

**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
January 29, 2021**

Meeting Minutes

I. REVIEW OF GRANT APPLICATIONS

This portion of the meeting was closed to the public, in accordance with the provisions set forth in Sections 552(b)(c)(4) and 552(b)(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix).¹ Members were instructed to exit the meeting if they deemed that their participation in the deliberation of any matter before the Council would represent a real or perceived conflict of interest. Members were asked to sign a conflict-of-interest/confidentiality certification to this effect. The *en bloc* vote for concurrence with the initial review recommendations was affirmed by all Council members present. During the closed session, the Council concurred with the review of 414 ORIP applications with requested first-year direct costs of \$328,002,862.

II. 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 11:00 a.m. on Friday, January 29. The meeting attendees are identified below. 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: Franziska B. Grieder, D.V.M., Ph.D., Director, Office of Research Infrastructure Programs (ORIP), DPCPSI

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

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

Jeffrey R. Botkin, M.D., M.P.H., The University of Utah, Salt Lake City, UT

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

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.

Patricia D. Hurn, Ph.D., R.N., University of Michigan, Ann Arbor, MI
R. Paul Johnson, M.D., Emory University School of Medicine, Atlanta, GA
Paul J. Kenny, Ph.D., Icahn School of Medicine at Mount Sinai, New York, NY
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
Michael D. Lairmore, D.V.M., Ph.D., University of California, Davis, Davis, CA
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., Joslin Diabetes Center, 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
Kevin B. Johnson, M.D., M.S., Vanderbilt University Medical Center, Nashville, TN

2. Liaisons

Joseph M. Betz, Ph.D., Acting Director, Office of Dietary Supplements, DPCPSI
Janine A. Clayton, M.D., Director, Office of Research on Women's Health, DPCPSI
Maureen M. Goodenow, Ph.D., Director, Office of AIDS Research, DPCPSI
Susan K. Gregurick, Ph.D., Director, Office of Data Science Strategy, DPCPSI
Franziska B. Grieder, D.V.M., Ph.D., Director, ORIP, DPCPSI
Christopher J. Lynch, Ph.D., Acting Director, Office of Nutrition Research, DPCPSI
Rebecca Meseroll, Ph.D., representing **George Santangelo, Ph.D.**, Director, Office of Portfolio
Analysis (OPA), 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,
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 R. Wilson, Ph.D., Director, Tribal Health Research Office, DPCPSI

3. *Ex Officio* Member Present

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

4. Presenters

Dara R. Blachman-Demner, Ph.D., Health Scientist Administrator, OBSSR, DPCPSI
Gene Civillico, Ph.D., Stimulating Peripheral Activity to Relieve Conditions (SPARC) Program
Manager, OSC, DPCPSI

Graham A. Colditz, M.D., Dr.P.H., M.P.H., Council of Councils Member
Franziska B. Grieder, D.V.M., Ph.D., Director, ORIP, DPCPSI
Christine Hunter, Ph.D., Deputy Director, OBSSR, DPCPSI
Michael D. Lairmore, D.V.M., Ph.D., Council of Councils Member
Terry Magnuson, Ph.D., Former Council of Councils Member
William T. Riley, Ph.D., Director, OBSSR, DPCPSI
Douglas Sheeley, Sc.D., Program Leader, OSC, DPCPSI
Erica Spotts, Ph.D., OBSSR, DPCPSI
Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH

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 B. Grieder, D.V.M., Ph.D., the executive secretary for the NIH Council of Councils, reviewed the following:

- Council members are Special Government Employees during the days of Council meetings and are therefore subject to the rules of conduct governing federal employees.
- Each Council member submitted a financial disclosure form and conflict-of-interest statement in compliance with federal requirements for membership on advisory councils. The financial disclosures are used to assess real and perceived conflicts of interest, and Council members must recuse themselves from the meeting during discussions of any items for which conflicts were identified.
- Time is allotted for discussion between the Council members and presenters, but time for comments from other meeting attendees is limited. The public may submit comments in writing; instructions are available in the *Federal Register* notices for the meeting, which were published on November 25, 2020, and January 11, 2021.
- Minutes from the September 11, 2020, 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 May 20–21, 2021, and either in person or virtually on September 17, 2021. Although these dates are reserved, the duration of each meeting is not yet confirmed.

