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
January 25–26, 2024

Meeting Minutes

Day 1

I. CALL TO ORDER AND INTRODUCTIONS

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 10:01 a.m. on Thursday, January 25, 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
Maria Rosario G. Araneta, Ph.D., M.P.H., University of California, San Diego, La Jolla, CA
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
Rick Horwitz, Ph.D., Allen Institute for Cell Science, Seattle, WA
Rafael Irizarry, Ph.D., Harvard T.H. Chan School of Public Health, Boston, MA
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
Richard D. Krugman, M.D., University of Colorado Anschutz Medical Campus, 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
Anna Maria Siega-Riz, Ph.D., M.S., University of Massachusetts Amherst, Amherst, MA

Lauren Silvis, J.D., Tempus, Inc., Bethesda, MD
Russell N. Van Gelder, M.D., Ph.D., University of Washington School of Medicine, Seattle, WA

Council Members Absent

Michael Kotlikoff, V.M.D., Ph.D., Cornell University, Ithaca, NY
Rhonda Robinson-Beale, M.D., UnitedHealth Group, Minneapolis, MN

2. Liaisons

Andrew A. Bremer, M.D., Ph.D., M.A.S., FAAP, Director, Office of Nutrition Research (ONR), DPCPSI
Janine A. Clayton, M.D., FARVO, Director, Office of Research on Women's Health, 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, DPCPSI
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, DPCPSI
Karina L. Walters, Ph.D., M.S.W., Director, Tribal Health Research Office, DPCPSI

3. *Ex Officio* Member

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

4. Presenters

Monica M. Bertagnolli, M.D., Director, NIH
James N. Coulombe, Ph.D., Chief, Developmental Biology and Congenital Anomalies Branch, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)
Charles R. Dearolf, Ph.D., Director, Program Development and Support, Office of Intramural Research, NIH
Brionna Hair, Ph.D., M.P.H., Health Science Policy Analyst, OSC, DPCPSI
Susan K. Gregurick, Ph.D., Director, ODSS, DPCPSI
Franziska B. Grieder, D.V.M., Ph.D., Director, ORIP, DPCPSI
Robin I. Kawazoe, Deputy Director, DPCPSI
Janice S. Lee, D.D.S., M.D., FACS, Deputy Director for Intramural Clinical Research, Clinical Director, National Institute of Dental and Craniofacial Research (NIDCR)
Xiang-Ning Li, M.D., Ph.D., Director, Division of Construction and Instruments (DCI), ORIP, DPCPSI
David M. Murray, Ph.D., Associate Director for Prevention, NIH, Director, ODP, DPCPSI
Joni Rutter, Ph.D., Director, National Center for Advancing Translational Sciences (NCATS)
Nina F. Schor, M.D., Ph.D., Deputy Director for Intramural Research, NIH
Tara A. Schwetz, Ph.D., Director, DPCPSI

Karlie Sharma, Ph.D., Program Director, Office of Drug Development Partnership Programs, NCATS
Douglas Sheeley, Sc.D., Acting Director, OSC, DPCPSI
Jane M. Simoni, Ph.D., Associate Director for Behavioral and Social Sciences Research, NIH, Director, OBSSR, DPCPSI
Rick Woychik, Ph.D., Director, National Institute of Environmental Health Sciences (NIEHS)

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 January 9, 2024.

- Minutes from the September 7, 2023, 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 virtually May 30–31, 2024.

II. OPENING REMARKS

Dr. Schwetz acknowledged departing Council members—Drs. Maria Rosario Araneta, Rick Horwitz, and Gary Koretzky—and noted NIH staff changes, including Dr. Andrew Bremer as Director of ONR, Dr. Diana Finzi as Acting Associate Director for AIDS Research and Acting Director of OAR, and herself as Director of DPCPSI. She affirmed that DPCPSI works to identify and address emerging scientific opportunities, knowledge gaps, and critical challenges; fosters collaboration; develops methods to enhance NIH-wide research goals; and serves as an experimental testbed for NIH-wide innovation. DPCPSI's values include respect for the work, those who engage in it, and the diversity of their perspectives; coordination; partnership across NIH, HHS, and the federal government; and promoting excellence and inclusiveness. Dr. Schwetz encouraged Council members to consider how to leverage all DPCPSI resources to better coordinate activities across NIH.

Dr. Schwetz noted that fiscal year 2024 (FY24) already is in progress but the NIH budget has not been confirmed. The President's initial proposed budget included a 3.9 percent increase focused on several key areas, with the Institutes, Centers, and Offices (ICOs) remaining at FY23 levels. Dr. Schwetz pointed out that even a flat budget has a significant impact on ICOs because of inflation, and although leadership remains hopeful that no drastic cuts will be instituted, they are planning for all scenarios.

Dr. Schwetz emphasized the NIH commitment to addressing the forces driving the decrease in early career scientists, noting that an Advisory Committee to the Director (ACD) working group that reviewed this issue provided several recommendations. Dr. Schwetz highlighted several NIH priorities, including the Helping to End Addiction Long-term® (HEAL) Initiative, which seeks scientific solutions to the national opioid public health crisis; the national mental health crisis, particularly among youth; maternal health and outcomes, including the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) initiative; and the Researching COVID to Enhance Recovery (RECOVER) Initiative, the world's largest enrolling clinical cohort study for long COVID. Dr. Schwetz also noted the recently launched 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. She also commented on the Artificial Intelligence Machine Learning Consortium to Advance Health Equity and Researcher Diversity, or AIM-AHEAD, program, which seeks to increase the participation and representation of researchers and communities that are underrepresented in artificial intelligence (AI) modeling and application.

III. MID-COURSE UPDATE OF THE ORIP STRATEGIC PLAN 2021–2025

Dr. Grieder provided a midpoint update of ongoing programs and activities under the ORIP Strategic Plan, noting that research programs with an emphasis on infrastructure and resources require a much longer timeline to determine outcomes and depend on long-term, sustained support. The 2021–2025 ORIP Strategic Plan was developed during and includes lessons learned from the COVID-19 pandemic. For the current Strategic Plan, ORIP developed a reporting system for accomplishments, with highlights posted on the ORIP website, and these data will be used to develop the next Strategic Plan. In August 2023, an ORIP staff retreat was held to review accomplishments for all Strategic Plan teams; ORIP also engaged two Council members, Drs. Kent Lloyd and Susan Sanchez, to serve as liaisons during development of the next Strategic Plan.

The first theme of the Strategic Plan focuses on animal models used in biomedical research. ORIP supports a large number of diverse models, and Dr. Grieder highlighted accomplishments with mouse and nonhuman primate (NHP) models. She reviewed the history of the Mutant Mouse Resource and Research Center Consortium, which archives and distributes genetically engineered mouse strains and supports related investigations. These mouse models are supported by a broad range of ICOs, and the data show that the COVID-19 pandemic did not reduce the number of orders and increased the number of publications referencing these models. The Consortium identified 23 new mouse strains for antiviral development and preclinical testing during the active COVID-19 pandemic, and since that time, the Consortium has further developed technologies to aid the rapid expansion of large cohorts of animals for new pathogen testing. Dr. Grieder noted that in all ORIP-supported resources, providing training opportunities for young and new scientists remains a key goal.

NHP models are critical for all biomedical research and were used in the development of many COVID-19 vaccines. However, the availability of NHPs for biomedical research continues to present a challenge. In 2018, ORIP evaluated and analyzed NHP use for biomedical research, and the National Academies of Science, Engineering, and Medicine conducted a similar study more recently. NIH funds seven National Primate Research Centers that provide animals and specialized expertise and support for research. Dr. Grieder again emphasized the importance of long-term, sustained support for NHP resources

and noted that usage of NHPs supported by NIH is similar to usage of mouse models. For COVID-19 research, NHP models were used to address infection studies, vaccine and booster investigations, and treatment development. ORIP-supported projects also have been critical to studies of long COVID, and the National Primate Research Centers have been vital to the data sharing necessary to accelerate COVID-related research.

The second theme of the Strategic Plan is the Shared Instrumentation Program, which supports 25 institutes and centers (ICs) across all areas of NIH research. Although requests fluctuate with new technologies, imaging instruments and microscopes remain some of the top requests, followed by mass spectrometers. Instrumentation awards are made in almost all U.S. states, and ORIP has a strong program effectively supporting awards including to Institutional Development Award, or IDeA, states and historically under-resourced institutions.

The third theme centers on ORIP's support for the only training and career development program exclusively supporting veterinary scientists, whose background in veterinary medicine provides a one-of-a-kind perspective and understanding of comparative biology. Their unique contributions, especially during pandemics, highlight their specialized skills that significantly benefit biomedical research. ORIP supports both institutional (T mechanisms) and individual (K mechanisms) training for veterinary students and veterinarians.

The fourth Strategic Plan theme is awareness of ORIP resource programs and outreach activities, which is a continuous growth area for ORIP. This theme focuses on engaging ICOs and federal agencies to share awareness of ORIP-supported resources, collaborate, and co-fund research resources. ORIP staff conduct site visits, engage resource steering committees, and interact with the user communities; they also organize meetings with grantees and NIH colleagues and conduct outreach activities via social media. Dr. Grieder also noted that ORIP is the only DPCPSI office that supports a small business innovation research/small business technology transfer (SBIR/STTR) program, which funds proposals aligned with ORIP's mission and goals.

