral agents and viral suppression have improved, leading people to live longer, such that HIV infection has become a chronic condition. As people live longer, they are also more likely to develop CCCs. Common comorbidities cover NIDDK research areas, including obesity, diabetes, metabolic conditions, HIV-associated nephropathy and other kidney complications, HIV enteritis, noncommunicable liver diseases, and viral hepatitis. Importantly, underlying biological mechanisms for these conditions differ between people with HIV and those who do not have HIV. Investigators working at the intersection of HIV science and pathophysiology/metabolism are vital to seek out specific druggable targets and other innovations and for NIDDK to achieve a rigorous HIV CCC portfolio. In particular, early-stage investigators (ESIs) are needed for the future stability of this research community. The

plan would be for NIDDK to issue a funding opportunity announcement targeting ESIs to this area, in order to promote biological research on HIV CCCs within NIDDK's mission areas.

- **Digestive Diseases Research Core Centers (DDRCCs) Renewal:** Dr. Perrin next discussed the DDRCC (P30) program, which supports centers that provide research infrastructure and promote collaboration relevant to digestive and liver diseases research throughout the U.S. As such, it brings together basic and clinical researchers and promotes interdisciplinary approaches. Each center has a cohesive focus and theme as determined by the applicant organization. The program typically consists of 3-4 biomedical research cores, a pilot and feasibility program, an enrichment program, and an administrative core. As of FY 2020, there were 18 DDRCCs throughout the U.S. Examples of areas of focus include liver disease, inflammatory bowel disease, and GI inflammation (including celiac disease), microbiome, and epidemiology. The Division plan would be to issue a funding opportunity announcement for continuation of the DDRCC program.
- **Nutrition Obesity Research Centers (NORCs) Renewal:** Dr. Mary Evans presented a concept to renew the NORC (P30) program, which provides research infrastructure and collaboration for nutrition and obesity research at academic/medical centers throughout the U.S. Their goal is to foster interdisciplinary, basic, clinical, and public health research, bring together established and new investigators, and strengthen and provide cost-effective research resources to multidisciplinary research groups conducting nutrition and obesity research. NORCs, which are geographically diverse, typically consist of 3-4 research cores, a pilot and feasibility program, an enrichment program, and an administrative core. A clinical element is required, either a standalone clinical core or clinical research services across multiple cores. Two key priorities are the research base and the biomedical research cores. The NORCs must receive at least 50 percent of their research funding from federal agencies. Importantly, there is no minimum funding requirement from NIDDK due to the transdisciplinary nature of this research. NORCs must have a mix of senior, mid-career, and early-career investigators. Renewals are based on their productivity in terms of publications using NORC resources. The biomedical research cores provide state-of-the-art research services and demonstrated use of the cores by the research base as their members' needs evolve. The pilot and feasibility programs primarily fund junior investigators, including women and scientists from underrepresented groups. Renewals are evaluated on the strength, relevance, and productivity of past recipients of pilot and feasibility awards. NORCs also sponsor an enrichment core to support activities such as seminars, journal clubs, and community engagement. The Division plan would be to issue a funding opportunity announcement for an open competition of the NORCs program.

Council Questions and Comments

Comment from Council: Are the NORCs examining the relationship between obesity and COVID-19? Are there opportunities to collaborate between DDM and DEM via the Diabetes Research Centers, which are also examining connections between diabetes and COVID-19?

Dr. Evans responded that NORCs are indeed supporting COVID-19-related research. Additionally, there is interest in collaborating with the Diabetes Research Centers, and some initial conversations have taken place with DEM program directors.

Comment from Council: As NIH shifts its approach on how nutrition research is organized, how will these changes affect the NORCs?

Dr. Evans responded that the NORCs program would remain within NIDDK, with no structural changes planned. But staff will continue to collaborate closely with colleagues in the NIH Office of Nutrition Research.

Dr. Rodgers added that the hope is that the elevation of the Office of Nutrition Research to the NIH Office of the Director will increase the visibility of nutrition research and associated resources. That enhanced profile may benefit both that Office and other Institutes that house nutrition research.

