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

Council of Councils Meeting
September 17, 2021

Meeting Minutes

I. CALL TO ORDER AND INTRODUCTIONS

James M. Anderson, M.D., Ph.D., Director, DPCPSI, welcomed participants, NIH staff members, and members of the public to the meeting of the Council of Councils. The virtual meeting began at 10:00 a.m. on Friday, September 17, 2021. The meeting attendees are identified below. Dr. Anderson introduced Robert W. Eisinger, Ph.D., Senior Scientific Advisor, DPCPSI, the new executive secretary of the Council of Councils, and thanked Dr. Franziska Grieder for having served as the Executive Secretary for the Council for the past 9 years in addition to her responsibilities as Director of the Office of Research Infrastructure Programs (ORIP). Dr. Anderson then reviewed the day's agenda.

A. Attendance

1. Council Members

Council Members Present

Chair: James M. Anderson, M.D., Ph.D., Director, DPCPSI
Executive Secretary: Robert W. Eisinger, Ph.D., Senior Scientific Advisor, 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 MIT and Harvard, Cambridge, MA
Linda Chang, M.D., FAAN, FANA, University of Maryland School of Medicine, Baltimore, MD
Graham A. Colditz, M.D., Dr.P.H., M.P.H., Washington University School of Medicine in St. Louis, St. Louis, MO
Andrew P. Feinberg, M.D., M.P.H., Johns Hopkins University, Baltimore, MD
Rick Horwitz, Ph.D., Allen Institute for Cell Science, Seattle, WA
Patricia D. Hurn, Ph.D., R.N., University of Michigan, Ann Arbor, MI
Kevin B. Johnson, M.D., M.S., Vanderbilt University Medical Center, Nashville, TN
R. Paul Johnson, M.D., Emory University School of Medicine, Atlanta, GA
Sachin Kheterpal, M.D., M.B.A., University of Michigan Medical School, Ann Arbor, MI
Gary A. Koretzky, M.D., Ph.D., Weill Cornell Medical College, New York, NY
Richard D. Krugman, M.D., University of Colorado School of Medicine, Aurora, CO
Jian-Dong Li, M.D., Ph.D., Georgia State University, Atlanta, GA
Edith P. Mitchell, M.D., FACP, Thomas Jefferson University, Philadelphia, PA
Charles P. Mouton, M.D., M.S., The University of Texas Medical Branch at Galveston, Galveston, TX
Megan O'Boyle, Phelan-McDermid Syndrome Data Network, Arlington, VA
Rhonda Robinson-Beale, M.D., Blue Cross of Idaho, Meridian, ID
Susan Sanchez, Ph.D., The University of Georgia, Athens, GA
Jean E. Schaffer, M.D., Harvard Medical School, Boston, MA

Scout, Ph.D., National LGBT Cancer Network, Pawtucket, RI
Anna Maria Siega-Riz, Ph.D., M.S., University of Massachusetts Amherst, Amherst, MA
Russell N. Van Gelder, M.D., Ph.D., University of Washington, Seattle, WA

Council Members Absent

Maria L. Acebal, J.D., The Aspen Institute, Washington, DC
Paul J. Kenny, Ph.D., Icahn School of Medicine at Mount Sinai, New York, NY

2. Liaisons

Joseph M. Betz, Ph.D., Acting Director, Office of Dietary Supplements (ODS), DPCPSI
Janine A. Clayton, M.D., Director, Office of Research on Women's Health, DPCPSI
Wilma Peterman Cross, M.S., representing **David M. Murray, Ph.D.,** Director, Office of Disease Prevention, DPCPSI
Maureen M. Goodenow, Ph.D., Director, Office of AIDS Research, 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
Christopher J. Lynch, Ph.D., Acting Director, Office of Nutrition Research (ONR), DPCPSI
Rebecca Meseroll, Ph.D., representing **George Santangelo, Ph.D.,** Director, Office of Portfolio Analysis, DPCPSI
Karen L. Parker, Ph.D., M.S.W., Director, Sexual & Gender Minority Research Office, DPCPSI
William T. Riley, 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
Elizabeth L. Wilder, Ph.D., Director, Office of Strategic Coordination (OSC), DPCPSI
David Wilson, Ph.D., Director, Tribal Health Research Office, DPCPSI

3. *Ex Officio* Members Absent

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

4. Presenters

Kristen Ardlie, Ph.D., Director, Genotype Tissue Expression, Broad Institute of MIT and Harvard University
Philip J. Brooks, Ph.D., Program Coordinator, Office of Rare Diseases, National Center for Advancing Translational Sciences (NCATS)
Francis S. Collins, M.D., Ph.D., Director, NIH
Charles R. Dearolf, Ph.D., Director, Program Development and Support, Office of Intramural Research, NIH,
Joshua Denny, M.D., M.S., Chief Executive Officer, *All of Us* Research Program, NIH
Susan Gregurick, Ph.D., Associate Director for Data Science and Director, ODSS, DPCPSI
Christopher J. Lynch, Ph.D., Acting Director, ONR, DPCPSI
Sarika Parasuraman, Ph.D., M.P.H., Health Science Policy Analyst, OBSSR, DPCPSI
Laura Povlich, Ph.D., Program Director, Division of International Training and Research, Fogarty International Center

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

Robert W. Eisinger, Ph.D., the executive secretary for the NIH Council of Councils, reviewed the following:

- Council members are Special Government Employees during the day(s) 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 20, 2021.

- Minutes from the May 20–21, 2021, meeting are posted on the DPCPSI website. The minutes from this meeting also will be posted there.

C. Future Meeting Dates

Future Council meetings are scheduled to be held virtually or in person on January 27–28, May 19–20, and September 8–9, 2022. Although these dates are reserved, the duration of each meeting is not yet confirmed.

II. UPDATE: *ALL OF US* RESEARCH PROGRAM

Joshua Denny, M.D., M.S., the Chief Executive Officer of the *All of Us* Research Program, described the mission of *All of Us,* which is to accelerate health research and medical breakthroughs that enable individualized prevention, treatment, and care. The program seeks to nurture relationships over decades with 1 million or more participant partners from all walks of life to build and deliver large, rich, secure, and easy-to-access biomedical data sets. *All of Us* also aims to catalyze a robust ecosystem of researchers and funders who will use and support it. Innovative aspects of the program include: participant diversity; focus on considering participants as partners and returning value to them; longitudinal nature; ability to recontact participants; and support for many data types. *All of Us* also protects and prioritizes security and privacy for all participants and integrates environmental, lifestyle and biology in analyses. To date, more than 400,000 participants have enrolled from all 50 states, as well as U.S. territories. More than 250,000 electronic health records (EHRs) have been uploaded and harmonized; about 300,000 individuals have completed initial steps of the program; and biosamples from about 310,000 individuals have been collected. More than half the enrollees self-identified their racial and ethnic background as other than white. The program currently enrolls only those age 18 years and older with a wide range of ages represented.

