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)

Council of Councils Meeting
May 30, 2024
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 116 Office of Research Infrastructure Programs (ORIP) applications, 1,070 Office of Strategic Coordination (OSC) applications, and 14 Environmental influences on Child Health Outcomes (known as ECHO) applications, with requested first-year direct costs of $56,610,131, $648,211,933, and $631,304, respectively.

II. CALL TO ORDER AND INTRODUCTIONS

Tara A. Schwetz, Ph.D., Director, DPCPSI, welcomed participants, NIH staff members, and members of the public to the open session of the Council of Councils. The virtual meeting began at 11:15 a.m. on Thursday, May 30, 2024. The meeting attendees are identified below. Dr. Schwetz then reviewed the day's agenda.

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
Kristin Ardlie, Ph.D., Broad Institute of Massachusetts Institute of Technology and Harvard, Cambridge, MA
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
Monica Gandhi, M.D., M.P.H., University of California, San Francisco, San Francisco, CA
Rafael Irizarry, Ph.D., Dana-Farber Cancer Institute and Harvard Medical School, Boston, MA

[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.

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
Jean A. King, Ph.D., Worcester Polytechnic Institute, Worcester, MA
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
Rhonda Robinson-Beale, M.D., UnitedHealth Group, Minneapolis, MN
Susan Sanchez, Ph.D., The University of Georgia, Athens, GA
Lauren Silvis, J.D., Tempus, Inc., Washington, DC

Council Members Absent

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 School of Medicine, Seattle, WA

2. Liaisons

Andrew A. Bremer, M.D., Ph.D., M.A.S., FAAP, Director, Office of Nutrition Research (ONR), DPCPSI
Vivian Ota Wang, Ph.D. for Janine A. Clayton, M.D., FARVO, Director, Office of Research on Women's Health (ORWH), DPCPSI
Diana Finzi, Ph.D., Acting Director, Office of AIDS Research (OAR), DPCPSI
Susan K. Gregurick, Ph.D., Director, Office of Data Science Strategy (ODSS), DPCPSI
Franziska B. Grieder, D.V.M., Ph.D., Director, ORIP, DPCPSI
David M. Murray, Ph.D., Director, Office of Disease Prevention (ODP), DPCPSI
Karen L. Parker, Ph.D., M.S.W., Director, Sexual & Gender Minority Research Office, DPCPSI
Stefan M. Pasiakos, Ph.D., FACSM, Director, Office of Dietary Supplements (ODS), DPCPSI
Rebecca Meseroll, Ph.D. for George M. Santangelo, Ph.D., Director, Office of Portfolio Analysis, (OPA), DPCPSI
Douglas M. Sheeley, Sc.D., Acting Director, Office of Strategic Coordination (OSC), DPCPSI
Jane M. Simoni, Ph.D., Director, Office of Behavioral and Social Sciences Research (OBSSR), DPCPSI
Marina L. Volkov, Ph.D., Director, Office of Evaluation, Performance, and Reporting (OEPR), DPCPSI
Karina L. Walters, Ph.D., M.S.W., Director, Tribal Health Research Office (THRO), DPCPSI

3. *Ex Officio* Member Absent

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

4. Presenters

Diana W. Bianchi, M.D., Director, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)
Laura Biven, Ph.D., Lead, Integrated Infrastructure and Emerging Technologies (IIET), ODSS
Christine Cutillo, Health Data Scientist for Artificial Intelligence (AI) Ethics, IIET, ODSS
Susan K. Gregurick, Ph.D., Director, ODSS
Timothy LaVaute, Ph.D., Program Director, Division of Neuroscience, National Institute of Neurological Disorders and Stroke (NINDS)

Vivian Ota Wang, Ph.D., Deputy Director, ORWH
Stefan M. Pasiakos, Ph.D., FACSM, Director, ODS

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

Franziska 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 April 22, 2024.

- Minutes from the January 25–26, 2024, meeting are posted on the DPCPSI website. The minutes from this meeting also will be posted there.

