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 31, 2014

Meeting Minutes

I. WELCOME

James M. Anderson, M.D., Ph.D., Chair, welcomed participants, NIH staff members, and members of the public to the meeting of the Council of Councils (CoC). The meeting began at 9:45 a.m. on Friday, January 31, 2014, in Building 31, Conference Room 6, on the NIH Campus in Bethesda, Maryland.

Dr. Anderson welcomed the nine new members to the Council, Drs. Alderson, Belfort, Cuervo, Garber, Gierasch, Holmes, Kenyon, Magnuson, and Pelc. Dr. Anderson noted that Drs. Garber and Holmes were unable to attend the day's meeting, and Drs. Bustamante, Greenwald, and McClain were participating via teleconference. The attendees are identified below.

Following introductions and announcements from Dr. Franziska B. Grieder, Executive Secretary for the CoC, 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, OD, NIH
Executive Secretary: Franziska B. Grieder, D.V.M., Ph.D., Director, Office of Research Infrastructure Programs (ORIP), DPCPSI, OD, NIH
Philip O. Alderson, M.D., Saint Louis University, St. Louis, MO
Marlene Belfort, Ph.D., University of Albany, Albany, NY
Emery N. Brown, M.D., Ph.D., Massachusetts Institute of Technology, Harvard Medical School, Massachusetts General Hospital, Cambridge, MA
LaVarne A. Burton, M.A., American Kidney Fund, Rockville, MD
Carlos D. Bustamante, Ph.D., Stanford University School of Medicine, Stanford, CA
F. Xavier Castellanos, M.D., New York University School of Medicine, New York, NY
Janice E. Clements, Ph.D., The Johns Hopkins University School of Medicine, Baltimore, MD
Ana M. Cuervo, M.D., Ph.D., Albert Einstein College of Medicine, Bronx, NY
Steven T. DeKosky, M.D., University of Virginia, Charlottesville, VA
Lila Gierasch, Ph.D., University of Massachusetts, Amherst, MA
Susan F. Goekler, Ph.D., M.C.H.E.S., Directors of Health Promotion and Education, Washington, DC
Richard M. Greenwald, Ph.D., Simbex, iWalk, Thayer School of Engineering, Lebanon, NH
Barbara J. Guthrie, R.N., Ph.D., F.A.A.N., Yale University, New Haven, CT

Nancy L. Haigwood, Ph.D., Oregon Health & Science University, Beaverton, OR
Jeffrey A. Kaufman, M.B.A., Adenoid Cystic Carcinoma Research Foundation, Needham, MA
Norma Sue Kenyon, Ph.D., Wallace H. Coulter Center for Translational Research, University of Miami School of Medicine, Miami, FL
Grace LeMasters, Ph.D., University of Cincinnati College of Medicine, Cincinnati, OH
K.C. Kent Lloyd, D.V.M., Ph.D., University of California, Davis, CA
Terry Magnuson, Ph.D., UNC Chapel Hill School of Medicine, Chapel Hill, NC
Craig J. McClain, M.D., University of Louisville School of Medicine, Louisville, KY
Joyce A. Mitchell, Ph.D., F.A.C.M.G., F.A.C.M.I., University of Utah, Salt Lake City, UT
Robert F. Murphy, Ph.D., Carnegie Mellon University, Pittsburgh, PA
Norbert J. Pelc, Sc.D., Stanford University, Stanford, CA
James E. Schwob, M.D., Ph.D., Tufts University School of Medicine, Boston, MA
Gilbert C. White, II, M.D., Blood Research Institute, Blood Center of Wisconsin, Milwaukee, WI

Council Members Absent

Judy E. Garber, M.D., M.P.H., Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA
King K. Holmes, M.D., Ph.D., University of Washington, Seattle, WA

2) Liaisons

Janine A. Clayton, M.D., Director, Office of Research on Women's Health, DPCPSI, OD
Robert M. Kaplan, Ph.D., Director, Office of Behavioral and Social Sciences Research, DPCPSI, OD
David M. Murray, Ph.D., Director, Office of Disease Prevention, DPCPSI, OD
Wendy Wertheimer, Senior Advisor, Office of AIDS Research (OAR), DPCPSI, OD (representing OAR Director Jack Whitescarver, Ph.D.)
Elizabeth L. Wilder, Ph.D., Director, Office of Strategic Coordination, DPCPSI, OD

