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
September 12–13, 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 open session of the Council of Councils. The hybrid meeting began at 9:00 a.m. on Thursday, September 12, 2024 with an overview of the day's agenda.

The meeting attendees are identified below:

A. Attendance

1. Council Members

Council Members Present

Chair: Tara A. Schwetz, Ph.D., Director, DPCPSI, NIH
Executive Secretary: Franziska B. Grieder, D.V.M., Ph.D., Director, Office of Research Infrastructure Programs (ORIP), DPCPSI
Kristin Ardlie, Ph.D., Broad Institute of Massachusetts Institute of Technology and Harvard, Cambridge, MA
Linda Chang, M.D., M.S., FAAN, FANA, FISMRM, University of Maryland School of Medicine, Baltimore, MD
Monica Gandhi, M.D., M.P.H., University of California, San Francisco, San Francisco, CA
Rafael Irizarry, Ph.D., Dana-Farber Cancer Institute and Harvard 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
Jean A. King, Ph.D., Worcester Polytechnic Institute, Worcester, MA
Richard D. Krugman, M.D., University of Colorado School of Medicine, Aurora, CO
Kevin C. Kent Lloyd, D.V.M., Ph.D., University of California, Davis, Davis, CA
Rhonda Robinson-Beale, M.D., UnitedHealth Group, Minneapolis, MN
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., Washington, DC
Russell N. Van Gelder, M.D., Ph.D., University of Washington School of Medicine, Seattle, WA

Council Members Absent

Graham A. Colditz, M.D., Dr.P.H., M.P.H., Washington University School of Medicine in St. Louis, St. Louis, MO
Jennifer Jaie Manly, Ph.D., Columbia University Medical Center, New York, NY

2. Liaisons

Andrew A. Bremer, M.D., Ph.D., M.A.S., FAAP, Director, Office of Nutrition Research, DPCPSI
Sheila Caldwell, Ph.D., representing **Karina L. Walters, Ph.D., M.S.W.,** Director, Tribal Health Research Office (THRO), DPCPSI
Janine A. Clayton, M.D., FARVO, Director, Office of Research on Women's Health (ORWH), DPCPSI
Diana Finzi, Ph.D., Acting Director, Office of AIDS Research (OAR), DPCPSI
Susan K. Gregurick, Ph.D., Director, Office of Data Science Strategy (ODSS), DPCPSI
Franziska B. Grieder, D.V.M., Ph.D., Director, ORIP, DPCPSI
David M. Murray, Ph.D., Director, Office of Disease Prevention, DPCPSI
Karen L. Parker, Ph.D., M.S.W., Director, Sexual & Gender Minority Research Office (SGMRO), DPCPSI
Stefan M. Pasiakos, Ph.D., FACSM, Director, Office of Dietary Supplements, DPCPSI
George M. Santangelo, Ph.D., Director, Office of Portfolio Analysis, DPCPSI
Douglas M. Sheeley, Sc.D., Acting Director, Office of Strategic Coordination (OSC), DPCPSI
Janine M. Simmons, M.D., Ph.D., representing **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

3. *Ex Officio* Member Present

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

4. Presenters

Russ B. Altman, M.D., Ph.D., Kenneth Fong Professor of Bioengineering, Genetics, Medicine, Biomedical Data Science, and Computer Science, Stanford University, and Chair, *All of Us* Research Program Advisory Panel
Kristin Brethel-Haurwitz, Ph.D., Social & Behavioral Scientist Administrator, OBSSR, DPCPSI
Bettina Buhring, Ph.D., Program Director, Division of Comparative Medicine, ORIP, DPCPSI
Josh Denny, M.D., M.S., Chief Executive Officer, *All of Us* Research Program
Clay Mash, Ph.D., Cohort Program Officer, Environmental influences on Child Health Outcomes (ECHO) Program
Kathleen Neuzil, M.D., M.P.H., Director, Fogarty International Center
Douglas M. Sheeley, Sc.D., Acting Director, OSC, DPCPSI
Erica Spotts, Ph.D., Health Scientist Administrator, OBSSR, DPCPSI
Leslie Thompson, Ph.D., Health Science Policy Analyst, ECHO
Bruce Tromberg, Ph.D., Director, National Institute of Biomedical Imaging and Bioengineering (NIBIB)

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 August 8, 2024.

- Minutes from the May 30, 2024, meeting are posted on the DPCPSI website. The minutes from this meeting also will be posted there.

C. Future Meeting Dates

The next Council meetings are scheduled to be held February 6–7, May 29–30, and September 11–12, 2025.

II. DPCPSI UPDATES

Dr. Schwetz provided updates on DPCPSI activities. In October, Dr. Carolyn Hutter will become the Director of OSC and Dr. Geri Donenberg will become the Director of OAR. Recently published documents include ORIP and OAR's *Nonhuman Primate Evaluation and Analysis Report* and the SGMRO Annual Report, and ORIP recently held the 14th Comparative Medicine Resource Directors Meeting. In December, DPCPSI posted a request for information (RFI) to solicit public input on updating the *NIH Strategic Plan for Data Science for 2023–2028* and received 63 responses covering all the high-level goals of the plan.

SGMRO's Research Investigator Awards program has been expanded to include a mid-career award that will recognize exemplary researchers and help foster a highly skilled and diverse workforce in sexual and gender minority (SGM) health research, which is a priority in the current NIH SGM Research Strategic Plan. Several new efforts are supporting the White House Initiative on Women's Health Research, including creating a "front door" to centralize funding opportunities related to women's health across NIH. A notice of special interest related to women's health research has also been released, and institutes and centers (ICs) are updating their priorities related to women's health. ORWH also is participating in an omnibus solicitation for small business innovation and technology transfer programs.

Dr. Schwetz outlined NIH's response to a report by the Advisory Committee to the Director Working Group on Diversity's Subgroup on Individuals with Disabilities. DPCPSI has added several disability research and policy experts to its staff and formed an internal research coordinating committee, part of an effort to understand and build on NIH's entire disability research portfolio. Additional planned activities include engaging with disability communities and establishing a Council of Councils Disability Research Working Group.

THRO has been leading efforts to develop the NIH Indigenous Data Sovereignty Policy, which addresses the need to include Tribal approval when NIH-funded research is conducted on Tribal land or makes inference to a specific Tribe. Listening sessions are in progress, and an upcoming summit will be open to the public.

Dr. Schwetz also noted the upcoming NIH Behavioral and Social Sciences Research Festival and a pilot program for scholars in the science of science, which uses scientific methods to understand the scientific field. This program will address critical questions about improving processes, policies, and programs.

Discussion Highlights

- When asked about a concept related to science communication that was cleared but never funded, Dr. Schwetz explained that some discussions on the topic are occurring across NIH and OBSSR, especially given the importance of building trust with communities.

- Dr. Monica Gandhi emphasized the importance of supporting early stage investigators, such as increasing the paylines for K awards. Dr. Schwetz agreed that this pipeline is critical for the future of biomedical research.

- When asked to define what NIH considers "community" and whether it includes service providers and funding agencies to address system-level issues, Dr. Schwetz explained that NIH uses the term broadly and in a manner that allows for changes, based on context. The Communities Advancing Research Equity (CARE) for Health program is building primary care research opportunities and engaging primary care providers as part of the process.

- Dr. Schwetz explained that the Council of Councils Disability Research Working Group does not yet have a charge, but this initiative provides the opportunity to examine a portfolio across NIH and bring together experts in different facets of disability research. Creating the strategic plan will be the first step, and determining how to implement it will come next.

III. ORIP CONCEPT CLEARANCE (REISSUE): NATIONAL PRIMATE RESEARCH CENTERS PROGRAM [VOTE]

Bettina Buhring, Ph.D., Program Director, Division of Comparative Medicine, ORIP, presented on the National Primate Research Centers (NPRCs) program. The objective of the NPRCs is to enhance scientists' capabilities for nonhuman primate (NHP) research by providing animals, state-of-the-art facilities, and scientific and veterinary expertise. Up to seven NPRCs will be funded through this program, and the award project period for each will be 5 years. Currently, NIH supports NPRCs in Wisconsin, Georgia, Louisiana, Texas, California, Oregon, and Washington.