III. NIH UPDATE

Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director of the NIH, noted the increase in NIH's budget for fiscal year (FY) 2021 to \$42.9 billion, including a number of specific increases. Additional supplemental bills provide funding for work related to the COVID-19 pandemic; these funds are available through FY 2024, which provides flexibility to continue to respond to the pandemic.

Dr. Tabak provided an update on the presidential transition. Designees for science posts include Xavier Becerra as Secretary of Health and Human Services and Dr. Eric Lander as the Director of the Office of

Science and Technology Policy (OSTP), a role that Dr. Tabak noted will be a member of the President's cabinet for the first time. Dr. Lander already has begun to serve in his role of science advisor but is awaiting Senate confirmation for serving as the head of OSTP and a member of the cabinet. Dr. Francis Collins will remain the Director of the NIH, and Dr. Rochelle Walensky has been appointed the Director of the Centers for Disease Control and Prevention (CDC). Dr. Anthony Fauci remains the director of the National Institute of Allergy and Infectious Diseases (NIAID) and has taken an additional role as the Chief Medical Advisor to President Biden. Additional members of the Biden Health Team include Carole Johnson as COVID-19 Testing Coordinator, Dr. David Kessler as Vaccine Chief, Dr. Marcella Nunez-Smith as COVID-19 Equity Task Force Chair, and Jeff Zients as COVID-19 Response Coordinator. Dr. Rachel Levine is the designate for the Assistant Secretary for Health, and Dr. Vivek Murthy will return as the U.S. Surgeon General. Dr. Tabak noted President Biden's commitment to applying the lessons of the pandemic broadly, using science and technology to address pressing issues, and ensuring that all Americans benefit from scientific progress.

Dr. Tabak outlined the progress of the many efforts related to the COVID-19 pandemic. The NIH has made significant progress toward meeting several of the priorities outlined in its *NIH-Wide Strategic Plan for COVID-19 Research*. Dr. Tabak emphasized the importance of ensuring that the results of these efforts are made accessible and available to the entire nation, including all underserved and vulnerable populations. The Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Network, a collaborative effort among many government, industry, and nonprofit partners, focuses on rapidly creating vaccines, conducting preclinical work to identify new treatments, improving clinical trial capacity and effectiveness, and testing the most promising treatments and therapeutics. ACTIV has been very successful, and Dr. Tabak noted several examples of these successes, stressing that it is a true collaborative network.

Dr. Tabak emphasized that the 11 months required to develop a vaccine for COVID-19 is an extraordinarily short timeline, built on a strong foundation of basic research developed over time. The first two vaccine candidates use an mRNA platform, which allows a highly efficient move to the clinic and a highly immunogenic vaccine, and each has emergency use authorization. Interim results of a third vaccine, from Johnson & Johnson, were released recently and will be submitted to the U.S. Food and Drug Administration; Dr. Tabak noted that this vaccine requires only a single dose, unlike the existing vaccines, and has less stringent storage requirements. Additional vaccine strategies show promise, and Dr. Tabak expressed the hope that all candidates would be effective to assist in vaccinating as many people as possible throughout the world.

The pandemic has underscored disparities in communities of color, and many overlapping factors result in an increased risk of COVID-19 complications for people from minority populations. Dr. Tabak also noted the longstanding mistrust of research and the health care system among communities of color, which has presented difficulties in enrolling minority participants to clinical trials for the vaccines and has persisted in a hesitance, particularly among Black adults, to receive the vaccine. Dr. Tabak emphasized that the NIH has an obligation to address these disparities, which led to the creation of the Community Engagement Alliance (CEAL) Against COVID-19 Disparities. Dr. Tabak pointed out the importance of CEAL's guiding principles, including building and sustaining trusting relationships in the community, acknowledging the role of social determinants of health, moving at the speed of trust, working with trusted voices and messengers at the local level, and building public-private partnerships at the community level. He provided an example of community outreach to increase minority participation in clinical trials for the Moderna vaccine and emphasized the importance of applying these lessons beyond the pandemic.

Dr. Tabak outlined the projects in the Rapid Acceleration of Diagnostics (RADx) program and elaborated on the successes of several. RADx Tech used an innovation funnel at a very large scale to solicit many

applications for point-of-care testing, followed by expert validation of a small group of promising efforts. Dr. Tabak noted that this effort demonstrated how the NIH and government can work rapidly in creative ways. RADx Underserved Populations is working through two phases to rapidly implement testing interventions and collect data on disparities, infection rates, and disease progression in minority communities, which will support development of strategies to reduce these that are tailored to the communities most at risk. The second phase soon will support applying these advances on the population level. Dr. Tabak reiterated that the infrastructure established through these efforts should be maintained for the future to continue addressing issues disproportionately affecting minority communities.

