

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

**Special Meeting of the Council of Councils
April 5, 2024**

Meeting Minutes Draft

I. WELCOME AND OPENING REMARKS

Tara A. Schwetz, Ph.D., Director, DPCPSI, welcomed participants, NIH staff members, and members of the public to the meeting of the Council of Councils. The virtual meeting began at 1:00 p.m. on Friday, April 5, 2024. The meeting attendees are identified below.

A. Attendance

1. Council Members

Council Members Present

Chair: Tara A. Schwetz, Ph.D., Director, DPCPSI

Executive Secretary: Franziska B. Grieder, D.V.M., Ph.D., Director, Office of Research Infrastructure Programs (ORIP), DPCPSI

Maria Rosario G. Araneta, Ph.D., M.P.H., University of California, San Diego, La Jolla, CA

Linda Chang, M.D., M.S., FAAN, FANA, FISMRM, 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

Kevin B. Johnson, M.D., M.S., FAAP, FACMI, FIAHSI, FAMIA, University of Pennsylvania Health System and Children's Hospital of Philadelphia, Philadelphia, PA

Karen C. Johnston, M.D., M.Sc., University of Virginia, Charlottesville, VA

Barbara Kelley, Hearing Loss Association of America, Bethesda, MD

Paul J. Kenny, Ph.D., Icahn School of Medicine at Mount Sinai, New York, NY

Jean A. King, Ph.D., Worcester Polytechnic Institute, Worcester, MA

Gary A. Koretzky, M.D., Ph.D., Weill Cornell Medical College, New York, NY

Michael Kotlikoff, V.M.D., Ph.D., Cornell University, Ithaca, NY

Richard D. Krugman, M.D., University of Colorado School of Medicine, Aurora, CO

Kevin C. Kent Lloyd, D.V.M., Ph.D., University of California, Davis, Davis, CA

Jennifer Jaie Manly, Ph.D., Columbia University Medical Center, New York, NY

Susan Sanchez, Ph.D., The University of Georgia, Athens, GA

Lauren Silvis, J.D., Tempus, Inc., Washington, DC

Russell N. Van Gelder, M.D., Ph.D., University of Washington School of Medicine, Seattle, WA

Council Members Absent

Kristin Ardlie, Ph.D., Broad Institute of Massachusetts Institute of Technology and Harvard, Cambridge, MA

Monica Gandhi, M.D., M.P.H., University of California, San Francisco, San Francisco, CA

Rick Horwitz, Ph.D., Allen Institute for Cell Science, Seattle, WA

Rafael Irizarry, Ph.D., Dana–Farber Cancer Institute and Harvard Medical School, Boston, MA
Rhonda Robinson-Beale, M.D., UnitedHealth Group, Minneapolis, MN
Anna Maria Siega-Riz, Ph.D., M.S., University of Massachusetts Amherst, Amherst, MA

2. Liaisons Present

Susan K. Gregurick, Ph.D., Director, Office of Data Science Strategy (ODSS), DPCPSI
Franziska B. Grieder, D.V.M., Ph.D., Director, ORIP, DPCPSI
Douglas M. Sheeley, Sc.D., Acting Director, Office of Strategic Coordination (OSC), DPCPSI

3. Ex Officio Member Absent

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

4. Presenters

Monica M. Bertagnolli, M.D., Director, NIH
Susan K. Gregurick, Ph.D., Director, ODSS, DPCPSI
Felicia M. Qashu, Ph.D., Program Leader, OSC, 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. Reminders and Procedures

Franziska B. Grieder, D.V.M., Ph.D., the Executive Secretary for the NIH Council of Councils, 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 March 20, 2024.
- The minutes from this meeting will be posted on the DPCPSI website.

C. Future Meeting Dates

The next Council meeting is scheduled to be held virtually on May 30, 2024.

II. DPCPSI UPDATES

Dr. Schwetz noted that the *All of Us* External Advisory Panel—a Council of Councils working group—will assess the evolution of the *All of Us* Research Program and provide advice on strategic opportunities. The working group will report to the full Council at the September meeting, which will be held in person. Dr. Schwetz also noted the recent inception of the White House Initiative on Women’s Health Research, which aims to improve women’s health in the United States by accelerating research on the unique health needs of women across the life span and changing how women’s health research is approached and funded. NIH is committed to leadership in this area and has issued a notice of special interest identifying current open funding opportunities related to women’s health research across a range of health conditions at each institute and center (IC). The Office of Research on Women’s Health will create a dedicated “front door” for open funding opportunities related to women’s health research to make funding easier to find and apply for. NIH also is increasing support for innovators and early-stage small businesses engaged in research and development related to women’s health, which will help bridge the gap between basic science and commercialization and will identify and develop common data elements related to women’s health.