The NPRCs provide well-characterized animals with a known pedigree and genetics. Some NPRCs provide specific-pathogen-free animals, which are useful for infectious disease research. The NPRCs also provide such resources as advanced imaging capabilities, diagnostics, reagents, and assay services. The NPRCs support research fields across the entire NIH biomedical community by developing new NHP models for human disease, facilitating pilot projects, providing educational outreach for researchers and

the public, and providing training in NHP research methods. The NPRCs are organized as a consortium, and the members have formed 17 working groups focused on various topics that relate to research and management. Other discussion topics include best practices and challenges. Dr. Buhring explained that these working groups serve as a national forum for NHP centers across the United States.

Dr. Buhring briefly highlighted the major accomplishments of the NPRCs for fiscal year 2023 (FY23). During this time, the NPRCs supported more than 800 research projects and more than 1,700 investigators, most of whom were not affiliated with the consortium. About 2,000 NHPs were assigned to studies, and more than 600 trainees were supported. The NPRCs supported research in the areas of HIV, behavioral and systems neuroscience, viral and bacterial infectious diseases, reproductive health, molecular neuroscience, and many other areas. Dr. Buhring concluded by noting that NPRCs leverage the base grant funding to obtain additional funding from other areas, such as the host institutions or from program income.

Discussion Highlights

- The discussants, Drs. Susan Sanchez and Russell N. Van Gelder, provided their comments. Dr. Sanchez commented that NHPs remain an important component of the national biomedical research enterprise and that NPRCs are essential for providing access to NHPs for research, as well as unique services and training opportunities. Dr. Van Gelder commented on the importance of NHPs and supporting infrastructure for enabling advances in medicine and public health. He also highlighted the need for NIH to play a leadership role in this effort.

- Dr. Sanchez asked how sparsity of funding might affect the NPRCs and wondered about the need for infrastructure updates. She also inquired about updates to the NPRCs consortium website. Dr. Buhring remarked that NPRCs websites currently are in the process of being updated. Additionally, she noted that infrastructure updates are ongoing and can be funded through supplement awards. Dr. Buhring also explained that the NPRCs use different structures for generating program income.

- Dr. Van Gelder requested clarification on NIH's relationship with the NPRCs, as well as their governance and coordination with the research community. He also asked how the program will accommodate the recommendations of a larger NIH-wide working group for NHP research. Dr. Buhring stated that ORIP is currently focusing on the NPRCs consortium, and other levels of coordination will be considered in the future. Dr. Schwetz added that DPCPSI is working to coordinate NHP research across NIH more extensively, and working in partnership with other federal agencies as well.

- Ms. Lauren Silvis asked how NIH's recent efforts toward developing novel alternative methods (NAMs) across NIH will affect the future of the NPRCs program. Dr. Buhring responded that the NPRCs have been involved in the development of relevant NAM tools (e.g., organoids, artificial intelligence [AI]) and that one of the major contributions of the NPRCs to the field of NAMs can be validation of NAMs. Dr. Schwetz added that DPCPSI overall has been highly engaged in this topic.

- Dr. Rafael Irizarry asked how the NPRCs have addressed ethical concerns related to the use of NHPs in research. Dr. Buhring stated that the NPRCs place high importance on this topic, and it is considered at all levels and across all areas of research at the NPRCs. An NPRC working group on rigor and reproducibility in research is also addressing this topic. Dr. Stephanie Murphy added that the NPRCs consortium has also been actively engaged in discussions of ethics through various other forums (e.g., workshops).

- Dr. Jean King remarked that, in her experience, most researchers who work with NHPs give appropriate consideration to ethics. She also emphasized the importance of communicating the importance of NHP research to the public, as well as keeping public information up to date. Dr. Kevin Johnson suggested incorporating these perspectives into the messaging regarding the use of NHPs in research.

- Dr. Kent Lloyd inquired about any adjustments to the program in the new concept clearance. Dr. Buhring noted that new considerations include NAMs, as well as a plan for enhancing diverse perspectives.

Vote

A motion to approve the NPRCs Program reissue concept was forwarded and seconded. The motion passed with one abstention.

IV. OBSSR CONCEPT CLEARANCE (NEW): RESOURCE AND CAPACITY BUILDING TO ADVANCE THE SCIENCE OF AGGRESSION ACROSS SPECIES AND DISCIPLINES [VOTE]

Kristin Brethel-Haurwitz, Ph.D., Social and Behavioral Scientist Administrator, OBSSR, introduced a concept to support research and capacity building in research on the mechanisms of aggressive behavior through activities that build cross-disciplinary and cross-species bridges. Aggression can be defined as interpersonal behavior aimed at intentionally harming another individual. It is a significant and increasing threat to public health, making understanding, preventing, and treating aggressive behavior a critical challenge. Challenges in this area include the diversity of research foci, complexity of aggression, research that considers only the individual level and not the full social ecology, inability to separate behavior from environment, and environmental factors that can change biology and increase or decrease aggression over time. Complex human research also needs to be integrated with precise animal research, and communication between the fields must improve. Currently, complex subtypes of human aggression that map onto human developmental patterns and experiences are difficult to replicate in animal models; overlapping phenotypes are hard to separate in humans, and mechanisms of naturalistic aggressive behavior can be difficult or unethical to study in humans.

Despite the public health costs, mechanistic understanding of aggressive behavior has been under-researched. Aggression research does not have a central home at NIH, leading to inconsistent support for both research and workforce development. The areas of animal and translational science are particular gaps in NIH's aggression research portfolio, and disciplinary siloing has created gaps in cohesive understanding of mechanisms across species, life stages, levels of influence, and conditions.

This concept results from work by a subgroup of the NIH Violence Research Working Group, including an RFI and workshop, and initiative development led by OBSSR in collaboration with 12 other institutes, centers, and offices (ICOs). The workshop's hub-and-spoke approach examined gaps and opportunities from multiple disciplinary approaches to give a fuller picture of research needs. Aggression is a heterogenous set of behaviors with many proximal and ultimate causes emerging within a variety of multilevel biopsychosocial ecosystems. It is transdiagnostic of mental health and neurological disorders, varies and persists across the lifespan, is affected by exposure to adverse psychosocial environments, is exacerbated by substances and alcohol and environmental toxicants, emerges in dementias, can cause or exacerbate health inequities and disparities, and can be an adverse effect of various disease states or the side effects of intervention. This topic has NIH-wide relevance, and better understanding of the foundational biological, behavioral, and social mechanisms of aggression is critical for mitigating adverse health outcomes.

Dr. Brethel-Haurwitz noted some examples of specific needs in resource and capacity building and pointed out that the R24 mechanism has been used for emerging, transdisciplinary, and high-priority research areas that require ongoing, flexible, and dynamic support. This effort also directly responds to recommendations from recent Council of Councils working group reports focused on the behavioral and social sciences.

Discussion Highlights

- The discussants provided their comments. Dr. King stressed the urgency of the research need and supported the concept, especially the cross-species and team science aspects, asking how to speed translation from research to mitigation. Dr. Brethel-Haurwitz explained that although the concept focuses on mechanistic understanding, it has been developed with an eye toward applied interventions. Communication will be critical to support collaboration across disciplines. Dr. King recommended adding specificity to the concept to ensure that the scope is manageable enough to translate to interventions.

- Dr. Chang supported the concept but requested clarification on what kinds of projects are possible with an R24. Dr. Brethel-Haurwitz clarified that this concept is seen as a first step in response to the identified need for infrastructure, capacity building, and better communication between animal and human researchers and among researchers across disciplines. In response to additional comments about the urgency of this topic, Dr. Brethel-Hurwitz pointed out that this concept is one aspect of a larger violence research effort across NIH. Dr. Brethel-Hurwitz also responded to the suggestion of additional mechanisms by noting that this concept was developed in response to the identified need for researchers to align on basic concepts to provide a foundation for mechanistic research.