Discussion Highlights

- Dr. Schwetz emphasized that funding for RECOVER is obligated and cannot be redirected if budgetary requirements change, but additional resources would allow the study to expand.

- In response to a question about training programs for veterinary scientists, Dr. Grieder explained that limited funding makes developing combination programs difficult, but one priority for the coming year is to reevaluate existing training programs.

- When asked about the short supply of NHPs compared to the demand, Dr. Grieder pointed out that this is an NIH-level issue with many factors to consider. All areas of biomedical science benefit from NHP research, and ORIP is very engaged in the discussions.

IV. REISSUE ORIP CONCEPT CLEARANCE: SHARED INSTRUMENTATION PROGRAM

Xiang-Ning Li, Ph.D., Director, DCI, ORIP, presented a reissue concept for the Shared Instrumentation Program. The objective of this program is to support the acquisition of state-of-the-art, commercially available shared-use scientific instruments to enhance NIH-funded research. Funds available and the anticipated number of awards are contingent upon NIH appropriations and the submission of meritorious applications. The award period is 1 year, and ORIP manages the S10 awards for 5 years after issuance.

NIH established the Shared Instrumentation Program in 1982, initiating the S10 mechanism to support the purchase of scientific instruments for shared use. More than 5,700 S10 grants have been awarded since this time. Currently, three S10 funding opportunities are available: High-End Instrumentation, Shared Instrumentation Grant, and Basic Instrumentation Grant (BIG). NIH mandates institutional support and oversight by an internal advisory committee.

Dr. Li emphasized that the Shared Instrumentation Program benefits nearly all ICOs and has supported research in nearly all U.S. states. Each S10-awarded instrument supports an average of 17 NIH research grants, and the program has enabled numerous areas of research for thousands of investigators in hundreds of institutions nationwide. Additionally, the program has enabled the generation of data for tens of thousands of high-profile scientific publications.

Examples of S10-funded instruments include microscopes, biomedical imagers, spectrometers, ultrasound and photoacoustic imaging systems, flow cytometers, high-performance computers, protein and DNA sequencers, and X-ray irradiators. The Shared Instrumentation Program has received an average of 410 applications per year, of which 132 have been funded per year on average. ORIP's annual budget for this program has averaged $80 million in recent years.

Discussion Highlights

- The discussants, Drs. Horwitz and Linda Chang, provided their comments. Dr. Chang spoke on the importance of the program. She expressed concern that investigators must demonstrate prior expertise in the requested instrumentation, which could limit the applicant pool. Dr. Li responded that BIG is intended to provide opportunities for investigators from institutions that have not received a large number of S10 grants in the past. BIG enables accesses to instruments, facilitates research capacity building, and helps address this concern. Additionally, ORIP provides opportunities for investigators from resource-limited institutions. Dr. Schwetz added that she has discussed this topic with Dr. Grieder in the past.

- In response to a question from Dr. Horwitz, Dr. Li remarked that the current S10 budget is insufficient to meet the research community's needs. ORIP is working across NIH to obtain co-funding for projects that are aligned with various ICO missions. Dr. Lloyd inquired about approaches to reduce equipment costs by purchasing at government rates. Dr. Li agreed to look into this point further.

- In response to a suggestion about requiring institutional commitments to ensure access for early stage investigators, as well as investigators from underrepresented communities, Dr. Li provided further details on ORIP's support to resource-limited institutions, which is a step toward addressing this disparity. Additionally, he noted that the advisory committee plays a role in recruitment of instrument users. He agreed on the importance of fostering career development and diversity.

- When asked about seed grants for young investigators, Dr. Li noted that the overall program management is subject to U.S. Code and cannot be changed by ORIP's authority but that the office is using other funding mechanisms to provide relevant opportunities to the research community.

Vote

A motion to approve the Shared Instrumentation Program concept reissue was forwarded and seconded. The motion passed with no abstentions.

V. OSC CONCEPT CLEARANCE: VENTURE SPACE INITIATIVE(S)

Douglas Sheeley, Sc.D., Acting Director, OSC, DPCPSI, introduced the Common Fund Venture Space program, which aims to support novel high-risk short-term initiatives that are responsive to the needs of multiple ICOs and have the potential for significant impact within the biomedical and behavioral research communities. Venture Space Initiatives will be innovative and nimble, able to be launched quickly in response to emerging opportunities.

The Venture Space program was developed in response to a need to support high-risk short-term initiatives with a dedicated portion of the NIH Common Fund, which supports time-limited, goal-driven programs in scientific areas spanning the entire NIH mission. Common Fund programs are unique investments in scientific challenges and opportunities that no single ICO could address alone, and the Venture Space program will add flexibility to tackle a wider variety of topics at a faster rate to be more responsive to evolving situations. Venture Space funding will last for no more than 3 years, with clearly defined goals and milestones. The funding mechanisms and project timelines will be flexible to keep the projects responsive to changing needs.

Common Fund programs tend to invest in and expand new areas, but Venture Space Initiatives will be solicited from ICO directors and will depend on their priorities. The Venture Board, consisting of a rotating group of ICO directors, will review the proposals, and final approval will be made by the NIH and DPCPSI directors. Dr. Sheeley outlined two pilot initiatives: a novel ocular imaging technology and a systems biology data ecosystem.

Each Venture Space Initiative will generate specific deliverables appropriate to the scientific area, which could be information, methods, technologies, or devices. The budget is $5 million per year per initiative for no more than 3 years; the total Common Fund Venture Space investment will be $60 million per year by FY26.

Discussion Highlights

- The discussants, Drs. Koretzky and Russell Van Gelder, provided their comments. Dr. Van Gelder expressed enthusiasm for the program but pointed out that the word “venture” has associations with the area of venture capitalism. He added that use of the term “high-risk, high-reward” to distinguish this project suggests that other NIH research does not have high risks or rewards. Dr. Sheeley clarified that the name is not intended to refer to venture capitalism, and program staff are aware they may need to change the name and provide clear information on the goals. He agreed that all NIH activities are high reward but emphasized the need for specific attention to the high-risk areas this initiative emphasizes and noted that the term “high reward” tends to be used to reassure people about the level of risk.

- In response to a question about the role of this program in relation to similar programs, Dr. Sheeley explained that existing high-risk programs in the Common Fund invest in visionary research by particular individuals or a team, whereas this initiative will invest in proposals grounded in common cause across ICOs. Dr. Van Gelder recommended emphasizing feasibility to distinguish the program from the Advanced Research Projects for Health Administration (ARPA-H). Dr. Schwetz reminded attendees that ARPA-H is a component of NIH and added that ARPA-H’s programs may push advancement in a certain area with very targeted deliverables.

- Dr. Sheeley clarified that the initial board membership consists of directors representing ICs of varying sizes and roles, with varying level of experience with the Common Fund. Membership will have a staggered 2-year rotation, and the OSC director will serve as executive secretary.

- Dr. Koretzky suggested asking the research community for additional ideas for potential projects and adding extramural scientists to the boards. He emphasized the importance of metrics and suggested that the projects could be funded for 18 months and then evaluated, especially because this is a new program for NIH.

- Dr. Sheeley clarified that the Venture Space projects will have no expectation of commercialization, although the form of results may vary.

- Each Venture Space Initiative can provide regular reports to the Council on its progress.

- In response to a question about diversity, Dr. Sheeley explained that OSC has been working to broaden the applicant pool. Each Venture Space Initiative will be able to build diverse teams within the broad cross-section of research topics it will address.

Vote

A motion to approve the Venture Space Initiative(s) concept, with the inclusion of the comments raised, was forwarded and seconded. The motion passed with four abstentions.

VI. OSC CONCEPT CLEARANCE: COMPLEMENT ANIMAL RESEARCH IN EXPERIMENTATION (COMPLEMENT-ARIE)

Rick Woychik, Ph.D., Director, NIEHS, outlined the new Common Fund concept for the Complement-ARIE program, which aims to catalyze the development, standardization, validation, and use of human-based new approach methodologies (NAMs) that will transform the way basic, translational, and clinical sciences are conducted. The goals of the program are to better model and understand human health and disease outcomes across diverse populations, develop NAMs that provide insight into specific biological processes or disease states, validate mature NAMs to support regulatory use and standardization, and complement traditional models and make biomedical research more efficient and effective.

Model organism studies remain foundational for advancing scientific knowledge, but traditional animal models do not always predict human responses, and species-specific differences delay development of treatments significantly. Complement-ARIE will complement animal research to make biomedical investigations more efficient and effective by catalyzing the development, standardization, validation, and use of human-based NAMs to provide insights into the etiology of disease mechanisms across diverse populations. It also will promote the use of validated NAMs as gold standards to help other agencies make regulatory decisions. The past decade has seen dramatic advances in such areas as complex *in vitro* systems, bioengineering technologies, human data, and computational methods, and a wealth of data are available to support and enable complementary NAMs. Additionally, the U.S. Food and Drug Administration (FDA) Modernization Act 2.0 legislates that drugs may be registered without animal studies, opening up many new opportunities for drug development.