C. Future Meeting Dates

The next Council meeting is scheduled to be held in person on September 12–13, 2024.

III. NIH AND DPCPSI UPDATES

Dr. Schwetz reviewed the agenda and noted staff changes at NIH, including the appointment of Dr. Kathleen Neuzil, the new Director of the Fogarty International Center; the departure of Dr. Josh Gordon, the Director of the National Institute of Mental Health, and the appointment of Deputy Director Dr. Shelli Avenevoli as Acting Director; the appointment of Dr. Stephanie George as the Deputy Director of ODS; the appointment of Dr. Janine Simmons as the Deputy Director of OBSSR; and the appointment of Dr. Vivian Ota Wang as Deputy Director of ORWH. In DPCPSI's fiscal year 2024 (FY24) budget, ORWH received a small increase to fund workforce development, but the budget included significant cuts to the *All of Us* Research Program and the Common Fund. The budget also included language regarding the continuation of ONR at the FY23 level and the INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE (INCLUDE) Project at not less than $90 million.

Dr. Schwetz noted the results of recent scientific challenges. In the ODSS DataWorks! Challenge, which highlights examples of innovative data sharing and reuse, the grand prize winner this year was a team from Lifespan Health that collected and disseminated information on patients with cancer who were diagnosed with COVID-19. The four phase 2 winners of the Neuromod Prize, which focuses on accelerating the development of targeted neuromodulation therapies as part of the Stimulating Peripheral

Activity to Relieve Conditions Initiative, used very different approaches to stimulate a range of targets without effects on nontarget organs. The Common Fund Complement Animal Research In Experimentation (Complement-ARIE) Challenge, a crowdsourcing competition for innovative ideas on new approach methodologies to assist in more accurately identifying and modeling human biology, awarded 20 creative solutions across the focus areas that built on *in silico, in vitro,* or *in chemico* tools or integrated multiple approaches. Dr. Schwetz noted that research conducted by the ORIP-funded National Swine Resource and Research Center laid the foundation for these translational approaches.

Dr. Schwetz highlighted two new strategic plans. The ODP strategic plan, intended to help NIH research have a more immediate effect on the well-being of Americans by encouraging greater attention to the leading causes of death and the development and testing of preventive interventions, outlines guiding activities for the office for the next 5 years. ODP aims to help understand how the conditions and systems in which people are born, grow, live, work, play, and age affect health. ORWH also recently released the *NIH-Wide Strategic Plan for Research on the Health of Women 2024–2028*, which outlines strategic goals to help guide and inform NIH-supported research on the health of women.

Dr. Schwetz noted that the Nutrition for Precision Health Program, powered by *All of Us* and led by ONR, combines recent advances in biomedical science with data from the diverse participant cohort of *All of Us* to develop algorithms that predict individual responses to food and dietary patterns. This program was recently featured on *Good Morning America*, resulting in 4,400 new consents through that weekend.

NIH and ODP, in partnership with several other institutes, centers, and offices (ICOs), are launching a Pathways to Prevention program to collect evidence-based information relevant to managing menopausal symptoms and optimizing health in the early post-menopause period. The program will identify research needed to navigate this transformative life stage and promote well-being throughout midlife and beyond; expected results include a portfolio assessment and recommendations from an independent panel.

Dr. Schwetz commented on recent and upcoming meetings and workshops, including the INCLUDE investigators meeting, at which researchers gathered to build collaboration and discuss how NIH can advance Down syndrome research in the near future, and OBSSR's Future of Scientific Conferencing Workshop, which will gather diverse perspectives to explore the future of scientific conferencing in the behavioral and social sciences. She also reminded attendees of the NIH Cloud Laboratory, a no-cost, 90-day cloud adoption program that enables researchers to try cloud functions in an NIH-approved environment, with curated tutorials and support from NIH experts. Cloud Laboratory has been available to NIH staff and intramural researchers for several years; it is now available to recipients of NIH funding and researchers at institutions eligible for NIH funding, including those without an active NIH award.

