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

Council of Councils Meeting
September 1, 2017

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 8:16 a.m. on Friday, September 1, 2017, in Building 31, Conference Room 10, on the NIH Campus in Bethesda, Maryland.

Dr. Anderson welcomed members and noted that Ms. Maria Acebal and Drs. Eric Boerwinkle, Jonathan Epstein, and John Postlethwait were unable to attend and Drs. Guellermina Lozano, Charles Mouton, and J.eLeslie Winston were attending by phone. The meeting attendees are identified below. Dr. Andersone also introduced Dr. Christine Hunter, Deputy Director of the Office of Behavioral and Social Sciencese Research (OBSSR) and announced that Dr. David Wilson, Director of the Tribal Health Research Office,e was unable to attend.e

Following introductions and announcements from Franziska B. Grieder, D.V.M., Ph.D., 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
Sharon Anderson, M.D., Oregon Health & Science University, Portland, OR
Melissa Brown, M.D., M.N., M.B.A., Thomas Jefferson University, Philadelphia, PA
Molly Carnes, M.D., M.S., University of Wisconsin–Madison, Madison, WI
Jorge L. Contreras, J.D., The University of Utah, Salt Lake City, UT
Hakon Heimer, M.S., Schizophrenia Research Forum, Providence, RI
Patricia D. Hurn, Ph.D., R.N., University of Michigan, Ann Arbor, MI
Terry L. Jernigan, Ph.D., University of California, San Diego, La Jolla, CA
R. Paul Johnson, M.D., Emory University School of Medicine, Atlanta, GAe
Sachin Kheterpal, M.D., M.B.A., University of Michigan Medical School, Ann Arbor, MIe
Vivian S. Lee, M.D., Ph.D., M.B.A., The University of Utah, Salt Lake City, UTe
Kimberly K. Leslie, M.D., The University of Iowa Hospitals and Clinics, Iowa City, IAe
Jian-Dong Li, M.D., Ph.D., Georgia State University, Atlanta, GAe
Guillermina Lozano, Ph.D., The University of Texas MD Anderson Cancer Center,e Houston, TX

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, Galveston, TX
Keith A. Reimann, D.V.M., University of Massachusetts Medical School, Boston, MA
Scout, Ph.D., The Torvus Group, Beverly Hills, CA
J. Leslie Winston, Ph.D., D.D.S., Procter & Gamble Global Oral Care, Mason, OH
Nsedu Obot Witherspoon, M.P.H., Children's Environmental Health Network, Washington, DC
Gail Yokote, M.S., University of California, Davis, Davis, CA

Council Members Absent

Maria L. Acebal, J.D., Food Allergy Research & Education, Inc., Washington, DC
Eric Boerwinkle, Ph.D., The University of Texas Health Science Center at Houston, Houston, TX
Jonathan Epstein, M.D., Perelman School of Medicine at the University of Pennsylvania, Philadelphia, PA
John Postlethwait, Ph.D., University of Oregon, Eugene, OR

2. Liaisons

Rachel Ballard, M.D., M.P.H., representing **David M. Murray, Ph.D.,** Director, Office of Disease Prevention (ODP), DPCPSI
Cindy Davis, Ph.D., representing **Paul M. Coates, Ph.D.,** Director, Office of Dietary Supplements, ODP, DPCPSI
Karen Parker, Ph.D., M.S.W., Director, Sexual and Gender Minority Research Office (SGMRO), DPCPSI
Peter Kim, M.D., representing **Maureen Goodenow, Ph.D.,** Director, Office of AIDS Research, DPCPSI
William Riley, Ph.D., Director, Office of Behavioral and Social Sciences Research (OBSSR), DPCPSI
Elizabeth Spencer, R.N., representing **Janine 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 Absent

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

4. Presenters

Molly Carnes, M.D., M.S., Professor, Departments of Medicine, Psychiatry, and Industrial and Systems Engineering and Director, Center for Women's Health Research, University of Wisconsin–Madison
Francis S. Collins, M.D., Ph.D., Director, NIH
Eric Dishman, Director, *All of Us* Research Program
Carrie Finno, D.V.M., Ph.D., Assistant Professor, Population Health and Reproduction, School of Veterinary Medicine, University of California, Davis
Lorette Javois, Ph.D., Program Director, Developmental Biology and Structural Variation Branch, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)

Patricia Labosky, Ph.D., Program Director, OSC, DPCPSI
Michael S. Lauer, M.D., NIH Deputy Director for Extramural Research
Ellyn Miller, Founder and President, Smashing Walnuts Foundation
Stephanie Murphy, V.M.D., Ph.D., Director, Division of Comparative Medicine, ORIP, DPCPSI
Karen L. Parker, Ph.D., M.S.W., Director, SGMRO, DPCPSI
Mary Ellen Perry, Ph.D., Program Director, OSC, DPCPSI
Elizabeth L. Pier, Ph.D., Postdoctoral Researcher, Center for Women's Health Research, University of Wisconsin–Madison
Scout, Ph.D., The Torvus Group
Elizabeth L. Wilder, Ph.D., Director, OSC, DPCPSI

5. NIH Staff and Guests

In addition to Council members, presenters, and Council Liaisons, others in attendance includede NIH staff and interested members of the public.e

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 July 25, 2017.
- Minutes from the May 26, 2017 meeting are published on the DPCPSI website. The minutes from this meeting also will be published there.

C. Future Meeting Dates

Council meetings in 2018 will be held on January 25 and 26, May 17 and 18, and September 6 and 7; these dates are reserved, but the duration of each meeting is not yet defined.