3) Presenters

Jennifer Couch, Ph.D., Chief, Structural Biology and Molecular Applications Branch, Division of Cancer Biology, National Cancer Institute (NCI)
Richard J. Hodes, M.D., Director, National Institute on Aging (NIA)
Jon R. Lorsch, Ph.D., Director, National Institute of General Medical Sciences
Joan McGowan, Ph.D., Director, Division of Musculoskeletal Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases
Elizabeth A. Phelps, Ph.D., Silver Professor of Psychology and Neural Science, New York University
Philip Smith, Ph.D., Deputy Director, Division of Diabetes, Endocrinology, and Metabolic Diseases, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

4) NIH Staff and Guests

In addition to Council members, presenters, and directors, others in attendance included NIH staff and interested members of the public.

B. Meeting Procedures

Dr. Grieder reviewed the following:

- Council members are Special Government Employees on days of Council meetings and therefore are subject to the rules governing Federal employees.
- Each Council participant completed and submitted a financial disclosure form and conflict of interest statement as a Federal requirement for membership on advisory councils. Financial disclosures are used to assess real and perceived conflicts of interest, and Council members must recuse themselves from the meeting during discussion of items for which conflicts have been identified.
- Time has been allotted for discussion between the Council 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, published on December 27, 2013.
- Council members should not speak on the Council's behalf or on activities not yet cleared by the Council.
- Approved meeting minutes will be posted on the DPCPSI website.

C. Future Meeting Dates

The next Council meeting will be held on June 20, 2014. The final Council meeting in 2014 will be held on September 5, and in 2015, Council meetings will be held on January 30, June 19, and September 1.

II. DPCPSI UPDATE

A. Maximizing Efficiencies of Core Facilities

Dr. Anderson indicated that at the January 6, 2014, NIH Leadership Forum, Directors of NIH Institutes and Centers (ICs) and others discussed multiple topics, including increasing the efficiency of NIH-supported core facilities. Core facilities are defined as centralized shared research resources with dedicated personnel, equipment, and space that attempt to recover their costs through user fees. Core facilities are funded in multiple ways, and NIH cores are funded through many mechanisms.
Dr. Anderson focused on core services funded by P30, P50, P60, and U54 grant mechanisms. The organization of core resources is quite variable at different institutions, including institution-wide cores, Centers, and others. In addition, core management also varies widely. The topic of efficient management and use of core facilities is not new, and was addressed at two workshops held in 2009 and 2010 that were attended by many core directors. The workshop participants identified six areas of interest: (1) a centralized directory of information about cores; (2) training in basic business practices for directors; (3) the benefits of centralized versus decentralized management, on which no consensus was reached; (4) continuity of resources to support staff; (5) duplication and underutilization of core services, including funding of cores with similar functions by different ICs; and (6) the need to comply with and the difficulty in understanding Office of Management and Budget (OMB) Circulars A-21 and A-122.

Dr. Anderson shared information about the distribution of core funding by institution and by services offered within institutions. In fiscal year (FY) 2013, NIH awards to cores totaled approximately $2 billion, and the top 30 institutions received approximately one-half of that total funding. Spending on

cores was defined as spending for administration, research, and "cores activities." Dr. Anderson presented information on three representative universities that were recipients of 38 P30 grants awarded by 13 ICs, and encompassing support of 155 shared resource facilities. As one example, Dr. Anderson referred to services provided at "Institution B" included six animal resource cores (i.e., mouse models); two DNA sequencing service cores, which could be obtained much less expensively by outsourcing to commercial providers; three histology services cores; and so forth. The P30-funded histology cores were subprojects under the core grant support. Research on the institution's website, core websites, and online using NIH's RePORTER and Google identified seven additional active histology cores, including a P30-funded core that was not detected because it was funded by a no-cost extension, a core that had an ambiguous title, and a core that was associated with the Department of Pathology.

Dr. Anderson closed his remarks with observations about NIH support of core facilities and questions for the CoC. A significant level of NIH support goes to core facilities; redundancy might exist but is difficult to document; there is no systematic data collection to identify opportunities for sharing core services, although not all core services can be shared; and anecdotally, institutions are motivated to manage and share cores because they can become a liability. Dr. Anderson asked the members of the CoC for their opinions regarding whether opportunities for sharing core facilities exist.

