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 24, 2020

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 meeting began at 8:15 a.m. on Friday, January 24, 2020, in Building 35A/Porter, Room 620/630 on the NIH Campus in Bethesda, Maryland. Dr. Anderson noted that Drs. Graham Colditz, Patricia Hurn, Paul Kenny, and Rhonda Robinson-Beale and Ms. Maria Acebal were unable to attend and that Dr. Paul Johnson was attending by telephone. The meeting attendees are identified below.

Following introductions and announcements from Franziska B. Grieder, D.V.M., Ph.D., the executive secretary for the NIH Council of Councils, Dr. Anderson 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
Andrew P. Feinberg, M.D., M.P.H., Johns Hopkins University, Baltimore, MD
Rick Horwitz, Ph.D., Allen Institute for Cell Science, Seattle, WA
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
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
Terry Magnuson, Ph.D., The University of North Carolina at Chapel Hill School of Medicine, Chapel Hill, NC
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
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

Council Members Absent
Maria L. Acebal, J.D., The Aspen Institute, Washington, DC
Graham A. Colditz, M.D., Dr.P.H., M.P.H., Washington University School of Medicine in St. Louis, St. Louis, MO
Patricia D. Hurn, Ph.D., R.N., University of Michigan, Ann Arbor, MI
Paul J. Kenny, Ph.D., Icahn School of Medicine at Mount Sinai, New York, NY
Rhonda Robinson-Beale, M.D., Blue Cross of Idaho, Meridian, ID

2. Liaisons

Juliana Blome, **Ph.D.,** representing **David R. Wilson, Ph.D.,** Director, Tribal Health Research Office, DPCPSI
Cindy Davis, Ph.D., representing **Joseph M. Betz, Ph.D.,** Acting Director, Office of Dietary Supplements, DPCPSI
Yvette Edghill-Spano, Ph.D., representing **Maureen M. Goodenow, Ph.D.,** Director, Office of AIDS Research (OAR)
Susan K. Gregurick, Ph.D., Director, Office of Data Science Strategy (ODSS), DPCPSI
David M. Murray, Ph.D., Director, Office of Disease Prevention (ODP), DPCPSI
Karen L. Parker, Ph.D., M.S.W., Director, Sexual & Gender Minority Research Office, DPCPSI
William T. Riley, Ph.D., Director, Office of Behavioral and Social Sciences Research (OBSSR), DPCPSI
Elizabeth Spencer, R.N., representing **Janine A. Clayton, M.D.,** Director, Office of Research on Women's Health, DPCPSI
Elizabeth L. Wilder, Ph.D., Director, Office of Strategic Coordination (OSC), DPCPSI

3. *Ex Officio* Members Present

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

4. Presenters

Ravi Basavappa, Ph.D., Program Official, OSC, DPCPSI
Kevin B. Johnson, M.D., M.S., Chair, Sequence Read Archive (SRA) Data Working Group
Stephanie Murphy, V.M.D., Ph.D., Director, Division of Comparative Medicine (DCM), ORIP, DPCPSI
David M. Murray, Ph.D., NIH Associate Director for Prevention and Director, ODP, DPCPSI
George Santangelo, Ph.D., Director, Office of Portfolio Analysis (OPA), DPCPSI
Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH
Hannah Valantine, M.D., NIH Chief Officer for Scientific Workforce Diversity
Marina Volkov, Ph.D., Director, OEPR, DPCPSI

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

Dr. Grieder reviewed the following:

- Council members are Special Government Employees during the days of Council meetings and are therefore subject to the rules of conduct governing federal employees.

- Each Council member submitted a financial disclosure form and conflict-of-interest statement in compliance with federal requirements for membership on advisory councils. The financial disclosures are used to assess real and perceived conflicts of interest, and Council members must recuse themselves from the meeting during discussions of any items for which conflicts were identified.

- Time is allotted for discussion between the Council members and presenters, but time for comments from other meeting attendees is limited. The public may submit comments in writing; instructions are available in the *Federal Register* notice for the meeting, which was published on December 16, 2019, and updated on January 23, 2020.

- Minutes from the September 6, 2019, meeting are posted on the DPCPSI website. The minutes from this meeting also will be posted there.

C. Future Meeting Dates

Future Council meetings in 2020 will be held on May 15 and September 11.

II. COMMON FUND FUNDING OPPORTUNITY ANNOUNCEMENT REISSUE: HIGH-RISK, HIGH-REWARD PROGRAM—FOUR INITIATIVES

Ravi Basavappa, Ph.D., a program official with the OSC, reviewed the Common Fund's High-Risk, High-Reward (HRHR) research program, which fosters scientific leaps by supporting individuals of exceptional creativity who propose unusually innovative research with the potential for broad impact. The HRHR program expects investigators to have a vision of what they want to accomplish, but the goal often is more distant than traditional NIH-funded research. Preliminary data or a detailed experimental plan are not expected; applicants are asked to focus on such elements as the significance or innovation of their research or their personal fitness for the project. The application and review processes do not follow the standard forms, and any topic within NIH's mission can be investigated if justified. The investigator-initiated aspect and the 5-year duration of the awards ensures that the science investigated within the program changes constantly.