II. MECHANISM OF VITAMIN E DEFICIENT NEURODEGENERATION IN SMALL AND LARGE ANIMAL MODELS

Stephanie Murphy, V.M.D., Ph.D., Director of the Division of Comparative Medicine at ORIP, updated the Council on ORIP's initiatives for training veterinarian-scientists. NIH describes physician-scientists as scientists with professional degrees and training in clinical care who engage in independent biomedical research; this category includes both medical doctors and those with other health degrees, including veterinary degrees. Veterinarian-scientists offer a distinct perspective through their comparative

understanding of disease models, and they may conduct independent research or work within interdisciplinary research teams. This role is in contrast to clinical veterinarians at the NIH and elsewhere, who provide research and technical support for biomedical research studies using animal models and deliver maintenance and care for laboratory animals. The NIH administration has expressed interest in expanding a physician-scientist workforce that includes veterinarian-scientists, who currently comprise approximately 3 percent of the NIH-funded physician-scientist workforce. ORIP's training grants and career development programs are focused solely on assisting veterinarian-scientists. More than half of ORIP's training portfolio supports T grants for institutional training, and a new program targets F grants for individual training, which ORIP funded for the first time in fiscal year (FY) 2016. One-third of the training portfolio supports career development K awards, including Special Emphasis Research Career Award (SERCA) K01 grants, which provide developing veterinarian-scientists a mentored research experience that enables them to become independent researchers in areas related to comparative medicine, biomedical research, and translational science. In FY 2016, ORIP supported 27 SERCA K01 grants; however, support for the transition between a K01 award and the first R01 grant for developing veterinarian-scientists is needed. The Council approved a concept clearance in 2016 for ORIP to develop a limited-competition R03 small-grant program that enhances the ability of ORIP's SERCA K01 recipients to conduct research as they transition to independence. Additionally, ORIP assists veterinarian-scientists with the main obstacle to sustaining a research career—educational debt—by specifically supporting contract applications from veterinarian-scientists to the loan repayment program established by Congress, which repays up to $35,000 of educational debt annually in exchange for a commitment to engage in NIH mission-relevant research.

Dr. Murphy introduced Carrie Finno, D.V.M., Ph.D., Assistant Professor of Population Health and Reproduction in the School of Veterinary Medicine at the University of California, Davis, a recipient of an ORIP SERCA K01 grant focused on the molecular pathogenesis of α-tocopherol (α-TOH)-associated neuroaxonal dystrophy in animal models. Dr. Finno explained that α-TOH is the most commonly studied and potent form of vitamin E, a major lipid-soluble antioxidant that shares absorption and delivery pathways with cholesterol and may be critical to maintaining neurological health. Across species, vitamin E deficiency is characterized by deficits of the central and peripheral nervous systems, retina, and skeletal muscles, and the hallmark clinical sign is spinocerebellar ataxia. The majority of vitamin E is transported directly to the liver, where a tocopherol transfer protein removes the α-TOH and binds it to lipoproteins for transport to the rest of the body, including the central nervous system. Any disease resulting in fat malabsorption will lead to deficiencies in lipid-soluble vitamins and clinical signs attributable to vitamin E deficiency. One of these is ataxia with vitamin E deficiency (AVED), in which children develop spinocerebellar ataxia and pigmentary retinopathy. If recognized early, high doses of vitamin E supplements can stabilize the progression of the disease.

Dr. Finno noted that her primary research interest is how vitamin E deficiency leads to sensory deprivation, which her team studies using horse and mouse models. There is no antemortem diagnostic test for equine neuroaxonal dystrophy (eNAD), the term for AVED in horses, but the first clinical sign is loss of proprioception—the ability to sense one's limbs in space—which can be phenotyped in animals. Dr. Finno showed examples of how a neurological exam on a horse can identify signs of the disease by monitoring the horse's foot placement and balance during a dynamic neurologic examination that includes circling the horse. She noted that because the horse seen in the example could not support performance activities as intended and suffered from a poor quality of life due to ataxia, it was euthanized. At necropsy, Dr. Finno was able to diagnose eNAD; this diagnosis allowed the owners to develop breeding strategies to avoid the disease. Attempts to define an antemortem diagnosis have not yet been successful. Dr. Finno noted that the causes of AVED in children have been excluded in horses, but the site of vitamin E deficiency has been localized to the dorsal root ganglia.

Because horses have long gestation periods, with only one foal per year, and are expensive to maintain, Dr. Finno used her K01 grant to continue her investigations in a tocopherol transfer protein-associated null mouse model. At weaning, model mice already have significantly lower α-TOH concentrations than wild-type, despite not exhibiting signs of disease. Dr. Finno explained that wild-type mice on diets supplemented with high amounts of vitamin E have high α-TOH concentrations, while knockout mice show barely any increase in α-TOH on a highly supplemented diet. She showed examples of neurological exams on mice, in which mice navigated a balance beam or a horizontal ladder, and Dr. Finno's team quantitatively assessed their speed, balance, and foot misplacement, allowing the researchers to identify the AVED phenotype in mice at 6 months of age. Dr. Finno noted that the clinical and histological phenotype is rescued with high vitamin E supplementation; she described this as a prime example of nutrigenomics, or an integration of diet and genetics.

Dr. Finno explained her RNA sequencing studies in horses and mice to identify dysregulated genes and pathways and test protein function. Although most other studies to date have focused on the cerebellum, Dr. Finno's RNA sequencing of mice identified very few dysregulated genes in the cerebellum, with most activity in the spinal cord, indicating that the spinal cord actually is the start of clinical disease. Dr. Finno's studies showed an overall response of mechanisms that decrease cholesterol and oxidized lipoproteins in cells, including the liver X receptor. In the mouse, the team found a molecular signature associated with innate immune activation and inflammatory response. When the nuclear receptors were studied, vitamin E deficient mice showed activation of the liver X receptor and dysregulation of a retinoid-related orphan receptor (RORA), which is activated by unoxidized cholesterol to upregulate genes involved in synaptic maintenance. Recent studies also indicate that activation of either liver X or RORA is mutually exclusive. Dr. Finno and her team also performed electrophysiological evaluations that showed reduced membrane excitability of vitamin E deficient dorsal root ganglia neurons.