Complement-ARIE is appropriate for the NIH Common Fund because it is an NIH-wide effort that cannot be exclusively accomplished by any single IC and will require coordination of efforts with multiple ICs and potentially other federal partners. Complement-ARIE will also significantly advance understanding of human health, population diversity, and human disease etiology and will have near-term application in many related areas. The wide range of validated and standardized NAMs will ensure optimal use of resources, and the outcomes will synergistically promote and advance the missions of multiple ICOs.

NIH investment in alternative methods has increased and spanned a variety of scientific disciplines, and this program will build on activities across NIH. Although complex *in vitro* systems already are in development at many ICs, NIH lacks integrated methods that leverage interconnected data ecosystems;

this type of disruptive and transformative science can be accomplished only by a comprehensive NIH-wide Common Fund initiative.

Joni Rutter, Ph.D., Director, NCATS, outlined the strategic planning and stakeholder outreach activities used to better understand the key questions and areas of greatest need for Complement-ARIE. Three listening sessions were held with representatives from interested agencies, as was a federal interagency retreat, and the participants identified scientific needs centered on innovation and transformation and operational needs around integration, coordination, and collaboration. A landscape analysis enabled by AI identified needs in the areas of population diversity, variability, regulatory application, ethical and economic considerations, and workforce development. A Challenge Prize also will inform topic areas with crowd-sourced NAMs relevant to human biology or data infrastructure.

Dr. Rutter outlined the proposed program structure. Technology development projects and centers would stimulate the development of NAMs to fill in areas of greatest need, with emphasis on increased biological complexity and throughput, innovative combinatorial approaches, and data sharing. A data and NAM resource coordinating center will create integrated data structures, including standards for model credibility; improve FAIRness (findability, accessibility, interoperability, and reusability) of NAM-relevant data; and create a searchable NAM repository. A validation network for regulatory implementation will establish common data elements and standardized reporting, apply validation and quantification frameworks, and accelerate deployment and regulatory implementation of NAMs. Community engagement and training will be used to promote the development of an inclusive, diverse biomedical research workforce with the skills to build and use new NAMs and foster community engagement, taking into account societal and ethical considerations. Strategic engagement will involve a set-aside of about 2 percent to 5 percent of program funds to dynamically engage with emerging opportunities. A 10-year timeline and budget has been developed.

Complement-ARIE will use a comprehensive center model requiring embedded projects or *in vitro*, *in chemico*, and *in silico* approaches, as well as combinatorial approaches. Cores will include administrative, validation, resources, and training components. Phased milestone-driven projects that pilot some of the truly innovative approaches can also be transitioned for integration with the centers. Dr. Rutter emphasized that Complement-ARIE aligns with ACD working group recommendations, and a key theme of the project is the power of integrated and interdisciplinary work, which will be foundational to the success of NAMs.

<u>Discussion Highlights</u>

- The discussants, Ms. Lauren Silvis and Dr. Paul Kenny, provided their comments. Ms. Silvis expressed a positive reaction, noting that now is an appropriate time to expand this space. However, regulators can be very conservative, and it will be essential to demonstrate the basic safety of NAMs, which will be a significant challenge to their widespread adoption. She noted that the budget timeline is broad and might need to be more targeted over time to track what is most likely to be adopted. She encouraged them to keep this flexibility in mind as they develop the longer-term timeline and identify places to focus on real-world application of the science and have the greatest impact.

- Dr. Kenny agreed that the timing is right and emphasized the importance of standardized approaches and tools; he recommended work to improve current models at the same time new models are developed.

- Council members cautioned against using NIH funds to further support the pharmaceutical industry and wondered whether this project is the optimal use of resources. Dr. Woychik pointed

out that the tools created through this effort will be standardized and validated tools that can be used across the biomedical research enterprise supported by NIH.

- Funding decisions will be made similarly to most Common Fund programs: A general solicitation will call for proposals that encompass many human diseases and conditions, and applications will be subject to peer review and a special emphasis panel and will require a detailed implementation plan.

- Participants in the interagency listening session emphasized the need for standardization, which will encourage adoption across the biomedical community for both regulatory purposes and basic and translational research.

- Dr. Rutter clarified that Complement-ARIE is appropriate for the Common Fund instead of NCATS because of its potential to benefit many ICs and the broader biomedical community. The Common Fund also can work across agencies and help create standards.

- Dr. Woychik emphasized that this project is not meant to eliminate animal research, and Dr. Rutter added that the project focuses on human-based approaches. Complement-ARIE will use legacy data on animal models to validate its NAMs, but the focus on human-based systems will allow incorporation of genetic and population diversity, improving predictability. The 5-year timeline of Common Fund programs will provide an opportunity to review and update the program.

Vote

A motion to approve the Complement-ARIE concept was forwarded and seconded. The motion passed with one abstention.

VII. ODP STRATEGIC PLAN OVERVIEW

David M. Murray, Ph.D., Associate Director for Prevention, NIH, Director, ODP, DPCPSI, provided an overview of the proposed ODP Strategic Plan for FY24–28, which was informed by input that was gathered via a series ODP-hosted focus groups involving NIH prevention science experts, key federal partners, and other external parties. The plan incorporates five crosscutting themes and seven strategic priorities to guide ODP activities through 2028. The crosscutting themes are (1) dissemination and implementation, (2) workforce development, (3) risk and protective factors, (4) social determinants of health, and (5) preventive interventions.

The first strategic priority is to conduct portfolio analyses and an impact assessment by systematically monitoring NIH investments in prevention research and analyzing the progress and outcomes of that research. The objectives of this priority are to characterize and report on NIH prevention research projects based on the taxonomy for prevention research developed by ODP, assess the impact of NIH investments in prevention research, and partner with NIH ICOs and other federal agencies to disseminate ODP portfolio analysis resources. Planned activities include analysis of the NIH prevention research portfolio. The sampling frame has been expanded to cover all extramural research–focused activity codes. The coding protocol has been updated and is now built around both the International Classification of Diseases to capture the leading causes of death and disability, and around the Global Burden of Disease project to capture the leading risk and protective factors for death and disability. Assessments of the reach of ODP initiatives and NIH prevention research have resulted in publications on the influence of NIH efforts around opioids and the role of opioids in the treatment of chronic pain, as well as updates to clinical guidelines. New studies are underway, including portfolio analyses for the recent Pathways to Prevention (P2P) workshops, nutrition as prevention for improved cancer health outcomes, and

identification of risks and interventions to optimize postpartum health. Outcomes of interest include the uptake of clinical preventive services and effects on population health.

The second priority is the identification of research gaps and areas for investment or expanded NIH efforts. The objectives are to work with partners to uncover needs in prevention research, compare these needs with the current NIH portfolio, identify gaps, and work across ODP and with ICOs to identify the most promising and feasible research areas that warrant expanded effort. Related activities will include redesigning the annual survey on NIH activities that address U.S. Preventive Services Task Force (USPSTF) Insufficient Evidence statements and developing a public-facing report for the extramural research community to identify potential research opportunities. ODP has worked with the USPSTF and Agency for Healthcare Research and Quality to develop a research gaps taxonomy and will coordinate with NIH partners to create strategies to address high-priority gaps. The impact of the P2P Program will be assessed by evaluating how workshops and follow-up activities affected funding and federal-level support for work on identified research gaps.

The third strategic priority is to improve prevention research methods. The objectives for this priority are to ensure that ODP disseminates the most accurate and up-to-date information available pertaining to prevention science methods; provide training in prevention science methods to NIH staff and extramural investigators, including investigators and trainees from populations underrepresented in prevention research; serve as a resource for ICOs on prevention science methods as they develop new funding opportunities, workshops, meetings, and other activities; collaborate with ICOs to strengthen NIH policies and procedures to encourage the use of the best available methods in prevention research; and review and investigate prevention research methods. Activities in this area will include updating and expanding the Research Methods Resources website and reviewing the methods used in NIH-funded clinical trials. The proposed methods in all new phase 2 and 3 clinical trial applications that were funded in FY23 will be examined; the review will assess the extent to which the methods proposed in recent clinical trials are appropriate, and particular attention will be paid to trials involving randomization of groups or delivery of interventions to groups. The results of the review, and any subsequent recommendations, will be presented to ICO directors.

The fourth priority is to promote collaborative prevention research. The objectives for this priority are to establish infrastructure and facilitate processes to foster prevention research coordination across NIH and with public and private partners, coordinate and support collaborative initiatives to address prevention research gaps and promote integration of evidence-based interventions and policies into routine practices and settings, and advance evidence-based approaches for identifying future research gaps and priorities and collaborate on NIH-wide and federal government–wide activities to address them. Activities in this area will include leading the Health and Housing Group (a collaboration among NIH, the Centers for Disease Control and Prevention, and the U.S. Department of Housing and Urban Development) in such efforts as portfolio analyses, conferences, seminars, and data resource leveraging for secondary data analysis. ODP also will continue to support three active Scientific Interest Groups (i.e., Physical Activity, Comorbidity, and Screening) and collaborate on new NIH-wide research initiatives.