Dr. Basavappa outlined the four initiatives of the program. The Pioneer Award supports very ambitious ideas, and awardees are allowed significant flexibility to change research structure. The New Innovator Award is similar to the Pioneer Award but restricted to early stage investigators (ESIs). The Transformative Research Award is focused more on the project than the investigator(s), permits multiple PIs, and allows flexible budgets. The Early Independence Award allows exceptional junior investigators close to the end of their doctoral or clinical training to rapidly launch independent research programs. Independent evaluations of the Pioneer and New Innovator Awards have shown that research by awardees tends to be more innovative and impactful than research conducted by similarly qualified R01 investigators. Evaluators also found that the New Innovator awardees' careers were not harmed by pursuing high-risk research at a vulnerable stage of their careers. Evaluations for the Transformative Research and Early Independence Awards currently are underway.

An Advisory Committee to the Director (ACD) Working Group convened to assess the effectiveness and potential bias of HRHR initiatives submitted its final report in June 2019, finding that, overall, the program successfully supports high-risk, high-reward research and recommending its expansion, if possible. However, although women and investigators from underrepresented groups are not adversely affected by the review process, the Working Group found that these investigators are not applying at expected rates. Additionally, most awards are given to investigators at a small subset of institutions, and some topics are underrepresented in the portfolio of science that can be supported by this program. The Working Group's recommendations focus on enhancing outreach, developing new initiatives, and enhancing diversity. The full response and implementation plan are posted on the program website; Dr. Basavappa presented a subset of pertinent points.

The program has embraced the recommendation to expand outreach by increasing the number of meetings at which Dr. Basavappa and the HRHR team promote the program, including conferences and postdoctoral programs focusing on underrepresented groups and meetings that promote institutional diversity. The program is working with OBSSR to enhance outreach to the behavioral and social sciences community, and online resources have been expanded. In addition, a request for information was issued to solicit input from the community about why members of some minority groups might apply less often.

The first of three new initiatives recommended by the ACD Working Group would have been a collaboration between resourced and under-resourced institutions. OSC declined this recommendation because of its similarity to the existing Support of Competitive Research (SCORE) program and the existing support for multi-institution applications within the Transformative Research Award. The second recommended new initiative was a separate program for clinical outcomes, which the OSC also declined. All the HRHR initiatives already allow clinical research, but the high-risk aspect and the lack of a requirement for preliminary data may not be compatible with clinical research; Dr. Basavappa noted that clinical research conducted at the Institute and Center (IC) level could be tailored to a more flexible definition of "high-risk." The third new initiative recommended by the ACD Working Group was accepted in that NIH is planning a new "Katz Award" for ESIs. The Katz Award will not allow preliminary data, which will help ESIs to change direction from their previous work more easily.

In response to the ACD Working Group recommendations, the HRHR program has strengthened the language in funding opportunity announcements (FOAs) welcoming applications from diverse institutions and will include language explicitly welcoming applications and topics relevant to the broad mission of the NIH. Additionally, future outreach efforts will underscore that applications from any topic within the mission are welcome, and the HRHR program will work with the Center for Scientific Review to ensure appropriate reviewer expertise. The ACD Working Group also recommended piloting anonymized review; Dr. Basavappa pointed out that this would be difficult with the Pioneer and Early Independence Awards, which focus on the individual investigator, but the Transformative Research Award will be a good test case because the current review process focuses on the innovative potential of the ideas and can be anonymized relatively easily.

<u>Discussion Highlights</u>

- The discussants, Drs. Terry Magnuson and Susan Sanchez, provided their comments. Dr. Magnuson asked about a correlation between the centralized research infrastructure and the number of applications. Dr. Basavappa confirmed that well-resourced institutions tend to submit applications and reach the review process, but the correlation is not particularly strong.
- Dr. Sanchez recommended providing guidance for less experienced investigators regarding the unusual proposal format.

