U.S. Department of Health and Human Services
National Institutes of Health (NIH)
Office of the Director (OD)
Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI)

Council of Councils Meeting
May 15, 2020

Meeting Minutes

I. REVIEW OF GRANT APPLICATIONS

This portion of the meeting was closed to the public, in accordance with the provisions set forth in 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).[1] Members were instructed to exit the meeting if they deemed that their participation in the deliberation of any matter before the Council would represent a real or perceived conflict of interest. Members were asked to sign a conflict-of-interest/confidentiality certification to this effect. The *en bloc* vote for concurrence with the initial review recommendations was affirmed by all Council members present. During the closed session, the Council concurred with the review of 1,249 Common Fund, Environmental influences on Child Health Outcomes (ECHO), and Office of Research Infrastructure Programs (ORIP) applications with requested first-year direct costs of $2,085,705,859.

II. CALL TO ORDER AND INTRODUCTIONS

James M. Anderson, M.D., Ph.D., Director, DPCPSI, welcomed participants, NIH staff members, and members of the public to the meeting of the Council of Councils. The meeting began at 11:00 a.m. on Friday, May 15, 2020, via teleconference. Dr. Anderson thanked Dr. Terry Magnuson who will retire from the Council after this meeting for his service to the Council. The meeting attendees are identified below.

Following introductions and announcements from Franziska B. Grieder, D.V.M., Ph.D., the executive secretary for the NIH Council of Councils, Dr. Anderson reviewed the day's agenda.

A. Attendance

1. Council Members

Council Members Present

Chair: James M. Anderson, M.D., Ph.D., Director, DPCPSI
Executive Secretary: Franziska B. Grieder, D.V.M., Ph.D., Director, ORIP, DPCPSI
Maria L. Acebal, J.D., The Aspen Institute, Washington, DC
Maria Rosario G. Araneta, Ph.D., M.P.H., University of California, San Diego, La Jolla, CA
Kristin Ardlie, Ph.D., Broad Institute of MIT and Harvard, Cambridge, MA
Jeffrey R. Botkin, M.D., M.P.H., The University of Utah, Salt Lake City, UT

[1] For the record, it is noted that members absented themselves from the meeting when the Council discussed applications (a) from their respective institutions or (b) in which a conflict of interest may have occurred. This procedure applied only to applications that were discussed individually, not to *en bloc* actions.

Linda Chang, M.D., FAAN, FANA, University of Maryland School of Medicine, Baltimore, MD
Graham A. Colditz, M.D., Dr.P.H., M.P.H., Washington University School of Medicine in St. Louis, St. Louis, MO
Andrew P. Feinberg, M.D., M.P.H., Johns Hopkins University, Baltimore, MD
Rick Horwitz, Ph.D., Allen Institute for Cell Science, Seattle, WA
Patricia D. Hurn, Ph.D., R.N., University of Michigan, Ann Arbor, MI
Kevin B. Johnson, M.D., M.S., Vanderbilt University Medical Center, Nashville, TN
R. Paul Johnson, M.D., Emory University School of Medicine, Atlanta, GA
Paul J. Kenny, Ph.D., Icahn School of Medicine at Mount Sinai, New York, NY
Sachin Kheterpal, M.D., M.B.A., University of Michigan Medical School, Ann Arbor, MI
Gary A. Koretzky, M.D., Ph.D., Weill Cornell Medical College, New York, NY
Richard D. Krugman, M.D., University of Colorado School of Medicine, Aurora, CO
Michael D. Lairmore, D.V.M., Ph.D., University of California, Davis, Davis, CA
Jian-Dong Li, M.D., Ph.D., Georgia State University, Atlanta, GA
Terry Magnuson, Ph.D., The University of North Carolina at Chapel Hill School of Medicine, Chapel Hill, NC
Edith P. Mitchell, M.D., FACP, Thomas Jefferson University, Philadelphia, PA
Charles P. Mouton, M.D., M.S., The University of Texas Medical Branch at Galveston, Galveston, TX
Megan O'Boyle, Phelan-McDermid Syndrome Data Network, Arlington, VA
Rhonda Robinson-Beale, M.D., Blue Cross of Idaho, Meridian, ID
Susan Sanchez, Ph.D., The University of Georgia, Athens, GA
Jean E. Schaffer, M.D., Joslin Diabetes Center, Boston, MA
Scout, Ph.D., National LGBT Cancer Network, Pawtucket, RI
Anna Maria Siega-Riz, Ph.D., M.S., University of Massachusetts Amherst, Amherst, MA
Russell N. Van Gelder, M.D., Ph.D., University of Washington, Seattle, WA