The fifth strategic priority is to promote and facilitate tobacco-related regulatory and prevention science. The objectives of this priority are to lead the NIH-wide Tobacco Regulatory Science Program (TRSP) in partnership with FDA scientific leadership to help address tobacco regulatory research priorities; oversee and lead NIH ICOs and grant recipients in complying with policies and procedures unique to the NIH–FDA partnership in tobacco regulatory science; educate FDA and NIH staff on scientific goals, policies, and procedures of the TRSP; create opportunities for extramural investigators and federal staff to collaborate, network, and discuss FDA priority topics and share research results in prevention and tobacco regulatory science; and facilitate development of resources to address gaps in tobacco prevention science. Activities associated with this priority will include a funding opportunity consisting of $2.4 million in

support of efforts to study public health communications messaging about the continuum of risk for tobacco products and a new Opportunity Fund coordinated by the Tobacco Centers for Regulatory Science, which will respond to the evolving tobacco marketplace with high-priority, time-sensitive projects that address FDA research needs. ODP currently coordinates approximately $100 million in FDA funding annually to support tobacco regulatory science research.

Priority six is to promote and coordinate prevention research that addresses health disparities. The objectives for this priority are to coordinate NIH-wide funding opportunities and other research initiatives to develop and test new interventions and new strategies to disseminate existing interventions that address risk and protective factors for health concerns in populations experiencing health disparities; assess the NIH prevention research portfolio related to health disparities to identify research, infrastructure, and training gaps and develop strategies to address those gaps; and serve as a resource to NIH ICOs, federal partners, and the extramural research community on health disparities–related prevention research. These objectives will be accomplished through the Advancing Prevention Research for Health Equity (or ADVANCE) initiative, which will support training to promote diversity in prevention science and research on such topics as cancer screening, cardiometabolic risk factors, mental health, alcohol, and adverse childhood events.

The seventh and final priority is to highlight the value of prevention research by communicating NIH efforts and findings. The objectives of this priority are to improve the availability and visibility of information about prevention research and promote prevention-related events conducted by NIH and other federal agencies, inform ODP's audiences about the scope and impact of prevention research, and engage with partners to foster opportunities to enhance and support ODP's mission. In support of this priority, the ODP website will be updated with improved navigation and other changes that are informed by input from web analytics, usability testing, and feedback from ODP staff.

Discussion Highlights

- In response to a question about use of USPSTF guidelines to determine insurance coverage, Dr. Murray emphasized that ODP works closely with USPSTF to clearly identify gaps in prevention research and agreed that NIH contributions to preventive medicine should be highlighted.

- Dr. Richard Krugman expressed appreciation to ODP for supporting research on adverse childhood events. He commented that the connection between adverse childhood experiences and such negative outcomes as obesity, substance use, and suicide has been underappreciated by clinicians and prevention science researchers. Dr. Murray pointed out that adverse childhood events are an important consideration in populations that experience health disparities. This will be an area of focus for ODP in the coming years.

- Dr. Araneta recommended the inclusion of health disparities as a crosscutting theme that is considered for each of the seven priorities. Dr. Murray noted that in the new Strategic Plan, health disparities has been elevated from a crosscutting theme to its own priority; all teams will focus on health disparities even if that topic not listed as a crosscutting theme. Dr. Araneta also recommended that ODP investigate opportunities to partner with the Environmental influences on Child Health Outcomes (ECHO) Program and that environmental factors and the effects of climate change be integrated into the Health and Housing Group's programs. Dr. Murray noted that a collaboration with the ECHO Program has been established and that the ODP team lead responsible for the Health and Housing Group also serves as the lead on climate change issues.

- Council members suggested including the unique chronic stress experienced by people from underrepresented and minoritized groups in prevention studies related to stress.

VIII. PROPOSED DPCPSI REORGANIZATION

Robin I. Kawazoe, Deputy Director, DPCPSI, NIH, outlined the history and mission of DPCPSI and explained the proposed reorganization that would move the *All of Us* Research Program, Environmental influences on Health Outcomes (ECHO) Program, and INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE (INCLUDE) Project to DPCPSI, aligning all programmatic research and coordination functions in OD under the same division.

All of Us is a historic effort to collect and study data from 1 million or more people in the United States with the goal of better health for all. *All of Us* is the largest and most diverse research cohort of its kind and fosters a new era of medicine in which researchers, providers, and patients work together to develop individualized care. ECHO aims to understand the effects of environmental exposures on child health and development by combining observational and intervention research to enhance the health of children for generations to come. INCLUDE examines critical health and quality-of-life needs for individuals with Down syndrome and their families and works to increase participation of people with Down syndrome and their families in clinical research, expand the knowledge about Down syndrome and its links to other health conditions, and improve the health and quality-of-life for these individuals.

Ms. Kawazoe explained that the *All of Us* Research Program Office would move in its entirety to DPCPSI, the ECHO Program would be elevated to a Program Office similar to the other offices in DPCPSI, and management of the INCLUDE Project would move to the DPCPSI Immediate Office of the Director. She noted the proposed reorganization requires approval by the HHS Secretary, and it is hoped this will occur in early 2024. A request for public comments will be posted in the *Federal Register* and a website for comments will be posted to the DPCPSI website once NIH receives pre-clearance approval from HHS.

Discussion Highlights

- Ms. Kawazoe responded to a question explaining that the existing administrative office staff from the All of Us Research Program will be moved to the DPCPSI Office of Administrative Management so DPCPSI would gain those resources to support the programmatic additions. In terms of benefits of the reorganization, she noted that the programs already collaborate with DPCPSI and many of its offices and this change is expected to facilitate additional partnerships. Additionally, senior leadership from *All of Us* and ECHO previously worked with Dr. Schwetz in her role as Acting Principal Deputy Director of NIH so this would not represent a major reporting change. Dr. Schwetz added that she helped to establish ECHO and has co-chaired the INCLUDE Steering Committee for several years, and stated that DPCPSI is within OD, so the impact this change will have on the programs and offices is minimal.

- When asked if this reorganization would prompt consideration of reorganizing other large programs, Dr. Schwetz said no and explained that the funding for ECHO, INCLUDE, and *All of Us* was appropriated through OD, whereas other programs have their funding appropriated through ICs.

- Council members noted that changes to the management of prenatal conditions may affect the INCLUDE cohort.

IX. COUNCIL ENGAGEMENT AND ACTIVITIES DISCUSSION

Dr. Schwetz introduced a discussion concerning the Council and how it can strategically address key questions facing the extramural community. She reminded attendees that the Council performs second-level review and advises on policies and activities specifically pertaining to DPCPSI, emphasizing the need to balance the risk necessary for scientific discovery with NIH's responsibility as a steward of taxpayer money.

Discussion Highlights

- Council members recommended that DPCPSI identify concepts that will require a vote in advance to ensure they receive sufficient review and provide information on whether the Council's suggestions were incorporated into the final program. They also suggested developing a method for Council members to identify potential issues, ask clarifying questions in advance, and devise a template for Common Fund concepts identifying the category the concept falls under and how it meets the five merit criteria.

- Council members felt that because funding mechanisms may have been chosen for the concepts presented, there is a perception that some of the Council's ideas may not be implemented; however, establishing a role for the Council to embark on earlier in the process could be explored.

- Council members recommended adding an executive closed session, regular discussion of Council engagement, and an annual evaluation of the Council. They also requested information on decisions that have effects across ICOs—such as changes that affect foundational aspects of NIH research or DPCPSI funding—as well as clarification of how their votes on concepts will affect the funding timeline for that program.

- When asked whether the Council can support working groups, which reduce workload for the Council as a whole and offer participants an opportunity to work closely together, Dr. Schwetz encouraged Council members to consider which topics the Council may wish to propose for her consideration.

- Attendees discussed the importance of communication about science, given the unfortunate deaths from COVID and other diseases or conditions caused by misinformation and NIH's responsibility to promote health and well-being. It was also noted that a past proposal concerning this topic did not proceed, and the Council was not informed why. Council members suggested that the Council could support NIH by discussing its effects on population health initiatives with members of Congress.

- Council members supported the idea of holding an in-person meeting. Dr. Schwetz proposed holding the September meeting in person and reevaluating the format of future meetings as needed.

X. ADJOURNMENT FOR THE DAY

Dr. Schwetz adjourned the public session at 3:41 p.m. on January 25, 2024.

XI. 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 345 ORIP applications with requested first-year direct costs of $307,861,226.

Day 2

XII. CALL TO ORDER

Dr. Schwetz welcomed participants, NIH staff members, and members of the public to the second day of the meeting and reviewed the day's agenda. The open session of the virtual meeting began at 10:15 a.m. on Friday, January 26, 2024.