Discussion Highlights

- Institutions are vested in increasing efficiency in core facilities. Cores can become a liability to institutions when operated inefficiently, requiring additional institutional support; therefore, institutions likely would welcome opportunities for consolidation. For example, one university requires that all grants with funding for major instrumentation be reviewed for underutilization.

- Bridge funding and incentivizing the sharing of services would alleviate the pressure to seek funding for cores with overlapping services that is created by the potential for discontinuous funding. Incentives to share core services among different campuses of institutions or among different institutions within a geographic area would increase efficiency. One incentive might be not requiring participating institutions to pay the external indirect cost rate.

- Core facilities reviewed as part of Center grants are judged by less stringent criteria than those for high-end instrumentation grants, which include the environment, management, sustainability, and existing opportunities for sharing. These stricter criteria could be applied to core facilities within Center grants. In addition, competing and awarding grants to support core facilities separately from their currently aligned projects would require applicants to justify support for their core facilities in the context of similar shared resources at their institutions, and would help institutions manage and provide support for cores.

- Expanding the description of institutional facilities on grant applications to explicitly include core facilities might reveal overlaps among core services within institutions. If the potential grant applicant's institution has NIH-funded cores, grant applicants might be asked to identify opportunities for existing cores to provide services for the project from current services or supplemental core funding. The reduction in costs would provide an incentive for maximizing efficiency.

- A Council member pointed out that some apparent duplication of core facilities might result from the same physical core being named differently in different grant applications. This might be revealed by examining the names of the personnel at each of the nominally different core facilities.

- A Council member emphasized that NIH funding of core facilities is one of the most vital services that the NIH provides to institutions, and any changes to the program should be considered in a thoughtful and informed way.

B. Other DPCPSI Updates

Dr. Anderson provided background and an update on the topic of the use of chimpanzees in NIH-supported research. He summarized the background, noted in December 2010, the NIH requested the Institute of Medicine (IOM) assess the scientific necessity for the use of chimpanzees in NIH-supported research. After a year of review of current and likely future uses of chimpanzees in research, the IOM developed a set of principles and criteria that would govern the use of chimpanzees in research now and in the future. The NIH accepted the IOM principles and criteria and a Working Group of the Council of Councils was established to develop an implementation plan. As part of that plan, the Council recommended establishment of an independent evaluation panel—the Chimpanzee Research Use Panel (CRUP)—to review future proposed research projects to determine if they are consistent with the IOM principles and criteria and additional criteria recommended by the Council of Councils. The CRUP, a working group of the Council of Councils, will be composed of veterinarians, primatologists, and members of the public. The CRUP's review of all requests to use chimpanzees in NIH-funded research will be independent of the NIH scientific peer review process. The co-chairs of the CRUP—Drs. Barbara Guthrie and Gilbert White—met prior to today's Council meeting to review the process and establish operating procedures. Applications are being received currently, and Dr. Anderson indicated CRUP's recommendations will be presented to the full Council for consideration at future meetings.

Dr. Anderson provided a report on ORIP activities to evaluate new opportunities and needs from ORIP's Division of Comparative Medicine. These include improving the use of animal models to address the needs of human personalized medicine; ORIP organized a workshop on the topic in October 2013, resulting in a report that is available online at the ORIP website (http://dpcpsi.nih.gov/sites/default/files/Animal_Models_and_Personalized_Medicine_Meeting_Summary.pdf). A workshop also was organized by ORIP on the use of zebrafish to address questions of translational medicine. A report from this workshop is in preparation.

Dr. Anderson also updated the Council on the Science Education Partnership Award (SEPA) Program, which funds projects that focus on K through 12 education in science, technology, engineering, and mathematics (STEM), as well as community health literacy of NIH research. President Barack Obama's FY 2014 budget proposed discontinuing funding of the NIH's SEPA Program. The White House's Office of Science and Technology Policy, as well as a Federal committee that has been exploring the improvement of STEM education, recommended that the many federal STEM programs, which are distributed among different agencies, including the NIH, be consolidated. The appropriations bill report language for FY 2014, however, directs the NIH to continue funding its SEPA Program. As a result, the NIH plans to continue to fund noncompeting SEPA grants in FY 2014, fund new SEPA awards in FY 2014 that the CoC cleared in January 2013, and reissue a SEPA Funding Opportunity Announcement (FOA) to fund new awards in FY 2015.