- Dr. Scout, a member of the ACD Working Group for this topic, pointed out that ACD Working Group members were not informed of the HRHR program's response to the recommendations and suggested implementing such a procedure. He explained that the recommendation related to clinical research that was declined was specifically designed to allow for more applications related to behavioral research, which was more likely to be suggested by underrepresented minorities. He added that, although the recommendations have been implemented relatively recently, success ratios have not yet improved. Dr. Anderson planned to include updates on the success rates annually.
- When asked whether applications that nearly miss the cutoff for award might be more diverse, Dr. Basavappa explained that awards are not funded in strict score order but with consideration given to other elements, such as scientific opportunity, representation in a particular scientific area, and whether the research is crosscutting or spans the mission of multiple ICs; institutional diversity will be an additional future consideration.
- Dr. Basavappa confirmed that clinician-scientists now are slightly more successful than Ph.D. applicants.
- In response to questions about the language welcoming diverse applicants and applicants from diverse institutions, Dr. Basavappa displayed the language in the FOA related to institutional diversity, which has been approved by the Office of General Counsel at the NIH. He also showed the language related to investigator diversity. Dr. Anderson explained that the NIH cannot implement quotas, but diversity can be a specific priority at the program level.
- Dr. Anderson clarified that the Common Fund is considered an experimental space; the success of the HRHR mechanisms is supported by similar programs implemented by ICs.
- Dr. Basavappa confirmed that people without citizenship or permanent resident status are eligible.
- A Council member pointed out that 2019 awards supported only projects in wet laboratory science rather than including diverse kinds of science—such as dry laboratory science, data science, or community engagement—and emphasized that this does not reflect the leading edge of science in 2020. Dr. Basavappa agreed that investigators conducting these kinds of science should be encouraged to apply, regardless of whether similar kinds of science have been supported previously.
- Dr. Basavappa acknowledged that "innovation" is a concept that reviewers must assess subjectively.
- Council members recommended considering additional strategies to reach potential applicants who do not already know to visit the program's website, including creating a slide deck that Council members could share at their institutions and providing examples of successful nontraditional applications.
- When asked whether the funding is commensurate with the number of high-quality applications received, Dr. Anderson explained that this program is funded as much as possible within the balance of other Common Fund initiatives.
- In response to a question about failure rates, Dr. Anderson explained that the program's easy process for changing direction after failure encourages awardees to take risks, and many awardees do change their research structure substantially.

Vote

A motion to approve the reissue of the HRHR initiatives with the consideration of suggestions made during the discussion was forwarded and seconded. The motion passed with no abstentions.

III. ORIP/OAR FOA REISSUE/REVISION: HIV SCHOLARS K01 AND NEW R21 COMPANION FOA FOR THE HIV SCHOLARS K01 AWARDEES

Stephanie Murphy, V.M.D., Ph.D., the director of ORIP's DCM, outlined the reissue of the HIV Scholars Using Nonhuman Primate (NHP) Models program under the K01 mechanism, which provides salary, mentorship, and research support to ESIs in the field of HIV/AIDS translational studies and enables these ESIs to translate promising preclinical research from NHPs to human clinical trials. This mentored career development K01 program was initially focused on translational vaccine research using NHP models, but later expanded to include all preclinical high-priority HIV/AIDS research using NHP models. The goal of this program is to increase the number of new researchers using NHPs for preclinical HIV/AIDS studies. Dr. Murphy provided success statistics for the National Institute of Allergy and Infectious Diseases (NIAID) mentored training in AIDS vaccine research model that inspired this program. The key characteristics of this proposed reissue include 3 years of mentored career support; two required mentors that include an expert in the use of NHP models and an expert in clinical translational research; salary support up to $75,000 per year; and research support up to $100,000 per year. To be eligible for this program, applicants must hold a doctoral degree, have at least 3 years of postdoctoral experience, be no more than 10 years beyond their terminal degree, and be able to document an affiliation with an NHP facility. Dr. Murphy provided information on the success of the researchers who have participated in the first 3 years of the program, including independent funding, publications, and permanent research positions.

The next concept clearance—similar and related to the K01—is a new R21program that would provide support to help advance ESIs using NHP models in preclinical HIV/AIDS research by giving them a degree of independence to develop new research directions, as well as to position these researchers to be competitive for new research project funding. The *NIH Strategic Plan for HIV and HIV-Related Research for FY 2019–2020* identified a national need to train the next generation of HIV researchers, and ORIP's *Report of the Expert Panel Forum on Challenges in Assessing NHP Needs and Resources for Biomedical Research* has emphasized a pressing need to expand the pool of skilled NHP researchers in the United States. These two documents reveal an inadequate supply of researchers using NHPs to address preclinical topics in HIV/AIDS. The proposed R21 is similar to other ESI-targeted R21 grant programs used by other ICs to address the diminishing success rates for young investigators. Dr. Murphy provided several examples of other R21 programs for ESIs and noted that they appear to improve success rates.

The goals of the ORIP/OAR R21 program are to provide adequate funds to ESIs to perform HIV/AIDS research with NHP models, to allow recipients to pursue unique research directions independent of the funding support of their mentors, to facilitate transition of these ESIs to independence, and to increase the competitiveness of these individuals for R01 or equivalent awards. The key element of the expanded R21 program is the award of $200,000 per year for 2 years. Applicants must have 2 years of prior postdoctoral experience, be no more than 10 years beyond their terminal professional degree, and be able to document an affiliation with an NHP facility. They also must be performing preclinical HIV/AIDS research with NHP models. Applications can be submitted under the standard three AIDS receipt dates each year; Dr. Murphy anticipated receiving three to five applications per deadline, or 9 to 15 applications per year.