Study participants may enroll through a health care provider or organization or online. In-person events were paused in March 2020 in response to the COVID-19 pandemic, and more virtual capability was added. The program currently has returned to one-third of its previous enrollment capacity. Regardless of how study participants sign up, all participants first complete consent forms and provide authorization to share their EHR data. They can then complete surveys and submit physical measures and biosamples. Mobile devices and wearable information can be connected if desired. Standard surveys collect information on demographics and lifestyle, assessments of personal and family medical history, and health care access. A survey related to COVID-19 was distributed several times between May 2020 and February 2021. *All of Us* also conducted a study of early exposure to SARS-CoV-2 by testing 24,000 samples collected between January 2 and March 18, 2020, for antibodies to SARS-CoV-2. The study identified 7 COVID-19 cases earlier than the first reported cases in five states. The earliest positive sample was taken on January 7, 2020, likely indicating infection with SARS-CoV-2 several weeks prior to that. These results demonstrate one benefit of a prospective cohort that collects data on an ongoing basis from a diverse group of individuals across the country.

All of Us has been pioneering strategies to improve the researcher experience with this program. The central cloud-based research platform allows researchers to view other research projects and published papers using data from *All of Us*. In general, the program aims to make research findable, accessible, interoperable, and reusable (FAIR). This approach has been successfully done with the COVID-19 serology data. Researchers can follow a direct link – as with any published research analysis – to the exact data and analysis used for the study.

The program also strongly values ensuring that study participants have access to their own information. The results display for the COVID-19 serology study was developed allowing the nine people who received a positive result and those who tested negative to see their test results and the ability to talk to infectious disease experts.

Current data from study participants arrive in repositories and *All of Us* provides curation services to remove personal identifiers. Several levels of access to participants' data are available, including public information and research-level access. A data browser tool allows the public to explore information at a high, broad level, such as survey responses sorted by age. Registered researchers with access can explore data at the next technical level without needing to request additional approval. The Researcher Workbench, which can be used for collaborations, currently includes more than 1,000 registered researchers from more than 240 registered institutions across the country; more than 24 percent represent historically Black colleges and universities or Hispanic-serving institutions and nonprofit organizations. Researchers have been able to explore longitudinal data from EHRs and Fitbits even though most participants joined after the national launch in May 2018.

The controlled-access tier to program data is planned for release within the next several months and will include all of the information available to the other tiers, more detailed demographic and COVID-19 data, and whole genomes and genotyping array data. About 5,000 participants' genomes are sequenced per week, and 90,000 whole genomes and 130,000 arrays—more than 40 percent from individuals who do not identify as white—will be available when the tier is opened. Dr. Denny noted that the Nutrition for Precision Health Project mentioned later in this meeting, which aims to enroll *All of Us* participants in a study to develop algorithms to predict individual responses to food and dietary patterns, is one example of the types of ancillary studies enabled by the *All of Us* data set. The program also has begun returning genetic ancestry and trait information to individual participants; health-related genetics information will be available within the next year.

Discussion Highlights

- Dr. Denny predicted the *All of Us* platform could be used for interventional studies in the future although the protocols have not yet been developed. Study participants could be contacted for surveys or other projects. For example, participants were sent information on COVID-19 vaccine trials and many signed up. The diversity of the data set could be particularly useful, and the Nutrition for Precision Health Project will help inform the program how to develop the appropriate protocols for other studies.
- Dr. Denny confirmed that most of the research studies conducted with *All of Us* so far has been investigator-initiated.
- Dr. Denny clarified that the controlled-data tier will provide the first data linkages in the form of census data. Although a timeline for linking environmental data is not available, *All of Us* currently is preparing a strategic plan that will include consideration of how to protect identity with future linkages and access tiers.
- Dr. Scout commented on the importance of community participation in *All of Us* and noted that non-research colleagues often mention the program, demonstrating its success at including community organizations, recruiting underrepresented populations, and conducting specific initiatives to recruit underrepresented researchers.
- Dr. Denny explained that pediatric enrollment is planned within the next 5 years.
- Dr. Denny commented that cognitively impaired participants have been considered, but require additional consideration of complexities, such as the ability to consent. Although some participants likely have become cognitively impaired since enrolling; the consents are designed to remain active for the future so cognitive impairment would affect consents only for a new activity.
- When asked how to gather EHR data for those participants whose records are incomplete, Dr. Denny theorized that many strategies will be required to close those gaps, which the strategic plan will address.
- In response to a question about collaborations, Dr. Denny explained that data linkage presents some challenges, but *All of Us* is committed to exploring collaborations further.
- In response to a question about differences in outcomes related to the diversity of the *All of Us* study population, Dr. Denny clarified that several studies examine health disparities, so data from diverse populations have been illustrative. While the diversity of researchers involved with the program is increasing, more focused efforts are planned to reach researchers at historically Black colleges and universities, minority-serving institutions, Hispanic-serving institutions, and tribal colleges and universities.
- In response to a question about allowing health plans or institutions to access or contribute to the data, Dr. Denny stated the program would be very interested in working with other entities to make the data set more complete and aid enrollment.

III. REVIEW, DISCUSSION, AND VOTE—UPDATED COUNCIL OF COUNCILS OPERATING PROCEDURES

Dr. Anderson outlined proposed changes to the Council's operating procedures. The first change is to add programs from the NIH Lasker Clinical Research Scholars Program, OBSSR, ODSS, and ODS to the list of sources of concepts the Council will clear. The second change is to allow a quorum of Council members to vote in person, by telephone, or virtually. Dr. Anderson clarified that adding the ability to

vote by telephone or virtually will formalize the procedures the Council has been following since the beginning of the COVID-19 pandemic.