III. NIH UPDATE

Dr. Francis S. Collins, Director, NIH, expressed his enthusiasm about speaking to the CoC. He looked forward to engaging the members in conversations about opportunities in biomedical research, as well as some of the challenges that face the NIH. In particular, he would welcome questions and observations on the NIH's efforts to optimize the use of the resources that Congress has provided to the agency.

Dr. Collins recognized that recent years have presented difficulties for the NIH budget. The sequestration and government shutdown posed particular fiscal challenges and represented an interruption to ongoing research. Dr. Collins credited public support for ending such fiscal strategies. Dr. Collins reported that the FY 2014 budget provides a $1 billion increase relative to FY 2013 in appropriations for the NIH, representing a general increase of approximately 3 percent for the ICs. He expressed optimism that future funding of the NIH, as well as medical and scientific research, will be supported strongly. He pointed to broad recognition that investments in the NIH represent the best hope for improving the Nation's health and reducing health care costs, and are an excellent economic investment.

Dr. Collins' remarks then turned to challenges facing the NIH. Economic stresses and rapidly changing scientific opportunities represent challenges moving forward for the NIH's excellent peer review process. A "nimble" peer review system is required for the NIH's peer review process to respond to new trends in science. In addition, ensuring that scientific leaders—the "big thinkers"—are active participants in the review process is important to identifying and funding the most compelling science. For a healthy peer review process, the strength of the science assessed and funded also needs to be well-balanced across the diversity of disciplines in the NIH's peer review system.

Dr. Collins said that the NIH's peer review system could be evaluated by studying its "inputs" and "outputs." To achieve balance within the peer review system, metrics are needed to assess both the overall quality of research proposals received and the impact of the results achieved by funded research in the context of the relevant field of study. The NIH's Analysis of Review Group Outputs (ARGO) has begun to evaluate the structure of the NIH's peer review organization in the context of current scientific activities. In addition, DPCPSI is initiating an effort to use electronic data to identify emerging fields as early as possible, and many of the ICs also are embracing this approach.

A second challenge is developing new approaches to supporting science that foster creativity and productivity while accommodating budgetary constraints. The NIH Director's Pioneer Award Program, which is funded through the Common Fund (CF), has been highly successful. Pioneer Awards have a different evaluation model than R01 grants. R01 grant applications require detailed experimental plans and extensive preliminary data; the focus for Pioneer Award applications, however, is on the creativity of the applicant. Dr. Collins recognized the success of the Pioneer Award Program in identifying investigators who develop into highly productive researchers. Dr. Collins indicated that a number of the ICs plan to start programs similar to the Pioneer Award Program, increasing available resources beyond the CF so that the NIH will be able to increase investment in such approaches to funding research.

Dr. Collins noted that the process of applying for funding in biomedical research is highly competitive. Excessive competition creates pressure on investigators to focus on projects that are likely to result in high-profile publications in a short time period. Addressing difficult problems that are unlikely to produce publications quickly becomes less attractive. Focusing on "investing in the investigator," as typified by the Pioneer Award Program, might alleviate such pressures.

The third challenge addressed by Dr. Collins was enhancing the use of the NIH grant biosketch to assess an investigator's contributions to his or her field of research. Currently, the NIH's extramural review process tends to favor investigators who publish extensively in high-impact publications and are prolific. There is a need to assess investigators' contributions in a more holistic way that recognizes the collaborative nature of modern-day scientific research.

Finally, in a recent letter to *Nature*, Dr. Collins and NIH Principal Deputy Director, Dr. Lawrence Tabak, discussed the issue of reproducibility, as well as actions that the NIH might take to address it. Researchers, mainly from the pharmaceutical industry, have reported being unable to reproduce a large proportion of preclinical trial results. This poses a critical problem for translational medicine because preclinical studies form the basis for clinical trials. Dr. Collins highlighted some of the factors that have

led to problems with reproducibility. These include difficulties in replicating experimental protocols because of particularities of experimental conditions that were not considered sufficiently; the design of preclinical experiments that neglect the best practices that are required for human clinical studies such as randomization, statistical power calculations, and blinding; and publishing pressure that leads investigators to limit replication of their own experiments. Dr. Collins emphasized the need for better training of scientists regarding best practices for reproducibility; independently replicating preclinical studies before embarking on clinical trials; and recognition of the importance of the issue by journals, universities, and the investigators.