Dr. Tabak noted that the ongoing efforts at the NIH will acknowledge the inequities that exist in biomedical research. Five workstreams have been organized based on feedback from groups within and outside of the NIH to understand stakeholder experiences, consider the needs for internal and external workforces, improve communication, and continue to invest in health disparities research and pandemic-related issues.

Discussion Highlights

- When asked how the NIH can mandate reporting of minority subgroups, such as those who speak one of the many Asian languages, to identify communities in most urgent need of intervention, Dr. Tabak commented that the only way to approach such a complex issue would be to partner with local communities, which have a much better understanding of the diversity involved.
- In response to a question about plans for global partnership through ACTIV to address emerging variants, Dr. Tabak explained that many ACTIV partners are global companies and added that the Biden administration has reengaged with the World Health Organization, a crucial partner in this area. The NIH is working with CDC and other groups to enhance surveillance necessary to identify variants early and determine how to address them. Dr. Tabak emphasized that the global economy suggests that any global variants will reach the United States, underscoring the importance of global efforts.

IV. PRESENTATION OF THE UPDATED ORIP STRATEGIC PLAN (FY 2021–2025)

Dr. Grieder outlined the new ORIP strategic plan, which covers FYs 2021 through 2025. Under its tagline, “Infrastructure for Innovation,” ORIP focuses on trans-NIH activities in support of the NIH mission in three categories: grants in support of research resources within the NIH mission, activities that explore the next steps in science, and support for veterinary scientist training. ORIP recently played a significant role in the ACTIV program, focused on coordinating and participating in preclinical research planning for animal models. ORIP worked closely with the ACTIV team to assess and coordinate availability of animal models, determine which potential COVID-19 therapeutics to prioritize, promote the most promising agents, and lead the process of identifying resources required for this or future pandemics. ORIP also set up a website to list available animal models that can be used for COVID-19 studies, as well as ongoing ORIP-supported research and tools and resources for researchers.

Under the first ORIP Strategic Plan, ORIP staff contributed to 80 NIH working groups, both scientific and administrative, and organized nine workshops to engage NIH colleagues and extramural scientists, such as the recent 10-session Workshop on Validation of Animal Models. Dr. Grieder noted that ORIP’s support for veterinary scientist training is unique, and ORIP’s programs focus on institutional training awards across the entire United States at veterinary and medical schools, as well as other institutions. ORIP also supports individual training awards supporting veterinary scientists’ transition to independent investigator status.

Dr. Grieder highlighted two ORIP grant programs with broad impact: the Mutant Mouse Resource and Research Centers (MMRRCs) Consortium and the Shared Instrumentation Program. Mouse models account for 95 percent of all research animal models in biomedical investigation; MMRRCs import genetically modified mouse strains, ensure that they are disease free and accurate to their listings, preserve the strains, and distribute them to investigators. Usage of the MMRRCs and demand for mouse models was increasing steadily across Institutes and Centers (ICs) until the COVID-19 pandemic. The Shared Instrumentation Program provides existing instrumentation to be used on a shared basis by multiple investigators. About 400 applications are received per year, with about 100 awards made across the Nation. Funding is distributed based on, number of applications per instrument type, geographic distribution, and other factors, and funded instruments were in use about 75 to 80 percent of the available use time before the pandemic.

Drs. Michael Lairmore and Terry Magnuson—current and former Council members, respectively—participated in ORIP’s strategic plan development process. Input was gathered from internal stakeholders through two focus group meetings with NIH colleagues familiar with ORIP programs. Those meetings were held in person in February 2020. Input was also secured from external stakeholders. Three virtual external webinars also were held with resource grantees and resource users. The input gathered from these many stakeholders led to the formulation of four themes and associated strategies for the plan.

The first theme focuses on enhancing funding for animal models to plan for emerging future pathogens or other potential public health crises while supporting trans-NIH research areas. This theme includes a focus on appropriate animal care leading to reproducible results, with additional emphasis on nontraditional models and small businesses. The second theme focuses on innovative instrumentation and equipment, which includes support for continued acquisitions and modernization of research infrastructure. The third theme focuses on training veterinary scientists, specifically by supporting traditional, institutional, and individual training awards and supplements that promote diversity. The fourth theme focuses on building on existing collaborations, practicing outreach to extramural groups, and continuing Small Business Innovation Research (SBIR) opportunities.