Division of Kidney, Urologic, and Hematologic Diseases Concept

Dr. Tracy Rankin presented a trans-NIDDK concept.

- **Fogarty Global Health Fellows Program (D43) Renewal:** Dr. Rankin presented a request for continuing support for the Global Health Fellows Program that is housed in the Fogarty International Center. This institutional training program supports training and career development for global health scientists via one-year mentored research experiences in low- and middle-income countries. Each year since 2013, NIDDK has provided funds to support two or three fellows who conduct research within NIDDK's mission areas.

Council Questions and Comments

Comment from Council: How have COVID-19-related travel restrictions affected this program?

Dr. Rankin indicated that the Fogarty International Center manages the Global Health Fellows Program, so she did not know what strategy they used last year. However, since many fellows are recruited from low- and middle-income countries and about half of them are not U.S. citizens, international travel may not have been required for fellows to perform their research.

Dr. Rodgers thanked the Council members for their comments and turned the meeting over to Dr. Germino for an update on NIDDK's strategic planning process.

VIII. UPDATE: NIDDK STRATEGIC PLANNING PROCESS

Dr. Gregory Germino

Dr. Germino gave an update on the process for developing the NIDDK strategic plan. He reminded Council members that this overarching research plan for the Institute will complement ongoing disease-specific planning efforts. Steps so far have included efforts to gain ideas from leading researchers and patient advocates across the NIDDK mission, including from Council members and others on the strategic plan Working Group (and subgroups of the Working Group), and from a public request for information (RFI) that we released to seek ideas to advance the research.

NIDDK received input in response to the RFI from 80 organizations and individuals. NIDDK and the Working Group subgroups have analyzed and discussed those comments. Dr. Germino

presented a few examples of themes that emerged from this input, and emphasized that these examples would apply to diseases across NIDDK's mission:

- **Stakeholder involvement throughout the research process:** Stakeholders—including patients, caregivers, and community members, among others—bring key perspectives and valuable skills applicable throughout the research process from design to implementation of findings.
- **Social determinants of health (SDOH):** As discussed earlier in the Council Forum, looking into SDOH in diverse populations is another important theme. This may include studying dietary biomarkers linked to SDOH and developing ways to mitigate SDOH.
- **Disease heterogeneity:** This area of research opportunity may include the spectrum of disease across the lifespan, early life programming of disease, and developing an atlas of cell-to-cell variability.
- **Epigenomics:** This area looks into the molecular mechanisms of health and disease, including the impact of environmental factors, the relationship between the epigenome and health, and cell-specific epigenomic phenomena as relevant to disease.
- **Patient-centered outcomes:** Patient priorities, which may differ from researcher- or physician-selected measures, should be incorporated into clinical research.
- **Representation of underserved populations in clinical trials:** This would include strategies for achieving better representation, including partnering with community organizations and institutions serving minority populations.
- **Dissemination/implementation tailored for diverse populations:** Some comments centered on improving dissemination and implementation of evidence-based interventions tailored for diverse settings and populations, for example, by addressing complexities of medical care, patient preference, literacy, internet access, and other social and environmental factors.
- **Sustainability in intervention design and implementation:** This includes planning for continuing to deliver the intervention after the research project has ended. Engaging other stakeholders—such as healthcare delivery systems—can help ensure that the intervention fits within an existing healthcare system and can continue beyond the funding period.
- **Utility/access to big data for the broader scientific community:** Thoughts included building cross-disciplinary teams and developing a centralized resource to make data easier to access and use for scientists studying disease processes.
- **Biorepositories:** This might include promoting the collection and storing of samples and data relevant to NIDDK diseases and representative of the populations affected.
- **Workforce diversity:** As discussed earlier, building a more diverse workforce is a priority area.
- **Mentorship:** Ideas included promoting diversity among mentors and enhancing mentorship programs across institutions, which could increase the number of mentors for minority researchers. Other ideas included mentorship training and incentivizing mentorship.
- **Unanticipated events/challenges (e.g., COVID-19 pandemic):** This area is key to studying the impacts on health and effects of the responses, responding to future events and crises, and effectively sustaining the research enterprise during population-wide events and crises.