2. Liaisons

Joseph M. Betz, Ph.D., Acting Director, Office of Dietary Supplements (ODS), DPCPSI
Maureen M. Goodenow, Ph.D., Director, Office of AIDS Research
Susan K. Gregurick, Ph.D., Senior Advisor, Office of Data Science Strategy, DPCPSI
David M. Murray, Ph.D., Director, Office of Disease Prevention, DPCPSI
Karen L. Parker, Ph.D., M.S.W., Director, Sexual & Gender Minority Research Office (SGMRO), DPCPSI
William T. Riley, Ph.D., Director, Office of Behavioral and Social Sciences Research (OBSSR), DPCPSI
Elizabeth Spencer, R.N., representing **Janine A. Clayton, M.D.,** Director, Office of Research on Women's Health, DPCPSI
Elizabeth L. Wilder, Ph.D., Director, Office of Strategic Coordination, DPCPSI
David R. Wilson, Ph.D., Director, Tribal Health Research Office, DPCPSI

3. *Ex Officio* Members Absent

Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH

4. Presenters

Patricia Flatley Brennan, R.N., Ph.D., Director, National Library of Medicine (NLM); Co-Chair, Common Fund Working Group on Artificial Intelligence for Health Research

Cindy Davis, Ph.D., Director of Grants and Extramural Activities, ODS, DPCPSI
Malgorzata Klosek, Ph.D., Director, Division of Construction and Instruments (DCI), ORIP, DPCPSI
Karen L. Parker, Ph.D., M.S.W., Director, SGMRO, DPCPSI
William T. Riley, Ph.D., Director, OBSSR, DPCPSI
Marina Volkov, Ph.D., Director, OEPR, DPCPSI

5. NIH Staff and Guests

In addition to Council members, presenters, and Council Liaisons, others in attendance included NIH staff and interested members of the public.

B. Announcements and Updates

Dr. Grieder reviewed the following:

- Council members are Special Government Employees during the days of Council meetings and are therefore subject to the rules of conduct governing federal employees.

- Each Council member submitted a financial disclosure form and conflict-of-interest statement in compliance with federal requirements for membership on advisory councils. The financial disclosures are used to assess real and perceived conflicts of interest, and Council members must recuse themselves from the meeting during discussions of any items for which conflicts were identified.

- Time is allotted for discussion between the Council members and presenters, but time for comments from other meeting attendees is limited. The public may submit comments in writing; instructions are available in the *Federal Register* notice for the meeting, which was published on May 4, 2020.

- Minutes from the January 24, 2020, meeting are posted on the DPCPSI website. The minutes from this meeting also will be posted there.

Dr. Grieder also proposed a modification to Section 4, Part C, of the Council operation procedures to allow DPCPSI staff to provide additional funds for noncompeting applications for administrative supplements in response to the COVID-19 pandemic. Because a large number of applications are expected and will need expedited approval, Council discussions and votes on each application are not planned. Approved applications will be within the scope of the existing work and urgently necessary to manage the work during the pandemic. The change to the procedures would be removed after the emergency is declared over. Council members were informed that such noncompeting administrative supplements cannot exceed the amount of the parent award.

Vote

A motion to approve the change to the Council operating procedures was forwarded and seconded. The motion passed with no abstentions.

C. Future Meeting Dates

The final 2020 Council meeting will be held on September 11.

III. OEPR STRATEGIC PLAN

Marina Volkov, Ph.D., the Director of the Office of Evaluation, Performance, and Reporting (OEPR), explained that the OEPR works across the NIH in the areas of planning, performance, evaluation, and reporting to identify goals and priorities of NIH, track progress towards those goals and priorities, evaluate processes for identifying and achieving them, and communicating their results to NIH's many stakeholders.