Dr. Finno summarized her proposed mechanisms for vitamin E deficiency. With sufficient levels of α-TOH, cholesterol remains unoxidized, and oxysterols are blocked from integrating into the plasma membrane, maintaining normal ion channel activity. Cholesterol also activates RORA, which is essential for synaptic function. When α-TOH is insufficient, cholesterol is oxidized to become oxysterol, which integrates into the membrane, altering ion channel activity. Oxysterols also activate the liver X receptor, attempting to return the cell to lipid homeostasis, but in the process turning off RORA. Dr. Finno emphasized that α-TOH appears to have a strong role in modulating the inflammatory response during postnatal development, and vitamin E deficiency deactivates a nuclear receptor critical for neural development, decreases myelination, and decreases dorsal root ganglia membrane excitability. Her team has concluded that this molecular dysregulation may lead to the neurologic phenotype observed in children with AVED. Dr. Finno reiterated that the K01 SERCA award has been critical in supporting her team to perform these studies.

Discussion Highlights

- In response to a question about whether α-TOH is primarily an antioxidant or a transcription regulator, Dr. Finno explained that this is an ongoing debate. Its function is well-conserved across species, and although some researchers think it primarily serves one role or the other, Dr. Finno theorized based on her studies that it both acts as a cholesterol-moderating antioxidant and plays a role in cell signaling and gene transcription through its effects on nuclear receptors.

- When asked why horses diagnosed with vitamin E deficiency at young ages were not supplemented with sufficient vitamin E to recover function, Dr. Finno explained that her team does provide high levels of vitamin E to these foals. This stabilizes the symptoms, but these horses still cannot support riders and, because of the poor quality of life for an ataxic horse and costs involved in caring for horses, many owners cannot afford to keep horses that cannot be

ridden. Additionally, a necropsy allows Dr. Finno's team to make a positive eNAD diagnosis so owners can make decisions about breeding and avoid producing more horses afflicted with the disease. Dr. Finno explained that, in the case of the horse shown, her team screened all related horses at the farm and implemented a widespread vitamin E supplementation program. She added that horses get their vitamin E from pasture, but with the recent drought in California, many vitamin E deficient horses have been seen, including some that develop eNAD.

- Dr. Finno explained that all known vitamin E transport and metabolism genes have been excluded as responsible for eNAD. She hopes to find something novel with strong translational implications.

- When asked whether veterinary training should be in clinical or basic science, Dr. Finno commented that this issue garners much debate. She recommended that veterinary scientists pursue basic science training in their Ph.D. programs, because these concepts are not taught in clinical training but can be applied in the clinic setting. Encouragement of additional basic science training for veterinary scientists is necessary to elevate the state of the science in this field.

- When asked whether any programs balance the time commitment required for both clinical board certification and research training, Dr. Finno explained that most veterinary residencies are clinical, but some include a dual Master's degree. She theorized that colleges would be amenable to students who want to design a program that would incorporate both clinical and research training.

- In response to a question about potential dual degree programs for veterinary scientists through the NIH, Dr. Murphy noted that the Physician-Scientist Workforce Working Group Report published in 2014 examined dual degree training across health professional degrees. In response to this report's recommendations to shift support from institutional to individual training grants, ORIP supports an F30 mechanism. Ongoing discussions about other strategies such as expanding Medical Scientist Training Programs to include veterinarian professionals must take into account that not every veterinary school is within the vicinity of applicable extended graduate programs or medical schools. Dr. Grieder added that the National Center for Advancing Translational Sciences' Clinical and Translational Science Award is an additional pathway for veterinarian-scientists.

III. STUDYING NIH GRANT PEER REVIEW

Molly Carnes, M.D., Professor in the Departments of Medicine, Psychiatry, and Industrial and Systems Engineering and Director of the Center for Women's Health Research at the University of Wisconsin–Madison, discussed how cultural stereotypes and implicit biases might influence peer review of R01 applications. She noted several studies showing that black R01 applicants are less likely to be funded than white applicants, and women are less likely to receive Type 2 R01s than men. Reviewers can be influenced automatically by a variety of implicit reference standards, such as race, gender, or prestige. Dr. Carnes suggested that simply knowing the content of pervasive stereotypes about groups, regardless of whether the reviewer believes these stereotypes, could affect how the reviewer scores an application. She noted that, in particular, stereotypes of men align strongly with assumptions of the characteristics of scientific leaders. Using text analysis of donated proposal critiques, Dr. Carnes and her team found that applications submitted by women included more standout adjectives, and applications submitted by men included more negative evaluation words, yet the applications studied received the same scores. This

suggests that the gender of the investigator could introduce bias into the evaluation of an application in ways that contribute to the gender difference seen in Type 2 renewals.

To examine how these implicit biases affect study sections and whether the point scale would be interpreted differently by different reviewers or different study sections, Elizabeth Pier, Ph.D., a postdoctoral researcher at the Center for Women's Health Research at the University of Wisconsin–Madison, and her team created four study sections, three that met face-to-face and one that met via videoconference. Agreement on scores of the same application between reviewers within a study section was very low prior to the meeting, but improved after discussion; however, discussion decreased agreement on the same application between panels. Dr. Pier's team reviewed videos of the panels and noticed much discussion of the point scale, including justification or challenge of a reviewer's score, which the research team dubbed score calibration talk (SCT). Self-initiated score justification was more common than score challenges, but reviewers who were challenged were likely to revise their score. Additionally, if the Chair of the meeting initiated the SCT, the reviewer was far more likely to change the score. Dr. Pier's team concluded that SCT fosters consensus, which is inversely related to agreement between panels. Dr. Pier emphasized that awareness of this phenomenon and other communicative processes in the context of study section meetings can help researchers understand how subjectivity and implicit biases infiltrate objective decision-making. SCT could be investigated as a potential intervention to improve the objectivity of peer review.

René Etcheberrigaray, M.D., Deputy Director of the Center for Scientific Review (CSR), emphasized that the CSR considers bias a critical issue and has a major bias study in progress. He suggested that discussion should affect scores, but consensus is not the objective of discussion, adding that although peer review may never be completely objective due to its reliance on opinion, those opinions should be expert. Dr. Carnes noted that NIH's study of its own processes indicates how much it values high-quality science.

Discussion Highlights

- Dr. Pier acknowledged that many factors that could affect scoring could not be studied in this experiment due to its small size, including the difference in scoring between male and female reviewers and implicit biases against members of one's own group. Future studies also should assess how standing study sections evolve as the makeup of the panel changes.