IV. OSC CONCEPT CLEARANCE: SOMATIC CELL GENOME EDITING (SCGE) CLINICAL TRIALS

Timothy LaVaute, Ph.D., Program Director, Division of Neuroscience, NINDS, introduced a new limited-competition funding opportunity within the SCGE program to support small first-in-human and early-stage clinical trials. The SCGE is in its second 5-year period. The first phase was focused on genome-editing technology development, and one key feature of success was testing new editors or delivery systems in independent large- and small-animal reporting systems and ensuring that replication studies were positive. The findings have been disseminated and adopted by investigators across the field, including those funded in the second phase of the program. This phase, focused on therapy development, involves optimizing genome editing–based therapeutic leads for safety and efficacy and establishing the regulatory pathway to the clinic for genome editing as a platform technology.

This concept focuses on five U19 awards to enable Investigational New Drug (IND) studies. Each of these five awards contains three distinct projects—one "trailblazer," a project that is poised to advance a

therapeutic clinical candidate to an IND package submission within 5 years, and two "follower" projects that are at earlier stages of development but have clear paths to identify a clinical candidate within the 5-year funding period. Originally, advancing to clinical trials was not part of this initiative, but investigators progressed more quickly than expected. This concept aims to capitalize on this success by expanding the scope of the existing awards to allow human subjects research and by supporting first-in-human clinical trials of novel genome editing therapies. The concept also will allow SCGE principal investigators to re-budget existing awards or redirect funds toward clinical trial readiness activities. The program will ensure that diverse perspectives contribute to this activity by requiring applicants to develop strategies to better engage partners and illustrate best practices for sharing medically relevant information on the risks and benefits of genome editing, and thoughtful ways to engage marginalized populations in biomedical research on the risks and benefits of genome editing.

These clinical trials will be the culmination of years of work by SCGE investigators and move genome editing therapies into the clinic, which was one of the major goals of the SCGE program. It will also provide an example of genome editing therapeutics moving through the regulatory process from preclinical development to IND and clinical trials. The information generated on the regulatory process will be shared through the SCGE Consortium to the genome editing field at large and will provide a roadmap for genome editing therapies, from preclinical development to clinical trials. For patients, these trials will provide hope for cures for debilitating genetic disorders and diseases.

Discussion Highlights

- The discussants, Drs. Kevin C. Kent Lloyd and Jean King, provided their comments. Dr. Lloyd commented that SCGE is an example of the value of investing tax dollars in NIH research. Dr. King commended the program for leveraging its success and easing the regulatory process for the field.

- Dr. LaVaute confirmed that this concept will allow applicants to restructure the budget of their current awards and request additional funding to support clinical trials. He clarified that one original SCGE funding announcement allowed clinical trials, but this concept adds that ability for an initiative that originally did not allow them. He also confirmed that the clinical trials would have to be completed within the 10-year period allowed for Common Fund programs, but investigators could request no-cost extensions if necessary.

- Dr. LaVaute clarified that the program will encourage investigators to address diverse recruitment of patients in their applications. Dr. Lloyd suggested requiring, rather than encouraging, a plan for enhancing diversity, and Dr. King added that applicants should be asked to implement best practices in their studies and include team members from diverse backgrounds. Council members suggested stating that responsive applications would include experts in the science of inclusion.

- When asked whether this concept requires considerations for inclusion beyond NIH standards, Dr. LaVaute commented that SCGE has a responsibility to ensure that the funding announcement reminds investigators of the importance of diverse participants, particularly for genome editing therapy, which is a new field and will require extra effort to make people comfortable with the concept.

Vote

A motion to approve the SCGE Clinical Trials concept—including a component to enhance diversity with strong language to enhance diverse backgrounds, experts in the science of inclusion, and associated analysis—was forwarded and seconded. The motion passed with no abstentions.