Dr. Volkov outlined the goals of the OEPR strategic plan, beginning with the need to enhance and harmonize strategic planning across NIH Institutes, Centers, and Offices (ICOs) by providing a common framework and tools as mandated in the 21st Century Cures Act. The Office is working to produce the NIH-wide strategic plan for fiscal years 2021–2025 and will collaborate across the NIH to track progress on this plan. The OEPR also will increase awareness of ICOs' diverse strategic plans to identify common priorities and contributions to the NIH mission. The second goal of the OEPR strategic plan is to optimize progress monitoring. Several offices within DPCPSI are working with OEPR to build the Strategic Plan Tracking Tool, and the office also is working to build a shared understanding of measures used to track progress and create new efficiencies in mandatory performance reporting.

The OEPR also aims to strengthen NIH's assessment of activities and impacts. Every ICO already gathers evidence about the success of its programs, policies, and operations, but their methods vary. The OEPR plans to work with planning and evaluation officers in each ICO to build the systematic capacity to conduct evaluative work across the NIH as a whole. This effort is related to the implementation of the Foundations for Evidence-Based Policymaking Act of 2018, designed to improve evaluation of federal agencies. The OEPR is implementing this effort by identifying the current activities in NIH assessments, building the resources, and building expertise. Identifying outcomes is a critical component of this effort and will require working more closely with partners who use the evidence NIH produces to improve public health, such as other operating divisions within the U.S. Department of Health and Human Services.

The last goal in the OEPR strategic plan is to communicate the value of the NIH beyond research findings to include its impact on improving health and benefitting society. This goal involves coordinating mandatory reporting, collaborating with planning and evaluation officers to create communication strategies designed for policymakers, and working with the NIH communications networks to effectively disseminate information to the public about NIH's advancements in health, scientific achievement, and societal improvement.

Discussion Highlights

- Dr. Volkov clarified that ICOs will continue to report individually as the OEPR coordinates broad reporting efficiency and shared information.
- Dr. Volkov confirmed that the OEPR is working with ICOs to effectively communicate their impact, such as through case studies and on the NIH Impact pages (https://www.nih.gov/about-nih/what-we-do/impact-nih-research).

IV. ORIP CONCEPT CLEARANCE: MODERNIZATION OF RESEARCH FACILITIES GRANT PROGRAM

Malgorzata Klosek, Ph.D., the Director of ORIP's DCI, outlined the Modernization of Biomedical Research Facilities concept, noting that modern physical infrastructure is indispensable for advancing research and thus relates directly to ORIP's mission of supporting infrastructure for innovation. ORIP proposes creating a program to support improvements and updates to the physical infrastructure of

existing laboratory space and animal research facilities, including both upgrades to physical structure and acquisition and installation of fixed equipment. Approved projects would be justified by research or research-related needs to improve existing function or enable new capabilities, and upgrades of animal facilities would lead to improved care or better facility management. This concept complements ORIP's shared instrumentation and construction concepts, which the Council reviewed and approved within the last year. Projects under the new concept are anticipated to be 1-year grants and must be located in a core facility, institutional animal research facility, or other shared space.

Discussion Highlights

- The discussants, Drs. Patricia Hurn and Paul Johnson, provided their comments. Dr. Hurn commented on the concept's ability to support the health of animal subjects and make existing facilities more efficient and thus allow institutions to direct more funds toward COVID-19 adjustments. Dr. Johnson suggested considering adding metrics to evaluate return on investment and prioritization of projects, as well as emphasizing the potential of these projects to add jobs to the community.
- Council members suggested that a 1-year grant might be too short for the long timeline that many upgrade projects might require.
- Dr. Klosek clarified that $5–6 million in funding is available, matching funding from home institutions is not required, and program announcements likely would be made in the fall.

Vote

A motion to approve the Modernization of Biomedical Research Facilities concept was forwarded and seconded. The motion passed with no abstentions.

V. COMMON FUND CONCEPT CLEARANCE: DESIGN AND USE OF ARTIFICIAL INTELLIGENCE PLATFORMS FOR BIOMEDICAL AND BEHAVIORAL RESEARCH

Patricia Flatley Brennan, R.N., Ph.D., the Director of the NLM and co-chair of the Common Fund Working Group on Artificial Intelligence for Health Research, presented on the concept clearance for a new Common Fund program, Artificial Intelligence for Biomedical Excellence (AIBLE). The AIBLE concept aims to generate new biomedically relevant data sets amenable to machine learning analysis at scale. Note: Machine Learning is one type of Artificial Intelligence analysis strategies; it provides the general case for data needed to use these methods). These machine learning–ready attributes will be converted into rubrics and standards that will allow planning and evaluation; allow the creation of software and hardware to speed the annotation and structuring of data sets; immediately initiate collaboration with existing projects; generate new multimodal, metadata-complete, available data that will exemplify machine learning–friendliness; and use those rubrics to assess and improve select public health data sets of biomedical importance. Dr. Brennan explained that a well-organized and well-labeled data set is an essential first step for a large-scale artificial intelligence program, so complete metadata are critical.