Dr. Collins closed his remarks by drawing attention to the NIH's role in funding cutting-edge, transformative science. He stated that this is an exciting time for biomedical research. One illustration of the great strides being made in the field is that cancer immunotherapy was named the science breakthrough of the year by *Science* magazine. *Science* publishes an annual list of the top-10 scientific breakthroughs in the fields of physics, chemistry, biology, and medicine. In addition to cancer immunotherapy, the NIH also supported seven out of the nine other top advances in research in 2013 that were recognized by *Science*. Dr. Collins stated that such recognition is a tribute to the scientific opportunities, institutions, and creative and talented scientists that the NIH supports. He affirmed the NIH's commitment to continue to support the individuals and institutions that make possible such dramatic and important advances in biomedical research.

IV. DISCUSSION

The issue of reproducibility is widely recognized as important in the scientific community. A Council member cited recent efforts by the National Academy of Sciences' (NAS) Institute for Laboratory Animal Research, which has established a roundtable forum to respond quickly to reproducibility issues. The forum is educating researchers on proper experimental design and other issues of reproducibility, capitalizing on advances in clinical trials and applying them to preclinical studies. It also is important to understand the role of genetic background in reproducibility in preclinical trials.

A fundamental issue pertaining to reproducibility is the need for a greater understanding of statistics and the use of statistical methods to evaluate uncertainty. This understanding is needed among scientists as well as the general public. Some journals, such as the *New England Journal of Medicine*, have experts in statistics on staff but others such as *Nature* and *Science* do not. The lack of understanding of statistical analysis also leads to the inability to account for biases in large data sets and problems with reproducibility of results from such data sets. It is a new type of statistics in which many scientists lack training. The NIH could provide leadership in valuing statistical literacy.

Data sharing also is important for fostering reproducibility. The need for increased data sharing raises issues of establishing data repositories and protecting privacy, which the NIH is addressing actively. The NIH has recruited Dr. Philip E. Bourne as Associate Director for Data Science.

A recent article in *The Economist*, titled "How Science Goes Wrong," has attracted a large amount of attention from the general public and Congress. There was concern among the Council members that the public might interpret problems with reproducibility as evidence that funding to the NIH is being wasted. The outcome analysis approach, which emphasizes beneficial effects on public health, is a positive response by the NIH to such concerns.

The Council members strongly endorsed the Pioneer Award Program for its emphasis on creativity and high-impact results. They noted parallel success by the National Institute on Drug Abuse (NIDA) with its Avant-Garde Award Program for HIV/AIDS-oriented research, and suggested that it would be beneficial

to disseminate such programs to other ICs. There was concern, however, that the program might favor applicants from elite institutions.

It is important to recognize "superstars" at the beginning of their careers, perhaps through a Pioneer Award-like program; a particularly critical juncture is when investigators are competing for their second awards against established investigators. Personal interviews might help identify such individuals.

Council members expressed concern regarding the limitations inherent in the current system of study session review, including potential unconscious biases of reviewers, a relative lack of members of underrepresented minority groups in study sessions, and limited opportunities for input from the applicant to provide support from their scientific community for their application. A Council member expressed concern about unclear expectations regarding the role of study section chairs. The study section chair's role should include advancing consistency among study sections. Council members recognized the need for training to address role expectations and bias awareness.

Increasing minority representation in scientific research is important. Enhancing the diversity of the scientific workforce is a high priority at the NIH, including providing training for study section members and exploring potential biases in the review process. The NIH is installing a new Chief Officer for Scientific Workforce Diversity, Dr. Hannah Valantine. The NIH is implementing unconscious bias training for its extramural peer review staff, and is conducting experiments on the effects of investigator parameters on success rates. The NIH has been proactive in eliminating bias in the review process since the study by Ginther et al., "Race, Ethnicity, and NIH Research Awards," was published in *Science* in 2011, showing significantly lower success rates for African-American investigators. The Pioneer Award Program might be a mechanism for enhancing diversity by inviting submissions from investigators from underrepresented groups and atypical backgrounds. The program addresses the issue that a successful history of securing NIH funding confers a strong funding advantage on investigators in future applications. Concerns about institutional elitism within the program, however, have been raised.