Dr. Germino then presented the timeline for the strategic plan development from September 2019 with a draft framework presented to the Council to the release of the Plan at the end of this year. Based on input from the Working Group, RFI, and Council, the first draft is underway, with a goal of sending it to the Working Group for review in mid-2021 and then posting a draft on NIDDK's website for public comments later this year.

Dr. Germino closed by thanking the Working Group members from both the extramural community and from within NIDDK, and the many thoughtful respondents to the RFI. He especially thanked the Office of Scientific Program and Policy Analysis, particularly its Deputy Director, Dr. Lisa Gansheroff, who spearheaded and coordinated these efforts.

Council Discussion

Comment from Council: The clinical trials for the COVID-19 vaccine did not include underrepresented populations in sufficient numbers. If we view representation as necessary, then it will happen. The mosaic of our population should be represented. Cost is often mentioned, but cost should not be an issue compared to the benefits and value of it. The strategic plan must include a process for us to change our values and acknowledge that having a diverse group involved in research design will help move us in this direction.

Dr. Germino suggested that efforts like those mentioned in the presentation on underrepresented populations in science, including efforts to diversify the research workforce, establish community relationships, and build trust, will be critical for us to get closer to shared goals. Many aspects of the strategic plan involve reaching out and engaging communities to fulfill NIDDK's mission.

Comment from Council: What changes might be necessary to implement the current move towards team science? Will some funding programs (such as the PO1 mechanism) be phased out in favor of others? What alternative mechanisms could be used to bring investigators together in small groups to tackle a problem? The format of multiple principal investigators may not be suitable for that.

Dr. Germino acknowledged that this is an important challenge, and something that will be considered as part of the strategic planning process. He pointed out that the RC2 is a large grant program that does support groups of investigators cooperating to tackle a problem, along the lines of team science, albeit in a circumscribed way. Balancing the higher financial costs associated with team science with the impact on the rest of NIDDK's paylines are among the dynamic challenges that the Institute wrestles with to find that right mix allowing for establishment and support of teams while still allowing support for the investigator-initiated program, which has been a real driver of innovation and entrepreneurial activity.

IX. NIH DATA SHARING POLICY

Dr. Germino introduced Dr. Lyric Jorgenson, Deputy Director of the NIH Office of Science Policy, to provide an overview of the new NIH policy for data management and sharing (introduced in late 2020 to update the 2003 policy) and discuss implementation considerations.

Dr. Jorgenson summarized the new policy's highlights:

- The new policy replaces the previous data management policy from 2003 that specified that all NIH-funded awards greater than \$500,000 were subject to data sharing requirements.
- With the aim of fostering a culture of data stewardship, the new policy specifies that all NIH-funded research must have a data management and sharing plan in place.
- Compliance with the new policy may affect future funding.
- NIH has created extensive supplemental information to help grantees comply with the new policy.
- The new policy takes effect on January 25, 2023.

Dr. Jorgenson explained that NIH is interested in shifting toward a culture in which data sharing is the norm, not the exception. As the world's largest funder of biomedical research, NIH has a vested interest in data stewardship, as an integral part of ensuring that research investments transform health. The current priority is to provide resources necessary for the NIH grantee community to successfully implement the new policy when it goes into effect in two years.

The new policy reinforces the idea that data sharing can advance rigorous and reproducible research by facilitating validation of research results. It also makes high-value datasets accessible and helps accelerate future research directions through the ability to combine data in new and unique ways. Having data available increases opportunities for citation and collaboration and fosters that community of stewardship. Data sharing also promotes public trust in research, Dr. Jorgenson explained, by fostering transparency and accountability and demonstrating stewardship of taxpayer funds. Widespread data sharing helps ensure that investigators do not duplicate research unnecessarily, and it maximizes the contributions of research participants.