Drs. Lairmore and Magnuson provided comments as Council liaisons to the ORIP strategic plan. Dr. Magnuson suggested that the pandemic resulted in renewed appreciation for the importance of research infrastructure and ORIP activities. He pointed to how ORIP collaborates with ICs on research infrastructure, which aligns with the plan’s goal, and that they continue to strengthen research infrastructure while helping adapt to rapidly changing scientific challenges and opportunities. He also noted the plan’s emphasis on sharing information, support for research training for veterinary scientists, and diversity. Dr. Magnuson pointed out the importance of the fourth theme, spreading awareness of ORIP resources and programs across the scientific community, and commented that the scientific stewardship emphasized by the plan also is a key NIH theme. He emphasized that the plan is fresh and stresses novel approaches and ideas while engaging the scientific community to identify these ideas.

Dr. Lairmore commented on the robust information-gathering sessions with stakeholders, many of which raised the issue of reproducibility and the importance of minimizing animal model use with newer technologies. He noted the importance of enhancing ORIP’s visibility, particularly given the response to COVID-19. Dr. Lairmore recommended monitoring and documenting the implementation of the plan, as well as the metrics for success, and suggested emphasizing linkages between resource development and scientific discovery to demonstrate the impact of ORIP’s activities to the public. Dr. Lairmore also commented on the importance of veterinary scientist training.

Discussion Highlights

- Council members agreed that the elements highlighted in the plan are important to continued functioning of the NIH and reiterated the importance of developing metrics to ensure that the increase in infrastructure to respond to the pandemic is maintained. Dr. Grieder noted that distribution of ORIP resources and services is a more illustrative metric than publication numbers which are not consistently referencing the resources used in the published research.

V. COMMON FUND CONCEPT CLEARANCE: ILLUMINATING THE DRUGGABLE GENOME—CUTTING-EDGE INFORMATICS TOOLS FUNDING OPPORTUNITY ANNOUNCEMENT (REISSUE)

Douglas Sheeley, Sc.D., a program leader in the OSC, presented the reissue of the Common Fund concept clearance titled Illuminating the Druggable Genome (IDG)—Cutting-Edge Informatics Tools (CEIT) Funding Opportunity Announcement (FOA). The objective of the IDG program is to identify and provide information on proteins not currently well studied but within the protein families commonly targeted by drugs. This is a target-rich environment containing many proteins that have not yet been studied significantly, so druggable targets within this area are likely. The CEIT awards develop experimental and informatics tools to illuminate those targets and develop basic information about them to support further study. This reissue is an opportunity to develop additional informatics tools that can broaden the impact of the data and information becoming available through the IDG program.

The program supports three data and resource generation centers aligned with the three protein families under study—ion channels, G protein-coupled receptors, and kinases—as well as a Resource Dissemination and Outreach Center (RDOC) and a Knowledge Management Center that supports a user interface for data queries. This interface, PHAROS, allows users to discover what is known about proteins and identify appropriate targets for further work; the CEIT awards support tools that will improve use of PHAROS. The 2018 FOA resulted in three 2-year awards for tools that were highly complementary to the work of the Knowledge Management Center, and Dr. Sheeley emphasized that the project team is pleased with its success to this point.

The program needs a greater diversity of informatics expertise to more effectively use the breadth and depth of data available in PHAROS to model and elucidate the biological functions of the proteins studied. The reissue will attract the research community to the fundamental questions of how best to deploy predictive modeling and data analysis tools to these important, complex questions. The budget allocation for the reissue is \$1.4 million, which would fund three awards at approximately \$500,000 each in FY 2022.

Dr. Sheeley noted that a complementary activity, which is not part of the request for Council concurrence, is a Notice of Special Interest to support administrative supplements to investigators funded by the NIH but not in the IDG program, which would allow improved incorporation of single-cell data into PHAROS.

Discussion Highlights

- The discussants, Drs. Sachin Kheterpal and Jian-Dong Li, provided their comments. Dr. Li expressed his support for the program and commented on the success of the initial grants, which provide a solid foundation for continued support. He emphasized the importance of ensuring that community outreach is supported.
- Dr. Li asked about the assessment plan for the RDOC and any plans to provide training to those without experience in informatics. Dr. Sheeley explained that only the CEIT awards require concurrence at this meeting; the other elements of the IDG program are funded by other means,

and they are working well and actively engaged with the community. The RDOC has developed many resources and offers training and orientation to a number of scientific communities.