Serendipity is a vital part of scientific discovery. The peer review system needs to accommodate the possibilities for serendipitous discoveries by funding at a high success rate. Low success rates make the review process difficult for study sections. Historically, serendipitous discoveries such as integrins that would be unlikely to attract funding today have led to new fields of science. Shifting the emphasis in the review process toward creative thinking is important. Changing the NIH biosketch might be helpful, but there also is a strong emphasis in study sections on experimental design over investigator creativity.

V. REVIEW OF GRANT APPLICATIONS

This portion of the meeting was closed to the public, in accordance with the provisions set forth in Sections 552(b)(c)(4) and 552(b)(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix).[1] Members were instructed to exit the 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

[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.

was affirmed by all Council members present. During the closed session, the Council concurred with the review of 368 ORIP applications with total direct costs of $252,768,029.

VI. UPDATES ON PHASE II COMMON FUND PLANNING

Dr. Elizabeth L. Wilder, Director, Office of Strategic Coordination, DPCPSI, provided an introduction to the vision of CF and the selection criteria for CF programs. The CF supports goal-driven programs that are intended to have a major effect on biomedical research and typically involve multiple initiatives. The criteria for CF programs are the following: being of a transformative nature (e.g., data sets, reagents, tools, technologies); having the potential to catalyze research across the NIH within a 5- to 10-year period; having a synergistic component that will add value across multiple ICs; and filling a unique niche within the NIH and worldwide. The programs are selected through an annual strategic planning process that occurs in two phases: (1) identifying broad concepts and clearing them with the CoC, generally at the May to June meeting; and (2) obtaining expert input on the cleared concepts, conducting a portfolio analysis, and developing a refined proposal that is submitted to Drs. Collins and Anderson. Dr. Wilder stated that today's meeting offers an opportunity for Council members to provide input, including shaping the proposals to optimize relevance to the CF criteria, on four concepts that were cleared by the CoC and are being refined for the final proposal.

A. Glycomics

Dr. Jon R. Lorsch, Director, National Institute of General Medical Sciences, provided an overview of the goals, proposed strategy, and long-term outcomes developed by the Common Fund Glycoscience Working Group to accelerate the translation of glycoscience. Glycans, also called oligosaccharides, are complex chains of carbohydrates that act in many biological pathways and influence a wide variety of diseases. Glycans can be active biologically as conjugants to other biological molecules such as proteins. For example, glycans modulate the immune response, affecting inflammation and recognition of cancer cells by the immune system, and are important in the modes of action of many pathogens.

Although much progress in glycoscience has been made in the past decade, there is a lack of accessible tools for studying glycans, presenting a major roadblock to research that affects almost all of the NIH's ICs. Dr. Lorsch presented a case study that illustrates the need for accessible tools in glycoscience. A recent study found that the glycosylation of cell-surface glycans was altered in the neurons of individuals with schizophrenia. These results raise questions regarding the identity of the altered glycans and the proteins to which they bind, as well as the nature of the changes; there is a lack, however, of tools to easily and inexpensively sequence and synthesize glycans.

The Common Fund Glycoscience Working Group, comprised of members from many different ICs, was formed to address these gaps. The Working Group received expert advice on approaches for accelerating translation of glycoscience, including from the 2012 NAS report on glycoscience, a CF workshop held in 2013, and CoC members. In addition, the Working Group is conducting a portfolio analysis. Preliminary results indicate that the NIH's research investment is broad but not deep, representing less than 1 percent of the total NIH awards in 2013. The Working Group's proposed strategy is to fund three initiatives for developing the following:

- Accessible tools for probing and analyzing glycans and their interacting partners.
- Methods and technologies for synthesizing relevant glycans and their conjugates.
- Computational tools for integrating data on the genome, proteome, and glycome.

The long-term outcomes of these initiatives are to demonstrate proof-of-concept for technologies, establish relevance to public health, and move glycoscience translation from CF support to the NIH ICs for commercialization.

Discussion Highlights

- There was concern among Council members that CF programs are funded with an initial large investment, often with highly successful results, but few provisions are made to capitalize on successes. Dissemination of methodologies and publishing results, therefore, should be included in 5-year project plans.

- An advisory committee will be established for the glycomics initiative comprised of members of the biological research community, including representatives from NIH ICs who will target IC-specific research areas. Industry input will facilitate achieving the initiative's goal of successful commercialization, including developing affordable analytical kits and instruments.

- Training, which was included in the IOM report, is a priority for the initiative.