Dr. Brennan noted the recommendations made by the Advisory Committee to the Director (ACD) Working Group on artificial intelligence, specifically to support generation of new data sets and develop criteria to make those data sets machine learning–friendly. Dr. Brennan detailed the aspects that make a data set machine learning–ready, noting that the Working Group cautioned the ACD that the members will have to rethink how research is conducted to gather data that will accelerate knowledge developed through artificial intelligence methods. To operationalize these recommendations, the Working Group suggested first supporting the flagship data generation efforts to propel progress by the scientific community. The next step is to develop and publish the criteria for machine learning-ready data sets,

which is an evolving concept still being consolidated across the industry to develop standards for harmonization. Dr. Brennan emphasized the importance of developing and publishing standards for consent, as well as ethical principles for the use of machine learning in biomedicine.

The Common Fund Working Group proposes five initiatives within this concept: (1) developing data design centers to support the frameworks for creating and evaluating data sets; (2) developing software and firmware tools to accelerate the processes of artificial intelligence readiness, annotation, metadata completion, and new methods of scientific communication; (3) initiating supplements to existing projects that will generate new, enhanced data that are accessible; (4) creating new multimodal human data sets that exemplify the broad range of biomedical research data; and (5) developing new analytics to evaluate and use these data sets. This concept will last from 2021 to 2028, with a total funding requirement of $160 million over 7 years.

Dr. Brennan detailed plans for ICOs to lead each initiative within the concept and ensure that specific critical aspects would be addressed. In fiscal year (FY) 2021, the National Human Genome Research Institute will lead the development of the data design centers; the NLM and National Institute of Biomedical Imaging and Bioengineering will lead the development of hardware, software, and firmware tools; and ICOs across the NIH will support data enhancement supplements to existing awards. Development of gold-standard data sets will begin in FY 2022 or 2023, led by appropriate ICOs. The NLM also will lead the effort to assess existing data, starting from the first year of the project, by using the identified rubrics to assess and improve select public data sets. Dr. Brennan reiterated that this program will produce a group of artificial intelligence–ready data sets; rubrics that allow evaluation of data sets for machine learning–readiness; tools to accelerate the creation of such data sets; and infrastructure to support these data sets.

Discussion Highlights

- The discussants, Drs. Sachin Kheterpal and Rick Horwitz, provided their comments. In response to a question about the lack of emphasis on ethical concerns, Dr. Brennan explained that because ethics transcends all the initiatives, the Working Group did not set up a specific group to address those concerns but will center the coordination of ethics considerations in the data design centers. She also clarified that merging the cultures of product management and research will be critical to this effort and likely will involve the training component of the program.
- Drs. Horwitz and Brennan agreed on the need to shift mathematics education toward fields relevant to computer science, and Dr. Brennan noted partnerships with the National Science Foundation to assess evolving education needs. She also commented on the need to craft the request for proposals to incorporate smaller laboratories and strong team science.
- Dr. Brennan provided examples of questions that could be addressed through this initiative, such as overlapping factors that influence differences in response to the new coronavirus and ways to identify treatments with small sample sizes. She emphasized that identity management—the ability to collect information about an individual in a way that is helpful and not exploitative—is key.
- In response to a question about the importance of distributed data and interoperability, Dr. Brennan emphasized that the data design centers are intended to serve as an intersection, dissemination, and engagement model.
- When asked about data sufficiency, Dr. Brennan referred to a current program at the NLM addressing ways to remove bias from data and emphasized that the rubrics developed in the early stage of the program will incorporate such considerations.

Vote

A motion to approve the AIBLE concept with the consideration of suggestions made during the discussion was forwarded and seconded. The motion passed with no abstentions.