<u>Discussion Highlights</u>

- The discussants, Drs. Michael Lairmore and Paul Johnson, provided their comments. Dr. Lairmore pointed out that the clear need to train the next generation of HIV/AIDS researchers justifies the K01 program, and the rationale for the complementary R21 is similarly strong. He recommended monitoring the R21 program earlier than suggested, potentially after the program's first 3 years, and considering increasing the awards to 3 years. Dr. Johnson commended the

structured mentorship program and the co-mentorship of a clinical and an NHP researcher as key components of the K01's success and expressed his strong support for both concepts.

- In response to Dr. Johnson's concern that the 2-year project award would be too short for NHP research, Dr. Murphy explained that although NIH policy allows expansion of R21 programs to 3 years, this concept already is at the maximum allowable funding, so 2-year awards allow more support per year. Dr. Johnson agreed that in this case the 2-year funding was preferable.

Vote

A motion to approve the HIV Scholars K01 reissue and new R21 concept was forwarded and seconded. The motion passed with no abstentions.

IV. SRA DATA WORKING GROUP—INTERIM REPORT OF DRAFT RECOMMENDATIONS

Kevin Johnson, M.D., M.S., the co-chair of the SRA Data Working Group, reminded attendees that the Working Group's charge is to provide recommendations to the Council on key factors for storing and managing SRA data on cloud environments and to evaluate and identify solutions to maintain efficiencies in the storage footprint of the SRA. The SRA contains 24 petabytes of public and controlled access data that have been hosted across two commercial clouds—Google and Amazon Web Services—since 2019 as a part of the NIH Science and Technology Research Infrastructure for Discovery, Experimentation, and Sustainability (STRIDES) Initiative. Dr. Johnson emphasized that the SRA is a critical resource for the biomedical community. He highlighted SRA use cases, including tool development, catalogue and search optimization, and comparative analysis.

The SRA is large, complex, and frequently accessed, but because its growth is exponential, the SRA is unsustainable in its current form. The SRA is available in two formats—the original format and the normalized (extracted, transformed, loaded [ETL]) format—but only the ETL format currently is available to users. A significant portion of the SRA is composed of base quality scores (BQS), which represent an opportunity for data compression. The Working Group discussed options for maintenance of "hot storage" (i.e., immediately available) and "cold storage" (i.e., cheaper storage that requires "thawing" before use). In its meetings, the Working Group identified standard principles for SRA use and future considerations for SRA storage.

Three proposals were considered for recommendation to the Council. In Proposal 1, BQS would be eliminated from the normalized format and retained in the original format. A portion of the original files would remain in hot storage; the other half would be maintained in cold storage. In Proposal 2, the SRA would contain normalized files only; the original files would not be restored, and BQS would be retained. In Proposal 3, versions of normalized data with and without BQS would remain in the cloud. All original files would remain in cold storage, and a fraction of the normalized files would be kept in hot storage. The Working Group recommended Proposal 3, which involves the implementation of a predictive algorithm to minimize costs of cold and hot storage based on data access. Dr. Johnson emphasized the importance of educating the users and clearly communicating the cost models—including user costs and NIH costs—to the research community. He added that the Working Group recommends that the NIH continue to conduct research to inform changes to the model and consider funding efficiency optimization research to improve cloud-based access to data.

The Working Group intends to finalize its interim report to the Council by the end of January 2020. Members are collaborating with the National Center for Biotechnology Information to develop appropriate data collection methods for the data in the cloud. The Working Group will present its final recommendations by summer or fall 2020.

Discussion Highlights

- Council members commented that the proposed solution is not likely to be effective in the long term and does not address the larger issue with which the Working Group was tasked. Dr. Susan Gregurick, director of ODSS and co-chair of the SRA Working Group, commented that the NIH and Microsoft are discussing the possibility of hosting the SRA through Microsoft Azure.
- Council members suggested that the Working Group consider phasing out the BQS, which now are unnecessary for many researchers, and indexing a small number of references.
- When asked how the Working Group will ensure the SRA remains interoperable, Dr. Johnson emphasized the importance of ensuring the SRA remains usable and manageable for the research community that currently uses it before making any changes.
- Council members discussed strategies for controlling costs; Dr. Johnson noted that the Working Group is considering data-driven approaches and algorithmic strategies to reduce cost.
- Dr. Johnson commented that the Working Group has recommended funding to explore approaches using artificial intelligence (AI) to manage hot and cold storage.
- Dr. Gregurick reiterated that because the SRA is growing rapidly, optimization is critical. A data science fellowship position is available that would provide opportunities for exploration of global searches in the SRA using AI capabilities.