- Dr. Richard Krugman suggested connecting with *All of Us* and ECHO to identify children ages 3 to 8 years old with experiences that put them on the path to aggression. Dr. Chang suggested connecting with longitudinal data through the Adolescent Brain Cognitive Development℠ (ABCD) Study.

- Dr. Rhonda Robinson-Beale emphasized the importance of this topic to the public and its political nature, and also reiterated the importance of ensuring a tight focus. She pointed to the opportunity to use real-world evidence as a guide. Dr. Brethel-Haurwitz added that although the concept focuses on mechanistic research, it includes social and structural mechanisms, which have causal influences on aggressive behavior.

- When asked why this concept is not supported by a specific IC, Dr. Brethel-Haurwitz explained that the group of 13 collaborating ICOs notably recognize that the topic is relevant beyond the mission and priorities of any one IC.

Vote

A motion to approve the Resources and Capacity Building to Advance the Science of Aggression Across Species and Disciplines concept—with scope adjustments as needed, priorities set, and data included and reconsidering the mechanism, collaborating with others, and providing an update to the Council at the next meeting—was forwarded and seconded. The motion passed with no abstentions.

V. NIH UPDATE

Lawrence A. Tabak, D.D.S., Ph.D., NIH Principal Deputy Director, provided an update on NIH activities. Staffing changes include Dr. Joshua Gordon's departure from the National Institute of Mental Health

(NIMH) and Dr. Shelli Avenevoli's appointment as Acting Director; Dr. Kathy Neuzil's appointment as Director of the Fogarty International Center; and Dr. Sean Mooney's appointment as Director of the Center for Information Technology (CIT). Dr. Tabak also noted NIH winners of the Presidential Rank Award, the Distinguished Service Award from the U.S. Secretary of Health and Human Services, the HHS Career Achievement Award, and the Secretary's Award for Meritorious Service.

Dr. Tabak provided an update on the budget. This year, program-level support is $48.85 billion, a slight reduction from FY23. Dr. Tabak pointed out that the current fiscal year was very difficult for Congress, and this budget level shows strong support from Congress for NIH compared to levels received by other agencies. A large part of the change was driven by the ending of resources for the 21st Century Cures Act, which affects several notable initiatives. The proposed increment for the next budget is 5.7 percent.

The Scientific Management Review Board (SMRB) was part of the 21st Century Cures Act, established to advise and make recommendations to the Secretary and NIH Director on the use of organizational authorities. The Board has been dormant since 2016 but will be restarted in November and will begin by reviewing two reports from Congress on the best use of NIH resources. Dr. Tabak pointed out that many recommendations in the reports align with NIH goals, and NIH is open to all suggestions to improve efficiency. The SMRB will hold meetings that are open to the public under the Federal Advisory Committee Act (FACA).

Dr. Tabak commented on NIH Director Dr. Monica Bertagnolli's emphasis on the importance of ensuring that research is translated into better health. Lack of access is a major barrier to both care and research participation, and the lack of accurate representation compromises the generalizability of all NIH's work and further compounds health disparities. To expand research participant opportunities to broader communities, resources are needed to build infrastructure that will be sustained. Dr. Bertagnolli has a vision to connect research to primary care to optimize outcomes for patients and expand biomedical research data use to inform research and improve health outcomes. To engage primary care entities, NIH must provide supportive resources that allow clinicians to participate alongside their other responsibilities. The CARE for Health™ program has been launched to provide closer links between the primary care setting and opportunities to participate in clinical research. The program also attempts to build trust by addressing the community's needs and making a network that will be sustainable and durable. NIH will offer a suite of study options that sites can decide to participate in based on the best fits for their community's needs, and communities will be able to propose ideas later in the program. The program will address issues important to diverse populations and communities, particularly those traditionally underrepresented in biomedical research, such as the rural communities that are the focus of the pilot. Dr. Schwetz emphasized the importance of considering the burden on primary care providers while building the network and reiterated that the ultimate goal is to bring evidence-based care efficiently and effectively to patients.

Dr. Tabak noted that NIH progress accelerates when advanced scientific methods, such as new data analytics, are applied to data that include everyone and when new discoveries are rapidly and equitably adopted in clinical trials. He emphasized that data sets must encompass the entire population to be generalizable and that treatments developed must be affordable for the uninsured. The National Library of Medicine (NLM) will be central to these efforts, and the search for a new permanent NLM Director is nearing completion. NLM will advance information science and push the boundaries of data science. Expanding educational programs equitably across the nation will be critical, and NIH is making tools for analytical computation available throughout the country to support the involvement of under-resourced institutions. A federated system for cloud computing increases the power of interrogating multiple data sets of disparate types. NIH intends to provide a "front door" where biomedical and clinical researchers, domain experts, trainees, patients, advocates, and others can interrogate data using tools and training

provided by NIH, recognizing that the next great idea can come from anywhere. An integrated relationship among NLM, CIT, and ODSS, as well as with the ICOs, will be important.

Dr. Tabak closed by emphasizing the importance of curiosity-driven basic science as noted in a recent commentary in *eLife*.

Discussion Highlights

- Council members commented on the importance of partnerships in all efforts mentioned, as well as the importance of ensuring data are translated into usable information.

- When asked about the purview of the Council regarding SMRB decisions, Dr. Tabak explained that the SMRB is a FACA committee, its activities will be open and transparent, and the Council will receive regular briefings and will be engaged in deliberations as necessary. In response to a question about the role of the SMRB relative to proposals to reorganize NIH, Dr. Tabak explained that the deliberations of the SMRB will inform the discussions, but creating and dissolving institutes is the power of Congress. The exact actions of the SMRB remain to be decided. Council members recommended ensuring that the SMRB is proactive and sustainable. Dr. Tabak suggested that the SMRB's value will be demonstrated by purposefully addressing substantive issues with thorough debate and analysis.

- Dr. Tabak emphasized that Dr. Bertagnolli is eager to establish a strong working dialogue with the Centers for Medicare & Medicaid Services, which will improve the efficiency of real-world data collection.

- Dr. Tabak clarified that although primary care initiatives have been undervalued while basic science has had sustaining support, many efforts have focused on clinical work, so reminders of the importance of basic science are critical. He added that the trajectory of basic, translational, and clinical science is not linear.

- When asked what role the Council can play in advocacy related to possible restructuring of NIH, Dr. Tabak pointed out that all processes have an opportunity for stakeholders to make comments. This process is in the early stages, and the idea has prompted discussion. He hoped that any efforts would result in a more efficient NIH that could support research and training as efficiently as possible.

- Dr. Robinson-Beale emphasized the importance of strengthening the business side of NIH culture and recommended supporting a campaign to communicate the importance of basic science.

VI. 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

[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.

affirmed by all Council members present. During the closed session, the Council concurred with the review of 143 ORIP applications with requested first-year direct costs of $586,684,105.

VII. *ALL OF US* RESEARCH PROGRAM: KEY UPDATES INCLUDING NEW DATA RELEASE

Josh Denny, M.D., M.S., Chief Executive Officer, *All of Us* Research Program, discussed an upcoming data release from the *All of Us* Research Program. He reminded the attendees that the program's mission is to accelerate health research and medical breakthroughs, enabling individualized prevention, treatment, and care for all people. The program emphasizes nurturing deep partnerships with participants over decades; sharing data with researchers safely and securely; and catalyzing an ecosystem of researchers, community members, and funders.

The *All of Us* Research Program was first announced in 2015 and was launched nationally in 2018. The program published its first data releases in 2019. During the COVID-19 pandemic, the program released a workbench for researchers. Sequencing began in 2020, and the first genomic data set was released in 2022. In 2023, the program launched the Nutrition for Precision Health study. The initial pediatric cohort was added in 2024.