Dr. Jorgenson stressed the vital role of stakeholder input in developing the new policy. This included:

- Iterative development of policy priorities and provisions
- Public comment on draft policy and supplemental guidance
- Tribal consultation (the policy team completed an 18-month process to develop engagement with tribal nations in data-sharing practices)
- Harmonized approach that coordinated with other government agencies, such as the National Science Foundation, and with the Secretary's Advisory Committee for Human Research Protections

The collaborative process included:

- 2016: Solicited community input. RFI: Strategies on Data Management, Sharing, and Citation
- 2018: Solicited more community input. RFI: Proposed Provisions for a Draft Policy
- 2019: Solicited even more community input. Request for Comment (RFC): Draft Policy and Guidance
- 2020: Policy release date

Data Management and Sharing Policy Requirements

Dr. Jorgenson noted that the new policy will require each NIH applicant to develop a prospective data management and sharing plan to be submitted with their project application. The plan must indicate the type of data to be generated, where it will be shared, and the timing for these actions. NIH will also require compliance with plans approved by NIH Institutes, Centers, and Offices (ICOs). Once approved, the data management and sharing plan will become part of the terms and conditions that govern each award.

Dr. Jorgenson read the policy's definition of "scientific data" that should be shared from all NIH-supported research, including intramural, extramural, and contracts, to clarify any questions about what that entails: "Recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications." This definition excludes some research products, including biospecimens, lab notebooks, preliminary analyses, peer reviews, and physical objects.

NIH believes that data sharing should be the default, but there are exceptions that can be justified for ethical, legal, and technical factors. For example, if data sharing would violate a law or cannot be done while maintaining confidentiality, that research is exempt from the sharing requirements. Thus, researchers will not have to choose between following the policy or going against community standards or consent practices.

In terms of timelines, the policy specifies that data should be shared no later than at the time of publication or at the end of the award if data are unpublished. As for how long data will need to be shared, researchers will have latitude to decide this and will specify this in advance in their application based upon the project's particulars and relevant requirements, such as repository policies, retention requirements, and journal publication policies.

Dr. Jorgenson also expanded on NIH's additional expectations regarding responsible planning and implementation. She noted that, while all scientific data should be managed, not all data must be shared. However, in cases where data sharing is appropriate, it should be maximized. Plans should emphasize responsible implementation by outlining protection of privacy, rights, and confidentiality, and continuing to apply all existing laws, regulations, and policies. Grantees should also prospectively plan for how data will be used and shared, as part of informed consent, and what will happen during data submission, including whether access to data, including de-identified information, should be controlled.

Next, Dr. Jorgenson discussed NIH's decision that applicants should include a data management and sharing plan in the application's budget justification section. NIH recognizes that good data management and sharing practices come at a cost, but considers them worth the investment. By allowing applicants to account for data management and sharing costs in their budget justification sections, this information will become part of the peer-review process. Then NIH program staff will assess this aspect of the application during their review. Once the award is issued, plan compliance will be incorporated into the terms and conditions and will be monitored at regular reporting intervals, similar to other progress reports, and may factor into future funding decisions.

Supplemental Information

NIH staff have prepared several supplemental documents to assist applicants, with more to come, as needed. One supplementary document outlines allowable costs under the policy.

Reasonable costs include curating data/developing supporting documentation, preserving/sharing data through repositories, and local data management considerations. Infrastructure costs typically included in indirect costs and costs associated with the routine conduct of research, such as the cost of gaining access to research data, will **not** be considered data-sharing costs, Dr. Jorgensen said.

NIH staff have also prepared supplemental information to encourage the use of established repositories and maximize data sharing. This information helps investigators to identify appropriate data repositories with the following characteristics, developed in part with the White House Office of Science and Technology Policy: use of persistent, unique identifiers; ability to attach metadata; quality assurance processes; and security protocols in place. Additionally, NIH Institutes and Centers may designate specific data repositories, and may specify this in their funding opportunity announcements.

During this two-year window for implementation prior to the policy going into effect, Dr. Jorgenson said that additional supplemental information will become available, including tribal-specific considerations. NIH will also develop tools for estimating data management and sharing costs, similar to the focus of a 2020 report on forecasting costs by the National Academies of Sciences, Engineering, and Medicine (NASEM), and an upcoming workshop on changing the culture of data management and sharing, co-sponsored by the Office of Science Policy and NASEM. Additionally, NIH staff will clarify interactions with other NIH-wide and ICO-specific data-sharing policies.