VI. ODS CONCEPT CLEARANCE: ADMINISTRATIVE SUPPLEMENTS FOR RESEARCH ON DIETARY SUPPLEMENTS

Cindy Davis, Ph.D., the Director of Grants and Extramural Activities at ODS, presented the reissue of Administrative Supplements for Research on Dietary Supplements, which provides supplemental funds for NIH-supported research projects to incorporate dietary supplement research that is within the scope of the parent award. Dr. Davis explained that although supporting research to evaluate the health effects of dietary supplements and the underlying biological mechanisms by which they affect health is a congressional mandate and a key component of ODS' strategic plan, ODS does not have grant-funding authority, so the Office must partner with other ICOs or provide additional supplemental funding to existing NIH grants. These supplements increase the number and diversity of applications relevant to the mission of ODS, providing support for research in which the primary emphasis is on the effects of dietary supplements and their ingredients on health maintenance and disease prevention. Although the research must be within the scope of the parent grant, it is not limited to specific health conditions, organ systems, or population groups, and the ODS supports all types of research—including preclinical, clinical, behavioral, and epidemiologic—as long as the supplements are administered orally in physiologically relevant forms and concentrations. Supplements also must be rigorously identified and characterized to ensure reproducibility of the research. Budgets are limited to $100,000 in direct costs for up to 1 year, and the parent grant must have at least 18 months remaining at the time of submission. Between October 2019 and January 2020, ODS funded approximately 67 percent of the applications received.

Discussion Highlights

- The discussants, Drs. Maria Rosario Araneta and Anna Maria Siega-Riz, provided their comments. In response to Dr. Araneta's suggestion, Dr. Davis clarified that language could be added to the funding opportunity announcement (FOA) encouraging applicants to consider whether their research could be relevant to COVID-19, but ODS cannot influence what types of applications are submitted. She added that the National Institute on Minority Health and Health Disparities has been reluctant to join this FOA in previous versions, but she will reach out to them again.
- In response to a question from Dr. Siega-Riz, Dr. Davis clarified that although most previously funded researchers have completed their research within a year, ODS has allowed a few researchers to use the funds over 2 years when the parent grant had time remaining. She also explained that the funding is limited to $100,000 despite the large size of the supplement industry because they are supplements to existing grants, so most research on supplements is funded through other ICOs.
- When asked to note the successes of the program so far, Dr. Davis reiterated that the program is open to most types of funding activities. She explained that the program has been very successful and, in particular, has increased the diversity of types of applications, types of supplements included for study, types of research, and variety of ICOs submitting applications.

Vote

A motion to approve the reissue of the Administrative Supplements for Research on Dietary Supplements concept was forwarded and seconded. The motion passed with no abstentions.

VII. ESTABLISHING A BASIC BEHAVIORAL AND SOCIAL SCIENCES RESEARCH WORKING GROUP: IDENTIFYING EMERGING AND PROMISING BASIC RESEARCH WITH A PLAUSIBLE PATHWAY TO HEALTH

William Riley, Ph.D., the Director of the OBSSR, proposed a new working group of the Council named "Identifying Emerging and Promising Basic Behavioral and Social Sciences Research with a Plausible Pathway to Health." He explained that the NIH already strongly supports basic biomedical research and behavioral and social sciences research (bBSSR), but the last report about basic BSSR was produced in 2004. Dr. Riley noted the topics discussed in the previous report and commented on OppNet, a trans-NIH effort funded from 2010 to 2014 that incorporated researchers working in bBSSR but not previously funded by the NIH and increased the kinds of bBSSR funded by the NIH. However, after 2014, OppNet's funding became voluntary and decreased significantly despite increasing ICO support for bBSSR.

A number of current efforts could be leveraged to advance basic BSSR. The development of Research, Condition, and Disease Categorization codes and the founding of the Office of Portfolio Analysis since the previous report have allowed the OBSSR to analyze its own research portfolio with greater precision and explore subcategories of bBSSR. OBSSR also is concerned about assessing the translation of basic research into applied clinical intervention research and would like to ensure that research is focused on plausible pathways to translation.

The charges to the Council of Councils working group would be to explore whether NIH funding for basic BSSR has kept pace with the science, whether the NIH can improve its return on investment by identifying better emerging areas of BSSR relevant to the NIH mission, whether some areas of research should be deprioritized, and which efforts require additional trans-NIH support. Dr. Riley noted that Dr. Graham Colditz already has agreed to serve as a co-chair, and membership selection would proceed if the Council approves the working group. Members would include editors of basic BSSR journals, leaders of professional organizations, and promising early stage investigators and would be inclusive of gender and racial/ethnic diversity.