- When asked about potential next steps or training opportunities, Dr. Carnes explained that although unconscious bias assessment and training is difficult to design, the size of the NIH provides abundant opportunities to study bias further. Dr. Etcheberrigaray agreed that the Chair is the most consequential member of a study section; the CSR trains the many new Chairs recruited each year, but this training must be conducted carefully. He added that the CSR has been working closely with Dr. Hannah Valantine, the Chief Officer for Scientific Workforce Diversity.

- Dr. Pier noted that past studies showed that explicitly telling reviewers how many weaknesses align with each score improved reliability and agreement, but these studies were not conducted similarly to how real study sections operate. The process should be valid and fair, but it also should respect the diversity of reviewers' opinions. Dr. Pier's study was not large enough to accommodate random assignment; she emphasized that the subtlety of these biases underlying cognition makes them very difficult to study, and their effects may be stronger than those of explicit biases. Dr. Carnes added that a complex forthcoming experimental study, currently in the data collection stage, might provide more detailed answers.

- Dr. Pier acknowledged that the order in which the applications are discussed affects the amount of conversation. High-scoring applications were discussed early in the day, when reviewers were

inclined to longer discussions, but these discussions often were less nuanced than applications with more contentious scores, so changing this procedure could be beneficial.

- In response to a question about gender bias, Dr. Carnes explained that, overall, success rates at the NIH are equal between men and women, but gender differences occur in success rates for grants with greater prestige or higher budgets. She noted that gender is a powerful diffuse status cue, and men are overrepresented in areas of high status.

IV. NIH UPDATE

Francis S. Collins, M.D., Ph.D., Director of the NIH, reviewed the NIH budget, noting that the doubling of the budget that occurred between 1998 and 2003 reverted over the course of the following years, with budgets that were flat at best and sometimes, as in the sequester in 2013, losing significant funding. Congress currently is discussing the 2018 budget, but the House has included an increase for the NIH, and Senate discussions would occur the week following this meeting. Dr. Collins emphasized that the cycle of science is longer than the single-year budget cycle, making it difficult to manage without predictability.

Dr. Collins introduced the Next Generation Researchers Initiative, noting that young investigators have been particularly affected by NIH's reduced purchasing power. Hypercompetition for available positions and onerous administrative workloads make biomedical research a less attractive career pathway; Dr. Collins noted that a proportion of the next generation already has left the field or the country. Mid-career and early established investigators also may struggle with the transition between their first grant and sustainable funding. The 21st Century Cures Act explicitly requests that the director of the NIH promote opportunities for new researchers and early research independence. Beginning in FY 2017, directors of NIH Institutes and Centers will rearrange priorities to increase support for and provide a more favorable payline to early-stage and early established investigators. Dr. Collins noted that although peer review cannot predict which studies will be productive, this is the nature of science; funding the most promising applicants is the most likely strategy to support excellent science and the future of American biomedical research. Dr. Collins emphasized the importance of supporting NIH's meritocratic practices. He added diversity is greater among early-stage investigators, which could help shift NIH's overall demographic.

Dr. Collins commented on the opioid crisis, noting that the number of deaths from opioids now is greater than the number of deaths from AIDS at the height of the HIV epidemic and the annual number of deaths related to automobile accidents. This crisis is particularly troubling because one of the main causes is the medical establishment's erroneous belief that prescription opioids were effective for chronic pain. Although opioid prescriptions now are decreasing, opioid fatalities continue to increase; those who become addicted to prescription opioids, when denied access, turn to heroin as a widely available and cheap alternative. Heroin often is laced with synthetic opioids in ways that are not clear to the user, and these synthetic opioids are added in such small amounts that they are difficult to trace, yet they are so potent that a dose the user believes to be nonthreatening becomes fatal. Twenty-five million adults are struggling with chronic pain in the United States, and more than 2 million Americans are addicted to opioids, many after an initial prescription for pain. Treatment is well-documented, but programs without medication-assisted therapy are not widely available, and detox programs without medication-assisted therapy are not successful. The National Institute on Drug Abuse (NIDA) has been working hard to find non-addictive pain treatment solutions, and Dr. Collins commented on the many exciting potential strategies currently in development.

Dr. Collins also commented on recent discoveries highlighted on the NIH Director's Blog, including chimeric antigen receptor (CAR) T-cell therapy for pediatric cancer. He also noted that there are many potential applications of CRISPR-Cas technology across the NIH.

Discussion Highlights

- In response to a question about drug prices, Dr. Collins explained that the NIH has invested significant amounts in CAR T-cell therapy. Past efforts to place the NIH in a position to affect prices resulted in a sharp drop in industry collaboration, so although Dr. Collins agrees that this issue is critical, the NIH currently cannot take action.

- When asked whether NIH's patent guidelines will be updated to include CRISPR-Cas, Dr. Collins acknowledged that general discussions have occurred, but the issue should be investigated further.

- In response to a question about the cap for indirect costs, Dr. Collins noted that this topic is difficult to understand from an outside viewpoint; the reasons that costs differ across institutions are not immediately apparent. Discussions are ongoing as part of the budget process in Congress.

- When asked about areas that will be vulnerable in upcoming budgets, Dr. Collins acknowledged that although controversies may emerge about what kind of research the NIH should be conducting, Congress is well informed about medical research and traditionally has been willing to let the NIH base prioritizing decisions on scientific opportunity and public health need.

- Dr. Collins commended the 21st Century Cures Act's emphasis on diversity measures, noting his pride in having created Dr. Valantine's position. Exciting new initiatives include the Building Infrastructure Leading to Diversity (BUILD) Initiative, which provides summer research opportunities to students enrolled at universities without strong research programs. Dr. Collins commented that many future scientists from underrepresented groups are at such universities, so BUILD provides the real research experience critical for a student to commit to a career as a scientist. Additionally, a new mentoring initiative is creating the kind of network for underrepresented researchers that those from majority groups have always had; Dr. Collins noted that this program will help researchers navigate transitions between career phases, which often is where talented scientists without role models who look like them are lost.

V. COMMON FUND (CF) CONCEPT UPDATES AND VOTE

Elizabeth Wilder, Ph.D., Director of OSC, commented that investments from the Common Fund may help the promising areas of science targeted by these concepts to develop meaningful results sooner rather than later. She explained that the concept clearance process involves two members of the Council serving as discussants for each concept, followed by general discussion.