III. ESTABLISHING A NETWORK FOR RESEARCH IN PRIMARY CARE

Monica Bertagnolli, M.D., NIH Director, explained that the overall health of the U.S. population is declining and life expectancy is low compared with peer nations, despite higher spending on medical costs. This trend already had begun before the COVID-19 pandemic, but the pandemic exacerbated the problem. Health outcomes are worse in disadvantaged populations and are influenced by such factors as the diseases of despair—drug poisoning, alcohol abuse, and suicide—along with cardiometabolic disease. Dr. Bertagnolli emphasized that NIH must develop innovative ways to include underrepresented communities in meaningful research and harness existing research knowledge to guide clinical care. She commented that those who care for people directly and over the long term—especially primary care providers serving communities with disparities in health—are the optimal group to focus on for this initiative.

Felicia Qashu, Ph.D., Program Leader at OSC, introduced the concept for a Common Fund pilot program to establish a cross-NIH infrastructure to support clinical research in primary care settings. The initial investment over the next 2 years will be a pilot phase but can be expanded after assessing feasibility and budget requirements. Those who are disproportionately affected by diseases and illnesses often are those who have historically not been included in cutting-edge research opportunities, including people from racial and ethnic minority groups, older adults, and rural populations. When populations are not included in research, the results do not reflect the heterogeneity of the population or potential treatment effects, leading to evidence gaps and compounding health disparities. Lack of local opportunities to participate in clinical research is a major barrier—many people are interested and willing to participate, but location, distance, and cost are prohibitive. This lack of opportunity leads to a critical need to extend research participation to broader communities and integrate those opportunities where people seek care.

The proposed network is intended to facilitate and accelerate research advances, support broader adoption and implementation of research outcomes in clinical care, and improve health equity for all Americans. The network will be disease agnostic and will facilitate and amplify clinical research in mission areas across all NIH ICs. It will integrate innovative research with routine clinical care in real-world settings, improving the implementation of research outcomes, and will focus on sustained engagement with communities underrepresented in clinical research. The network will be planned, assessed, and built with consideration for what was learned about expanding research to communities during the COVID-19 pandemic. This program is appropriate for the Common Fund because it will enable clinical research participation to become an equitable opportunity in routine clinical care, support and amplify the missions

of all NIH ICs, providing NIH-wide expertise and coordination, and serve as a focal point for implementing study designs across the landscape of clinical research innovations.

The pilot phase will explore feasibility and scalability in a flexible way and assess how to sustain the infrastructure. An important part of planning is gathering input from key partners, including patient and community organizations, primary care organizations and providers, community health partners, hospital systems, research networks, and federal agencies. Listening sessions are planned with these groups and will focus on topics related to integrating research in primary care settings; the feedback will be used to further refine the program.

To jump-start this effort, the team plans to identify NIH studies already underway that could benefit from additional sites and support—especially through engagement with underrepresented communities—and partner with existing networks and resources to expand. Although the initial effort is modest, the program will strive to demonstrate value early through enhanced and more inclusive study accrual. If the first year is successful, new studies can be launched the following year, and capabilities can be expanded.