V. A FUTURE VISION FOR NICHD'S STRATEGIC PRIORITIES

Diana W. Bianchi, M.D., Director, NICHD, noted that NICHD's mission is to lead research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all. NICHD's 2020 strategic plan was its first in 20 years; the research themes are understanding the molecular, cellular, and structural basis of development; promoting gynecologic, andrologic, and reproductive health; setting the foundation for healthy pregnancies and lifelong wellness; improving child and adolescent health and the transition to adulthood; and advancing safe and effective therapeutics and devices for pregnant and lactating women, children, and people with disabilities. The new strategic plan will maintain those themes and adjust them to current needs.

NICHD's research portfolio consists of 55 percent pediatric health research, 30 percent reproductive health research, and 15 percent research on intellectual and developmental disabilities and rehabilitation, including adult rehabilitation. NICHD's research also includes a strong focus on "below the belt" research, including research on gynecologic health and disease, contraception, fertility and infertility, pregnancy and perinatology, maternal and pediatric infectious disease, obstetric and pediatric pharmacology and therapeutics, and population dynamics.

Dr. Bianchi highlighted several specific initiatives supported by NICHD. The Human Placenta Project, which investigates the developmental origins of health and disease related to harmful exposures early in life, has used enhanced imaging to gain a more detailed view of the placenta and how blood, oxygen, and nutrients flow across its vessels. Researchers also have begun investigating biomarkers that can be obtained noninvasively from maternal blood to reflect the health and function of the placenta and allow early intervention when necessary. NICHD has committed $3 million to research endometriosis, an extremely common condition that usually requires many years and an invasive procedure to diagnose. The Rapid Acceleration of Diagnostics (RADx) Tech mechanism will be used for the Advancing Cures and Therapies and ending ENDOmetriosis diagnostic delays (ACT ENDO) challenge to develop reliable noninvasive tests to enable early and accurate diagnosis and treatment. The Task Force on Research Specific to Pregnant Women and Lactating Women identified 15 recommendations to include pregnant and lactating people in safety and efficacy tests for medications; almost all recommendations are either close to implementation or have made significant progress toward implementation. Dr. Bianchi emphasized that this effort is ongoing but requires culture change.

Dr. Bianchi commented on several research areas NICHD supports. Data from one study of drugs commonly used during lactation indicate that almost no medication reaches the baby's blood, thereby providing parents with reassurance that continuing mothers on medication is safe for the baby. NICHD also supports several longstanding maternal and neonatal research networks and has opened them to external peer review and infrastructure improvements. A recent study in the global network to determine whether a single dose of azithromycin could reduce postpartum sepsis and death was stopped early due to clear maternal benefit.

Dr. Bianchi noted NICHD efforts in pediatric research and intellectual and developmental disability research. One area of interest is how reliance on technology and digital media affects child and adolescent development, including how the use of digital media correlates with emotional regulation and social competence in younger children and the relationships between social media content, behaviors, brain activity, health, and well-being in adolescents. The NIH Pediatric Research Consortium (known as N-PeRC) correlates child health research across institutes and centers (ICs) and has collaborated on the Helping to End Addiction Long-term® (HEAL) Initiative, public–private partnerships to develop pediatric medical devices, and an effort focused on the transition from adolescent to adult health care, particularly for people with chronic disease. Dr. Bianchi noted that the consortium also has worked to assess the effects of COVID-19 on children and define common data elements. Additional efforts focus on pediatric

clinical trials and expanding the workforce in pediatric research, such as an effort to include children younger than age 3 in treatments at the NIH Clinical Center using innovative gene therapy, which must be conducted as early as possible in life. NICHD is the home of the National Center for Medical Rehabilitation Research, which recently released a strategic plan aimed at enhancing the productivity, independence, and quality of life for adults and children with physical disabilities. Dr. Bianchi noted that ableism in medicine and how it acts as a barrier to care and contributor to health disparities is a recent area of interest.