Vote

A motion to approve the proposed modifications to (1) add the Lasker Award, ODS, ODSS, ONR, and OBSSR programs, and (2) change Section 2, Part G, Subsection 2 of the Council Operating Procedures was forwarded and seconded. The motion passed with no abstentions.

Dr. Anderson proposed that the Council hold the May annual meetings virtually after the pandemic eases, potentially in 2022.

Discussion Highlights

- Council members discussed the benefits and challenges of virtual and hybrid meetings. Virtual meetings may be less efficient, may hinder collegiality, and may be less valuable to junior investigators; hybrid meetings prevent equitable participation. However, this is an opportunity for the Council to show leadership and set a standard for virtual NIH meetings, which would make a statement about allocation of more resources to research than travel. Some members suggested one longer in-person meeting with key speakers and two virtual meetings.
- Dr. Anderson suggested that the January 2022 meeting may be held in person, if allowed based on the COVID-19 pandemic's progression and include further discussion of this topic.

IV. COMMON FUND CONCEPT CLEARANCE: SOMATIC CELL GENOME EDITING PROGRAM—PHASE 2 (VOTE)

Philip J. Brooks, Ph.D., Program Coordinator at the Office of Rare Diseases, NCATS, outlined the second phase of the Somatic Cell Genome Editing (SCGE Phase 2) Program. The second phase of this program aims to accelerate development of genome-editing therapeutic agents by facilitating studies that enable investigational new drug (IND) applications to the U.S. Food and Drug Administration (FDA); enabling pathways to regulatory approval; and disseminating successful strategies for initiating first-in-human clinical trials. Genome editing allows precise corrections in a patient's DNA or RNA; CRISPR-Cas9 and other genome-editing technologies have catalyzed the development of experimental gene-editing therapeutics, and thousands of genetic diseases are amenable to *in vivo* genome-editing approaches. The first round of this program, now in its fourth year, addressed a variety of gaps and produced several high-impact publications. The planning for Phase 2 is similar to that conducted for Phase 1. First, subject-matter experts discussed the program at a workshop, and then individual consultations with stakeholders and leading researchers were held. An environmental scan was conducted of *in vivo* gene-editing therapeutics in clinical trials, industry genome-editing pipelines, and the NIH genome-editing therapeutics portfolio.

The field has advanced considerably since the Phase 1 effort, which focused entirely on technology development. Phase 2 proposes approximately $45 million per year for 5 years to develop a portfolio of initiatives spanning the continuum from technology development to clinical trials. Initiative 1 will support 3-year awards to develop, optimize, and validate broadly applicable new IND-enabling genome-editing assays. Ideally, these approaches would become a standard part of the regulatory submission for genome editing. Initiative 2 supports 5-year awards for broad-based, multidisciplinary approaches to genome-editing therapy development targeting one or more diseases affecting specific cell types, and it is broadly applicable to other diseases that affect those cell types. Initiative 3 aims to develop an IND for a clinical trial using *in vivo* gene editing for more than one disease at a time—for which the platform capacity of genome editing is ideal—and then support a small clinical trial. This initiative likely will contain a 3-year

preclinical phase and a 2-year clinical stage. Consultations with FDA would be required, and activities would be led by clinical investigators experienced in conducting clinical trials involving rare diseases. Initiative 4 is a dissemination and coordinating center (DCC), which will focus on analysis of approaches to accelerate and approve IND submissions for genome editing.

This concept fits the Common Fund criteria for research that is transformative, catalytic, synergistic, crosscutting, and unique. The ability to reduce the risk of multiple approaches for *in vivo* genome editing therapeutics can be transformative. This initiative will establish proof of concept and support platform tools and experiences that will be catalytic to other research. The program will be synergistic with ongoing studies supported by various NIH Institutes and Centers (ICs) and industry partners. Program areas must be relevant to multiple diseases spanning multiple NIH ICs. This unique program is designed to reduce the risk of these highly impactful projects.

Initiative 1 assays would be aligned with regulatory requirements. The extensive data sets in Initiative 2 could be used to support multiple gene-editing INDs in disease and cell types that would be relevant to various ICs. Initiative 3 would develop a publicly funded template for obtaining an IND and conducting clinical genome editing trials of more than one disease at a time to leverage the platform capacity of genome editors. This would be particularly useful for rare diseases unlikely to be supported in specific clinical trials. Initiative 4 would identify and disseminate best practices.

Discussion Highlights

- The discussants, Drs. Kristin Ardlie and Jian-Dong Li, provided their comments, noting that Phase 1 made significant progress, and expressed support for this initiative. Dr. Li asked about plans to monitor the long-term effects of genome editing given that the program lasts for 5 years and conducts clinical trials only during the last 2 years. Dr. Brooks agreed that this point needs to be addressed. While the Common Fund does not allow additional phases to this program, the institutions or industry partners conducting the trials could implement long-term monitoring.
- Responding to Dr. Ardlie's questions, Dr. Brooks commented that the program believes that projects funded under Initiative 1 will be able to adapt to rapid changes in the field, but program staff will verify this assessment as the project progresses. Ideally, assays developed during Initiative 1 will be integrated into projects in Initiative 2 and Initiative 3.
- When asked how researchers will know what cell type is relevant to the gene of interest, Dr. Brooks clarified that this program would best fit diseases with a known target cell type.
- Dr. Brooks theorized that one potential challenge for general application of viral vectors, such as AAV, is the ability to scale up broadly applicable delivery vehicles to treat common diseases. Given the recent experience with mRNA vaccines, a messenger RNA encoding a genome editor and a nanoparticle may be one promising method.
- In response to a question about moving into trials sooner rather than later to identify practical challenges, Dr. Brooks explained that the goal is to first explore the regulatory path for clinical trials of more than one disease by focusing on the goal of obtaining an IND approval from FDA. Once the project obtains an IND, clinical trials will assess the practicality of the approach.
- Council members encouraged Dr. Brooks to add ethical reviews of the applications. Although the project is focused on somatic editing rather than germline editing, which the NIH does not allow, clinical trials will require ethical oversight. Dr. Brooks agreed with this point.
- When asked about the likelihood of FDA approval for a broadly targeting editor, Dr. Brooks explained that FDA is planning a guidance document for genome editing with one disease and multiple guide RNAs, so that, in his opinion, extending that to multiple diseases seems likely.

One goal of this program is to streamline the regulatory pathway. Dr. Brooks suggested that discussing this with FDA early in the regulatory process, and with specific questions has been useful in other NIH-funded projects.