The program currently involves 830,000 participants and more than 12,000 researchers, exceeding previously set benchmarks. All 50 U.S. states, and most U.S. territories, are represented in the program. Some participants have shared biospecimens, and others have consented to share electronic health records. About 47 percent of participants identify as a member of a racial or ethnic minority group. Other measures of diversity include disability, income, sexual and gender minorities, and rural location; these measures for diversity are continually assessed and updated as needed.

Data are collected from participants through a set of common surveys that include questions on such measures as social determinants of health, mental health and well-being, lifestyle, and behavior, as well as physical measures and biosample collection. Approximately 2 million surveys have been completed by participants. Participants can also submit data via fitness watches—either their own or provided by the program. Participants are given access to their genetic health information (e.g., disease risk, pharmacogenetics), as well as ancestry and other non-health-related genetic data.

Data are available to researchers through multiple access tiers: public, registered, and controlled. The team deliberately has focused on creating on-ramps for minority-serving institutions and is working to provide seminars, workshops, and training for less advantaged and early stage researchers. The program opened to international researchers in late 2023 and now has representation from six continents and 135 institutions; the program also opened to commercial access in July. Dr. Denny briefly highlighted publications resulting from researchers using the data.

All of Us continually works to make new resources available in its cloud-based environment. Researchers do not download the data, which increases transparency, allows for auditing, provides greater protection, and engenders more trust with the participant population. The environment contains web-based tools for building data sets, and R Studio and SAS are now available. Researchers can share their workspaces with others, which enhances reproducibility, collaboration, and promotes tool creation.

Dr. Denny noted that several recent publications have highlighted the *All of Us* resource and its capabilities. He briefly highlighted major research outcomes and underscored the importance of understanding variant data across populations. The program is intended to serve as a foundation for ancillary studies across NIH ICOs; to date, 22 NIH ICOs are partnering in this capacity. Nutrition for Precision Health is the largest of these studies and represents a partnership among 18 ICOs; this study

was recently featured on *Good Morning America*. Dr. Denny also highlighted projects in collaboration with NIMH and the National Institute of Environmental Health Sciences.

The data available through *All of Us* offer opportunities for cost and time savings in research and enhance capabilities for studies of understudied populations, including women, racial and ethnic populations, and sexual and gender minority populations. The program is working with Tribal partners and formed a Tribal Collaboration Working Group. Through these efforts, the team established a process for engaging with individuals who self-identify as American Indian/Alaska Native and developed specific educational materials in partnership with Tribal communities. The program also formed Indigenous-led research demonstration projects with early access to data. The goal of these efforts is to guide the release of the program's next data set and allow Indigenous researchers to be some of the first people to tell these stories on top of the data.

Dr. Denny highlighted recent workbench developments. With forthcoming data, the program's total participants will increase to more than 600,000. High-level racial and ethnic descriptions were previously released, and self-identified subcategorizations of racial and ethnic groups soon will be available through the controlled tier. Dr. Denny also remarked that stable, adequate and predictable programmatic funding remains a challenge. He noted that a pediatric cohort is in development and will be expanded when funding is available.

Discussion Highlights

- Dr. Van Gelder asked about the maintenance cost for program data sets, as well as options in the event that budgetary rescue is not provided. Dr. Denny agreed on the importance of addressing this topic and explained that the program has established a plan for operating within a lower budget. He emphasized that protecting participants is a top priority, and infrastructure for this capability is in place. Dr. Van Gelder added that this issue is present across many NIH data programs. Dr. Denny also underscored the importance of NIH-wide partnerships for support in this area.

- Dr. Krugman asked whether the surveys collect data on physical and sexual abuse or neglect during childhood. Dr. Denny explained that the program's mental health and well-being survey asks questions on this topic. That data set will likely become available to researchers within the next year. Dr. Krugman asked whether this question would be asked of the new child participants. Dr. Denny agreed to follow up on this question with his colleagues.

- In response to a question from Dr. Irizarry, Dr. Denny explained that the highlighted publications represent work from researchers using *All of Us* data, and most of the authors are not affiliated with the program. In response to a question from Dr. Chang, Dr. Denny clarified that many of these researchers may be funded by other NIH programs. Dr. Chang wondered about NIH grant mechanisms that allow researchers to mine *All of Us* data. Dr. Denny responded that the program has worked in partnership with NIH ICs to fund administrative supplements and other research grants.

- Dr. Irizarry asked about the rationale for not allowing outside users to download data. Dr. Denny remarked that this decision was informed by discussions from participants and is intended to build trust with communities. He explained that data could not be monitored or controlled after such a download. He expressed his interest in making the data more accessible to researchers while maintaining trust with participants. Ms. Silvis suggested that *All of Us* strengthen its messaging efforts to prevent unauthorized access and protect data.

- Dr. Irizarry asked whether power calculations have been performed to determine the number of participants needed. Dr. Denny clarified yes, as part of the original working group report to the NIH Director, and that the program's goal is to work toward common disease aggregation on gene–environment interactions. He noted that large sample sizes are particularly important for rare diseases research. He added that including pediatric participants will be beneficial.

- Dr. Denny affirmed that *All of Us* is pursuing public–private partnerships, including with Fogarty, the NIH Clinical Center, and intramural programs. Dr. Johnson also inquired about general data protection regulations; Dr. Denny responded that key components have been addressed.

- Dr. Lloyd commented that the Knockout Mouse Project (KOMP) was focused on determining *in vivo* function of all genes in the genome; he wondered whether KOMP and similar programs are important to *All of Us* for informing gene functions. Dr. Denny emphasized the importance of integrating such resources. Dr. Chang asked whether *All of Us* has considered partnerships with other NIH efforts (e.g., ABCD, HEALthy Brain and Child Development [HBCD] Study, ECHO). Dr. Denny stated that his team is discussing opportunities in this area.

VIII. *ALL OF US* REFLECTION AND ADVANCEMENT WORKING GROUP REPORT [VOTE]

Russ Altman, M.D., Ph.D., Kenneth Fong Professor of Bioengineering, Genetics, Medicine, Biomedical Data Science, and Computer Science, Stanford University, and Chair, *All of Us* Research Program Advisory Panel, presented a recent report by the *All of Us* Reflection and Advancement Working Group. He explained that the *All of Us* Advisory Panel serves as an independent advisory board and meets several times per year to provide feedback and catalyze continued progress. The Advisory Panel helped establish 5-year goals, and subgroups have focused on issues of special sensitivity or importance.

The *All of Us* Reflection and Advancement Working Group is one such subgroup and includes members from academia, industry, and government. Its purpose and charge were to assess the evolution, achievements, challenges, and opportunities for the program. Their report will lay the groundwork for the program's next period. They sought to provide recommendations that were exciting and innovative and offer advice in light of the program's current funding constraints. The report is organized around responses to questions across four areas: charting progress, cultivating established trust, ensuring health equity, and envisioning the future and sustainability.

The report outlines progress toward the program's goals and growth of researchers and programs. Dr. Altman underscored the program's remarkable scientific success. The Working Group made the following recommendations: (1) Build and engage a diverse cohort, (2) maintain engagement with participants, (3) establish pediatric cohorts, (4) maintain robust platforms for intake and dissemination, (5) ensure that the diversity of researchers matches the diversity of the cohort, (6) maintain trust with participants through transparent communication and supplementary study opportunities, (7) become a key resource for translational research and inform equitable health care, (8) use the resource for collaborative projects that help with saving costs, (9) ensure stable core budget and establish cost-effective practices aligned to long-term priorities, and (10) serve as a research arm for national health emergencies. Dr. Altman also underscored the importance of continued funding for maintaining the established program cohorts.