Dr. Bianchi highlighted several NIH-wide programs in which NICHD is involved. The FY24 budget includes a $40 million appropriation to continue the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) Initiative, which aims to reduce preventable causes of maternal morbidity and mortality and develop local solutions for implementation to address health care disparities, particularly in maternity care deserts. Dr. Bianchi noted a major need to develop diagnostics that can be applied postpartum—when 60 percent of maternal deaths occur—to identify those at serious risk of complications or death. IMPROVE also aims to expand the knowledge and capabilities of local communities by developing research infrastructure and partnerships for implementation research. Dr. Bianchi also pointed out the importance of developing electronic health record standards for pregnancy.

NICHD also supports the INCLUDE Project's investigation of conditions that are more common or much rarer in people with Down syndrome. The project already has significantly increased the number of investigators engaging in Down syndrome research. INCLUDE enables high-risk, high-reward basic science studies that include people with Down syndrome; ongoing clinical trials that address issues relevant to people with Down syndrome; and development of new resources in this area. Dr. Bianchi described the Advancing Clinical Trials in Neonatal Opioid Withdrawal (ACT NOW) initiative, which is one of NICHD's most successful recent clinical trials. ACT NOW used a less invasive, family-oriented approach to treating infants withdrawing from *in utero* exposure to opioids that is now being incorporated into the standard of care.

<u>Discussion Highlights</u>

- Dr. Richard Krugman asked whether efforts could be focused on the area of physical and sexual abuse and other adverse childhood experiences known to affect conditions NIH addresses in a fractured way. Dr. Bianchi pointed out that NICHD considers trauma of all kinds but agreed that traumas frequently underlie health conditions; she planned to include this suggestion in upcoming strategic planning meetings.

- In response to a question about mother-to-fetus HIV transmission studies, Dr. Bianchi explained that much of the HIV research portfolio is coordinated by OAR but that NICHD supports several international groups studying women and infants with HIV. In the United States, one ongoing challenge for NICHD is the increasing rates of HIV among young men who have sex with other young men.

- When asked about progress toward enrolling children and young adults in *All of Us*, Dr. Bianchi explained that an infrastructure to recruit children has been developed; recruitment will start with children born to people already enrolled. Although the budget cuts to *All of Us* are significant, several ICs intend to provide support to maintain the momentum for adding pediatric participants.

- In response to a question about high rates of maternal mortality for Black people, Dr. Bianchi pointed out that the IMPROVE Initiative specifically addresses social and behavioral factors

related to health disparities. She noted that the differences in mortality are only partially related to access, commenting that the problem is complex but is a major focus of IMPROVE.

VI. ODSS CONCEPT CLEARANCE: PREPARING THE NEXT GENERATION OF BIOMEDICAL RESEARCH TEAMS FOR ETHICAL AI—WORKFORCE AND CURRICULA DEVELOPMENT

Susan K. Gregurick, Ph.D., Associate Director for Data Science, NIH, and Director, ODSS, introduced a workforce and curricula development concept to prepare the next generation of biomedical research teams for ethical AI. HHS and NIH have many crosscutting activities to develop and utilize AI, but NIH lacks a focused initiative that includes all ICs in AI training. This concept has the potential to touch many researchers across NIH and encompass the full life cycle of data in AI.

Laura Biven, Ph.D., Lead, IIET, ODSS, noted that this concept was designed using feedback from the Council on a similar concept presented in the past. ODSS conducted a landscape assessment to understand the current state of training and development in relevant core competencies. This concept also focuses specifically on some key aspects of how biomedical research can benefit from AI.

The first proposed initiative in this effort is a multidisciplinary K01 postdoctoral program for ethical AI in biomedical and behavioral research, providing postdoctoral researchers with the opportunity to engage in research with mentors for their biomedical discipline, AI, and ethics. This program will help a broad pool of researchers reach independence at the intersection of biomedicine, AI, and ethics and will support a portfolio of research that addresses the entire NIH mission. Trainees will have one primary mentor but ideally a team of mentors, who may come from multiple institutions, will address the multidisciplinary nature of this program.