- In response to a question about prospects for commercialization and plans to ensure equity in access to these treatments, Dr. Brooks commented that commercial partnerships might be an option for SCGE Phase 2. However, NIH has little control over drug pricing. Council members pointed out the need to remain mindful of equity and access to the results of NIH investments of taxpayer money. Dr. Brooks agreed.

Vote

A motion to approve the Somatic Cell Genome Editing Program—Phase 2 concept was forwarded and seconded. The motion passed with no abstentions.

V. 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 155 ORIP applications with requested first-year direct costs of $744,534,176 and 173 OSC Common Fund applications with requested first-year costs of $138,752,304.

VI. UPDATES FROM THE NIH

Francis S. Collins, M.D., Ph.D., Director of NIH, updated the Council on recent staffing changes. He summarized the intense focus NIH has placed on COVID-19—specifically therapeutics and vaccines through the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) program and diagnostics through the Rapid Acceleration of Diagnostics (RADx) program. The success of vaccine-related efforts was based on many years of basic science research on messenger RNA and coronavirus spike proteins, leading to the rapid development of the vaccine candidates. The two mRNA vaccines, Pfizer and Moderna, have very high efficacy and reasonable safety records. Despite a strong start to the United States vaccination campaign, the combination of vaccine hesitancy and the Delta variant has led to a current rate of about 150,000 cases and 2,000 deaths per day. The Delta variant is incredibly contagious and outcompetes all other variants that are currently circulating. Dr. Collins commented that the United States is one of the hardest-hit countries in the current phase of the COVID-19 pandemic.

Dr. Collins noted that the first priority is to vaccinate the remaining unvaccinated individuals, but booster shots for vaccinated individuals—particularly more vulnerable populations—were under consideration by FDA at the time of this meeting. Vaccine elicited immunity against infection seems to be waning, especially in regard to highly transmissible Delta variants. Recent data from Israel, which vaccinated its population about 3 months before the United States, show that those in all age groups who received vaccinations earlier are having more breakthrough infections. Although many of these breakthrough cases may be less severe than in unvaccinated individuals, cases of prolonged symptoms, known as long

[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.

COVID, remain possible. Severe breakthrough infections were much more common in individuals 60 years and older as time from vaccination increased, and the same trend, with less frequency, occurred in other age groups. Dr. Collins commented that these data are convincing in suggesting booster shots for those 60 years and older, with additional considerations for other age groups. Data from Israel show a substantial increase in protection from both infections and severe disease after a booster shot. No information is available on whether transmission also is reduced.

In regard to therapeutics, Dr. Collins noted that monoclonal antibodies have shown success only when given early in the disease progression, but immunomodulatory strategies are only successful later in the progression. Anticoagulation strategies also have shown benefit in hospitalized patients, but not at later stages of the disease course. He pointed out that knowing most compounds tested through ACTIV were unsuccessful is useful. A new program, the Antiviral Program for Pandemics, will search for a more targeted approach to block the viral lifecycle.

Dr. Collins noted that the COVID-19 pandemic has illuminated many health disparities. In response, NIH developed the Community Engagement Alliance Against COVID-19 (CEAL) initiative, which aims to connect with community experts and ensure clinical trials are inclusive of underrepresented and vulnerable populations. Another new initiative, Researching COVID to Enhance Recovery (RECOVER), aims to follow 30,000 participants to study the predictors of long COVID. The diagnostics effort through RADx that was designed to speed the development of rapid, point-of-care, and at-home tests resulted in 32 new technologies that now are commercially available. RADx included a focus on underserved populations, who often have less access to testing. He commented that some of the RADx activities may help improve access during the next pandemic with diagnostic platforms that can be applied broadly.

Dr. Collins outlined the Advanced Research Projects Agency for Health (ARPA-H) initiative, a proposed new entity at NIH that will identify programs that fall into a gap between existing sectors and, if successful, could provide remarkable advances quickly. ARPA-H requires a different structure and culture than other initiatives, and it will focus on use-driven ideas that will return benefits to patients rapidly.

Dr. Collins also provided an update about the UNITE Initiative, an effort to address structural racism in the biomedical research community. More than 100 NIH intramural and extramural researchers are participating in one of the five UNITE groups. This initiative recognizes that NIH needs to: expand the diversity of its workforce; advance research on health disparities that is more focused on interventions; improve the NIH intramural and extramural biomedical research culture; and improve its transparent communications with stakeholders. A Common Fund initiative focused on transformative health disparities research and a request for applications to examine the effects of structural racism and discrimination are planned. NIH also will share the demographics of its own workforce more publicly.

Discussion Highlights

- In response to a question about platform technologies, Dr. Collins noted that efforts are in place to use the lessons learned from the response to the COVID-19 pandemic to prepare for future pandemics, including platforms that can be utilized broadly. One step would be to target the 20 most likely next pandemic pathogens and begin preparing vaccines and antivirals for those pathogens now.
- When asked about a change to FDA regulations for vaccines, Dr. Collins commented that FDA has suggested that making minimal changes to the COVID-19 vaccines to adjust to variants would require smaller trials to approve.

- Council members encouraged NIH to learn more about the Telemedicine and Advanced Technology Research Center (TATRC), which has a similar goal to ARPA-H and may be able to provide guidance in planning for ARPA-H.
- In response to a question about whether ARPA-H would address rare disease research, Dr. Collins commented that ARPA-H has been proposed, but not yet been enacted and it will depend on whether Congress includes it in the fiscal year 2022 appropriation to NIH. After ARPA-H has been established, the projects will be decided by a director and program managers. He suggested that rare diseases could be an area of considerable interest and a high priority if a project was proposed that is aligned with ARPA-H goals. Other projects related to rare diseases could include an upcoming gene therapy program through the Accelerating Medicine Partnership with FDA to standardize gene therapy approvals.
- Dr. Collins commented that IC directors are beginning to submit ideas for ARPA-H projects and collaborations; however, the ARPA-H director will decide which projects to support.
- Dr. Collins stated the RECOVER project would aim to deliver the latest findings to primary care providers and specialists treating long COVID patients. Many institutions with long COVID clinics are participating in RECOVER and simultaneously testing potential treatments and collecting results. He stressed how little is understood about the condition and the necessity of gathering more information before beginning clinical trials. The early stages of the RECOVER project will center more on data gathering including gaining knowledge of what is happening in real-world clinics and sharing that information.
- When asked if recipients of NIH grants will be required to describe their efforts toward addressing structural inequalities, Dr. Collins responded that the E group in the UNITE initiative is examining extramural grant partners and encouraging them to improve beyond NIH itself. While the group has not yet outlined its recommendations, Dr. Collins acknowledged the high levels of interest in seeing change happen.