- Dr. Kheterpal added his support and commented on the rapid success of the PHAROS website in making a large quantity of information understandable to a broad audience in a short time.
- Dr. Sheeley clarified that data integration is facilitated by the Knowledge Management Center, but some of the CEIT awards have included integration of data into larger contexts. A number of new proteins have been illuminated—associated with a phenotype—through the IDG program, and additional grants have been developed to research those connections further. Dr. Sheeley emphasized that directly identifying a drug target through this program is unlikely, but the IDG program can support the discoveries that will lead to further academic research. Dr. Anderson clarified that, because grants most often are written to study genes already known, the importance of this program is to illuminate genes that have never been studied.
- Dr. Sheeley explained that the IDG program has a robust experimental component, with major efforts to develop chemical probes for the function of proteins and assessment at transcription levels. The Knowledge Management Center integrates those results with other information available to construct a knowledge base that can be queried. This reissue is for the construction of tools for querying that data and integrating it with other established resources.

Vote

A motion to approve the reissue of the IDG CEIT FOA concept was forwarded and seconded. The motion passed with one abstention.

VI. COMMON FUND CONCEPT CLEARANCE: STIMULATING PERIPHERAL ACTIVITY TO RELIEVE CONDITIONS STAGE 2

Gene Civillico, Ph.D., Program Manager for the SPARC Program, presented the concept clearance for the program's second stage. SPARC focuses on rational mechanistic targeting of device interventions by applying advancements in neuroscience to areas of the body other than the brain. Neuromodulation devices often are built on simplistic scientific bases, resulting in unclear mechanisms and efficacy. The four clinical priority areas in the initial phase of SPARC were mapping structure and function, advancing interface tools, establishing therapeutic feasibility through translation, and developing collaborative data resources. A fifth initiative was added in 2019 to support anatomical and functional studies of neurovisceral circuits carrying pain signals.

Although SPARC has made significant progress in mapping, tools, and clinical studies, more efforts are needed to advance therapeutics on a short timescale. Two main principles serve as the framework for the next stage of the program. The first principle is focus; although SPARC-funded teams have learned about many areas of the body, focus is needed to demonstrate the value in an undiluted way. The second principle is increased transformation into innovative devices for patients. Many of SPARC's industry collaborators are too large to support the innovation and speed that investigators need to develop next-generation strategies, so the next phase of SPARC will support an academic–small company hybrid ecosystem.

The SPARC-V initiative will focus the current ecosystem's power on describing the anatomy of the human vagus nerve at the level of interface with devices. In three sub-initiatives, SPARC-V will construct connectivity profiles for a diverse cohort of human vagus nerves, conduct parameter sweeps on existing implanted vagus nerve stimulators, and continue development of the sparc.science portal and associated tools to host and work with these data. The vagus nerve was chosen as a focus for this initiative because vagus nerve stimulation is an established treatment modality that applies across the missions of SPARC's

partner ICs, and particularly promising opportunities are available in several applications—but a leap forward in understanding is required to become successful.

The SPARC-O initiative focuses on the need for more flexible clinical-grade platforms independent from existing companies. Applicants will propose interoperability specifications and compatible modules that can be combined into custom hardware profiles and supported sustainably. The third initiative, SPARC-X, supports prize challenges for demonstrations of next-generation vagus nerve capabilities with increasingly difficult stages. Dr. Civillico commented that SPARC-V, SPARC-O, and SPARC-X will serve as a coda to the SPARC program and allow continued development of the SPARC portal to support these programs and animate the field.