Mary Ellen Perry, Ph.D., Program Leader at OSC, presented the concept on somatic cell genome editing. Many incurable diseases have become theoretically treatable through new technologies like CRISPR-Cas, a simpler and more versatile genome editing approach that has begun to democratize gene editing approaches. Therapeutic development is inefficient, however, and development costs are high. Dr. Perry explained that gene editing involves targeting and correcting or disrupting a specific nucleotide sequence of a genome in a living cell. A common technique binds a nuclease to the DNA at a specific location, and the cell's machinery can repair the break caused by the nuclease and thereby replace the faulty gene. Prior to the development of CRISPR-Cas, a binding protein directed the nuclease to the desired DNA sequence, and each new sequence targeted required a new protein to be engineered. CRISPR-Cas9 uses a guide RNA, which is much simpler to synthesize than a protein, to direct the Cas9 nuclease. This system is both easier to use and more versatile; in some cases, lesions can even be repaired without breaking the DNA.

Attendees at a recent workshop identified opportunities in this area that the NIH could facilitate. A working group of NIH program staff from multiple ICs deliberated on these recommendations and proposes that a consortium of investigators in multiple areas develop new technologies to address these opportunities. New initiatives include reporter mice to verify targeting of novel nuclease systems, assays to address biological effects, improved delivery of gene editing machinery, and an expanded genome editing toolkit. A coordination center for this consortium would facilitate interaction between components and with other agencies that have activities in this space. Potential results include increasing access to investigational new drug (IND)-enabling technologies, which could lead to accelerated filings of new INDs for gene editing therapies and approval of these therapies, and development of new therapeutic approaches and potential cures for monogenic diseases.

The discussants, Drs. Guillermina Lozano and Terry Magnuson, commented on the timeliness, import, and potential impact of this concept. Dr. Magnuson recommended including an ethical, legal, and social implications (ELSI) component, commenting that the ELSI components of new technologies are the aspects most publicized and discussed. Dr. Perry responded that the team intends to include ELSI topics in the coordinating center to facilitate interactions with regulatory agencies. In response to a question, Dr. Perry acknowledged that although many Common Fund programs have an international consortium, this has not yet been considered for this concept. When asked how this project fits the requirement that Common Fund programs must be cross-cutting, Dr. Perry listed several potential applications: CAR T-cells are candidates, as are safe haven genes in the liver that could be targeted to treat certain diseases without targeting the causal gene. She added that this technology could be applicable to almost any condition, including Duchenne muscular dystrophy and infectious diseases. Dr. Wilder confirmed the consensus that this concept is appropriate for Common Fund support.

Patricia Labosky, Ph.D., Program Director at OSC, presented the concept on mechanisms of pain, noting that this is a trans-NIH effort because pain can affect every organ and every tissue in the body. The opioid crisis, as Dr. Collins noted, has roots in the prescription of opioids for chronic pain. Objective biomarkers for chronic pain would help identify which patients are at risk of transitioning from acute to chronic pain, which is the point at which opioids are often less effective. Discovery of such biomarkers will require extensive patient phenotyping. This concept proposes to follow patients from the onset of acute pain, such as after a trauma or surgery, and identify common signatures in patients who transition to chronic pain. Simultaneously, a group of patients who have undergone similar events in the past but already transitioned to chronic pain would be phenotyped to identify associated signatures. In addition to determination of signatures of the transition to chronic pain or ongoing chronic pain, these studies also would gather data about effective pain management strategies. In the initial stage, applicants from three sites would work together to coordinate their different scientific languages, determine how to unify pain management, and decide which clinical measures they will use to assess patients.

The discussants, Drs. Patricia Hurn and Sachin Kheterpal, commended the concept for its cohesiveness and timeliness, as well as its foundation of previous work, and noted that it is catalytic but may require additional components to ensure it will be transformative. Dr. Labosky responded that the project will include both psychosocial assessments and neuroimaging. When asked about the data sharing plan, Dr. Labosky explained that data sharing is most effective when a resource center ensures that all parties adhere to the same standards and that only data submitted to the resource center are used. Dr. Wilder added that this data resource would be made available to the broader community for analysis. In response to a question about pain in cancer patients, Dr. Labosky acknowledged that the team chose to focus on non-cancer patients as a starting point, but increased understanding of pain management the objective signatures identified could become applicable to cancer pain. Nora Volkow, M.D., Director of NIDA, commented on the differing characteristics of cancer pain and chronic non-cancer pain, adding that discovery of a biomarker for chronic pain would make this project transformative. Dr. Wilder confirmed the consensus to support this concept.

VI. COMMON FUND PROGRAM BACKGROUND AND UPDATE

The Gabriella Miller Kids First pediatric research program, founded by an Act of the same name, is in its third year, an ideal time to assess its progress and determine how to maximize its future impact. Ellyn Miller, founder of the Smashing Walnuts Foundation, explained that her daughter Gabriella was 9 years old when diagnosed with an inoperable brain tumor the size of a walnut; Ms. Miller and her husband founded Smashing Walnuts to empower Gabriella and themselves to work through a difficult journey. Gabriella's treatment occurred during NIH's sequestration and, like many children with cancer during that time, Gabriella was on a protocol that was stopped. She began speaking in public, often to large crowds, and the Miller family began to reach out to elected officials to inform them about the prevalence of childhood cancer, which led to additional awareness successes. Ms. Miller emphasized that when Gabriella was given the power to make a difference in the world as her cancer progressed, that power was given back to others. A video of Gabriella encouraging people to take action prompted former House Majority Leader Eric Cantor to add her name to the Kids First bill that funded this program to increase research on childhood cancers and birth defects. Ms. Miller emphasized the importance of the relationships the family built through their awareness campaigns, which are essential for each year's appropriation of funding for the program and occasionally lead to offers of additional funding. She emphasized the importance of understanding that samples studied in the laboratory were provided by a person whose bereaved family made the decision to donate their tissues to save future lives. Ms. Miller added that researchers have the ability to change the prognosis of childhood cancer, and she is committed to ensuring that they have the funding to succeed.