VII. COMMON FUND CONCEPT CLEARANCE: HARNESSING DATA SCIENCE FOR HEALTH DISCOVERY AND INNOVATION IN AFRICA (VOTE)

Laura Povlich, Ph.D., a Program Director in the Division of International Training and Research at the Fogarty International Center, presented on the Harnessing Data Science for Health Discovery and Innovation in Africa (DS-I Africa) program, which was cleared by the Council in September 2019. The goal of the program is advancing new health discoveries and catalyzing innovation in health care, public health, and health research in Africa through the application of data science. Sub-goals of DS-I Africa included: catalyzing new collaborations and exploring the state of the health data science field in Africa; advancing health data science research in Africa and supporting new African and global partnerships that spur innovation and enhance impact; increasing health data science capacity in Africa; exploring the ethical, legal, and social implications (ELSI) affecting health data science from an African perspective; and facilitating the development of a trans-African network of data scientists and coordinating the administrative functions of the network.

The first stage of the program has implemented several activities successfully. A virtual symposium and webinar series held in August through October 2020 included more than 2,000 registrants from 50 disciplines and 36 African countries and allowed networking among academic, public, and private-sector participants. About 80 percent of survey respondents met at least one potential collaborator through the symposium. Four funding opportunity announcements (FOAs) were released, and a large number of applications were submitted. DS-I Africa is funding seven research hubs, seven research training

programs, four ELSI research projects, and one open data science platform and coordinating center. The awardees and collaborators represent 18 countries across Africa.

These early successes also have illuminated some ways to improve the program through additional FOAs. Significant interest in health data science and innovation is expressed by African investigators with novel ideas, but many new and early-stage investigators working in the health data science field, as well as newly formed collaborative teams, tend to have limited success with complex applications. This is an opportunity to leverage these researchers' expertise and make the consortium more inclusive. The program also recognizes the need for a variety of capacity-building mechanisms for an Africa-wide data science consortium. Degree-focused research training is proceeding, but the program recognizes that other modalities could be implemented to enhance capacity.

DS-I Africa proposes two new FOAs to enhance the consortium in fiscal years 2023 through 2025. The Partnership for Innovation Research Projects would support discrete research projects led by African investigators to expand the DS-I Africa network. Applicants would propose innovative health data science research and solutions in Africa with a new nonacademic partner that enhances the impact of the research. This FOA would target $3 million per year to support 12 or more awards, with at least half designated for new or early-stage investigators to enhance the career pipeline and retention of health data scientists in Africa. The second FOA, Research Education Awards, would complement or enhance existing long-term training awards in the DS-I Africa Consortium by filling gaps and extending the reach of the consortium's education programs. This FOA would target $1 million per year to support at least five awards. Aligned with the existing goals of the program, the Partnership for Innovation Research Projects will advance health data science research in Africa and support new partners, and both FOAs will increase health data science capacity in Africa.

Discussion Highlights

- The discussants, Drs. Sachin Kheterpal and Kevin Johnson, provided their comments. Dr. Kheterpal expressed enthusiasm for the initiative and requested details about the relationship between the previous and new FOAs. Dr. Povlich explained that because the new FOAs are designed to expand the existing infrastructure, new projects will not be required to connect to previous hubs. While currently supported institutions have experienced researchers and existing capacity, more discrete single research projects could support newer investigators who have not been able to compete previously. Many new and early-stage investigators in this field lack the institutional capacity to compete for awards, but have significant creative ideas. Those researchers need a way to connect to the consortium and its benefits.
- Dr. Kevin Johnson concurred with Dr. Kheterpal's points and commented that requiring nonacademic partners may limit the pool of eligible early-stage investigators. Dr. Povlich noted that the new initiatives would be open to both early-stage and established investigators, but at least half of the awards would be designated for early-stage investigators. Nonacademic partnership is a central theme for DS-I Africa, but the program is developing strategies for applicants to collaborate with new partners. The digital workshop held in 2020 identified a pool of eligible potential partners.
- Dr. Povlich confirmed that the budget requested is in addition to the funding approved in 2019.

Vote

A motion to approve the DS-I Africa concepts was forwarded and seconded. The motion passed with no abstentions.

VIII. NIH LASKER CLINICAL RESEARCH SCHOLARS PROGRAM (VOTE)

Charles R. Dearolf, Ph.D., the Director of Program Development and Support in the Office of Intramural Research, provided an overview of the NIH Lasker Clinical Research Scholars Program, which is designed as a career development program for clinical researchers at the tenure-track level. He commented that at the September 2020 Council meeting, the Council was supportive of the concept in principle, but postponed a vote on soliciting new applications and requested additional clarity on program goals, metrics of success, and the mentoring component. The program conducted a survey of scholars' views and a bibliometric analysis of their productivity. Dr. Dearolf commented that the results indicate that the program is on the right trajectory, but the results are limited by the program's duration and size. He asked the Council to vote to continue the program with a more extensive evaluation planned that will include outside review.

Dr. Dearolf described the Lasker Clinical Research Scholars program that aims to develop leaders in clinical research by supporting selected investigators in the early stages of their independent careers. The program allows the Lasker Scholars to take advantage of the environment and resources in intramural NIH research while simultaneously establishing themselves as peer-reviewed, NIH-funded investigators. Candidates are early-stage clinical researchers who can conduct independent clinical research, but do not hold a tenured position. Lasker Scholars come to the NIH for 5 years, which can be extended for 2 additional years. Current Lasker Scholars can request an additional year in the intramural program to compensate for lost productivity due to the COVID-19 pandemic. Following their time in the NIH Intramural program, Lasker Scholars can either leave for a position at an outside research institution and receive an R00 award for 3 years and up to $500,000 in direct costs per year, or they can remain in the NIH intramural research program. The funding for the Lasker Clinical Research Scholars is provided by the NIH IC that made the award. ICs decide whether to participate each year based on their projected resources and scientific needs.