Discussion Highlights

- The discussants, Drs. Linda Chang and Paul Kenny, provided their comments. Dr. Kenny supported the initiative and commented that these are logical next steps for the SPARC program with significant potential to advance the field.
- Dr. Chang asked about plans to develop a program similar to SPARC-V for the sympathetic nervous system in the periphery. Dr. Civillico explained that although SPARC has supported many investigations of sympathetic pathways, the emphasis on the vagus nerve is a practical choice because it is an established delivery route for this therapeutic modality that still can be improved. He also noted that, if a more targeted approach can show value in delivering parasympathetic stimulation, that this could be a similar approach to sympathetic stimulation in the future.
- Dr. Chang also asked how bioengineers will be recruited to expand the data sharing initiative. Dr. Civillico explained that the existing data still are being curated and published, and many researchers are waiting to put their data on the platform. One aim for the remaining 3 years of the program is to ensure that the portal is resourced and efficient enough to support any researchers who wish to use it.
- Dr. Chang asked for additional clarification on the prize competition, which Dr. Civillico explained had not yet been decided. Dr. Anderson added that DPCPSI is responsible for overseeing the policy processes involved in challenge prizes and would help in this case, likely supporting multiple stages and winners.
- Dr. Civillico explained that, although devices such as cochlear or retinal implants have been successful, SPARC's status as a Common Fund program requires that it maintain a focus on research that does not fit the mission of a single IC. Participants pointed out that existing devices generate a large experiential database but information exchange is lacking between ICs about the vagus nerve efforts.
- In response to a suggestion of using a number of smaller awards, such as SBIR or STTR grants, rather than one larger challenge, Dr. Civillico noted that many SPARC mechanisms do not discriminate between small businesses and academic institutions, and many small companies have been funded. Dr. Anderson pointed out that SBIRs are used by ORIP and could be used in other OD programs.

Vote

A motion to approve the SPARC Stage 2 concept was forwarded and seconded. The motion passed with no abstentions.

VII. UPDATE: BASIC BEHAVIORAL AND SOCIAL SCIENCES RESEARCH WORKING GROUP

Graham Colditz, M.D., Dr.P.H., M.P.H., a co-chair of the Basic Behavioral and Social Sciences Research (bBSSR) Working Group and a Council of Councils member, provided an overview of the working group's progress to date. An overview of bBSSR at the NIH in 2004 focused on justifying the importance of funding bBSSR; advancements in bBSSR at the NIH since then support a new analysis of priority areas. The charge to the working group is to determine whether the funding for bBSSR is keeping pace with the science, return on investment can be improved, any emerging areas of research are not adequately supported, and if these areas can be accelerated, should they be addressed by individual ICs or by a trans-NIH effort.

Dr. Colditz emphasized the geographic diversity of the working group members and the breadth of disciplines represented. The working group began meeting in September, and initial meetings included several presentations from OPA showing the relationships between awards, applications, and funding rates for various types of bBSSR. Ongoing input includes surveys and town halls to gather NIH program staff priorities, and multiple discussions have occurred around strategies to increase workforce diversity and how diversity relates to topic areas in bBSSR.

Priority areas identified by the working group cover a broad range of issues, some applicable to behaviors that have been highlighted during the COVID-19 pandemic, such as initiating and sustaining behavior change. The working group is in the process of synthesizing its ideas into a report, which will be presented to the Council in May. Dr. Colditz commented on the strong engagement from members of the working group and the particular focus on consideration of workforce diversity and the role of topic choice on principal investigator diversity.

Discussion Highlights

- In response to a question about research on child abuse or neglect, as well as other forms of violence, William Riley, Ph.D., a co-chair of the working group and Director of OBSSR, explained that, with respect to violence, bBSSR would relate to the causes of violence and potential resilience factors for victims. He added that the analysis has shown that the NIH funds a significant amount of distal, foundational work but less research on proximal, translational types of research, such as research specific to violence or other specific content areas.
- When asked whether the working group's tasks correlate with any work at the NIMH, Dr. Riley clarified that the vast majority of bBSSR at the NIH is IC-specific, and much of the growth has occurred in neuroscience-related areas of bBSSR. The working group intends to assess whether any trans-NIH needs are not being addressed by current funding.

VIII. OBSSR CONCEPT CLEARANCE: REISSUE R25 SHORT COURSES ON INNOVATIVE METHODOLOGIES AND APPROACHES IN THE BEHAVIORAL AND SOCIAL SCIENCES

Erica Spotts, Ph.D., a Health Scientist Administrator at OBSSR, presented the concept clearance for the reissue of an RFA for Short Courses on Innovative Methodologies and Approaches in the Behavioral and Social Sciences, which uses the R25 mechanism. This program fills gaps in behavioral and social science

education not provided by most standard academic programs, and it encourages the integration of behavioral and social science and non-behavioral and social sciences to reach as broad an audience as possible. The intended population varies by application, but usually covers all career stages starting in graduate school. This RFA provides 4-year support, and the courses are intended to be offered at least once each of the 4 years of funding, sometimes more often depending on the program. Faculty mentors are encouraged to be from diverse backgrounds, should have expertise and experience relevant to the proposed program, and must be committed to continuing their involvement through the total period of the award. In 2019, application budgets were limited to \$200,000 in direct costs per year.