Lorette Javois, Ph.D., Program Director of the Developmental Biology and Structural Variation Branch at the NICHD, pointed out that passage of the Gabriella Miller Kids First Research Act ended the taxpayer contribution to the presidential nominating convention and transferred $126 million from that fund into a pediatric research initiative fund held by Congress, and it authorized Congress to appropriate $12.6 million each year for 10 years to the Common Fund to establish a pediatric research program. The major initiatives of the program at its inception included identifying cohorts of children with childhood cancers or structural birth defects and their families, sequencing their DNA, and compiling the sequences and clinical data into a publicly available data resource to foster collaboration and accelerate diagnostics and therapeutics. The first year of funding was provided to existing sequencing centers; this allowed the program to start its projects immediately and simultaneously solicit applications for dedicated sequencing centers in subsequent years. Cohorts were solicited via the X01 mechanism, which grants access to the dedicated sequencing centers rather than funding. Over the course of 3 years, the program has selected more than 18,000 genomes to go into the sequencing pipeline, representing 23 cohorts. Although funds are divided equally between birth defect and cancer research, cancer is more expensive to sequence, so comparatively fewer samples are processed. Sequencing centers currently are funded through 2018, but that could be extended.

The data resource center was funded this year with an award to the Children's Hospital of Philadelphia (CHOP); building this resource requires development of the public-facing portal, facilitation of data deposition into the relevant repositories, and harmonization of data across cohorts. Dr. Javois added that all activities are facilitated by an administrative and outreach core, which also helps the program maintain a strong connection to the advocacy community that ensures each year's appropriation. Additional funding possibilities, independent of the Kid First appropriation, include a funding opportunity announcement (FOA) soliciting R03 grants that will provide data analysis funds to those researchers working with Kids First data or researchers who are willing to deposit their Kids First-relevant genomic and clinical data into the Kids First data resource upon completion of their analysis. There are many options for how the program can proceed from this point; while sequencing is scheduled to end after 2018 and data mining and data demonstration projects proposed through 2024, sequencing could be extended

for several more years to provide more data and allow time for data harmonization before funding transitions to data mining projects.

Discussion Highlights

- Dr. Javois acknowledged that lack of data harmonization limits the utility of data from existing cohorts, but she explained that many of these have data use limitations that complicate cross-cohort analyses. If the sequencing component of the program is extended, data could be gathered under general use consents. CHOP also may be able to incorporate additional data sets through their numerous affiliations. Attendees pointed out that these options provide strong evidence for extending the sequencing time. Dr. Javois commented that additional sequencing also will allow more time for data to reach the public domain prior to initiation of the data mining effort.

- Dr. Javois explained that about twice as many applications were received related to birth defects than cancer, partly because this program is restricted to studying trios—the affected child and his or her parents—because other programs at the NIH, including *All of Us*, already include components related to personalized medicine for pediatric cancer. The high cost of sequencing tumors at twice the coverage of a normal sample also is a factor. Dr. Wilder commented that the joint focus on cancer and defects was intentional, as this is a Common Fund program and thus should involve multiple fields; the hope is that this research will identify mechanisms that underlie both types of conditions. Dr. Javois added that there are developmental links, as children with structural birth defects are much more likely to develop pediatric cancer.

VII. 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 55 ORIP applications with requested first-year direct costs of $14,846,032.

VIII. COUNCIL OPERATING PROCEDURES

Dr. Anderson reviewed proposed changes to the Council operating procedures, including changing the name of the Precision Medicine Initiative to *All of Us*, clarification of procedures for appealing an unfunded application, removal of a redundant section, changing the score cutoff for early concurrence applications, and clarification of the cutoff for total supplemental costs. When asked to clarify the second point, Dr. Grieder explained that the operating procedures do not explicitly state that the application could be provided if requested; the update is to make the procedures specifically match longstanding practice. The Council approved the update.

[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.

IX. UPDATE: *ALL OF US* RESEARCH PROGRAM

Eric Dishman, Director of the *All of Us* Research Program, noted that at his last update to the Council, the program had selected some initial awardees and published survey findings of what the general public hoped to learn. A year later, the program is tracking enrollment of real people in the first version of the real protocol. The program currently is in "closed beta phase" to support a gradual roll-out and infrastructure building, so participants may join only with a special code. The significant work and pilot projects completed in the initial stages were essential to the rapid growth of the program, as was the 21st Century Cures Act, which supports essential data sharing and privacy provisions and provides stable funding that allows the program to plan for the next 10 years. The next step is a national launch, anticipated for late this year or early next year.

The *All of Us* mission is to accelerate health research and medical breakthroughs to enable individualized prevention, treatment, and care for everyone. One main strategic objective is to nurture relationships with many people, from many different backgrounds, for many years—*All of Us* intends to reflect the diversity of the United States. Such trusted relationships will encourage participants to stay with the project long term. *All of Us* also intends to deliver one of the largest, richest biomedical data sets and to make it easy, safe, and free to access for a wide variety of researchers, including groups that would not be able to build a comparable cohort on their own, such as citizen scientists or researchers at community institutions. Additionally, the program's focus on developing partnerships ensures a robust system of researchers and funders who will use and support the resource.

Within several weeks, *All of Us* will begin testing its direct volunteer capabilities. The direct volunteer pathway to enrollment allows anyone in the U.S. to enroll with *All of Us* through a web interface, phone call, or mobile app. A participant who wants to enroll in the program completes the enrollment and consent process, which includes sharing electronic health record (EHR) data, capturing baseline physical measurements and biosamples, and connecting to mobile health technologies. One important consideration is how to ensure that participants do not need to be close to an academic medical center to participate in the program, hence the importance of the direct volunteer pathway. Mr. Dishman also emphasized the importance of local connections in facilitating personal health care and strengthening relationships.