Discussion Highlights

- Dr. Lloyd commented that other programs (e.g., Million Veteran Program) are undertaking similar efforts. He inquired about the program's goals for collaboration with existing efforts. Dr. Altman stated that for the ancillary and supplementary studies, the group recommends that *All of Us*

maximize its opportunity to identify partners who want to ask related questions and are willing to fund the data or analysis. He also commented on the opportunities for meta-analysis among globally substantial cohorts. *All of Us* staff are interested in pursuing this matter.

- Dr. Irizarry asked for more information on the program's rationale for seeking to obtain 1 million participants. Dr. Altman clarified that the Working Group relied on assessments by *All of Us* staff. He reiterated that enhancing diversity and incorporating a pediatric cohort both necessitate a large sample size.

- Dr. Irizarry voiced concerns that the resource might be underused by researchers. Dr. Altman acknowledged that the lack of ability to download data is cumbersome for researchers. He noted, however, that moving the data would be costly. Several other large databases have moved toward similar models for this reason. He also noted that such a system helps ensure equitable data access. Dr. Altman also noted the need for further discussions on this topic.

- Dr. Robinson-Beale commented that other studies and capabilities exist that are aligned or similar to *All of Us*; opportunities for collaboration and consolidation could be considered. The program structure also can serve as a model for SMRB. She also suggested creative thinking, including a broadened definition of the term "researcher" to include other partners (e.g., provider groups) not typically associated with this label.

- Dr. King commented on the challenges of obtaining a diverse participant pool in research. She noted that *All of Us* can serve as a valuable resource in this area given its progress in this metric.

Vote

A motion to approve the *All of Us* Reflection and Advancement Working Group Report was forwarded and seconded. The motion passed with no abstentions.

IX. REVIEW/VOTE ON THE COUNCIL OPERATING PROCEDURES

Vote

The motion to approve the Council operating procedures without changes was forwarded and seconded. The motion passed with no abstentions.

X. ADJOURNMENT FOR THE DAY

Dr. Schwetz adjourned the meeting for the day at 3:51 p.m. on September 12, 2024.

Day 2

XI. WELCOME

Dr. Schwetz called the second day of the meeting to order at 9:09 a.m. on September 13, 2024, and outlined the day's agenda.

XII. ECHO CONCEPT CLEARANCE (NEW): EXPANDING ACCESS TO ECHO COHORT DATA AND BIOSPECIMENS THROUGH X01 [VOTE]

Leslie Thompson, Ph.D., Health Science Policy Analyst, ECHO Program, introduced a new concept to enhance ECHO's impact and value while fostering collaboration and equity of opportunity through

expanded access to ECHO data and biospecimens. The new concept involves issuing a new program announcement with special receipt, referral, and/or review considerations (PAR) for an X01 Resource Access Program. Dr. Thompson noted that ECHO investigators across the United States contribute and access identifiable data and biospecimens to the ECHO Program via the secure ECHO Data Platform and the ECHO Cohort Biorepository. This access is facilitated through UG3 and UH3 Exploratory/Developmental Phased Award Cooperative Agreements. The proposed concept will broaden access to the secure ECHO Data Platform and the ECHO Cohort Biorepository for both ECHO and non-ECHO investigators through an X01 mechanism. An additional mechanism—notices of funding opportunity (NOFOs) for F32 and R36 awards to enable non-ECHO pre- and postdoctoral trainees to access de-identified ECHO data through the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Data and Specimen HUB (DASH)—will be discussed during the next presentation.

The ECHO Program aims to understand the effects of a broad range of early environmental influences on child health and development. ECHO research focuses on five key areas affecting public health: pre-, peri-, and postnatal health; upper and lower airway outcomes; obesity and its consequences; neurodevelopment; and positive health and well-being. An ongoing program goal is to enroll more than 50,000 children in observational studies (i.e., the ECHO Cohort) of participants of different races, genders, ages, and backgrounds. The ECHO Institutional Development Awards (or IDeA) States Pediatric Clinical Trials Network conducts intervention research. ECHO observational and intervention research comprises more than 1,200 investigators at more than 180 health research institutions across 42 states, Washington, D.C., and Puerto Rico. During the first cycle of ECHO's observational research (September 2016–August 2023), data from more than 100,000 participants (including more than 65,000 children) from approximately 70 ongoing longitudinal maternal–child studies were harmonized, and more than 100,000 specimens were deposited in the ECHO Biorepository. The second cycle of the ECHO Cohort, which began in September 2023 and will continue through May 2030, involves ECHO researchers' following up with more than 30,000 child participants and recruiting more than 30,000 new pregnant parents.

The plan has been to establish ECHO as a national resource by making ECHO cohort data and biospecimens available to the broader scientific community. A major step toward this goal has been making de-identified data available through controlled access to the NICHD DASH. The next step involves expanding access for investigators in the broader scientific community who are asking important research questions that may require analyzing personally identifiable information (PII) on ECHO Data Platforms or biospecimens in the ECHO Biorepository. ECHO prioritizes the prompt use of biospecimens to address current hypotheses, avoid sample decay, and reduce long-term storage costs. However, the ECHO Laboratory Core has a limited budget for new biospecimen assays proposed by ECHO investigators. An ancillary studies process will therefore be advantageous for addressing storage and usage challenges by expanding access to the biospecimens and for making ECHO a resource to the broader scientific community. ECHO's definition of an ancillary study is a study that derives funding from a non-ECHO source and uses ECHO's non-publicly available data or biospecimens.

ECHO proposes to issue a PAR for an X01 mechanism that would allow investigators from within and outside of ECHO to ask important research questions that require analysis of data housed on the secure ECHO Data Platform or assays of biospecimens in the ECHO Biorepository. The X01 mechanism will allow the ECHO Program Office to oversee project and resource access; protect the interests of ECHO Sites, Cores, and Centers; protect the interests of ancillary study investigators; and monitor investigator development in future years. For ancillary study proposals, investigators will request a letter of support from the ECHO Steering Committee, apply for non-ECHO funding (if they do not already have funding in hand), and simultaneously apply for an ECHO X01. Once investigators have funding and an ECHO X01, they can proceed with the ancillary study. They may revise and return to the Steering Committee

with an updated proposal if necessary. X01 applications would involve standard NIH due dates in February, May, and October and would undergo review for scientific and technical merit by a federal panel. The X01-supported studies will be funded by NIH ICOs and federal agencies via traditional mechanisms.

Discussion Highlights

- The discussants, Drs. Krugman and Anna Maria Siega-Riz, provided their comments. Dr. Krugman asked whether the organization he co-founded, the National Foundation to End Child Abuse and Neglect (EndCAN), could encourage EndCAN-funded investigators to apply for ECHO X01 awards and about the relative costs of such studies. He noted that the field remains focused on forensic and legal studies while basic scientific research on child abuse pediatrics remains underfunded and understudied. Dr. Thompson could not share specific costs associated with X01-supported studies, but he noted that ECHO should compile and disseminate this information with potential applicants. As a follow-up comment, Dr. Krugman explained that each year, EndCAN offers two or three grants of up to $25,000 annually for 2 years to support junior investigators early in their research careers. Dr. Thompson emphasized that potential X01 researchers will have to consider staffing costs, costs associated with supporting the ECHO Cores and Centers that will facilitate access to and analysis of the data.

- Dr. Krugman asked whether information about experienced abuse was being gathered from child participants in the ECHO Program. Dr. Thompson emphasized the detailed and complex data collection protocol implemented within ECHO Cohort studies, which encompasses a range of genetic, societal, and psychosocial environmental features.

- Dr. Siega-Riz highlighted the evolution of the ECHO Program from the National Children's Study and complimented the program's achievements. She pointed out that the request for ancillary proposals via the X01 mechanism was an innovative and cost-effective concept that should be supported. Dr. Siega-Riz added that transparency surrounding costs associated with withdrawing ECHO biospecimens would help investigators with budget planning.