Dr. Spotts reviewed the progress that the program has made to date. Eight awards were made in 2013 in a variety of topics, and all the programs made improvements to the courses in response to changing needs and requirements. Ten awards were made in fall 2019, but the COVID-19 pandemic resulted in some awardees postponing their courses and others holding virtual variations. Dr. Spotts provided several examples of the courses, noting that many had participants from many countries, with many unique faculty and students, and students from many specialties have participated. Dr. Spotts also emphasized that over the course of these two RFA periods, OBSSR has been able to fund some programs that would not otherwise have found a home at the NIH, such as a course on mixed modeling, consistent with this program's history of unique support.

Discussion Highlights

- The discussants, Drs. Patricia Hurn and Edith Mitchell, provided their comments. Dr. Hurn expressed her support for the program but noted that the COVID-19 pandemic has resulted in an explosion of methodological courses offered remotely, so this program may be challenged to determine what to offer that remains unavailable and provide clear direction to new applicants. Dr. Hurn emphasized that more prescription might be necessary now that the “typical academic environment” is offering more course options. She also emphasized the importance of and value in interprofessional or interdisciplinary options and recommended strengthening the requirement for mentors from diverse backgrounds.
- Dr. Mitchell expressed support for the program, noting the opportunities it offers to diverse learners, and recommended a vote for resubmission.
- Dr. Spotts clarified that this RFA has not specifically coordinated with the bBSSR working group because the RFA was finalized before the working group began its report, but she expressed openness to integrating the working group's ideas. Dr. Riley added that this RFA is now being offered every 2 years to allow increased responsiveness to changes in the field, so although the bBSSR working group findings may not be captured in this cycle, they can be captured in the next 2-year renewal.
- Council members emphasized the importance of using the behavioral challenges illuminated by the COVID-19 pandemic to initiate better adherence to public health strategies and adherence to overall public health strategies.

Vote

A motion to approve the reissue of the R25 Short Courses on Innovative Methodologies and Approaches in the Behavioral and Social Sciences concept, with consideration of the discussions, was forwarded and seconded. The motion passed with no abstentions.

IX. PROPOSED NEW WORKING GROUP ON INTEGRATION AND REALIZATION OF THE BENEFITS TO HEALTH FROM BEHAVIORAL RESEARCH AT THE NIH

Dr. Christine Hunter, Ph.D., Deputy Director of OBSSR, explained that the fiscal year 2021 appropriations bill guidance for directs the convening of an advisory panel of behavioral scientists and community experts to complete an assessment providing recommendations on how to better integrate and realize the benefits to overall health from behavioral research at the NIH. In response to this directive, OBSSR proposes a working group of the Council of Councils to serve as the panel and provide recommendations. Dr. Hunter noted that although another working group already is discussing behavioral and social sciences research, the questions addressed are different. Whereas the other group focuses exclusively on identifying research needs and gaps in bBSSR, this group will consider how basic and applied behavioral and social sciences research are integrated across the NIH.

The breadth of behavioral and social sciences research (BSSR) funded at the NIH is tracked in broad. The OBSSR works to enhance the impact of all across the NIH. Part of this involves coordinating and communicating about BSSR, but OBSSR also has an overall goal of integrating BSSR into the broader NIH research enterprise. Dr. Hunter noted examples of large trans-NIH programs for BSSR, including both basic science efforts and more translational and applied efforts. Recent COVID-19 efforts also involved staff across the NIH coming together to address social, behavioral, and economic research gaps and opportunities related to the pandemic. Dr. Hunter emphasized that multilevel integration is necessary to fully understand both the causes of disease and effective prevention and treatment approaches.

The proposed charge for the working group is to assess the current status of behavioral and social sciences in NIH-supported research and training and identify existing processes that should continue or be enhanced, as well as new opportunities for enhancing the processes, coordination, and integration of BSSR across the NIH. The working group would seek input from experts in behavioral and social science who are familiar with NIH' processes and would prepare a report with recommendations about methods to encourage greater integration and relevance across the NIH, including, but not limited to, the functions of the OBSSR. Drs. Hunter and Kenny are the proposed co-chairs of the working group, with 8–10 proposed members from behavioral and social science experts already serving on NIH advisory boards, which would ensure that the members are familiar with NIH functions and already special government employees, accelerating the initiation of this working group.