When asked whether *All of Us* collects measures of sexual and gender identity, Mr. Dishman replied that self-reporting is included, and the program also focuses on helping participants understand what may be in their EHR. He added that state laws about health record disclosure vary. In response to a question about international partnerships, Mr. Dishman identified similar programs that had been consulted about both practical questions and shared protocol elements. He noted that, even with a million participants, incidences of very rare conditions will remain small, so a network of multiple large cohorts will be key to answering certain scientific questions. When asked whether quality of life assessments are included, Mr. Dishman explained that starting the program with a small number of assessments and expanding to more complex measures as the program grows is essential. He emphasized the importance of studying not only disease but also those factors that affect health and quality of life on a holistic level.

One major principle guiding the program's design is the idea that all health is local: building a network of health provider organizations and community partners is essential to ensuring local operation. *All of Us* intends to meet participants where they are, both physically and culturally, for which the direct volunteer program is critical, as is increasing the research capacity of Federally Qualified Health Centers, where many of the most vulnerable individuals in the country receive their care. To meet the program's diversity goals, applicant organizations include their catchment areas and plans for engaging diverse parts of the population. Mr. Dishman emphasized the importance of defining specific plans to reach special populations, including children, American Indian and Alaska Native participants, and incarcerated

participants. The current beta phase includes more than 130 locations that are distributing participant codes; about 2,000 participants have finished the full consent process and submitted biospecimens, and local staff are receiving feedback from these participants that will help improve the system prior to the full roll-out. Current challenges include navigating site-specific institutional amendments and ensuring that the system works with older computer systems at participating locations. Additionally, state consent laws are revised frequently, necessitating changes to the interface and revised approvals. Mr. Dishman added that program staff are considering whether to test the burst capacity of the system prior to a national launch to ensure that it can handle large numbers of participants enrolling simultaneously.

When asked about plans for incidental findings, Mr. Dishman emphasized that *All of Us* focuses on the responsible return of information; they are developing a provider engagement strategy, and additional genomic consent will be added at a later stage. Although the capacity of each location to conduct genetic counseling varies, Mr. Dishman hopes the large numbers of participants in this program will drive down the cost of genetic sequencing.

X. IMPLEMENTATION OF NIH CLINICAL TRIALS AND TRANSPARENCY REFORMS

Michael Lauer, M.D., NIH Deputy Director for Extramural Research, described a 2012 article in the *British Medical Journal* that revealed that the main results of more than half the trials funded by the NIH were not reported within 2.5 years of study completion. Dr. Lauer emphasized that because the public has paid for this work, the results should be made publicly available; unpublished trials waste government resources and participants' time, and they dishonor participants' contributions, which were intended to further scientific research and discovery. An audit of NIH's oversight of its trials recommended development of a central database of metadata, which is essential for the NIH to responsibly manage the trial portfolio and act as a steward of taxpayer funds.

To address these issues, the NIH began by publicizing its definition of clinical trials in 42 CFR Part 11, which emphasized that a fundamental premise of all NIH-funded research is that the results will be disseminated. Scientists have an ethical obligation to ensure that volunteers' burden has a result; to fulfill this obligation, a study should be registered within 21 days of enrolling the first patient, and results should be reported within a year of the end of the study. In addition to the registration and reporting requirements, applications will be changed to facilitate collection of metadata that will link the registration to a specific grant, creating a database that can be monitored so the NIH can responsibly steward its trial portfolio. Additionally, all trials will be connected to designated FOAs. Dr. Lauer emphasized that the changes are intended to make the process as simple as possible; he recognized that these requirements are significant in that they are changes to the culture of the field, but they also reaffirm the basic components of the scientific method. He noted that the NIH has declared its intent to withhold funding if unable to verify adequate registration and results reporting, but the hope is that researchers will comply with these regulations voluntarily to ensure that clinical trials are made more ethical, transparent, and responsible.

Discussion Highlights

- Dr. Lauer emphasized that researchers should not worry that results will not be accepted for publication; the results are required only to be posted on clinicaltrials.gov, not necessarily published. He added that journals have recognized that this does not represent publication, so papers using these results will be considered.

- In response to a question about whether clinicaltrials.gov fits the kind of research performed in all fields, such as cognitive or social science, Dr. Lauer suggested that the NIH would work with

researchers to ensure that the database meets the needs of the public and the scientific community. Studies will continue to be reviewed by study sections with the appropriate expertise. Dr. Lauer emphasized that these regulations ask only that researchers register the study with a description similar to a methods section and report results with a table of baseline characteristics and outcomes, activities that researchers likely would complete already.

- Dr. Lauer clarified that these policies do not apply to purely observational studies, epidemiological studies, or perturbations for the purpose of measuring a process rather than modifying it. He emphasized that the policy is a living document that will be revised regularly. He also acknowledged the difficulties in developing messaging for this process that is clear to both researchers and patients.

- When asked about a plan for monitoring and enforcement, Dr. Lauer explained that a number of processes are in place to link registration data and use algorithms to find studies that have not been reported. He emphasized that the NIH is more interested in ensuring that results are reported than punishing researchers for failing to report them.

- Dr. Lauer agreed that connecting with academic institutions, business offices, and professional societies will be critical to this effort; he hoped that both individual researchers and institutions would be motivated to comply with these policies.

XI. SEXUAL AND GENDER MINORITY RESEARCH OFFICE

Karen Parker, Ph.D., M.S.W., Director of SGMRO, thanked the Council for its support of the SGMRO over the past 2 years. The office recently published the FY 2015 Portfolio Analysis, which reviews sexual and gender minority (SGM) research across the NIH, and the 2016 Sexual and Gender Minority Research Office Annual Report, which assesses initiatives and activities related to SGM health across the NIH. One of SGMRO's goals is to expand the knowledge base of SGM health and wellbeing through NIH-supported research. This is being addressed through a FOA focused on the health of SGM populations with eight participating components throughout the NIH. Another initiative addressing SGM health is Administrative Supplements in SGM Health Research, which includes 19 components and 13 funded applications in FY 2017. Additionally, an R21 through the Fogarty International Center that studies ways to reduce stigma in HIV prevention treatment and care in low- and middle-income countries includes several SGM populations.