Dr. Dearolf reported that this program was initiated 10 years ago and has had 36 scholars to date. The 36 current and past Lasker Scholars started the program at an average age of 41years. Dr. Dearolf expressed satisfaction that the program has awarded a balanced number of men and women, as well as seven investigators who are in underrepresented demographic groups. Eleven ICs have supported Lasker Clinical Research Scholars, and several scholars have completed the program with distinguished results. He commented that the majority of the Lasker Scholars have started in the last few years. Four Lasker Clinical Research Scholars have earned tenure at the NIH; two of these have applied for the R00 funds, and the other two remain at the NIH. Another awardee of the program left for a position in industry. He stated that a definitive evaluation of the program cannot yet be performed because it is a relatively new endeavor with few meaningful comparison groups available due to the small number of Lasker Scholars and the limited length of the appointments so far. Dr. Dearolf commented that the program is performing as desired and requested continued support.

Dr. Dearolf noted that encouraging promising clinical researchers to pursue biomedical research benefits public health and aids in the prevention and treatment of disease. As most of the Lasker Clinical Research Scholars program funding is provided by NIH's intramural program, the extramural scientific community benefits from the program. NIH's intramural program also benefits from the long-term NIH career options this program provides. Lasker Scholars have the opportunity to take advantage of the resources of intramural NIH, including the Clinical Center - the nation's largest hospital devoted entirely to clinical

research - which has a culture supportive of translating findings from the laboratory to the clinic and enabling first-in-human studies. The Clinical Center also provides state-of-the-art resources and a centralized institutional review board and bioethics department to facilitate regulatory aspects. The Lasker Scholars have protected time to conduct their research and have a reduced number of academic service obligations. He noted that some of the awardees in this program have maintained affiliations as adjunct faculty with their previous institutions.

Dr. Dearolf reported that mentoring is an important component of the program with scholars meeting with IC-level mentors or mentoring committees periodically. The Lasker Scholars choose their mentors. Since most of the Lasker Scholars are part of a larger laboratory or branch, there are opportunities for additional mentorship provided by the chiefs of these groups. The NIH Office of Intramural Research also provides several faculty development activities. Several Lasker Scholars have developed informal peer interactions with others in this program from their IC. Many Lasker Scholars have themselves volunteered to serve as peer mentors, and others have been members of the NIH Distinguished Scholars Program, which supports investigators with a documented history of improving diversity and inclusion in the biomedical workforce.

Dr. Dearolf noted that qualitative and bibliometric metrics will continue to be used to assess the long-term success of the program. The qualitative metrics assess the Lasker Scholars' contributions and recognition within the scientific community. He reported that the DPCPSI Office of Portfolio Analysis conducted a bibliometric analysis of the program that considered publication counts, the relative citation ratio, the clinical impact, and the approximate potential to translate. Comparison groups were extramural principal investigators with a clinical degree and evidence of clinical research who are starting their first R01 awards and a second group developed with coarsened exact matching. Despite the limitations of analyzing a small number of Lasker Scholars with a short duration of appointment, the analysis did not identify any statistically significant differences between the Lasker Scholars group and either extramural comparison group currently. Additional analysis will be possible after more time has passed, and more data are available.

Discussion Highlights

- The discussants, Drs. Russell Van Gelder and Jean Schaffer, provided their comments. Dr. Van Gelder noted that several of the current Lasker Scholars have extremely successful rates of productivity. However, several others had less impressive records of publication, which concerned Dr. Van Gelder given the expense of the program. He noted that the survey results were less transparent than ideal and not always encouraging, particularly the ~50% satisfaction with mentoring. Dr. Van Gelder supported the overall concept of the program and its continuation, but recommended a short renewal of 2 years to allow a formal extramural evaluation of the program. Dr. Schaffer agreed with Dr. Van Gelder's suggestions.
- Dr. Schaffer cautioned that career satisfaction surveys may be a relatively weak metric of success. While the bibliometric analyses showed no statistical difference between the Lasker Scholars and a comparison group, actual primary data would have helped to place this conclusion into context. The Clinical Center is an outstanding facility for clinical research. However, some areas of clinical science are not well-represented, a factor that may limit the pool of applicants for this program. Another potential limitation is that the move(s) entailed in the program may discourage some potential applicants from consideration of the program or potentially impact productivity. Dr. Dearolf explained that when researchers apply, he recommends that they discuss their research plans with a contact from an IC to determine whether the Lasker Program would be appropriate.

- Dr. Dearolf explained that the 36 Lasker Scholars were selected from 135 applicants, many of whom had conducted independent research previously. Council members suggested assessing the productivity of applicants who were not chosen as Lasker Scholars as a comparison group.
- Council members wondered if some of the Lasker Scholars could be supported at their home institutions to broaden the benefits of the program and decrease the requirements associated with moving to and from the NIH intramural program.
- When asked about the program's support for researchers from underrepresented groups, Dr. Dearolf commented that 7 of the 36 current Lasker Scholars are members of underrepresented populations. Dr. Michael Gottesman, the Deputy Director for Intramural Research, explained that the program has collaborations with the local community, such as an agreement with Howard University to exchange clinical researchers. Dr. Gottesman noted that everyone who applies to a tenure-track position at NIH must demonstrate a commitment to diversity, equity, inclusion, and accessibility.
- In response to a question about mechanistically oriented investigators, Dr. Dearolf commented that the ICs select the research areas they are interested in.

Vote

A motion to approve the reissue of the NIH Lasker Clinical Research Scholars Program concept as presented was forwarded and seconded. The motion failed, receiving 7 yes votes, 10 no votes, and 1 abstention. A new motion to approve the reissue of the concept for 2 years with a required formal external review of the program was forwarded and seconded. The motion passed with one abstention.

IX. SEQUENCE READ ARCHIVE (SRA) DATA WORKING GROUP FINAL REPORT (VOTE)

Susan Gregurick, Ph.D., the Associate Director for Data Science and Director of ODSS and Kristin Ardlie, Ph.D., the Director of Genotype Tissue Expression at the Broad Institute of MIT and Harvard University presented the final report of the Sequence Read Archive (SRA) Data Working Group. Dr. Gregurick presented background information on SRA. The SRA is a large and diverse data set representing genomic diversity from various sources. To enhance the usability of SRA, this data resource was transferred to the cloud beginning in 2019 through a partnership with the NIH Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) Initiative. Two copies of the SRA—comprising both controlled-access human and open-access sequences—are maintained through the Google Cloud Platform (GCP) and Amazon Web Services (AWS). The SRA has increased exponentially in size over the past several years, creating challenges for both storage and use.