Dr. Germino opened the floor to questions from Council.

Council Questions and Comments

Comment from Council: How will the data-sharing policy apply to long-term, longitudinal observational studies that may overlap multiple grant cycles, particularly given different timelines for data collection and publication? Does that mean grantees would have to release large amounts of raw data every four or five years to comply with the policy?

Dr. Jorgenson responded that this question would be good fodder for an FAQ. She noted that the COVID-19 pandemic has shown how helpful the prompt release of data can be. Longitudinal data, however, are less likely to be helpful when released piecemeal. She suggested that applicants discuss this in their proposals, noting that data release will occur at the designated time, not necessarily at the end of the award period. If there were no additional award, then data deposit would occur at that time. Program staff will evaluate whether the plan for timing of the data deposit is reasonable.

Comment from Council: How will the new policy affect international collaborations and different regulations and policies across countries?

Dr. Jorgenson responded that depositing data in international repositories could be part of an approved data-management plan. The NIH's priorities are to be able to access the data and maximize sharing via established repositories. The NIH is currently working through questions about the effects of policies such as the European Union's General Data Protection Regulation and will issue clarifications when available.

Comment from Council: If deposition of data includes an explanation of the experiment performed, this effort could result in a source of information on different types of experiments

performed and their results, including negative ones that are less likely to be published, which could become enormously valuable in terms of efficiency and cost-effectiveness in developing new directions for research.

Dr. Jorgenson agreed and pointed to the model of ClinicalTrials.gov, which is designed to capture all findings, both positive and negative. Replicating that model is important in broader data sharing because of the value of NIH's investment and as a tool to focus future research by tracking what has been done previously.

She added that, although she did not include this in her presentation, NIH is exploring how to make the data management and sharing plans publicly available online. This would help other scientists plan their own future experiments more efficiently, but NIH has yet to determine an appropriate mechanism for this.

Comment from Council: The research community will need to be educated about how to handle data management and sharing plans, so that study sections are standardized in how they consider them (i.e., not as part of the scorable component).

Dr. Germino responded that this issue has been discussed in the policy council group, including whether the locus of review should be with peer review or post-peer review by program staff. The policy council decided that this review should occur during program staff review for consistency throughout an Institute or even NIH as a whole. Staff will receive appropriate training to achieve consistency.

Comment from Council: How will "factual recorded data" be interpreted in the case of basic science studies that may include thousands of data products (e.g., microscopy images, Western blot gels, PCR reactions)? Does all that data have to be described and deposited? That would require an enormous amount of effort.

Dr. Jorgenson responded that the intent of the policy is to provide flexibility for investigators to determine which data are of value to share and which are extraneous. This is admittedly difficult and ambiguous in the case of basic research and comes back to the principle that all data should be managed but not all data should be shared. These issues will be explored during the upcoming workshop with NASEM, and further guidance will be shared with the research community.

Dr. Germino thanked Dr. Jorgenson for her presentation and leadership on this important new NIH policy.

X. INTRAMURAL RESEARCH PROGRAM UPDATE

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).

XI. BLUE RIBBON PANEL REVIEW OF THE NIDDK INTRAMURAL RESEARCH PROGRAM

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).

Dr. Rodgers then turned the meeting over to Dr. Malik for housekeeping details for the subcommittees and closed Council meetings scheduled for the following morning.

ADJOURNMENT DAY ONE

Dr. Rodgers

DAY TWO: Thursday, January 28, 2021

XII. OPEN SESSION OF SUBCOMMITTEE MEETINGS

See Minutes posted on NIDDK Council Minutes Website.

XIII. CLOSED SESSION OF SUBCOMMITTEE MEETINGS

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).

XIV. CLOSED SESSION OF THE FULL COUNCIL

This portion of the meeting was closed to the public, in accordance with the determination that it concerned matters exempt from mandatory disclosure under Sections 552(b)(c)(4) and 552(b)(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix).

XV. ADJOURNMENT DAY TWO

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 215th meeting of the NIDDK Advisory Council was adjourned at 1:45 p.m on January 28, 2021.

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