The second proposed initiative is an R25 that focuses on developing undergraduate or graduate curricula, modules, or trainings and assessments for AI-ready biomedical and behavioral researchers, providing the opportunity to train these researchers in the skills needed to create findable, accessible, interoperable, reusable (FAIR), and AI-ready data, and to collaborate with AI experts and ethicists. The third initiative is an R25 that focuses on people who will become bioethicists or ethicists who collaborate with AI researchers to address the lack of expertise at the intersection of ethics, data, and AI. These two R25 initiatives will require applicants to propose training activities and relevant competencies. Applicants should have a clear plan for assessment and dissemination, as well as a recruitment plan to enhance diversity and focus on future biomedical researchers and bioethicists.

Dr. Biven pointed out that these cohorts will participate in joint meetings and practicum opportunities to develop an ecosystem-based workforce. The phased approach for this program will nurture a community of experts at the intersection of biomedicine, AI, and ethics who will be integrated into the NIH community. ODSS plans to provide tools and infrastructure for sharing outputs with other institutions, and future solicitations could invite other organizations to begin using these outputs. Partnerships with industry or other agencies will be pursued to ensure future opportunities for trainees.

Christine Cutillo, Health Data Scientist for AI Ethics, IIET, ODSS, highlighted the findings from the landscape study that ODSS commissioned to identify core skills and competencies needed for biomedical researchers to make data FAIR and AI ready. Researchers in this area identified five ethics-first competencies needed to further this goal with (1) data set documentation; (2) ontology use and data encoding; (3) data cleaning and formatting; (4) data curation and sharing; and (5) AI-assisted reuse of existing data sets. ODSS also has sponsored supplemental funding opportunities focused on training, ethics, and data that garnered interest across NIH and a robust response from the research and education communities, showing a strong interest in training that bridges the gap between data science and biomedical training.

Dr. Gregurick emphasized that biomedical research work is a key component of the government's priorities in AI, noting that NIH has a responsibility to train researchers to ensure that important considerations for biomedical research are addressed from the beginning of all AI-related activities.

Discussion Highlights

- The discussants, Drs. Kevin Johnson and Rafael Irizarry, provided their comments. Dr. Johnson commended the emphasis on training undergraduates, the intent to support lesser-resourced institutions, and the plan to create a multidisciplinary community. He suggested including collaborative activities at the beginning of the program and shifting funding from sustainability to support this, noting that creating tools and infrastructure will lead to sustainability naturally, and early group information will be helpful for developing a new program. He also recommended specifying whether K01 awardees will be required to create and follow a teaching plan.

- Dr. Gregurick clarified that nothing would preclude an institution from receiving both R25 and K01 awards. Dr. Schwetz added that the Engagement and Access for Research-Active Institutions initiative (known as EARA) is another pathway to engage a variety of efforts and could be discussed at a future Council meeting.

- Dr. Irizarry recommended focusing the concept to counter the vague public perception of the definition of AI. Dr. Gregurick agreed that AI is a broad field, explaining that a single application is unlikely to cover all needs in training and ethical development, so applicants could be asked to identify focus areas. She added that the field of ethical AI is new, so building the foundation for it at universities is critical. Dr. Biven and Ms. Cutillo emphasized that the collaborative and multidisciplinary nature of this concept will ensure researchers learn to co-innovate.

Vote

A motion to approve the Preparing the Next Generation of Biomedical Research Teams for Ethical AI—Workforce and Curricula Development concept was forwarded and seconded. The motion passed with no abstentions.