The director of the National Institute on Minority Health and Health Disparities (NIMHD) recently designated SGM groups as a health disparity population at the NIH; this official status legitimizes SGM researchers' work and sends a message to the community that the NIH is committed to better understanding their health through research. The NIH also is adding a gender identity marker to the EHR at the Clinical Center, and is training clinicians in the importance of collecting these data, making the NIH a more affirming environment for SGM individuals. SGMRO also has been in discussion with *All of Us* to ensure data on sexual orientation and gender identity (SOGI) are collected. Dr. Parker pointed out that one of the new awards that Mr. Dishman mentioned was to the San Francisco General Hospital Foundation, specifically to engage the LGBT community in *All of Us* efforts.

In addition, SGMRO focuses on removing barriers to NIH-supported research on SGM health and well-being. Creation of SGMRO was the first step in addressing this goal, and members of the office participate in a number of coordinating committees and working groups to stay informed about research and data collection across federal agencies. Dr. Parker emphasized her role as a connector for researchers and program officers with questions about SGM-related topics. SGMRO also communicates widely with

external parties to publicize their research priorities, commitment to SGM health, and availability as a resource.

Another goal of SGMRO is to strengthen the community of researchers who study SGM health. Dr. Parker emphasized that the relationship-building on which the office focuses helps researchers to understand that there are places at the NIH that will help them. SGMRO co-sponsors the NIMHD's summer research institute, ensuring that SGM health research is reflected in the faculty makeup and connecting with participants who conduct SGM-related research.

Additionally, SGMRO evaluates the progress on the NIH SGM research strategic plan by regularly consulting action plans for each strategic goal and validating research, condition, and disease categorization (RCDC) codes to ensure the quality of their data portfolio. Between 2010 and 2016, SGM-related projects increased by 44 percent. About 73 percent of SGM-related work at the NIH is in HIV/AIDS, but many projects are related to mental health and substance abuse. Research projects comprise the majority of funding, followed by K awards and cooperative agreements. There are also approximately 60 training or career development awards in SGM health. Dr. Parker pointed out that many SGM-related projects are concentrated at the handful of institutions that have become hubs for this research, but it is important to ensure that researchers at other institutions also can connect to a mentoring network and that, if they identify as an SGM individual, they can be affirmed at work to ensure that they remain in research.

Dr. Parker explained that the 21st Century Cures Act encourages the director of the NIH to improve SGM-related research; this includes facilitating the development of valid and reliable methods for research relevant to SGM populations. The SGM Research Working Group of the Council of Councils met the day prior to this meeting and provided feedback to the SGMRO on several initiatives planned for FY2018. A measurement workshop, for example, would identify gaps in data collection in SGM-related measurement literature and result in a research agenda in SGM-related measurement. The Best Practices in SGM Research Manual would assist investigators with developing competitive applications and educate peer reviewers who evaluate SGM-focused applications. Regional SGM research workshops would focus on strengthening the community of scholars across the country, and an SGM Early Investigator Award would promote SGM health research among early-stage investigators. The Working Group will review the NIH SGM Research Strategic Plan at next year's meeting and provide the Council with a report and recommendations.

Scout, Ph.D., The Torvus Group, provided further updates from the Working Group, noting that SGMRO's work is built on a long history of researchers across federal health agencies working to ensure that SGMs are not a forgotten or masked population. Although SGM populations have some clear health disparities, poor data collection makes it difficult to find solutions. The Working Group discussed whether researchers interested in SGM health can build careers that encompass broader health issues than HIV; Dr. Scout noted that some ICs may be considering changes to their priorities, which may change funding and inadvertently impact the SGM research portfolio. He also commented on the portfolio analysis, noting that few of the training awards are training centers; some recipients may be at institutions that may not have enough mentorship.

Dr. Scout explained that disorders of sexual development are biological, chromosomal, or hormonal issues that manifest near birth or puberty. People with these conditions often identify as intersex. The Working Group engaged in much discussion of the level at which SGMRO currently addresses these disorders. It may be possible to use RCDC codes to identify how much funding is dedicated, but until that can be developed, the Working Group recommends text analysis. Dr. Scout emphasized the need to ensure that SGMRO material adequately reflects disorders of sexual development and suggested that a literature review also is needed. The Working Group recommends discussions with the NICHD, which

has conducted much of the work in this area. Dr. Scout noted that the community of individuals with disorders of sexual development is fractured, and SGMRO should focus on listening to all perspectives and understanding the issues.

The recent designation of SGMs as a health disparity population is likely to increase inclusion of SGMs in disparity-related initiatives across ICs, but an unintended consequence is that current FOA construction cannot accommodate simultaneous inclusion of SGM and racial and ethnic minority centers, despite overlap between these populations. The Working Group also considered whether NIH's peer reviewers understand that SGMs now are included in this population; one reviewer who misunderstands the importance of a study can skew the score and prevent the application from being funded. Dr. Scout pointed out that, for many years, a researcher interested in SGM research had to seek out a single project officer willing to discuss it, then code the language of the study to ensure the project would be considered a valuable use of government funds. Dr. Scout also suggested that the field needs more national conferences at which the community can convene.

The Working Group strongly recommended that the Council encourage inclusion of an explicit focus on sexual orientation, gender identity, and disorders of sexual development in the next reauthorization of the Scientific Workforce Diversity Initiative (BUILD). Dr. Scout emphasized that that which cannot be seen cannot be measured, so the first step in understanding the SGM biomedical workforce is to collect data.

Discussion Highlights

- When asked whether support for SGM-related research will decrease during the current administration, Dr. Parker explained that the level of support from the NIH has not changed, and inclusion of SGM populations is becoming ingrained across ICs. Dr. Anderson added that the NIH is here to support the health of everyone.

- Dr. Parker and Dr. Scout supported an attendee's suggestion to connect with medical education and student groups regarding SGM initiatives.

XII. CLOSING REMARKS

Dr. Anderson thanked the Council members and speakers for their contributions at this meeting. He reminded the members that the next Council meeting is scheduled for January 25–26, 2018, noting that the actual length of the meeting has yet to be determined.

XIII. ADJOURNMENT

Dr. Anderson adjourned the meeting at 4:01 p.m. on September 1, 2017.

XIV. CERTIFICATION

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

10/09/2017

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

Date

10.9.2017

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

Date