Discussion Highlights

- In response to a question about how reproducibility will be addressed, Dr. Riley explained that several large bBSSR studies already have explored this issue, but the working group could incorporate further consideration as part of its assessment of the state of bBSSR.
- Dr. Riley commented on the difficulty in defining basic versus applied BSSR, noting that factors and mechanisms often are considered aspects of basic BSSR, whereas interventions are considered applied BSSR.
- Dr. Riley clarified that the behavioral health field has developed some reasonably effective interventions for some varieties of common conditions, such as depression, but implementation has been inconsistent. However, some gaps remain in translating other aspects of these common conditions to interventions. He emphasized that the working group aims to identify, in particular, such gaps in which a clear, plausible pathway exists to translate basic research to applied research.

- In response to a question about integrating implementation, Dr. Riley explained that some basic BSSR could influence implementation strategies, and OBSSR has had initial discussions with the National Center for Advancing Translational Sciences about how to better integrate research.

Vote

A motion to approve the creation of the working group was forwarded and seconded. The motion passed with one abstention.

VIII. NIH FY 2021–2025 SEXUAL AND GENDER MINORITY RESEARCH STRATEGIC PLAN

Karen L. Parker, Ph.D., M.S.W., the Director of the SGMRO, presented on the next NIH sexual and gender minority (SGM) research strategic plan, reminding attendees that the NIH updated its definition of SGM to be as inclusive as possible of those across the spectrum of sexual orientation and gender identity or expression, as well as intersex populations and those with a difference in sex development. She presented on the history of the SGMRO, which coordinates health research related to SGM populations across ICOs. Under the current strategic plan, the SGMRO expanded its staff, increased the number of funded SGM-related projects by 37.2 percent, and developed several signature programs, including regional workshops that provide NIH grantspersonship training. The current strategic plan was developed in collaboration with many groups, including NIH stakeholders, the SGM Research Working Group of the Council of Councils, and the public via listening sessions and a Request for Information.

Some overarching considerations became clear from these conversations that should inform any SGM-related research at the NIH. The first is intersectionality—considering how the interlocking and interdependent systems of oppression across social categories may result in unique health disparities. Collecting data across these categories for SGM populations may include considerations of military service, experiences with homelessness or the foster care system, and migrant status. Aging is another overarching consideration; although issues to consider in research change across the lifespan for all populations, SGM populations have specific, unique needs related to aging. Several SGM subpopulations also are under-researched, including the bisexual community, two-spirit people, and intersex populations. Additionally, certain relevant research frameworks must be considered in research with SGM populations, such as using a trauma-informed research perspective. Community-based participatory research also is important to ensure that SGM populations are included in decisions about SGM-related health research.

Dr. Parker outlined the scientific themes and research opportunities identified in the strategic plan, emphasizing that these are examples and not the only themes. Better strategies for tracking SGM status in clinical research are needed, and additional research is needed on differences of sex development and intersex populations. SGM populations also are not routinely considered in some clinical outcomes, such as pregnancy outcomes or reproductive aging. In addition, BSSR is important in SGM research, including such issues as stigma, the effects of nondiscrimination laws, social support, and resilience. Chronic diseases and comorbidities also are understudied within SGM populations. Finally, novel measures must be developed that work better for SGM populations, and better understanding of existing measures is needed.

Dr. Parker explained the operational strategic goal areas. The first operational goal area is to advance rigorous research on the health of SGM populations, including both the extramural community and the internal NIH community. This goal could be accomplished through continued scientific workshops to identify research opportunities, expanding awareness of NIH's SGM-relevant work in the community and within the NIH. The office also recommends increased grant support for SGM-related research from ICOs.

The second operational goal is to increase partnerships and collaborations within the NIH and with the extramural community, such as by encouraging SGM expertise on NIH review panels and encouraging cultural competency training.

The third operational goal is to foster a highly skilled and diverse workforce in SGM health research; the office already has been engaged in activities in support of this aim, including offering the regional workshops, developing additional resources and tools related to SGM health research, and developing a grant mechanism to support institutional training efforts. Dr. Parker emphasized that because SGM research and support of SGM researchers remains a nascent field, the NIH should support institutions in providing mentorship, networking, and other processes that can help researchers succeed.