To maintain cost on both cloud service providers, SRA is partitioned between "hot" (i.e., active and computable) and "cold" (i.e., archived) storage. Cold data can be "thawed "and moved into computable, active memory at the expense of NIH. The 2020 SRA Working Group had proposed several funding models for SRA storage in the cloud. A hybrid model was recommended and implemented in 2020 allowing for the distribution of the data between hot and cold storage. Dr. Gregurick noted that the partnership of AWS and the Open Data Sponsorship Program has enabled storage of open-access data through the open data platform in AWS, which has reduced costs for SRA storage in 2021 by roughly $2 million. The Working Group noted that allocating more data to cold storage would further reduce costs.

The 2021 Working Group was charged by this Council to focus on evaluation of the SRA as a resource and related issues, including but not limited to: (1) analysis and evaluation of strategies for/changes to SRA data storage, management, and access, including impact for the biomedical research community; (2)

recommendations on data retention, data models and/or data usage that will keep costs to NIH within sustainable levels while maintaining community access to this large public data resource; and (3) vision for future needs or opportunities, including sustaining the SRA as a community resource.

Dr. Ardlie outlined the Working Group's four recommendations: (1) Promote cloud usage and ensure SRA data usage with equity and sustainability; (2) explore data usage, access frequency, and tolerance for cloud data retrieval in the cost model; (3) consider incentives for researchers using the SRA to develop tools and algorithms for cloud computing; and (4) evaluate the impact of the SRA. The Working Group compiled bullet points outlining considerations for each recommendation.

Several key performance principles for evaluating the success of the SRA were identified. These items were grouped by data quality (i.e., creation and distribution of data formats that meet criteria for fitness for purpose; distribution of SRA, biosample, and bioproject metadata with sequence data; development of tools to support search of data; and improvements to the value of data) and equitable user access (i.e., distribution of data in hot and cold storage, support for data access for both cloud and non-cloud users, replication of the SRA among STRIDES cloud service providers, user costs on data retrieval and egress to different cloud platforms, training and outreach for competency, and development of partnerships among U.S. government agencies).

The report also included a section on future work and considerations. The Working Group members suggested establishing an advisory committee to provide further input on this topic. Future areas for consideration include user-centered focus, interoperability standards to extend impact and reduce cost, streamlining guidance for cloud costs, intermediate or processed data provided on cloud platforms, a funding mechanism to support optimizing the existing cloud computing tools, promotion of multi-cloud optimization of highly used and new tools, and promotion of the submission of robust sample metadata.

Discussion Highlights

- Dr. Anderson commented that the Council does not edit or rewrite the report or recommendations; rather members are asked to vote on whether the report and recommendations are adequate and may elect to convey further views on the report in a letter to Dr. Collins.
- Dr. Gregurick noted that Microsoft Azure recently partnered with NIH through the STRIDES Initiative. Dr. Gregurick will work with the National Center for Biotechnology Information to determine the best way to engage Azure to include the SRA.
- When asked about adding analytic tools for basic users on cloud platforms, Dr. Ardlie explained that optimization of tools differs among cloud environments and that Recommendation 4 addresses this point. Use of tools differs among communities, and a funding mechanism is needed to optimize tools for multiple communities. Council members emphasized the importance of considering the needs of novice users.

Vote

A motion to accept the SRA Data Working Group Final Report was forwarded and seconded. The motion passed with no abstentions.

X. ONR CONCEPT CLEARANCE: ADVANCED TRAINING IN ARTIFICIAL INTELLIGENCE FOR PRECISION NUTRITION SCIENCE RESEARCH—INSTITUTIONAL RESEARCH TRAINING PROGRAM (VOTE)

Christopher J. Lynch, Ph.D., the Acting Director of ONR, presented on the new Advanced Training in Artificial Intelligence for Precision Nutrition Science Research (AIPrN) T32 program. This training program will support the development of a diverse research workforce that will possess advanced competencies in artificial intelligence (AI) and machine learning (ML) to apply innovative transdisciplinary approaches to an increasingly complex landscape of Big Data on nutrition- and diet-related chronic diseases. ONR plans to fund 8 to 12 highly meritorious programs for up to 5 years. Participants at ONR's Precision Nutrition Workshop in January 2021, noted a critical need for this type of training because the usual advanced courses in nutrition and biomedical sciences do not include training in AI, data science, and computational approaches required to analyze the increasingly diverse data sets being made available. This training can help nutritional researchers develop algorithms that could make pivotal discoveries and tackle complex biomedical challenges in diet-related chronic diseases. He noted that none of the existing 1,809 NIH T32 programs focus on AI or ML, and only 28 programs were related to bioinformatics or data science. Two of those 28 programs were related to nutrition, showing a need for this type of program.

Trainees in this proposed new program will acquire core knowledge in three overarching relevant areas: AI, including ML, with competencies in computer science and informatics; biostatistics and mathematics; and nutrition science, chronic disease pathophysiology, and systems science in a chosen health domain relevant to the ICs participating in the program. The aspects of AI and biostatistics studied should be directly relevant to nutrition systems science. The program is intended for both predoctoral and postdoctoral trainees, and predoctoral trainees would be appointed in the early stages of their doctoral program for a minimum of 2 years, with an additional 1 to 2 years as justified by program plans. ONR intends to convene and facilitate annual cross-site exchanges among the faculty and trainees for team building. Each institutional training program would include interdisciplinary faculty, and applicants will be required to assemble an interdisciplinary team of scientific mentors to design and direct a program matched to the applicant's expertise. Applications must include mentors from both nutrition science and AI-related disciplines, and trainees ideally should have at least two primary mentors with different areas of expertise to foster a cross-disciplinary training experience.

Discussion Highlights

- The discussants, Drs. Anna Maria Siega-Riz and Andrew Feinberg, provided their comments. Dr. Siega-Riz expressed her strong support, confirming that few opportunities in this field currently exist for this proposed program and this training will be needed to make full use of data sets, such as *All of Us*. She commended the emphasis on prioritizing trainees who are from underrepresented backgrounds and making the grants available within diverse institutions that have policies and procedures in place to support equity in the workforce and conduct health disparities. She commented that this program would ease some of the many challenges faced by students who want to undertake such training, and the cross-program team building would allow award recipients and faculty to begin creating a network within this field. Dr. Siega-Riz expressed concern that some applicants could be enrolled in an M.S./RD credentialling program. Given the complexity of such programs, adding this AI/ML training might be too much to accomplish, but Dr. Siega-Riz expressed her hope that some best practices could be developed to overcome this obstacle.