- In response to concerns expressed by Dr. Van Gelder about whether study sections would deny research funding to investigators who had not yet secured X01 awards, Dr. Thompson emphasized that applications will be submitted to NIH simultaneously. She added that the rationale for this approach was the shorter review period compared to two sequential applications and reviews. Dr. Thompson encouraged Council members to share ideas for mitigating the risks associated with the parallel applications. Dr. Van Gelder pointed out that a Special Emphasis Panel focusing on ECHO awards could coordinate with research-related study sections to review both grants simultaneously.

- Dr. Chang asked why an investigator would need to access PII on the ECHO Data Platform and whether this would violate patient confidentiality. Dr. Thompson responded with the example of geocoding and timestamping information, which could be used to connect to databases beyond ECHO for a better understanding of exposures and outcomes. Dr. Chang agreed that database interoperability was a major challenge but stressed that PII should never be released because of the potential for linking de-identified data to participants' addresses and other personal information. Dr. Thompson mentioned discussions within the ECHO Program about potential measures taken by the Data Analysis Center to secure participant data. He noted that X01 investigators would be trained before being given security credentials to enter into the ECHO Data Platform to perform their analysis within that secure environment; no data will be released beyond the ECHO Data Platform.

- The ancillary study investigators would have limited data access, i.e., access to the data needed for their analysis only.

- Dr. Robinson-Beale asked whether ECHO's data specifications and processes were being aligned or standardized with other NIH programs (e.g., *All of Us*). Dr. Thompson noted that all ECHO protocols are available to the public. ECHO also regularly engages with members of such NIH programs as *All of Us*, the ABCD Study, the HBCD Study, and various NIH Councils and working groups that address data policy and standardization issues. In response to a question from Dr. Robinson-Beale about whether connecting with other databases was a goal of the ECHO Program, Dr. Thompson responded that the program relies on its diverse network of researchers to work collaboratively and explore all possible options for ECHO data.

- Drs. Gandhi and Thompson discussed the importance of best practices and cost efficiency in biospecimen banking. Dr. Thompson pointed out that the concept aims to improve the value of money spent on research and ensure that resources are being leveraged effectively.

- Dr. King echoed Dr. Chang's concerns about sharing PII belonging to ECHO participants, especially in the context of child abuse. Drs. Johnson and Schwetz suggested that ECHO use the third-party anonymization model implemented by *All of Us*.

- Dr. Lloyd asked whether the demand for access to ECHO resources beyond the ECHO research community justified the X01 concept. Dr. Irizarry pointed out that making NIH-funded data and resources publicly available is one of NIH's major strategic goals, and Dr. Siega-Riz commented on the important opportunities for productive and creative research associated with the shared ECHO resources.

- Dr. Sanchez remarked on the need to investigate cheaper biospecimen preservation methods, especially in areas where technologies for testing currently are limited.

- Dr. Schwetz explained that the Council will be updated on any program modifications (e.g., to address privacy and cybersecurity concerns). The nature of the update (e.g., full presentation or email update) will depend on the extent of the changes.

Vote

A motion to approve the ECHO concept clearance, Expanding Access to ECHO Cohort Data and Biospecimens through X01, using the export certification model and considering other issues raised during the discussion, was forwarded and seconded. The motion passed with three abstentions.

XIII. ECHO CONCEPT CLEARANCE (REISSUE): DISSERTATION AND POSTDOCTORAL FELLOWSHIP GRANTS FOR THE ANALYSIS OF PUBLICLY ACCESSIBLE ECHO DATA [VOTE]

Clay Mash, Ph.D., Cohort Program Officer, ECHO, presented a reissue concept for funding opportunities to support graduate students and postdoctoral fellows conducting research involving data from the ECHO cohort. This program aims to expand research in the high-priority areas of maternal and child health by stimulating investigator trainee–driven analyses of ECHO data through the reissue of two companion requests for applications: an R36 Dissertation Grant and an F32 Individual Postdoctoral Fellowship Award. The opportunity will support the training of new investigators in the analysis of large longitudinal data sets to investigate child health outcomes.

The ECHO Program was established in 2016 and currently is undergoing its second cycle of recruitment, data collection, and biospecimen banking. Harmonized, de-identified data from the ECHO Cohort are now available in the NICHD DASH, a centralized resource that allows researchers to access data from ECHO and other studies via controlled-access mechanisms. The NICHD DASH contains data on approximately 32,000 pregnancies and 31,000 child participants, and the ECHO Data Analysis Center posts new data at regular intervals. Data from 63,215 ECHO Cohort participants include demographics, environmental exposures, and pregnancy and birth details. The harmonized data sets across various domains are available to 63 unique registered users.

To maximize the scientific value of data generated by the ECHO program, two NOFOs were announced in 2023: RFA-OD-23-020 Dissertation Grant (R36) and RFA-OD-23-019 Ruth L. Kirschstein National Research Service Award (NRSA) Individual Postdoctoral Fellowship (F32). A CSR Special Interest Panel reviewed applications, and six awards were funded. Funded R36 projects involved identifying neurocognitive correlates of reading impacted by adversity exposure; tracing the effects of environmental exposure to tobacco and cannabis smoke and vapor emissions on children's mental health symptom trajectories; understanding longitudinal trajectories of environmental factors and depression among minoritized adolescents; studying prenatal per- and polyfluoroalkyl substances (PFAS) exposures and associations with common childhood infections and allergies; and assessing the influences of prenatal phthalate exposure on early childhood obesity and potential protective dietary strategies. The funded F32 project evaluated associations between prenatal exposure to endocrine-disrupting chemicals and child neurodevelopmental disorders mediated by cytokines and DNA methylation. Grantees were supported via biannual meetings with their program officer who assists with orientation to ECHO data and liaises with the ECHO Measurement Core and Data Analysis Center as necessary. Ongoing evaluation of grantee progress included assessments of degree or fellowship completion, presentations at professional meetings, authorship of publications, and transition to employment in the field of training.

Dr. Mash provided an overview of the proposed funding opportunity reissue. Dissertation students who have an approved proposal by the start of the award will be eligible for the R36 Dissertation Grant. The duration of the award will be 1 to 2 years, and the award budget will cover the student's stipend and research-related costs. Recent graduates of doctoral programs in relevant fields will be eligible for the F32 Postdoctoral Fellowship Award. The duration of the award will be 2 to 3 years, and the award budget will cover the fellow's stipend, training, and research-related costs. ECHO plans to commit approximately $1,260,000 in total costs during FY26 to FY28 for up to eight 2- or 3-year awards.

Discussion Highlights

- The discussants, Drs. Johnson and Krugman, provided their comments. Dr. Johnson asked about the discrepancy between the 107,000 total participants and the harmonized data from approximately 65,000 participants. Dr. Mash noted that the latter figure referred to the number of child participants who are followed until the age of 21 years.

- Dr. Johnson asked about advertising the awards more broadly (especially to investigators at children's hospitals). Dr. Mash explained that a communications plan was developed to advertise the first cycle of awards; ECHO currently is planning an expansion of the initial communication strategy. Dr. Mash explained that the initial round of awards was intended to include a small number of grantees. Because of the success of the first cohort, the program itself is being expanded rapidly.

- Dr. Robinson-Beale encouraged Dr. Mash to advertise the awards to diverse investigators, especially those associated with provider organizations that typically do not receive NIH funding. She noted such investigators are more aware of on-the-ground issues. She provided the example

of unnecessary costs associated with the extended time required to diagnose and treat autoimmune diseases. Dr. Mash agreed that increased involvement of such researchers in the program would yield powerful outcomes.

- Dr. Siega-Riz remarked on challenges faced by early career clinicians–investigators who lack the time to explore and analyze available resources.

Vote

A motion to approve the reissuance of the concept for Maximizing the Scientific Value of Data Generated by the ECHO Program (R36/F32) was forwarded and seconded. The motion passed with no abstentions.