Discussion Highlights

- The discussants, Drs. Karen Johnston and Graham Colditz, provided their comments. Dr. Johnston supported the concept and emphasized the importance of intentionally including participants who are representative of the community participating in the study, as well as ensuring that the program can be sustained through the life span of the research programs.
- Dr. Qashu clarified that initial listening sessions will be small to gather open and focused input; a subsequent public event will summarize the feedback and solicit additional input. Dr. Johnston pointed out that some populations may be unable to make themselves available for listening sessions within the short start-up timeline. Dr. Schwetz and Dr. Bertagnolli emphasized that this is intended to be an ongoing effort with sustained engagement; many primary care providers have limited availability, and the best ways to reach these settings will be identified over time.
- Dr. Bertagnolli clarified that potentially applicable studies will be identified across NIH and noted that a list of these studies will be provided to a small number of selected sites for comment. Providers also will be able to identify questions that they need answered; structured coordination of responses to such requests is planned. Dr. Bertagnolli emphasized that the pilot phase would focus deeply on a small number of sites rather than wide implementation, which also is necessary under the limited NIH budget.
- When asked how the program will integrate existing research networks based in primary care practices, Dr. Qashu explained that the program will work with the selected sites as partners. Dr. Bertagnolli reiterated that the pilot phase will include a small number of sites and noted that she hopes this program will lead to improvements in collaborative research.
- Dr. Colditz also expressed support for the concept and asked how the program can bridge key gaps. Dr. Bertagnolli emphasized that the small scale of the pilot program is intended to help identify gaps and strategies for bridging them. She noted that significant variability is expected across practices, and sites will be able to select studies that they are able to execute. Dr. Schwetz added that leveraging existing efforts is a common theme of the program.
- Dr. Richard Krugman recommended that the program encourage participants to address the impact of physical, sexual, and emotional abuse in childhood on the adult health conditions that will be studied.

- Drs. Bertagnolli and Schwetz emphasized the importance of learning from the pilot phase the necessary infrastructure and approaches that will best facilitate engaging with the populations most in need.
- Council members emphasized the importance of addressing diseases of despair. Dr. Bertagnolli pointed out that the long-term relationships developed in primary care are critical to the program's longevity.
- Dr. Bertagnolli clarified that a new aspect of this program is that the existing programs may not span all of NIH, so bringing the research capacity of all of NIH to underrepresented populations will help NIH respond to the needs of these populations more inclusively by coordinating and supplementing existing programs. Council members recommended careful selection of metrics and measures to define success.

Vote

A motion to approve the Network for Research in Primary Care concept was forwarded and seconded. The motion passed with no abstentions.

IV. PROPOSED COUNCIL OF COUNCILS WORKING GROUP ON THE ARTIFICIAL INTELLIGENCE/MACHINE LEARNING CONSORTIUM TO ADVANCE HEALTH EQUITY AND RESEARCHER DIVERSITY (AIM-AHEAD)

Susan Gregurick, Ph.D., NIH Associate Director for Data Science and ODSS Director, outlined the planned Council of Councils working group on AIM-AHEAD, which is nearing the end of its third year. The consortium improves the participation of underrepresented researchers and communities in the development and use of artificial intelligence (AI) by providing research opportunities, capabilities, and technologies. Some of the program's successes include building capacity and infrastructure in four areas: the design and development of data repositories, ethics and data governance, data curation and harmonization, and concierge services to support open AI and machine learning (ML) tools.

AIM-AHEAD uses a hub-and-spoke model with a coordinating center and several cores with specific areas of focus. The program has supported a large number of researchers and issued more than 274 awards, many through fellowships, pilot or consortium projects, and community engagement projects. Many consortium members and institutions participate in AIM-AHEAD's mentorship program, and studies are co-designed with communities as collaborators.

Given the accomplishments of AIM-AHEAD have made a substantial impact to date, input from the Council is sought on the consortium's current status and proposed future priorities, including strengthening the network with a focus on community engagement, increasing the ability to develop and deliver computing infrastructures that leverage data to address health disparities, promoting disease prevention strategies, assessing how to overcome AI ethics and equity challenges, and strengthening AI/ML capacity in underrepresented communities through training. The charge for the proposed working group is to review the work, goals, and progress to date and provide recommendations for enhancing the future of the program and assessing success.

Discussion Highlights

- Council members requested additional information on how AIM-AHEAD has supported democratization of AI and suggested greater emphasis on bias mitigation in data and support for training, including education for people who may be unfamiliar with AI. Dr. Gregurick confirmed

that these efforts are in progress and commented that expanding into the clinical space could be a good opportunity.

- Council members suggested considering how this effort has improved the health of the nation and effects on underrepresented communities, particularly given the goals of the proposed primary care research network.

V. ADJOURNMENT

Dr. Schwetz adjourned the meeting at 2:30 p.m. on April 5, 2024.

VI. CERTIFICATION

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

Tara A. Schwetz, Ph.D.
Chair, NIH Council of Councils
Director, DPCPSI, OD, NIH

Date

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

Date