V. NEW COMMON FUND PROGRAM CONCEPT: FACULTY INSTITUTIONAL RECRUITMENT FOR SUSTAINABLE TRANSFORMATION

Hannah Valantine, M.D., the NIH Chief Officer for Scientific Workforce Diversity, introduced the concept for the Faculty Institutional Recruitment for Sustainable Transformation (FIRST) program. The overall goal of the program is to create cultures of inclusive excellence at NIH-funded institutions by establishing and maintaining scientific environments that can cultivate and benefit from a full range of talent. The program's three objectives are to establish (1) a faculty cohort model for hiring, multilevel mentoring, and professional development; (2) integrated, institution-wide systems to address bias, faculty equity, mentoring, and work/life issues; and (3) a Data Coordination and Evaluation Center (DCEC) to conduct independent program evaluations of impact at the faculty/institutional level and of departmental/institutional culture change, as well as initiative-wide metrics of faculty success, recruitment, and professional development at pre-tenure career stages. The estimated funds for this project are $241 million over 9 years. Dr. Valantine described the considerable gap for underrepresented minority recipients and female recipients of doctoral degrees in NIH-relevant fields entering into the professoriate and how the representation gap for U.S. biomedical faculty may persist because of institutional cultures that lack necessary elements of inclusion and equity.

Dr. Valantine detailed the two major components of the FIRST program: the faculty cohort and the DCEC. The faculty cohort component would strive to hire 120 new faculty over 3 years. Proposed cohorts would comprise a minimum of 10 faculty per institution, composed of three to four scientists within several scientific areas. It would include professional mentoring and development, as well as institutional programming to reduce isolation, increase community building, and foster career advancement. The faculty cohort request for applications (RFA) would comprise 12 staggered awards: four 6-year awards would be made each year for 3 years. The DCEC would work with the FIRST institutions to develop the overall evaluation plan and to ensure that the individual institution evaluation plans are aligned. Faculty success metrics assessed would include time to tenure and tenure rate; research productivity and bibliometrics; time to independent funding; appointments and promotion-committee reviews; diversity of principal investigator group trainees, hires, and collaborators; and interdisciplinary collaborations.

Metrics of institutional culture change also would be assessed. The DCEC RFA would be issued in the first and fourth years, aligning with the first and second cycle, respectively. During the first cycle, the charge would be to devise metrics, coordinate communication between the institution and the faculty, and initiate the study. In the second cycle, the charge would be to continue communication across the institutions and faculty and to complete the analysis.

Dr. Valantine commented on several practical issues that must be addressed. First, hiring 10 new research faculty over 1–2 years might present a greater challenge for institutions with less overall research support. Start-up packages and programming funds may need to be larger to provide sufficient allocation of resources to less research-intensive institutions to ensure adequate support for the cohort. Sliding scales may also be considered. Although each awardee institution is expected to support at least 10 new faculty who can be spread across multiple departments, an optimal number and arrangement may exist. Institutions also can propose collaborations, but must show that interaction between cohort members will be frequent and fluid.

Discussion Highlights

- The discussants, Drs. Charles Mouton and Jean Schaffer, provided their comments. Dr. Schaffer wondered whether the pipeline is sufficient to sustain a program of this size, individual institutions are capable of applying for the award, and collaborating institutions would be able to work together given their differing resources and programmatic needs. Dr. Valantine responded that many institutions hire approximately 20–25 research faculty each year; the aim will be to encourage them to consider each candidate's support for a culture change around inclusion and diversity, in addition to their scientific credentials. Regarding under-resourced institutions, she explained that the FIRST program is considering whether those institutions should have a smaller cohort or could join through partnerships.
- Dr. Schaffer made several other suggestions: (1) Existing data on the cohort approach and the metrics of success of those faculty should be explored, (2) the RFA should state explicitly that a major institutional match will be required, and (3) lessons learned from other programs developed to address the professional demands of young faculty should be leveraged. Dr. Mouton pointed out that requiring institutional dollars would put smaller institutions at a disadvantage and supported in-kind contributions and partnerships as alternatives.
- Dr. Mouton expressed his strong support for the program, noting that the cohort model has been shown to be effective and promote success. He proposed extending the 5-year cycle to 7 years to provide researchers with sufficient time to benefit from the cohort relationship and allow their science to succeed. He noted past studies identifying issues with the NIH review process; Dr. Valantine responded that the FIRST program, by virtue of its mentoring and networking, will provide the cohort with greater skills to be competitive for R01s, although she acknowledged that it does not directly address the potential for bias in peer review.
- Dr. Valantine clarified that the cohort itself will be diverse, not only composed of individuals who prioritize diversity, to mitigate the stigma around programs that are created for a single identity group.
- When asked about the metrics of success, Dr. Valantine explained that in addition to assessing metrics, the program aims to promote a shift in the culture in a cohort member's department and across the institution.
- Dr. Walter Koroshetz, the director of the National Institute of Neurological Disorders and Stroke (NINDS), expressed NINDS' enthusiasm for the program and emphasized the discrepancy between the number of trainees and the number of R01 holders who are women, underrepresented

minorities, and people of various socioeconomic backgrounds. He added that the greatest impact at a department level will be seen if clusters are created within each cohort—for example, if three faculty are hired within a single department.