XIV. OBSSR CONCEPT CLEARANCE (RENEWAL): SHORT COURSES ON INNOVATIVE METHODOLOGIES AND APPROACHES IN THE BEHAVIORAL AND SOCIAL SCIENCES (R25 – INDEPENDENT CLINICAL TRIAL NOT ALLOWED) [VOTE]

Erica Spotts, Ph.D., Health Scientist Administrator, OBSSR, introduced the 2025 and 2027 reissues of the Short Courses on Innovative Methodologies and Approaches in the Behavioral and Social Sciences concept, which aims to support educational activities to develop crosscutting methodologies and analytics needed to rapidly advance behavioral and social sciences that are not already well addressed by existing educational programs widely available to the research community. Historically, OBSSR has funded six to eight applications during each cycle of the program, and the project period is 4 years.

The program intends to fill gaps in behavioral and social science education not provided by most standard academic programs. It encourages integration of behavioral and social science with non-behavioral and social science to reach as broad an audience as possible. The focus population is the choice of the applicant, but most projects focus on all career stages, beginning with graduate students. Dr. Spotts outlined sample topics and pointed out that mentors are encouraged to be from diverse backgrounds, have expertise and experience relevant to the proposed program, and be committed to continuing their involvement through the total period of the award. In 2023, application budgets were limited to $200,000 in direct costs per year.

Dr. Spotts reviewed the history of the program and the topics funded, such as causal analysis, mixed methods, community-based participatory research, randomized controlled trials, dynamic systems modeling, mobile health, power analysis for multilevel and longitudinal studies, dissemination and implementation, intervention optimization, and data management for data sharing. She noted that all courses were improved over time in response to changing needs, including successful pivots in response to the COVID-19 pandemic. She also provided statistics on course attendance and structure, pointing out that many courses include continued interaction with instructors or peers after the course.

Discussion Highlights

- The discussants, Drs. Gandhi and Robinson-Beale, provided their comments. Dr. Gandhi emphasized the importance of supporting early stage investigators and the appropriateness of the R25 mechanism, especially at this efficient cost. She supported the concept but recommended emphasizing a focus on early stage investigators, as well as providing data on the number of participants at each career stage. Dr. Robinson-Beale recognized the importance of this concept for spreading knowledge of behavioral and social science, stimulating research across other areas, and supporting standardization. She also recommended seeking collaborators across NIH to help apply the research in real-world contexts.

- Dr. Spotts pointed out that about 10 other ICs have been involved over the life of this program, showing its crosscutting, NIH-wide importance and helping fund projects that would not be supported by a single IC. She added that many applications include partnerships between researchers and community-based organizations.

- When asked about the geographic distribution of these awards, Dr. Spotts pointed out that they strongly encourage the recipient of the award to recruit as broadly as possible. Attendees are difficult to track across these small, 4-year grants, and the topic of the course will affect the degree of impact it has on a participant's career. Dr. Schwetz added that tracking trainees in general is a challenge for all agencies.

- Dr. Spotts clarified that the length of courses varies by program. Some courses may run for several days or weeks but include follow-up with mentors for several years after or peer groups that continue to interact online. Council members emphasized the importance of ensuring that participants develop a full understanding of the methods and pointed out that sustained contact could help with tracking the program's impact.

Vote

The motion to approve the Short Courses on Innovative Methodologies and Approaches in the Behavioral and Social Sciences concept reissue was forwarded and seconded. The motion passed with no abstentions.

XV. COMMON FUND VENTURE PROGRAM UPDATE

Douglas M. Sheeley, Sc.D., Acting Director, OSC, welcomed incoming OSC Director Dr. Hutter and provided an update on the Common Fund Venture Program, which is intended to "do amazing things with modest funding" by supporting smaller, focused, but still bold initiatives to accomplish an outsized impact with a modest level of funding for a short period of time. These initiatives run for 3 years with about $5 million per year, and the first two were launched in FY24. The Venture Program initiatives must meet the program criteria for Common Fund as a whole: the work must be transformative, high impact, catalytic, goal-driven, synergistic, and innovative. Venture Program initiatives also should be bold, have the potential for outsized impact, and be able to be implemented rapidly.

The first two initiatives were the Oculomics Initiative, which uses emerging imaging capabilities in ophthalmology to look for biomarkers of systemic disease, and the Systems Biology Data Platform, which uses data from the Accelerating Medicines Partnership Initiative to develop molecular phenotypes across systems and diseases. The Common Fund has released an annual RFI for the last few years to gather input that influences the development of Common Fund programs, including Venture initiatives. The Venture Program scope includes all areas NIH supports, so the goals of each initiative should be clear, and inclusion of diverse scientific and cultural perspectives is actively encouraged. OSC is working to actively improve collaboration and ensuring outreach is conducted to a broad range of potential participants.

Dr. Sheeley outlined two initiatives for FY25 and FY26. The first is an effort to improve newborn screening with whole-genome sequencing. Currently, most newborns in the United States are screened by public health laboratories for a variety of genetic disorders using biochemical assays. Many states screen for a small number of diseases, but as interventions become available, families should have access to screening that would enable treatment for rare diseases as early as possible. The goals of this initiative are to support a centralized laboratory for analysis and interpretation of results; focus on a limited gene panel of serious, life-threatening diseases present in infancy; and provide equitable access to genome sequencing. The program also will include a community advisory board to expand expertise in newborn screening and help define when genetic and metabolic screening is appropriate.

Dr. Sheeley explained that this project would meet Venture and Common Fund criteria by changing newborn screening procedures to provide greater and more equitable access, catalyzing broad improvement of quality of care, boldly providing actionable genetic information for earlier intervention, and using existing and emerging technologies to move forward quickly with a small, focused program. He hoped this project would demonstrate scientific and ethical feasibility and provide a model for expanding the application of this screening.

The next initiative is a broad effort to advance noninvasive optical approaches for biological systems, a project predicated on the idea that current optical imaging technologies have inadequate resolution and sensitivity for potential clinical applications. The basic problem is the trade-off between deep views into tissues and good sensitivity and resolution. Program goals are to enable development of next-generation noninvasive imaging platforms and incorporate approaches that advance optical interfaces. This is a technology development program supporting designing and optimizing hardware and prototypes, and it will require diverse teams, including physicists, biologists, and engineers. The program aims to encourage partnerships across institutions and across research organizations and to provide research and training opportunities to encourage those who can contribute to this opportunity to do so. OSC will ensure this program is advertised broadly to include a diversity of ideas and perspectives.

If successful, this program would catalyze follow-on activities supported by a number of ICs, and it has clear metrics for defining success and adapting elements as needed. It will provide an opportunity to uplift activities important to many ICs, and it must include bold combinations of microscopy and optics principles in ways that are not yet apparent. Adding key elements of current research to this program will allow researchers to generate technologies with outsized impact. Dr. Sheeley emphasized the hope that this program will support technologies that allow researchers to see physiological processes directly, on a much more intimate timescale, in real time, and in a way that can be used to follow clinical processes, including progress and treatment of diseases.

Discussion Highlights

- Dr. Sheeley clarified that Common Fund programs are chosen by gathering information from the community at large, then providing a framework to develop ideas for programs, but this process occurs collaboratively across ICOs. The Venture Program uses a streamlined process in which a subset of ICO directors review the proposals.

- Dr. Van Gelder asked for clarification on the definitions of programs that are “bold” or “nimble” and emphasized the need to avoid the implication that NIH could be using these grants to accomplish less risky actions. He asked about the anticipated failure rate and pointed out the difficulty of staying ahead of the curve in areas of technological advancement. Dr. Sheeley explained that a specific failure rate cannot be identified, but the program will be accepting of failure. When asked how the value of this program would be shown, Dr. Sheeley pointed out that some initiatives have specific goals that can be used to assess success, and others can be analyzed in terms of whether they were responsive to changes in the field.