XIII. UPDATE ON THE DEVELOPMENT OF THE OBSSR STRATEGIC PLAN 2024–2028

Jane M. Simoni, Ph.D., Associate Director for Behavioral and Social Sciences Research, and Director, OBSSR, DPCPSI, provided an update on the development of the OBSSR Strategic Plan for 2024–2028. Dr. Simoni pointed out that the promise of even great biomedical breakthroughs can fall short without the attention to behavioral and social sciences research (BSSR) that would support uptake and acceptance. In humans, all interventions are biobehavioral, not solely biomedical, and BSSR helps shape health policies and improve health outcomes in areas that affect almost all the disorders and conditions addressed by NIH ICOs.

OBSSR coordinates all health-relevant BSSR at NIH and identifies gaps, challenges, and opportunities related to BSSR. The majority of OBSSR's budget is distributed directly to ICs to co-fund BSSR. Priority areas include behavior change maintenance and mechanisms of impact; social connection and health; and multilevel research, including on social determinants of health, other broad factors that may affect health, and the integration of BSSR into the biomedical research enterprise.

To develop its next strategic plan, OBSSR reviewed the current strategic plan, issued two requests for information, engaged in listening sessions with NIH staff and leadership, gathered feedback from the BSSR Coordinating Committee, and reviewed reports from two Council working groups on NIH-wide BSSR opportunities and integration of BSSR at NIH.

OBSSR's mission is to enhance the impact of health-related behavioral and social sciences research, coordinate behavioral and social sciences research conducted or supported by NIH and integrate these sciences within the larger research enterprise, and communicate health-related behavioral and social sciences research findings to various stakeholders within and outside the federal government. In its vision, newly created this year, OBSSR envisions a world in which the synergistic intervention of the behavioral and social sciences with biomedical research leads to enhanced scientific discovery, efficacious treatment and health-promotion interventions, and equitable implementation strategies that will improve health for all.

OBSSR's three research priorities are (1) synergistic inquiry, which focuses on integrating behavioral and social sciences into every relevant aspect of NIH and catalyzing a new BSSR knowledgebase;

[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.

(2) investigational innovation, which includes promoting novel measures, designs, and analytics; and (3) implementation and impact to accelerate sustained adoption of BSSR findings in practice and policy. Operational priorities include upholding diversity, equity, inclusion, and accessibility (DEIA); building equitable collaborations within and outside NIH; and improving communication among scientists and with the public. Health equity is a theme across all priorities, and OBSSR will work to develop and diversify the BSSR workforce.

The BSSR Coordinating Committee meets monthly, ensuring that OBSSR remains informed about IC priorities and BSSR opportunities. OBSSR also communicates with the broader community through regular lectures and research festivals, webinars, newsletters, and scientific workshops focused on specific topics.

Discussion Highlights

- Dr. Simoni clarified that any notice with an intervention can be written in a way that includes BSSR. Each ICO has a liaison on the BSSR Coordinating Committee, which helps OBSSR learn about upcoming opportunities and suggest adjustments to the language.

- In response to a question about the current state of mental health in the United States, particularly in the wake of the COVID-19 pandemic, Dr. Simoni explained that OBSSR coordinates interventions to the COVID-19 pandemic and has worked broadly to help ICs prioritize social support interventions in their notices of funding opportunities (NOFOs).

- Council members suggested adding physician/nurse/healthcare professional burnout and necessary policy changes to the Strategic Plan, noting that early supplements might be helpful in this area.

- When asked about success metrics, Dr. Simoni commented that although the Strategic Plan does not focus on metrics, a complementary implementation plan offers flexible metrics options. She noted the difficulty of showing a causal relationship between OBSSR priorities and health outcomes and suggested that a community-level epidemiology dashboard could help.

- In response to a question about specific initiatives to address child abuse and neglect, Dr. Simoni noted that OBSSR has not specifically reviewed this topic but has proposed a Common Fund program on aggression and has been broadly interested in violence. Dr. Krugman encouraged OBSSR to consider the factors in current society that put 3- to 8-year-old boys on the path to become aggressors.

- When asked about challenges to advancing BSSR at NIH, Dr. Simoni outlined several areas in which OBSSR is working, such as a long-standing NIH-wide effort to examine adherence and behavior maintenance, NIH's multilevel research into social determinants of health, and work with the National Center for Complementary and Integrative Health to address the impacts of stress.

- Dr. Schwetz pointed out that uptake of the COVID-19 vaccine illuminated the need for more behavioral and social science strategies.

- Dr. Simoni noted that community participatory research is part of the Strategic Plan, but the lack of BSSR expertise on the Council shows the difficulty of integrating research across disciplines.

XIV. NIH UPDATE

Monica M. Bertagnolli, M.D., Director, NIH, provided an update on NIH, illustrating how her life experiences have given her a powerful sense of the transformative potential of research from many perspectives and a deep appreciation for the critical importance of equity and access by all people to research and its benefits. She thanked Dr. Lawrence Tabak for serving as Acting NIH Director for almost 2 years and Dr. Schwetz for her service as Acting NIH Principal Deputy Director, and also noted other staff changes, including the addition of Directors Drs. Jeanne Marrazzo and Kimryn Rathmell at the National Institute of Allergy and Infectious Diseases (NIAID) and National Cancer Institute, respectively; Dr. Stephen Sherry as Acting Director of the National Library of Medicine; Ms. Kate Klimczak as Director of the Office of Legislative Policy and Analysis; Dr. Lyric Jorgenson as NIH Associate Director for Science Policy; and Mr. John Burklow as Chief of Staff.

Dr. Bertagnolli reminded attendees that the Center for Scientific Review's proposal for simplified review criteria, developed with input from major extramural communities, will improve the focus on key questions needed to address scientific and technical merit and reduce the influence of scientific reputation. The rollout of the new criteria began in October 2023, and training resources and communications are planned in the lead-up to implementation.

In December 2023, the ACD Working Group on Diversity Subgroup on Individuals with Disabilities issued recommendations for how NIH can support inclusion of people with disabilities in the scientific workforce and the research enterprise. NIH is updating its mission statement to remove language that can be perceived as ableist; the proposed new statement is "to seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to optimize health and prevent or reduce illness for all people." Responses to a public request for information on this statement currently are being reviewed. People with disabilities have been formally designated as a health disparities population, and the National Institute of Minority Health and Health Disparities has released a NOFO for research related to novel approaches and interventions to address the intersection of disability, race, ethnicity, and socioeconomic status on health care access and health outcomes. The disability subgroup of the NIH Steering Committee DEIA Working Group is also critical to input on this issue, and NIH is currently reviewing additional recommendations. The subgroup focused on culture, ableism, and research policies and systems, seeking to optimize involvement of individuals with disabilities in all activities.

Dr. Bertagnolli reiterated NIH's support for early career scientists and noted that new investigators are disproportionately affected in a contracted budget, risking the loss of a generation of researchers, so decisions will be made with the goal of supporting early career scientists and trainees. She pointed out that great ideas and potential are left behind, even at current funding levels; the Intramural Research Program is particularly sensitive to budget cuts. Dr. Bertagnolli emphasized the need for NIH to do everything possible to continue funding the best science and developing the next generation of researchers.

Dr. Bertagnolli continues to meet with leaders across NIH to develop her plans and guiding principles, noting that NIH's work is not finished when scientific discoveries are made—it is finished when all people live long and healthy lives. She emphasized the unprecedented opportunity to embrace and increase access to innovation and the need to focus on what NIH can do to ensure that advances reach all who need them. Dr. Bertagnolli also emphasized the importance of earning trust by including those who stand to benefit from research as partners in discovery. Although fundamental science remains critical, the field needs to be more effective at connecting scientific knowledge to everyday life. Dr. Bertagnolli is focused on ensuring that the biological insights identified in NIH laboratories are pursued in ways that speed their application to improving the circumstances of real people and that such factors as income, age, race, and geographic location are not barriers to participating in clinical research and receiving care.

Dr. Bertagnolli emphasized the opportunity to accelerate progress by applying advanced scientific methods to comprehensive and inclusive data, as well as rapidly and equitably adopting new discoveries into clinical care. Knowledge and technology have developed sufficiently to support evidence-based, data-driven health care for every patient, but more research and investment in infrastructure are necessary to realize the potential for improving health. Dr. Bertagnolli emphasized that NIH will continue to progress innovative and ambitious initiatives to propel the fusion of biomedicine and AI.

Discussion Highlights

- Dr. Bertagnolli acknowledged concerns about changing the mission statement and pointed out that although many people with a disability do not view it as something that needs to be fixed, NIH should pay attention to make sure they can live their best life.

- In response to a question about budget pressure, Dr. Bertagnolli pointed out that the support of legislators is encouraging and NIH is committed to using whatever funding is granted to deliver the best for the people they serve.

- When asked about goals over the next 5 years, Dr. Bertagnolli hoped to capitalize on the explosion of data technology to truly build a learning health system, which will require multilevel collaboration across HHS. She hoped that results from the laboratory can be translated more quickly and nimbly into results for people, and she emphasized the importance of ensuring that these solutions be available for diverse populations and people in remote locations.

- In response to a question about intersectionality and whole-person health, Dr. Bertagnolli emphasized the complexity of ensuring that all people can live longer and healthier lives. She added that longitudinality is difficult to introduce into research, recognizing that early childhood is critical for setting the stage for the rest of a person's life, but noted that research also must assess aging throughout the life span.