- Council members suggested collaboration with organizations that have strong existing networks for women and underrepresented minorities, as well as keeping the eligibility language broad while explicitly noting specific groups, such as sexual and gender minorities. Dr. Valantine explained that the FIRST program aims to hire scientists who have shown a commitment to diversity and inclusion, which she considers a broad and inclusive definition. Council members commented that institutions that have demonstrated a commitment to diversity and inclusion are at an advantage.
- Council members' additional suggestions included a flexible sample size, increased diversity in NIH study sections, and detailed information about the methodology to describe the structural elements of cultural change and implicit bias in the application.
- Dr. Kevin Johnson, who is on the National Advisory Committee for the Robert Wood Johnson Foundation's Harold Amos Medical Faculty Development Program, recommended considering ways to better fund advisory committee members who serve as mentors. Occasionally, these members must recommend that an individual leave one institution to succeed at another.

Vote

A motion to approve the FIRST program with the consideration of suggestions made during the discussion was forwarded and seconded. The motion passed with no abstentions.

VI. REVIEW OF GRANT APPLICATIONS

This portion of the meeting was closed to the public, in accordance with the provisions set forth in Sections 552(b)(c)(4) and 552(b)(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix).[1] Members were instructed to exit the room 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 436 ORIP applications with requested first-year direct costs of $321,842,425.

VII. THE OFFICE OF PORTFOLIO ANALYSIS STRATEGIC PLAN: FISCAL YEARS 2021–2025

George Santangelo, Ph.D., the director of OPA, explained that OPA's purpose is to prepare and analyze data on NIH-sponsored biomedical research to inform trans-NIH planning and coordination, serve as a resource for portfolio management, employ resources to conduct assessments in support of portfolio analyses and priority setting, research and develop new analytic tools and resources to enhance management of NIH's portfolio, and provide training on portfolio analysis tools and methodologies. OPA's highest goal is to enable administrators and decision-makers to evaluate and prioritize current and emerging areas of research that will advance scientific knowledge and improve human health. OPA also

[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.

strives to ensure the NIH research portfolio is balanced and free of unnecessary duplication, leverages collaborative and crosscutting research, and stimulates the emergence of transformative ideas.

Dr. Santangelo described several examples of OPA efforts in recent years. For example, in 2016, OPA developed the Relative Citation Ratio (RCR) metric, a new and validated way to measure the influence of biomedical research papers. OPA also adapted Google's word2vec algorithm to analyze semantic content. Recently published findings show that topic choice is an important contributor to the lower rate of NIH awards to African American scientists. OPA AI tools also have been used to track and predict the impact of NIH decision-making in the areas of clinical impact, technology transfer and patents, the development of drugs and devices, the rate of scientific progress and emergence, and overlapping proposals submitted to different funders. For example, OPA used word2vec to identify the overlap between the NIH and National Science Foundation portfolios, and to create a heat map of NIH-funded publications between 1981 and 2015 that indicates which topic areas are growing or shrinking.

Dr. Santangelo detailed the three objectives of OPA's 2021–2025 strategic plan: (1) to improve OPA's ability to use data that can help to optimize biomedical research investments; (2) to exemplify and promote the highest standards of transparency, reproducibility, data sharing, dissemination, and implementation of OPA-validated research and development that improves decision-making; and (3) to exemplify and promote the highest standards for science of science investigators who focus on the biomedical research enterprise. He remarked that analytical agencies and organizations regularly seek OPA's assistance with tools, approaches, databases, and recruiting and that many consider OPA as a model for building an analytical team. Dr. Santangelo concluded by making a bold prediction—that the NIH will be the first funder of science, including both the government and private sector, to succeed in predicting the outcomes of its investments with data analytics and AI/machine learning. OPA already has developed a method to identify topics of research likely to experience a breakthrough, and it currently is developing methods to quantify the relationship between investments and the advancement of scientific knowledge. NIH decision-makers can use these data improvements to prioritize support and potentially accelerate discovery in both mature and emerging areas of biomedical research.

Discussion Highlights

- A Council member suggested that the NIH follow a model like the Department of Defense's Telemedicine & Advanced Technology Research Center, which establishes new opportunities for investments that did not succeed as expected. Dr. Santangelo noted the existence of a cross-agency portfolio analysis community of interest and expressed hope for synergies to result from this group.
- In response to a question about how OPA can leverage its capabilities prospectively, Dr. Santangelo stated that OPA is using the co-citation linkages between papers to detect signals of future breakthroughs in biomedical research.
- Although OPA consultations are for NIH staff, the office does engage with non-NIH staff. The OPA website contains frequently asked questions, case studies, and other resources, some of which are accessible to those outside the NIH.
- A Council member suggested evaluating impact on medical management. Dr. Santangelo reiterated that neither RCR nor any measure of influence is equal to impact and that many elements are still difficult to capture.
- In response to a question about retrospectively studying the impact of NIH training programs on career development, Dr. Santangelo agreed that these types of longitudinal studies are very

important; however, tracking trainees is quite challenging. OPA has successfully tracked trainees by leveraging biosketch information to extract mentor–mentee relationships.