- When asked how the sequencing project will avoid duplication of effort with other initiatives, Dr. Dominique Pichard, Director of the Division of Rare Diseases Research Innovation (DRDRI) at the National Center for Advancing Translational Sciences, explained that although many programs are addressing genetic sequencing of newborns, the Venture Program’s initiative specifically works to ensure sequencing is instituted equitably.

- In response to a question about genetic diseases without existing treatments, Dr. P.J. Brooks, Deputy Director of DRDRI, explained that the number of diseases that can be treated, especially

with the rise of genome editing, is increasing rapidly. This effort will be integrated with improvements in gene editing technology, so undertaking this project now makes sense.

- Dr. Sheeley explained that scientific communication is being considered as an important aspect of implementation. Dr. Pichard added that the community advisory board works to create local connections with the communities that will be served. Ms. Barbara Kelley emphasized the need to consider health literacy levels when designing communication.

- In response to a question about whether this initiative will include the private sector, Dr. Sheeley explained that the initiatives will have as broad an eligibility as possible. He clarified that the broad research community contributes ideas for new initiatives, and Dr. Robinson-Beale encouraged expanded communication around the ability for many institutions to submit ideas.

- Dr. Sheeley explained that every initiative is proposed by a coalition of ICs and developed in ways that ensure they remain multidisciplinary.

XVI. OSC CONCEPT CLEARANCE (NEW): HARNESSING DATA SCIENCE FOR HEALTH DISCOVERY AND INNOVATION IN AFRICA (DS-I AFRICA) STAGE 2 [VOTE]

Bruce Tromberg, Ph.D., Director, NIBIB, presented a concept for stage 2 of the DS-I Africa program. He explained that the program's core group includes representatives from NIBIB, Fogarty, NIMH, and NLM, and a total of 21 ICOs have partnered with the program. DS-I Africa's original motivation was to support a coordinated effort to connect disparate groups in health data to science and innovation across Africa and address health challenges. The program goal is to explore how advances in data science, applied in the African context, can spur new health discoveries and catalyze innovation in health care and health research.

Dr. Tromberg shared a recent reflection from the World Economic Forum Youth Perspectives. In the digital age, technology has the power to revolutionize the socioeconomic landscape of Africa, providing young African professionals the opportunities to acquire knowledge, develop innovative ideas, and connect with the global community. Stage 1 of the program funded 38 awards in 22 countries. Seven research hubs bring together partners across academia, government, and industry. Seven research training programs and six education programs have been established. Other components include four Ethical, Legal, and Social Implications research projects, as well as a Coordinating Center and the eLwazi Open Data Science Platform.

The program is facilitating research in various areas, including precision public health, viral and bacterial surveillance and modeling, diagnostics and decision support, youth mental health, and climate change and health. Dr. Tromberg emphasized that these projects embody many of the hoped-for outcomes for this program. The consortium has applied data science approaches to develop new solutions for critical health care problems; developed new data science and digital health innovations; leveraged new scientific advances in synthetic data generation to overcome barriers to data sharing; and developed new African institutional capacity for data storage, management, and analysis. These accomplishments span the areas of innovation, education, and collaboration.

Kathleen Neuzil, M.D., M.P.H., Director, Fogarty, discussed the future of the DS-I Africa program. She presented the results of a portfolio and landscape analysis of the program. NIH is the leading funder in this space, and other entities are increasing investments in data science. Opportunities for the next stage include continuing to build on the past investments, aligning activities with government and the private sector, considering sustainability through collaborations, and engaging with the African science councils and African Open Science Platform. Dr. Neuzil noted that more time is needed to translate some of this research into health outcomes that meet the demand for research training. Future activities in this space

include scaling up training activities and "train the trainer" activities so more people can be reached. The team also proposed a flexible and adaptable strategic investment funding model.

Stage 2 program goals and initiatives include advancing health data science research and innovation through partnerships, increasing health data science capacity, exploring ethical and social implications of emerging data science, fostering a network of data scientists and collaborators, and responding effectively to opportunities for collaboration and to rapid changes in the field of data science. New areas of focus include early stage data repositories, and strategic innovation. Stage 2 initiatives will focus on research (fostering translation and responding to emerging technologies and approaches), capacity building (focusing on a wider audience), ethical and social implications (de-emphasizing the legal implications component), the ecosystem (expanding eLwazi, scaling outputs of the training programs, supporting early stage data repositories), and a Strategic Innovation Fund (supporting a flexible budget).

Dr. Neuzil emphasized the importance of adapting quickly to address emerging issues in partnership with African organizations, other global funders, and commercial partners. Anticipated results from the program include recognized centers of excellence, advances in policy related to AI and data science technology, a network of scientists supported by a transforming data ecosystem, a sustainable platform of interdisciplinary and multisectoral collaborations, demonstrated feasibility of data science innovation to improve health in Africa, increased capacity for African-appropriate tools, new applications and products, and new scientific knowledge that improves clinical practice and health.

The program is requesting $95.65 million over 5 years. Increased costs reflect requests for an additional research hub, an additional training program, the extension of the Partnership for Innovation Projects and the Research Education Programs from 3 to 5 years, the four early stage data repositories, and the Strategic Innovation Fund. No-cost extensions might be employed to bridge an anticipated 3- to 4-month gap between stages 1 and 2. Dr. Neuzil emphasized that the program addresses all of the Common Fund criteria: goal-driven, novel, transformative, catalytic, and synergistic.

Discussion Highlights

- The discussants, Drs. Kristin Ardlie and Irizarry, provided their comments. Both discussants expressed support for the concept while voicing concerns about sustainability and highlighting the value of training through this program. Dr. Ardlie noted that this program is similar to others within the Common Fund data ecosystem, and she underscored the importance of helping users understand what data are available and where to find them.

- Dr. Neuzil agreed that sustainability is a major challenge, and cooperation with African partners (including governments) will be crucial. Dr. Tromberg added that the global research community is facing similar issues, and cooperation will be key for trying different approaches across communities. He added that education is key for implementing AI responsibly and ethically.

- Dr. Irizarry expressed concern about the capabilities for coordination and database building. He suggested reworking the proposal with details on specific training projects to be funded. Dr. Neuzil underscored the value of the Coordinating Center to enhance collaboration and work toward sustainability. Dr. Tromberg noted that database and tool development will be important for driving the initiative forward, and having an aspirational goal over the next 5 years is critical. Dr. Schwetz added that sustainability is a major challenge, and other investments are being discussed.

- Dr. Laura Povlich, Fogarty Program Officer, noted that the eLwazi team is working in close collaboration with the African Open Science Platform, which is an initiative of the South African government in collaboration with other countries across the continent. This effort meets program

goals in making African data sets more findable and accessible and indicates that grantees are considering approaches for sustainability.

- Dr. Siega-Riz inquired about the demographic information, including gender, of the training programs. Dr. Povlich highlighted the importance of promoting the inclusion of women in data science and noted that all of the programs have satisfactorily met the gender recruitment and equity program criteria. She noted that this is challenging to achieve in certain countries, but all the centers are working toward gender equity. Dr. Siega-Riz spoke on the importance of transparency in this area.

- Dr. King suggested several potential program partners: Society of Neuroscientists of Africa, International Brain Research Organization, and World Women in Neuroscience. She emphasized that African researchers have been leaders in data science, and she underscored the importance of training and noted that the communities have been enthusiastic. Dr. Gandhi added that training can help ensure sustainability.

Vote

Dr. Schwetz proposed that this concept be revisited and voted on during the February 2025 meeting.

XVII. CLOSING REMARKS

Council members voted to hold the February 2025 meeting virtually and the May 2025 and September 2025 meetings in person.

XVIII. ADJOURNMENT

Dr. Schwetz adjourned the meeting at 12:39 p.m. EDT on September 13, 2024.

XIX. CERTIFICATION

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

Schwetz, Tara (NIH/OD) [E] Digitally signed by Schwetz, Tara (NIH/OD) [E] Date: 2024.11.08 13:46:22 -05'00'

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: 2024.11.08 12:56:59 -05'00'

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

Date