- Dr. Feinberg expressed his strong support, noting that this program could serve as an example of how to integrate AI or ML into T32 programs. He emphasized the need to provide a clear

representation of AI and a description of what the AIPrN requires to applicants and recommended changing the joint training from being encouraged to a requirement. Dr. Feinberg also noted the importance of considering the effects of policy recommendations on the program and suggested including the ability to conduct sensitivity analyses.

Vote

A motion to approve the concept clearance for the AIPrN—Institutional Research Training Program concept was forwarded and seconded. The motion passed with no abstentions.

XI. OBSSR CONCEPT CLEARANCE: TIME-SENSITIVE OPPORTUNITIES FOR HEALTH RESEARCH (VOTE)

Sarika Parasuraman, Ph.D., M.P.H., a Health Science Policy Analyst in OBSSR, introduced the Time-Sensitive Opportunities for Health Research concept, which would establish a FOA with a rapid turnaround time to support novel, time-sensitive research. The research would be aimed at investigating biological or behavioral outcomes related to unexpected events, particularly enactment of a new policy, a natural event, or a change to the existing environment or infrastructure. The proposed mechanism is a program announcement with special receipt, referral, or review considerations (PAR) structured as a bi-phasic R61/R33 (with clinical trials not allowed) that would support a maximum of 2 years for the first phase of research to collect baseline and pre-implementation data and a maximum of 3 years to support the follow-up work. This time-sensitive mechanism would meet an important need identified by multiple ICs. The expedited nature would enable NIH to translate research immediately to advance science, and it would have far-reaching implications for a better understanding of success or lack of success to inform policy and program implementation.

IC and Office (ICO) representatives have expressed repeated interest in exploring a broad crosscutting initiative for time-sensitive behavioral and social science focused research across multiple ICOs, a need that aligns with OBSSR's mission and NIH's history. A NIH working group with program and scientific review officers experienced in this type of research emphasized the importance of defining time sensitivity. For these purposes, time sensitivity reflects an urgency in the data collection opportunity rather than time sensitivity of the research as a whole. While the time sensitivity of data collection may be somewhat unpredictable, a clear scientific value and feasible study design may make it possible. Otherwise, the window of opportunity to collect key baseline data will be limited/constrained. Current FOAs in this area fund projects within 4 to 6 months, which can yield much more useful data than the typical award timeline of 9-12 months from application submission to grant award.

Dr. Parasuraman noted several previous time-sensitive FOAs addressed such issues as: the effect of salad bars on student food consumption; a study of the impact of drug-related policy changes on public health; and exposure to environmental pollutants after disaster events. More recently, projects related to COVID-19 have shown the importance of flexible and nimble time-sensitive mechanisms. She outlined several more detailed examples, such as a study of the effects of a change in school start times on student health that needed to collect its baseline data before the change to start times. A study of the effects of changes in opiate prescribing laws on prescribing practices, perspectives of stakeholders, and availability and presence of opiates in the state required baseline data collection on prescribing practices before the law was enacted. She cited another study that assessed the effects of perfluoroalkyl and polyfluoroalkyl substances (PFAS) on marine fish and shellfish because the policy landscape around regulation and remediation was evolving quickly, the researchers wanted to collect baseline data quickly before the regulations took effect to be able to assess changes.

Dr. Parasuraman reported on key considerations identified by the working group including the need to focus on the methodological rigor of the study designs and support primary data collection for baseline or pre-implementation data. Research should apply experimental methodologies that have been used successfully for natural experiments in the past, primarily those that would strengthen the ability to identify causal inference. The inclusion of a comparison group, if possible, would be encouraged strongly, especially because randomization might not be possible for this type of research. The working group also strongly supported strict responsiveness criteria to ensure that applications are appropriate for a time-sensitive award. Additionally, applications should clearly establish the generalizability and relevance of study findings for United States populations, which aligns with expectations that results will be returned quickly.

Discussion Highlights

- The discussants, Drs. Graham Colditz and Maria Rosario Araneta, provided their comments. Dr. Colditz pointed out that the program has a monthly rolling submission deadline, which is important for rapidly supporting highly meritorious applications. He added that populations affected by natural disasters often are low income and under-resourced, so this approach can help with issues of equity in conducting research across populations.

- Dr. Araneta suggested including unnatural events - such as domestic and foreign attacks of violence - and considering regionally time-sensitive events in addition to nationally time-sensitive events. She asked about the potential for additional ICOs to participate in this initiative and the possibility of adding an administrative supplement to existing grants to expedite urgent research priorities. Dr. Parasuraman explained that they still are conducting outreach, so additional ICOs may participate. OBSSR plans to issue one PAR with ICO partners that may or may not participate depending on their individual priorities. Regarding the administrative supplement, she clarified that they are still exploring all their options, so she will bring that suggestion to the working group. She added that this program is envisioned as a short-term pilot, so any feasibility challenges can be addressed before determining if this is a viable long-term funding strategy and mechanism.

- In response to a question about communicating results of studies to the public, Dr. Parasuraman acknowledged the need to disseminate research findings in the field. Investigators would be encouraged to accomplish their study aims in an expedited way, and communication of findings will be a part of that. Previous funding opportunities included components for partnerships with community groups, which also would be important for outreach.

Vote

A motion to approve the concept clearance for the OBSSR Time-Sensitive Opportunities for Health Research concept was forwarded and seconded. The motion passed with no abstentions.

XII. CLOSING REMARKS

Dr. Anderson thanked the Council members and speakers for their contributions at this meeting. He reminded the members that the next Council meeting is scheduled for January 2022 and may be virtual or in person.

XIII. ADJOURNMENT

Dr. Anderson adjourned the meeting at 5:04 p.m. on September 17, 2021.

XIV. CERTIFICATION

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

James M. Anderson -S

Digitally signed by James M. Anderson -S
Date: 2021.11.02 20:27:05 -04'00'

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

Date

Robert Eisinger

November 2, 2021

Robert W. Eisinger, Ph.D.
Executive Secretary, NIH Council of Councils
Senior Scientific Advisor, DPCPSI, OD, NIH

Date