- When asked how the Council could best serve her goals for NIH, Dr. Bertagnolli commented that the Council represents the depth and breadth of all of NIH's work, and one of the most important things they can do is eliminate silos. She emphasized the need to deliver clinical research and data strategies that cross multiple conditions and to identify common needs. Dr. Bertagnolli expressed her appreciation for the Council members and the time and effort they devote to NIH, and she pledged to listen to and act on their advice.

XV. OSC CONCEPT CLEARANCE: GABRIELLA MILLER KIDS FIRST PHASE 3

James N. Coulombe, Ph.D., Chief, Developmental Biology and Congenital Anomalies Branch, NICHD, requested approval for the third phase of the Gabriella Miller Kids First Pediatric Research Program. The 2014 Gabriella Miller Kids First Research Act authorized 10 years of funding to "supplement not supplant," existing NIH efforts in pediatric research. Kids First was tasked with building a data resource to advance collaborative research and data sharing specifically focused on childhood cancer and structural birth defects, both of which are leading causes of death in childhood with shared genomic variants and signaling pathways and significant shared risk. In the current phase, Kids First has expanded whole-genome sequence and clinical and phenotypic data available from many conditions and piloted the addition of long-read DNA sequencing and proteomic assays. The program has continued development and improvement of the Kids First Data Resource Center and deployed a server based on Fast Healthcare Interoperability Resources (FHIR) standards. Kids First also has engaged the expertise of the community in the development of analytical tools and other activities to enhance the utility of the data.

Collectively, childhood cancers and structural birth defects are far too common, but individual conditions are mostly rare, and collecting patient populations for adequately powered genomic studies is challenging. Kids First was conceived to surmount this problem by building a data resource of high-quality genomic data from affected children and their parents harmonized against a common reference genome with variants identified through the same analysis workflow. The data in Kids First can be readily analyzed individually or in combination with data from different studies of a given condition or across conditions and can be shared broadly. Kids First has generated or made available data from more than 27,000 individuals from 33 studies representing conditions affecting a variety of biological systems and anatomical locations. Additional data at various stages in the production pipeline will become available in the future.

The Kids First Data Resource Center (DRC) has built a portal for clinical and phenotypic data associated with genomic sequence data, available with a registration and click-through agreement, with the goal of democratizing data access. A user can work with data across studies and conditions to determine the feasibility of their projects, then use the Cavatica platform to bring Kids First data into an individualized workspace and add analytic tools, their own data, and other authorized users. Kids First also collaborates with many other programs to make the data interoperable and pilot new data generation and analysis tools. A wide variety of investigators have accessed the data and it will enable groundbreaking pediatric research including, basic mechanistic and gene regulatory studies, and accelerated identification of biomarkers and potential drug targets. Use of the data and the number of publications citing Kids First is increasing.

Two scenarios are possible for the future of Kids First. The Senate and House each have bills that would extend the Kids First program, and both bills are on the legislative calendars. If the legislation passes into law, program responsibility will be assigned to DPCPSI, with yearly appropriations, a 5-year congressional report, and prioritization of work that does not overlap with existing NIH efforts. If the program is not renewed, it will wrap up in calendar year 2025 using FY24 funds, and ICs will maintain the data resources. Regardless of which scenario occurs, Kids First will continue to support democratized data access, and NIH will maintain full control of how the genomic data are managed and distributed. Kids First will continue as part of the NIH data ecosystem, keeping faith with the patients and families who have contributed.

If the program is extended, the proposed activities will be aimed at amplifying the value of the current program and the resources Kids First has built. Kids First will augment data generation by expanding data types and cohort diversity, as well as adding clinic-based data sources. The program will improve data accessibility, offering advanced tools that require minimal training and, in parallel, expanding training in cloud-based computational analysis. Kids First also will involve research professionals and patient communities in efforts to enhance the value of the data. By establishing connections with clinical centers and patient registries, Kids First will add new sources of pediatric data, and new sequencing and variant curation centers would enhance the data available. Data from electronic health records can be ported to the DRC with associated genomic information and variant annotations, and Kids First will continue cohort-based genomic data generation, with additional emphasis on diversity of populations and conditions. The functionality of the Kids First genomic data also can be improved through addition of FHIR-based electronic health record data and publication of a community-based pediatric FHIR implementation guide. Dr. Coulombe emphasized that Kids First is building a community of collaborative researchers eagerly engaged in solving previously intractable problems—they are accelerating research progress and fervently hope to continue.

Discussion Highlights

- The discussants, Drs. Kristen Ardlie and Kevin Johnson, provided their comments. Dr. Ardlie supported the program and asked for more details on the budget, collaborations, and proposed data types. In response to questions about the information available on the public website, Dr. Coulombe clarified that most features require a very basic registration, but the DRC is currently updating the website, so he planned to suggest adding summary features.

- Dr. Coulombe clarified that only a limited number of the studies are disease specific, most of which were added early in the program. Kids First encourages those resources to attempt to reconsent participants for broader sharing, but that process is difficult and sometimes impossible.

- Dr. Coulombe explained that although Kids First is a relatively small program for NIH, about a quarter of the budget has been used for the DRC, and the rest has funded data generation.

- Dr. Johnson emphasized the unique nature of Kids First and the strength of the DRC. He pointed out that the initial vision of the Act called for the program to supplement—not supplant—existing NIH research efforts, which have expanded in the past 10 years to include several related projects. Dr. Coulombe clarified that the proposed new legislation recognizes the work of other programs by stating that Kids First should prioritize not duplicating other NIH efforts. He agreed on the need for nimble data resources and collaboration but emphasized that Kids First has a unique focus on allowing researchers the opportunity to become familiar with existing tools without using multiple platforms. As other related programs mature, collaborations can be revisited, but at this time, the separate DRC is appropriate. He added that Kids First now looks for ways to respond to grantees' ideas and provide creative ways to move the program forward.

- In response to a suggestion about expanding tool development, Dr. Coulombe explained that most efforts to date have been supported by small grants to individuals and cloud credits, but the program emphasizes interoperability for both data and tools.

- Dr. Coulombe clarified that Kids First has recruited cohorts using the X01 mechanism, which relies on investigator applications, but the program is open to expanding enrollment.

- Dr. Sheeley noted that if Kids First is transferred from the Common Fund to DPCPSI, OSC can use its experience administering Common Fund programs to help facilitate Kids First.

Vote

A motion to approve the Gabriella Miller Kids First Phase 3 concept was forwarded and seconded. The motion passed with two abstentions.

XVI. REISSUE CONCEPT CLEARANCE: NIH LASKER CLINICAL RESEARCH SCHOLARS PROGRAM

Nina F. Schor, M.D., Ph.D., Deputy Director for Intramural Research, NIH, outlined the request for reissue of the Lasker Clinical Research Scholars Program, a career development program that supports clinical researchers in the early stages of their independent research careers. Three to six awards are made per year, and the project period includes 5 to 7 years of intramural work as an independent principal investigator, after which participants can remain within the NIH Intramural Research Program and work toward tenure or conduct 3 years of NIH-funded research at an extramural institution. In September 2021, the Council approved reissuing this NOFO for 2 years but requiring review by an outside panel. The

program was reviewed on June 29, 2023, by the Advisory Committee to the Deputy Director for Intramural Research, which recommended strong support for continuing and expanding the program.

Charles R. Dearolf, Ph.D., Director, Program Development and Support, Office of Intramural Research, reminded attendees that the number of clinicians who are full-time researchers has been decreasing over many years. Recognizing this concern, the Lasker Scholars program was initiated in 2011 to support clinical researchers. The program makes an 8- to 10-year investment in selected researchers at the early stage of their independent tenure-track career. This allows them to take advantage of the environment and resources of the Intramural Research Program while simultaneously establishing themselves as peer-reviewed, NIH-funded investigators. The focus candidates for this program are early stage clinical researchers who have the ability and experience to conduct independent research; the program includes physician, dentist, and nurse researchers. Career paths for clinical researchers are not always linear, so the program has a broad eligibility requirement, requiring only that candidates cannot already be tenured.

The Lasker program ensures that society benefits from the scholars' research contributions, and the expanded career options make the Intramural Research Program more attractive. The program also enhances the NIH goal of supporting extramural clinical research. The scholars benefit by having a supportive environment in the nation's largest clinical research hospital, the NIH Clinical Center. The Intramural Research Program supports translation of research findings into the clinic and offers state-of-the-art resources, a centralized institutional review board, and a bioethics department. Scholars can devote most of their time to research activities without the obligation to see patients or apply for additional funding. The R00 component also makes the scholars more attractive to outside institutions because they have documented success competing for NIH funds.

Since the beginning of the program in 2011, it has supported 44 scholars, with a balance between men and women, and seven of the scholars have been members of underrepresented groups in research. They are sponsored by 11 ICs and work on a wide range of important clinical problems. Seven scholars have obtained tenure in the Intramural Research Program. Eleven have reached the R00 branch point, and eight chose to remain at NIH. Three scholars left NIH prior to completion of the initial intramural phase for senior positions in industry or Kaiser Permanente, but all remain engaged full time in biomedical research activities, and the scholars who chose the R00 received more advanced positions.