VIII. ASSESSMENT OF PREVENTION RESEARCH MEASURING LEADING RISK FACTORS AND CAUSES OF MORTALITY AND DISABILITY SUPPORTED BY THE NIH

David Murray, Ph.D., NIH's Associate Director for Prevention and the director of the ODP, remarked on ODP's systematic review of NIH's prevention research portfolio. He explained that the ODP defines prevention research to include primary and secondary prevention in humans, together with relevant methods development. To conduct its review, ODP worked with staff across the NIH to identify activity codes that were likely to support NIH prevention research. Exclusions included basic and preclinical research; awards for facilities, infrastructure, and loan repayment; intramural research; contracts; and most methodological research. Included were all remaining R, P, and U activity codes with at least 500 awards or at least $500 million in awards between FY 2012 and FY 2017, and only Type 1, 2, and 9 awards (i.e., new projects) were considered. The remaining set of 12 activity codes represents about 90 percent of all R, P, and U research activity at the NIH, and about 84 percent of the dollar investment in research at the NIH.

ODP's findings showed that during FY 2012 through FY 2017, 16.7 percent of NIH research supported by extramural grants and collaborative agreements qualified as prevention research under ODP's definition. Of that portfolio, 51.4 percent, or 8.6 percent of the total NIH research portfolio, addressed a leading risk factor or cause of death; 31.4 percent addressed a leading risk factor or cause of disability; 3.3 percent measured more than one leading cause of death as an exposure or outcome; 8.8 percent measured more than one leading risk factor for death as an exposure or outcome; and 24.6 percent included a randomized intervention that addressed a leading risk factor or cause of death. The 48.6 percent of the NIH prevention research portfolio that did not address a leading risk factor or cause of death focused on such exposures or outcomes as genetics, infectious disease, education/counseling, medication/devices, mental health, and health care delivery, among others. Dr. Murray pointed out that the investment in certain areas, such as alcohol and drug use, is larger than its relative burden and that the amount of cancer prevention research significantly decreased between FY 2012 and FY 2017. Analysis of FY 2018 and FY 2019 data is ongoing.

Dr. Murray concluded by asking the Council to consider whether the NIH should reshape its prevention research portfolio to emphasize projects that address the leading risk factors and causes of death and disability, projects that address multiple risk factors or causes of death and disability in the same study, or the development and testing of preventive interventions to address the leading risk factors and causes of death and disability.

Discussion Highlights

- Several Council members supported reshaping the portfolio, including conducting fewer but larger studies that investigate the intersectionality of multiple factors, as well as interventional studies. One member suggested focusing on communities or groups of individuals with higher risk. Dr. Murray agreed that prevention research investment should be focused on areas that can provide the greatest return.
- A Council member explained that feedback on applications and the grant review process could be used to improve scientist training at the faculty and doctoral levels. Dr. Murray stated that the ODP currently is studying the differences between unfunded and funded applications.

- Dr. Murray clarified that behavioral and social science research often falls into the definition of prevention research and that genetics in the context of ODP's analysis is defined broadly.
- Council members noted the great potential for prevention research through the *All of Us*℠ research program. Dr. Murray added that a large fraction of the *All of Us* use cases collected were prevention-oriented.

IX. NIH UPDATE

Lawrence Tabak, D.D.S., Ph.D., the principal deputy director of the NIH, briefly commented on the NIH budget, then discussed the importance of incorporating AI into biomedical research. Although a number of opportunities to implement AI in biomedical research exist, each raises ethical and legal issues that must be addressed. An ACD Working Group of experts in AI was convened to discuss how to bridge the fields of computational science and biomedical research to use AI across the NIH. The Working Group recommended that the NIH support flagship data generation efforts to propel progress in AI use by the scientific community by generating billions of data points suitable for machine learning use. These data can be used to address key biomedical challenges, but the Working Group cautioned that the development of AI approaches in biomedicine and biomedical approaches in AI must occur in concert to ensure that both fields can interoperate and advance successfully. The ACD Working Group emphasized the need to improve the criteria and technical mechanisms for data access given that the current state of access is extremely lacking, particularly for large curated data sets. Additionally, the Working Group noted the need to strengthen the ethical considerations for data set use. It also recommended continuation of two training programs to develop the next generation of researchers who are skilled in both computer science and biomedicine.

Dr. Tabak updated the attendees on the INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndromE (INCLUDE) program. INCLUDE focuses on adding individuals with Down syndrome to mainstream clinical studies to understand how interventions affect them differently and how individuals with Down syndrome can help researchers understand their different propensity for, or resilience to, certain conditions. Dr. Tabak explained that the preliminary steps in this project included conducting basic science studies, connecting existing resources with ongoing trials to include individuals with Down syndrome, and creating a medical home for individuals with Down syndrome within the clinical trials network. He noted that this effort involves nearly every IC and displayed the increasing funding trend for Down syndrome research at the NIH over the past several years.