VII. ODS STRATEGIC PLAN 2025–2029: A BLUEPRINT FOR A COORDINATED DIETARY SUPPLEMENT RESEARCH AGENDA AT NIH

Stefan M. Pasiakos, Ph.D., FACSM, Director, ODS, introduced guiding principles for the next 5 years of ODS. Dietary supplements are used by many Americans, but the science behind them is often inconclusive and constantly evolving. ODS focuses on developing information about the safe and effective use of dietary supplements by coordinating cutting-edge dietary supplement research. Dr. Pasiakos emphasized that ODS intends to approach its work with respect, curiosity, pragmatism, and accountability.

ODS lacked a permanent director between 2019 and when Dr. Pasiakos joined the office, and the previous strategic plan ended in 2021; the office aims to publish the new strategic plan within the next several months and begin implementing it in 2025. The new strategic plan centers on three overarching goals: (1) prioritizing coordination and support of dietary supplement research at NIH by emphasizing the scientific disciplines that serve as the basis for the office's activities; (2) enabling progress by using all available tools to be an effective and efficient office that strategizes and implements best methodological practices for studying dietary supplements and that funds a robust, meaningful, and relevant research portfolio; and (3) implementing systems and policies that support all ODS scientific efforts.

Dr. Pasiakos emphasized the need for ODS to function as an interactive, proactive, and priority-based coordinating office by centering efforts on shared priorities, referred to as crosscutting themes in the strategic plan. The first theme, diverse populations, emphasizes the importance of understanding how unique population characteristics and intersectionality affect the use and effectiveness of dietary supplements. The second theme, healthy life span, focuses on how nutritional needs and health concerns change throughout life and the associations between dietary supplement use, disease prevention, and health optimization across life stages. The third theme, resilience, centers on studies of the mechanisms by which dietary supplement ingredients provide potential health benefits.

ODS has three research objectives: (1) coordinate extensive research analysis to identify dietary supplement research knowledge gaps, (2) collaborate with ICO staff to identify research topics that align with ICO interest areas and ODS crosscutting themes, and (3) coordinate the development of timely and innovative dietary supplement research initiatives for each of the crosscutting themes across ODS' three research programs. The first program, biological sciences, focuses on understanding the biological mechanisms through which dietary supplements may influence health and the interactions between diet, dietary supplement use, individual health behaviors, and individual exposomes or environmental exposures that may influence health. The second program, population sciences, focuses on identifying nutrient exposures or deficiencies within the American public that may affect health, especially in diverse subgroups. The third program, analytical sciences, prioritizes advancing the study of the composition, quality, stability, and efficacy of dietary supplements and their ingredients.

ODS also has two capacity programs that aim to develop best practices for dietary supplement science and identify strategic and appropriate funding mechanisms to stimulate efficient and effective research. ODS will work with NIH colleagues and partners through the first program, focused on methodology, to develop and implement best practices and population-based research designs and data collection tools. The second program, focused on research funding strategy, will increase the ODS focus on coordinating and initiating collaborations across NIH. Identifying the best funding mechanism for facilitating efficient research will boost ODS' capacity as a coordinating office. This program will aim to use knowledge of NIH funding procedures to stimulate new science, coordinate new efforts, and align ICs to address contemporary issues in relevant fields.

ODS also supports an operations and resources program that aims to translate and disseminate dietary supplement research findings, support dietary supplement databases, support the use of portfolio analyses and other tools for NIH to evaluate its research, and coordinate collaborations within NIH and with other federal agencies. ODS aims to develop and improve communications resources to ensure that information about dietary supplements reaches those who can use the information effectively. The office also manages several databases that provide detailed information about dietary supplements and research conducted on them. ODS' management and administrative support program will bolster the office's efficiency, accountability, and productivity and will support workshops, workforce development, budget, program analysis, and administrative activities.

<u>Discussion Highlights</u>

- When asked for major impacts from the office in the past 30 years, Dr. Pasiakos pointed out that ODS has been at the forefront of advancing the field, including understanding the contents of natural products and how they affect health, standardizing vitamin D assessment, understanding trends in dietary supplement use related to nutrient intake and health, and informing dietary guidelines. The ODS databases provide critical information, including on prenatal vitamins, multivitamins, and mineral supplements, which are some of the most heavily used dietary supplements.