The fourth operational goal is to encourage data collection on SGM individuals, both in SGM populations in research and within the biomedical research workforce. This could be accomplished by leveraging existing data sets by encouraging ICOs and external partners to collect sexual orientation and gender identity data. Researchers also should consider data resources, data sharing, and data privacy and security, particularly as collection of these data becomes more common.

Dr. Parker discussed the management and accountability built into the strategic plan. The SGMRO produces a research portfolio analysis yearly and an annual report, which will continue to be published under the new strategic plan. As in the previous strategic plan, the new plan will include a midcourse review by the SGM Research Working Group of the Council of Councils. Annual SGM health research listening sessions will continue to gather feedback from the community, and the Office will continue presenting on current SGM health research and related developments at the NIH.

Discussion Highlights

- In response to a question about the limitations of electronic medical records in collecting SGM-related data, Dr. Parker agreed on the need to collaborate with others to ensure appropriate data collection.
- Dr. Parker pointed out that, in the 5 years that data on the SGM portfolio have been tracked, the portion of the SGM research portfolio related to HIV/AIDS has decreased, indicating that a broader portfolio of research importance to SGM health is being supported.

IX. INSTITUTIONAL IMPACT OF AND ADJUSTMENTS IN RESPONSE TO THE COVID-19 PANDEMIC

Council members commented on the effects of the COVID-19 pandemic on their work and institutions.

Discussion Highlights

- Dr. Scout noted an increased interest in collecting sexual orientation and gender identity (SOGI) data, commenting that because the SGM population has increased health disparity risks, including increased tobacco use, outcomes of a pulmonary pandemic are likely to be significantly different, and tracking of SOGI data is critical to identifying those differences. Dr. Edith Mitchell recommended that the NIH use its resources to encourage a unified approach to increasing electronic health record notation of SOGI information.
- Dr. Richard Krugman noted that the cancellation of clinical procedures reduces the revenue available for research, and Dr. Anderson added that the scope of the implications for research remains unknown.

- Drs. Russell Van Gelder and Michael Lairmore commented on the rapid response of the scientific community, which has been supported by the infrastructure of NIH research. Dr. Van Gelder encouraged the NIH to consider students and trainees as a vulnerable population to which the NIH can extend assistance. He also expressed concern about the politicization of science.
- Dr. Andrew Feinberg commented that biomedical research should be supported to encourage discovery as the best route out of the pandemic, and increased funding also is necessary to increase safety and protections for those conducting this research.
- Dr. Hurn commented on NIH's actions as a strong binding force for the scientific community and the creativity of human subject researchers in adapting mechanisms to continue conducting their research remotely. She recommended follow-up studies on how remote methodologies have been used and publication of success stories.
- Dr. Charles Mouton commended the use of remote technologies to continue delivering education and the increased public appreciation for the value of science and scientific collaboration. He also encouraged the scientific community to address the needs of communities that cannot social distance, such as nursing home and prison populations. Dr. Mitchell pointed out that the pandemic has demonstrated the gaps in knowledge of contributing factors to increased mortality rates in vulnerable populations.
- Dr. Susan Gregurick, Director of the Office of Data Science Strategy, noted an effort to work with several big data projects at NIH to assess the data and identify gaps and opportunities related to the pandemic.

X. CLOSING REMARKS

Dr. Anderson thanked the Council members and speakers for their contributions at this meeting. He reminded the members that the next Council meeting is scheduled for September 11.

XI. ADJOURNMENT

Dr. Anderson adjourned the meeting at 3:30 p.m. on May 15, 2020.

XII. CERTIFICATION

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

James M. Anderson -S

Digitally signed by James M. Anderson -S
Date: 2020.06.11 07:51:53 -04'00'

James M. Anderson, M.D., Ph.D.
Chair, NIH Council of Councils
Director, DPCPSI, OD, NIH

Date

Franziska B. Grieder -S

Digitally signed by Franziska B. Grieder -S
Date: 2020.06.11 07:45:42 -04'00'

Franziska B. Grieder, D.V.M., Ph.D.
Executive Secretary, NIH Council of Councils
Director, ORIP, DPCPSI, OD, NIH

Date