Dr. Tabak then reviewed the efforts to address sexual harassment in biomedical research, noting the need to address both the most overt kinds of harassment and the many less obvious practices that enable a culture of harassment. The overarching themes of the report produced by NIH's ACD Working Group on Changing the Culture to End Sexual Harassment include the need for increased transparency and accountability in reporting, especially for sexual harassment, and the need for restorative justice mechanisms. Dr. Tabak explained that because the research enterprise is seen as a meritocracy, institutions might forgive inappropriate behavior by someone considered a great scientist. He added that the NIH also must consider how its funding practices contribute to a culture that drives women out of science. The NIH has revised its policies, created an Anti-Harassment Steering Committee and a new program to encourage civil behavior and has instituted a suite of tools, resources, and training to report and combat harassment, supported by a strong communication effort.

Dr. Tabak also outlined the results of the NIH survey regarding the prevalence of harassment, which showed that one in five respondents had experienced at least one incident of sexual harassment within the past 12 months. The most vulnerable populations include women, trainees, younger individuals, sexual and gender minority individuals, and individuals with disabilities. Dr. Tabak noted that more than half the

respondents did not talk about the harassment, and those who did not consider their supervisor supportive were more likely to experience sexual harassment. In addition, those experiencing bullying were more likely to experience gender and sexual harassment. Dr. Tabak pointed out that these results amplify themes shown in surveys conducted by other institutions. He emphasized that the goal of harassment is to exert power over the victim and this unacceptable practice is a major obstacle preventing women from achieving their rightful place in science, but the NIH can and must improve.

Discussion Highlights

- Dr. Scout, a member of the ACD Working Group on this topic, clarified that instituting restorative mechanisms is less a practice to achieve justice but more focused on combatting cultures of toxicity that incentivize institutions to protect researchers who may be high-performing while misbehaving.
- When asked about ways the NIH can influence the extramural community to reduce harassment, Dr. Tabak explained that extramural research organizations are explicitly required to provide a safe environment for the conduct of research. The NIH intervenes when informed of an unsafe environment, communicating with institutional representatives and, when necessary, removing the individuals responsible for inappropriate behaviors. He added that the grant is rarely terminated because that would harm the people who already have been aggrieved, so the NIH works with the institution to find an appropriate individual to take charge of the grant.
- In response to a question about harassment that may be identified without rising to the level of a formal complaint, Dr. Tabak explained that the NIH has taken steps to improve record-keeping so that patterns of harassment can be tracked. He emphasized that the broader community now understands that the NIH takes this issue seriously, which has increased reporting and eased the process of responding.

X. PROCESS FOR UPDATING THE NIH-WIDE STRATEGIC PLAN (FISCAL YEARS 2021–2025)

Marina Volkov, Ph.D., the director of DPCPSI's OEPR, remarked on the effort to update the NIH-Wide Strategic Plan for FYs 2021–2025 by clearly articulating the priorities of NIH and presenting an update on the previous Plan. Dr. Volkov presented the process and timeline for the Plan's development, noting that the framework for the Plan currently is in its public input phase and asking attendees to publicize the Request for Information (RFI) within their networks. The final plan is expected to be approved around December 2020.

The framework for the FY 2021–2025 NIH-Wide Strategic Plan includes an overview, a description of NIH's strategy, a few bold predictions for America's future, and an appendix. Within the description of NIH's strategy are three objectives: (1) advancing biomedical and behavioral sciences; (2) developing, maintaining, and renewing scientific research capacity; and (3) exemplifying and promoting the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science. Objective 1's efforts include driving foundational science; preventing disease and promoting health; and developing treatments, interventions, and cures. Objective 2 aims to cultivate the biomedical research workforce, as well as support research resources and infrastructure. Objective 3's goals are to foster a culture of good scientific stewardship, leverage partnerships, ensure accountability and confidence in biomedical and behavioral sciences, and optimize operations. Dr. Volkov concluded by noting several cross-cutting themes, such as increasing and enhancing diversity and promoting collaborative science.

Discussion Highlights

- A Council member described the inherent challenge in adhering to organizational strategic plans and asked for reflections on the FY 2016–2020 NIH-Wide Strategic Plan. Dr. Volkov responded that an effort is underway to monitor progress on individual IC strategic plans, which contribute to the NIH-Wide Strategic Plan.
- Dr. Volkov agreed with a recommendation that the NIH pursue collaborations with other government agencies, such as the National Science Foundation and the Centers for Medicare & Medicaid Services. The NIH currently is working to understand its outcomes, as well as who uses the evidence base it produces and how.

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 15, 2020.

XII. ADJOURNMENT

Dr. Anderson adjourned the meeting at 3:55 p.m. on January 24, 2020.

XIII. 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: 2020.02.27 14:43:03 -05'00'

02/27/2020

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

Date

Franziska B. Grieder -S

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Date: 2020.02.27 14:14:30 -05'00'

Feb 27, 2020

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

Date