Janice S. Lee, D.D.S., M.D., FACS, Deputy Director for Intramural Clinical Research, Clinical Director, National Institute of Dental and Craniofacial Research, outlined the independent review of the program. The Advisory Committee to the Deputy Director for Intramural Research was provided with an overview of the program, a summary of all scholars and their top publications, a bibliometric analysis of each scholar, and a comparison to extramural early stage investigators conducted by OPA. The committee also received a summary of individual activity for the clinical protocols at the NIH Clinical Center, results of a survey of the scholars conducted in 2021, a letter of support from the Lasker Foundation, and a list of scholars who were proceduralists. The meeting included two scientific presentations by tenured scholars and an open discussion with a panel of six current scholars.

The committee felt strongly that support for the program should continue because the features of the program are critical to its participants' success. The committee also endorsed continuing the mentoring program and suggested focusing on increasing program visibility. Committee members encouraged NIH and Lasker to consider ways to engage academic medical centers and expand the program. The committee recommended documenting the accomplishments of the program and publishing them in a peer-reviewed journal, which would allow the program to be promoted more broadly.

The program has begun addressing some of the recommendations. Scholars are expected to have a mentoring committee, and the program provides professional development workshops. Informal peer mentoring occurs both within and across ICs, creating a community among the scholars. Twelve of the

scholars also are part of the NIH Distinguished Scholars Program, which supports investigators who have a documented history of improving diversity and inclusion in the biomedical workforce, and this cross-membership facilitates additional mentoring and cohort activities.

Discussion Highlights

- The discussants, Drs. Krugman and Karen Johnston, provided their comments. Dr. Johnston supported the program and emphasized its importance. She also emphasized the opportunity to evolve the program in line with the recommendations, noting that the survey indicated dissatisfaction with mentoring and work–life balance components. Dr. Johnston pointed out that the applicant pool can be further invigorated, so this is an opportunity to think about diversifying that pool, including scientific diversity.

- Dr. Johnston asked whether the scholars were struggling with their clinical identity and need to maintain the skill set involved in seeing patients. Dr. Lee pointed out that the Clinical Center is known for rare and undiagnosed diseases, which limits the type of practice a person can have, but it provides a unique opportunity for research. This element has been discussed with the scholars, some of whom have chosen to maintain affiliations with clinical programs. The program is working to refine the logistics of fostering partnerships and balancing workload.

- Dr. Schor explained that the applicant pool has tended to be relatively small and geographically close to NIH, but the program already has begun efforts to promote the opportunity more broadly.

- Dr. Krugman suggested marketing the program beyond academic medicine publications, including forming partnerships with health science centers to provide applicants an opportunity for clinical experience. He emphasized that excellence in clinical research requires support for both research and clinical work, which the Clinical Center may not be able to provide sufficiently.

- When asked about the lack of pediatric specialists, Dr. Dearolf explained that although NICHD has not participated in past application rounds, several scholars do have pediatric specialties.

- Dr. Dearolf pointed out that the Lasker Foundation is sponsoring two scholars to attend the American Society of Clinical Investigation meeting and serve as ambassadors.

- Dr. Dearolf clarified that veterinarians are not currently eligible to participate in the program.

- Dr. Dearolf explained the broad approach in which the program currently is publicized. Dr. Lee pointed out that NIH does not have the breadth of focus areas that a normal tertiary care center would have, which may be one limit. She added that all the Lasker scholars are principal investigators who oversee a number of protocols, many of which require significant work, and the large majority of scholars are very active at the Clinical Center without the addition of outside clinical volume. Dr. Lee noted that the salary has deterred some applicants, but other benefits of the program include not having to generate revenue and being able to conduct research without other burdens. Those who participate are passionate about devoting their time to research.

- In response to a question about designated mentoring, Dr. Lee explained that a number of workshops to improve the mentors are in development.

- Council members suggested working to recruit applicants younger than the current average age of 41, who may be more interested in pursuing the short-term opportunity that the program provides.

- Dr. Dearolf explained that individuals have to terminate employment at their previous institution to become federal employees, although they often can maintain an adjunct appointment. Council members pointed out that this is a major barrier to application support from candidates' institutions, as is asking candidates to apply through the extramural grants mechanism, which informs their institutions that they are looking for other jobs. Dr. Schor explained that intramural and extramural funding barriers complicate this issue.

Vote

A motion to approve the NIH Lasker Clinical Research Scholars Program concept was forwarded and seconded. The motion passed with one abstention.

XVII. PROPOSED COUNCIL OF COUNCILS WORKING GROUP TO EVALUATE THE NIH GENERALIST REPOSITORY ECOSYSTEM INITIATIVE (GREI) AND VOTE

Susan K. Gregurick, Ph.D., Director, ODSS, presented a proposed charge for a Council of Councils GREI Working Group, which would align with one goal of the NIH Strategic Plan for Data Science: Modernize the data repository ecosystem, support storage and sharing of individual data sets, and better integrate clinical and observational data into biomedical data science. She emphasized that data resources are key enablers of modern biomedical research.

GREI began as a 15-month pilot, conducted from 2019 to 2020. A community workshop on the role of generalist repositories and data sharing in February 2020 provided insights into the importance of coopetition across data repositories. ODSS also conducted an independent assessment of the generalist repository landscape. The goal of GREI, which was officially launched in January 2022, was to develop collaborative approaches for data management and sharing and better enable search and discovery and reuse of NIH-funded data in the generalist repositories.

The primary mission of GREI is to establish a common set of cohesive and consistent capabilities, services, metrics, and social infrastructure across various generalist repositories; a secondary mission is to raise general awareness and facilitate researchers to adopt FAIR principles to better share and reuse data. GREI activities include implementing consistent capabilities, increasing access to and discovery of NIH-funded data, conducting outreach and training on FAIR data practices, and engaging the research community. GREI has resulted in such outcomes as tailored community training, a common core metadata schema, and best practices for sharing data.

The initiative will end in February 2025, and ODSS is interested in better understanding the impact of GREI. Dr. Gregurick stated that NIH seeks Council recommendations to guide the future focus of GREI. The Working Group's charge is to provide an assessment of GREI's progress to date and to provide recommendations for the future of this initiative. Specific aims are to review the current scope and goals of GREI, as well as progress to date; provide recommendations on future GREI objectives and goals based on progress and the biomedical research community's needs; and provide recommendations on future success measures for the GREI initiative, accounting for a diverse community of researchers.

Discussion Highlights

- Dr. Gregurick clarified that GREI is working with established repositories to improve efficiency and consistency and is collecting metadata and providing use cases for the research community. Other efforts include community building and support for developing FAIR data sharing plans. NIH is interested in understanding the impacts of these activities and developing a plan for future

efforts. Dr. Gregurick agreed that the Working Group could consider incentives for data sharing and reuse.

- Dr. Gregurick agreed on the importance of federating repositories with appropriate metadata and other standards, as well as incentives for data creation and open storage, noting that NIH is interested in exploring these opportunities at a larger scale in the future.

- Council members emphasized the need for financial strategies to support long-term sustainability.

- An informal vote was conducted; all Council members were in favor of the working group.

XVIII. OSC FINAL REPORT: ILLUMINATING THE DRUGGABLE GENOME

Karlie R. Sharma, Ph.D., Program Director, Office of Drug Development Partnership Programs, NCATS, presented a report-out on the Common Fund's Illuminating the Druggable Genome (IDG) Program. She explained that the "druggable genome" is defined as the subset of the human genome that expresses proteins potentially able to bind drug-like compounds. More than 4,500 proteins have been described in the druggable genome, but the existing clinical pharmacopeia is represented by only a few hundred targets. The goal of IDG is to catalyze research to improve the research community's understanding of the properties and functions of proteins that are currently not well studied within commonly drug-targeted protein families. IDG has defined three protein families that contain a significant number of understudied proteins and are relevant to human disease: ion channels, G protein–coupled receptors, and kinases.

IDG was launched in two parts: a pilot phase and an implementation phase. The goals of the pilot phase were to adapt scalable technology platforms for IDG protein families and develop a knowledge and information management platform. Outputs from the pilot phase included core understudied protein data sets; understudied protein interrogation platforms; predictive algorithms; and Pharos, a protein exploration search engine. The goals of the implementation phase were to identify phenotypes of understudied proteins; provide reagents and tools; and create an enriched, minable knowledge base (i.e., Pharos). Outputs from the implementation phase included the Pharos interface and underlying database; reagents available through several repositories; improved understanding of nearly 100 understudied proteins and their role in human disease; and updated, improved, and expanded high-throughput platforms for interrogating the understudied genome.

The IDG Program Core Consortium includes Data and Resource Generation Centers, a Knowledge Management Center, and a Resource Dissemination Outreach Center. Additionally, the program funded several awards: Cutting-Edge Informatics Tools Awards (to deploy tools to enhance the community's ability to process, analyze, and visualize data around the understudied proteins); R03 pilot projects (to support the generation of preliminary data and tools around eligible understudied proteins to elucidate function in the context of human disease and support R01 applications and drug discovery projects); and SBIR/STTR awards (to initiate early research leading to the commercialization of assays or products).