- In response to a question about regulation of supplements, Dr. Pasiakos explained that the Dietary Supplement Health and Education Act stipulated that NIH should facilitate research on dietary supplements and that the U.S. Food and Drug Administration (FDA) is responsible for regulation as defined by the law. Drs. Pasiakos and Schwetz emphasized that ODS and the FDA collaborate closely in their distinct responsibilities.

- When asked about short-term goals and sustainability, Dr. Pasiakos noted that although the strategic plan focuses on the future of ODS, existing programs and resources relevant to the office's new objectives, including public health information and trainee programs, will continue.

- In response to a question about sustainability, Dr. Pasiakos pointed out that many ODS efforts have been in progress for years and that the office works closely with trade organizations, laboratories, and professional societies to ensure its work is appropriate.

- In response to a question about ODS' plans related to controversial products, such as cannabidiol (CBD), Dr. Pasiakos pointed out that the National Center for Complementary and Integrative Health is involved in research related to CBD, but ODS is not, because FDA does not classify CBD as a dietary supplement.

VIII. WHITE HOUSE WOMEN'S HEALTH RESEARCH INITIATIVE

Vivian Ota Wang, Ph.D., Deputy Director, ORWH, explained that females and males can experience diseases differently in terms of frequency and magnitude and that NIH has an enduring commitment to women's health research. The *NIH-Wide Strategic Plan for Research on the Health of Women 2024–2028* provides a foundation for NIH's efforts in this area, with strategic objectives focused on research areas, research capacity, and research conduct. Integration of sex and gender into biomedical research is a general NIH principle, and NIH also invests in initiatives to help women in science careers reach their full potential.

The newly released strategic plan uses research, training, and education as its foundation and focuses on the areas of data science and management, basic and translational science, and community engagement. ORWH works to transform women's health throughout the life span by considering how the intersection of social and biological factors affects the health of women; supporting the development of data science, innovative research methods and measurements, and cutting-edge technologies for the health of women; supporting biomedical workforce training and promoting women scientists' career development; advancing basic science and translational research to improve the health of women; and encouraging community engagement and promoting implementation science.

The White House Initiative on Women's Health Research was announced in November 2023, and an executive order on advancing women's health research and innovation was released in March 2024. The executive order focuses on integrating women's health across the federal research portfolio by strengthening research and data standards on women's health in relevant research and funding opportunities. It prioritizes investments to encourage high-impact research and innovation in women's health research and galvanizes new research on women's midlife health, one of the pivotal points at which chronic diseases emerge. The initiative also commits to assessing unmet needs to support women's health research. The executive order creates a multiagency crosscutting program to envision and potentially fund advanced new interdisciplinary health research toward transforming women's health research.

NIH has launched an effort to close women's health research gaps across the life span and develop new interdisciplinary women's health research that crosses traditional IC missions. Efforts in this initiative include creating a "front door" to NIH funding opportunities on women's health, standardizing data to support research on women's health, supporting private-sector innovation through additional federal

investments in women's health research, creating a comprehensive menopause research agenda, and using biomarkers to improve the health of women through early detection and treatment.

No points were raised for discussion.

IX. CLOSING REMARKS

Dr. Schwetz invited Council members to submit topics for discussion at future meetings and thanked the members for their input and discussions. She reminded them that the next meeting is scheduled to occur in person on September 12 and 13, 2024.

X. ADJOURNMENT

Dr. Schwetz adjourned the meeting at 3:41 p.m. EDT on May 30, 2024.

XI. CERTIFICATION

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

Schwetz, Tara (NIH/OD) [E] Digitally signed by Schwetz, Tara (NIH/OD) [E]
Date: 2024.08.05 23:47:26 -04'00'

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

Date

Franziska B. Grieder -S Digitally signed by Franziska B. Grieder -S
Date: 2024.08.05 08:05:17 -04'00'

8-5-2024

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

Date