Discussion Highlights

- In response to a question about the value of identifying real-world gaps in the understanding of behavioral health and social sciences, Dr. Hunter explained that the working group will need to identify metrics of successful integration, particularly the integration of behavioral and social science across the translational continuum, which would include the application of behavioral science to real-world settings and implementation science.

Vote

A motion to establish the working group on the Integration and Realization of the Benefits to Health from Behavioral Research at the NIH was forwarded and seconded. The motion passed with no abstentions.

X. NIH CONCEPT CLEARANCE: FIREARM INJURY AND MORTALITY PREVENTION RESEARCH

Dara Blachman-Demner, Ph.D., a Health Scientist Administrator at OBSSR, presented a concept clearance for FY 2021 Firearm Injury and Mortality Prevention funding. Firearm violence, injury, and mortality is a significant public health issue—the involvement of firearms in violent events increases the risk for injury and mortality, and witnessing these events increases the risk of physical and mental behavioral health conditions. The NIH has been supporting research with investigator-initiated and other efforts for a number of years, but in FY 2020, specific congressional language provided \$12.5 million on firearm injury and mortality prevention with a recommendation for a broad approach that assesses causes as well as methods of prevention, including crime prevention. This language also had a number of requirements related to open data and ensuring politically unbiased research projects. The release date of the FY 2020 concept was March 20, 2020, resulting in a truncated timeline; Dr. Blachman-Demner anticipated a longer timeline and more robust response with this year’s appropriation of another \$12.5 million.

The previous concept included an R61 for exploratory research for new awards and competitive revisions to R01s and R21s. As a broad, trans-NIH initiative, the concept included as many IC priorities as possible and addressed health care and community settings, multiple levels of potential intervention and risk, and a variety of vulnerable populations. The types of research considered included more accurate and efficient screening procedures in health care settings, ability to appropriately identify individuals who may be at risk, and pilot intervention work, as well as implementation research. In FY 2020, seven R61s across a range of ICs and topics were funded, and two supplements were funded through the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development and National Institute on Aging.

The FY 2021 reissue is being finalized, but the appropriation language is the same, so the concept likely will address a similar range of populations and topics. The project team is considering additional mechanisms, such as supporting longer project periods that would allow for time to assess intervention impacts. This would result in support for fewer awards but is a logical next step after the range of smaller projects supported in FY 2020. The program also is considering supporting phased awards with the option for ICs to incrementally fund the second phase, which would allow additional ICs with portfolios not ready for R01s in this field to participate.

Discussion Highlights

- The discussants, Drs. Richard Krugman and Charles Mouton, provided their comments. Dr. Krugman noted that the proposed work complements research at CDC in this area, and the grants from the previous year have provided a strong foundation. He commented on the difficulty of ensuring that funded awards fit the requirement to be politically unbiased. Dr. Mouton concurred and asked whether any political repercussions had occurred in response to the previous awards. Dr. Blachman-Demner explained that the previous year’s funded projects are just starting, and NIH staff have experience navigating the media in politically charged issues. Dr. Riley added that researchers in the behavioral and social sciences have experience working with politically charged topics, so OBSSR is familiar with supporting rigorous research that evaluates programs and policies without advocating or promoting any of those policies.
- In response to Dr. Mouton’s question about the potential number of awards and potential granularity, Dr. Blachman-Demner explained that it will depend on applications, but if they move toward funding longer R01s, they would be able to fund fewer of them. They consider it important, however, to allow more in depth examinations at the granular level but will strive to balance deeper dives with exploratory research.

- Dr. Blachman-Demner planned to look into a suggestion to collaborate with the National Center for Health Statistics. She also commented further on collaborations with CDC and the National Institute of Justice, noting that they ensure that their research is complementary and does not overlap. Although these parties address the topic from different perspectives, the relatively small amount of federal funding in this area makes it important to coordinate the research.
- In response to a question about strategies for presenting the outcomes in a way that is politically unbiased but can be used for interventions, Dr. Blachman-Demner reiterated that because most of the projects are just starting, the program will have time to plan for dissemination. She referred to the expertise of NIH’s communications staff but also noted the importance of ensuring that the appropriate and effective messaging is identified.

Vote

A motion to approve the concept clearance for Firearm Injury and Mortality Prevention Research was forwarded and seconded. The motion passed with one abstention.

XI. 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 May 2021 and also will be virtual.

XII. ADJOURNMENT

Dr. Anderson adjourned the meeting at 3:38 p.m. on January 29, 2021.

XIII. CERTIFICATION

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

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