Dr. Sharma briefly presented the Pharos landing page, which allows users to search by target of interest, disease, and ligand. She noted that the search functionality includes all genes, not only those that encode understudied proteins. Pharos categorizes targets by four levels of development: Tdark (i.e., targets about which virtually nothing is known), Tbio (i.e., targets that lack known drug or small-molecule activities but are described in some publications with some available data), Tchem (i.e., targets that have least one bioactive, drug-like compound), and Tclin (i.e., targets that have at least one approved drug). She showed the Pharos visualization tools for protein expression. Other notable features of Pharos provide information on approved drugs, active ligands, protein–protein interactions, pathways, structures, and IDG-generated resources.

The number of Pharos users has grown over time, and Pharos is contributing to existing efforts focused on illuminating dark proteins. Additionally, IDG has collaborated with several internal and external partners to pursue new opportunities. In Italy, for example, Fondazione Telethon and Fondazione Cariplo are supporting research that uses Pharos to study Tdark proteins in the context of rare diseases of genetic and nongenetic origins. In September 2022, IDG partnered with the Knockout Mouse Phenotyping Program (KOMP2) to develop mouse models for understudied ion-channel knockouts.

The R03 pilot projects serve as an example of the program's success. More than 120 specific dark proteins were studied via 98 awards, with over 60 publications to date. Additionally, 29 early stage and new investigators were funded. Dr. Sharma noted that other NIH ICs have followed IDG's model for project funding. She briefly highlighted selected achievements by program awardees and noted that further results will be generated in the future. She also showed data on publications associated with dark proteins. Other program impacts include sustainability of Pharos and other resources (e.g., through public repositories), increased interest around understudied protein families, and demonstration of the value of these targets to human disease. Dr. Sharma noted that a series of papers on the druggable genome was recently published in *Drug Discovery Today*. She concluded by underscoring the value of engaging representatives from multiple NIH ICOs in this effort.

Discussion Highlights

- Council members expressed support for the program and emphasized the importance of keeping Pharos active and up to date, and Dr. Sharma confirmed the program is considering how best to stay up to date.

- When asked about the demographics of new investigators, Dr. Sharma confirmed the program's interest in engaging young scientists and offered to provide further details after the meeting.

- Dr. Sharma provided additional details about the protein families of interest, explaining that the kinase and G protein–coupled receptor groups developed more extensive base platforms during the pilot phase. Studies of ion channels are inherently more challenging to perform. Additionally, the groups approached their topics differently; the kinase group addressed kinases at a network level, whereas the G protein–coupled receptor group looked more at individual receptors.

XIX. OSC FINAL REPORT: GLYCOSCIENCE

Dr. Sheeley reported on the accomplishments of the NIH Common Fund Glycoscience Program (GSP). Glycans are structurally diverse and information-rich carbohydrate modifications that play key roles in nearly every aspect of human biology and disease. Glycoscience is associated with numerous challenges, including the requirement for specialized and expensive equipment; ambiguity in structure determination; and the lack of access to resources, tools, databases, and experts for tackling technical challenges and training newcomers. In 2012, NIH commissioned a National Academies of Sciences, Engineering, and Medicine study of the field of glycoscience to address these issues. The study's conclusion—that a roadmap for transforming glycoscience from a field dominated by specialists into a widely studied and integrated discipline would lead to a more complete understanding of glycans and help solve key challenges—led to the development of the NIH Common Fund GSP.

The goal of the GSP was to create accessible methods and resources to study glycans for use by the broader biomedical research community. A total investment of $111 million over 7 years supported four initiatives: (1) facile methods and technologies for the synthesis of biomedically relevant glycans ($38 million), (2) accessible analytical tools for structure determination and functional assays ($55 million), (3) informatics tools for data integration and analysis ($10 million), and (4) supplements to

nonspecialists to support the early adoption of program resources ($5.7 million). Dr. Sheeley expressed gratitude to the staff of the Common Fund Glycoscience Working Group for their efforts over the course of the program.

The GSP resulted in the development of a toolbox of accessible methods and resources. New catalytic and chemoenzymatic methods for the synthesis of glycans and complete glycan libraries have been established. Automated platforms that can easily be adapted by core facilities are available. Analysis, labeling, and modeling technologies with demonstrated proof-of-concept and public health relevance are being commercialized. A unified informatics effort is integrating glycoscience into other molecular databases. This glycoscience informatics effort, a knowledge base named GlyGen, develops and disseminates computational and informatics resources and tools related to glycoscience research. GlyGen includes training resources and is integrated with protein and glycan databases around the world. GlyGen queries return information related to glycosylation positions and structures for any protein.

Brionna Hair, Ph.D., M.P.H., Health Science Policy Analyst, OSC, DPCPSI, outlined an evaluation of the GSP that was requested by OD and performed by the Common Fund in collaboration with NIAID's Policy Planning and Evaluation Branch and the contracting group Ripple Effect. Bibliometric analysis of GSP awards, resources, and publication data was combined with qualitative analysis of in-depth interviews with glycoscientists and nonspecialists.

The first key topic that was addressed by the evaluation was the number of new glycoscience resources that were developed and made available to the community by the GSP. 56 GSP resources were included in the evaluation of the program, including 18 synthesis resources, 37 tools, and 1 informatics resources. These 56 resources were disseminated in over 150 peer-reviewed publications (81 synthesis resource publications, 71 tools publications, 2 informatics publications). Overall, 21 resources (38%) were associated with websites, and 15 resources (27%) have been commercialized. When interviewed, both nonspecialists and glycoscientists indicated that they were more likely to have learned about the GSP and GSP resources from connections with collaborators and colleagues, conferences and meetings, and NIH dissemination efforts than from publications.

The second key topic addressed by the evaluation was the extent to which specialists and nonspecialists adopted resources developed by the GSP; this topic was addressed using citation metrics and interviews. Overall, more than 4,000 publications cited GSP resources (2,041 synthesis resource citations, 2,248 tool citations, 81 informatics citations), and approximately 2,800 of the total were unique citations. Between 2015 and 2022, the number of citations increased each year for each initiative. Citation of GSP resources was most popular in the fields of organic chemistry, analytical chemistry, biochemistry and molecular biology, and general chemistry. GSP resources were cited in such diverse areas as developmental biology, chemical physics, polymer sciences, immunology, medicinal and biomolecular chemistry, virology, and biotechnology. GSP resources were most frequently cited by researchers in the United States (33%), China (23%), Germany (6%), the United Kingdom (5%), and Japan (4%). In a random sample of 687 publications, 67% of citations were published by nonspecialists, and 33% of citations were published by glycoscientists. Glycoscientists were more likely to cite resources from the synthesis initiative, and nonspecialist scientists were more likely to cite resources from the tools initiative.

The final key topic addressed by the evaluation was the extent to which the GSP facilitated access to glycoscience resources; this topic was addressed using interview data. One concept that emerged in several interviews was the importance of collaborations with glycoscientists to enable the adoption of the program's resources. The interviewees also discussed barriers to adopting GSP resources, including user and funding limitations. Many interviewees shared their belief that the GSP provided valuable tools and expanded the glycoscience field and that GSP resources had provided a foundation for future funding.

Dr. Hair highlighted several limitations of the analysis. Only 20 researchers were interviewed, and it is possible that the interviewees' opinions are not generalizable. Citations were used as a proxy for awareness and utilization of GSP resource publications. Inferences about the full sample of authors on all citing publications cannot directly be made based on the subsample of citing publication authors used for analysis and classification. Dr. Hair reviewed takeaways from the evaluation, noting that specialists and nonspecialists alike viewed GSP resources as scientifically rigorous, high-quality, innovative resources that provided value to researchers and expanded the field of glycoscience. She thanked the researchers who participated in the evaluation interviews and the Ripple Effect, NIAID, and OSC staff who performed and oversaw the evaluation.

Discussion Highlights

- When asked about efforts to sustain resources developed by the GSP, Dr. Sheeley explained that the resources were designed to be disseminated as they were developed, which has been accomplished. The only resource that requires ongoing NIH funding is the informatics website, which is now being supported by the National Institute of General Medical Sciences. The evaluation was thorough and informative; Dr. Sheeley noted that use of contractors to evaluate Common Fund programs is not always practical due to the expense, but it is considered under special circumstances.

- Dr. Sheeley affirmed that Pharos and the GSP informatics resource are integrated and cross-linked.

XX. CLOSING REMARKS

Departing Council members commented on the opportunity to participate in both a golden era of bioscience and a vulnerable time in history and encouraging the Council to evolve with NIH goals.

XXI. ADJOURNMENT

Dr. Schwetz adjourned the meeting at 3:15 p.m. on January 26, 2024.

XXII. CERTIFICATION

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

Tara A. Schwetz -S Digitally signed by Tara A. Schwetz -S
Date: 2024.05.13 16:00:54 -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: 2024.05.13 09:23:36 -04'00'

5-13-2025

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

Date