- Establishing a database, as recommended by the IOM, is a critical component of advancing the field. Council members recommended that the database be open-source and cross-referenced, as specified by the IOM. Database development will need to address issues such as representing the complex structure of glycans, establishing searching algorithms, and integrating data with DNA and protein sequences.

- The proposed balance of funding between developing analytical and data integration tools reflects the initiative's intention of initially funding analytical tool development through the R21 grant mechanism, and then, as a cost-effective approach, continuing development under the Small Business Innovation Research (SBIR) Program. Database development also ultimately would be supported by the ICs rather than the CF.

- The Bill and Melinda Gates Foundation is supporting research in glycoscience, providing a potential opportunity to collaborate with the NIH.

B. Citizen Science

Dr. Jennifer Couch, Chief, Structural Biology and Molecular Applications Branch, Division of Cancer Biology, NCI, described the Citizen Science CF Initiative, including the proposed goals, deliverables, and long-term outcomes for citizen science at the NIH. Citizen science is a collaborative approach that enables citizens to participate actively in scientific research; it is an approach that has proven highly successful in fields such as astronomy and ecology. The premise of citizen science in biomedical research is that the public can provide creativity and problem-solving skills that are complementary to conventional approaches. Data analysis (e.g., the online game cell slider), as well as data contribution and collection (e.g., personal genetic testing), are examples of potential contributions from citizen science to biomedical research. Privacy and other issues, however, pose unique challenges in biomedical citizen science research.

The Citizen Science Working Group, whose members have a diversity of expertise across the ICs, was formed to gather information and refine the concept of citizen science support by the NIH. The Working Group conducted a workshop on citizen engagement in biomedical research in May 2013, which included representatives from a wide range of commercial enterprises; participated in a Wilson Center Roundtable Discussion on Open Innovation and Science in November 2013; consulted experts in fields such as bioethics and data science; and conducted a portfolio analysis of projects within the NIH, which revealed

limited funding of mobile health (mHealth), games, and community and public participation efforts. The Working Group determined that challenges to citizen science include the following:

- Newness of methodologies in biomedical research.
- Policies, regulations, and practices that are not compatible with citizen science.
- The need for flexible infrastructure and governance models that maintain data security, integrity, and scientific rigor.
- Adapting citizen science methods to biomedical research and determining the methods that are effective.
- Disseminating tools, best practices, and training resources.
- Developing evaluation criteria.

Regarding opportunities for biomedical citizen science research, the Working Group learned the following:

- Citizens are eager to participate if provided with the right tools.
- Citizens are motivated to share information, particularly if they perceive that they can make a positive impact on research.
- Initial applications, largely developed external to the NIH, have proven useful.
- Citizen science provides an opportunity to accomplish research that traditional methods do not.

The Working Group proposed goals for the Citizen Science CF Program. These include creating a scientifically rigorous environment to test methods; assessing which questions are best addressed using the approach; disseminating successful methods to the biomedical research community; assessing infrastructure and data processing needs; investigating the ethical, legal, and social implications of citizen science methods; and developing metrics to evaluate the value added by citizen science. The Working Group envisioned forming a Citizen Science Consortium in which a coordinating center would connect resource centers; a data science center; a challenge resource center; research assessing the ethical, legal, and social implications of biomedical citizen science; and games development. The Consortium would deliver the following:

- Rigorously tested methods.
- Best practices.
- Evaluation criteria.
- A clearinghouse for the larger community for the dissemination of opportunities and methods.

The long-term outcomes of the Citizen Science CF Program anticipated by the Working Group were to involve the NIH in the critical stage of biomedical citizen science development and assess the value added by the approach to biomedical research.

Discussion Highlights

- There are opportunities for public-private partnerships with companies such as 23andMe, as well as for partnering with programs like the Patient-Centered Outcomes Research Institute (PCORI). PCORI's mission is comparative effectiveness research and outreach to members of the public to identify the types of research that are valuable to them, which harmonizes with some of the goals of citizen science.

- Social media likely will play important roles in citizen science, such as recruitment. There will be issues affecting the interpretation of such data, however, if they are merged with existing cohorts.

- Another issue with citizen science will be the effects on members of the public who participate in such research.

- It will be important to have broad representation of the population in citizen science research. Some communities such as African Americans and Native Americans might be averse to participating because of negative historical experiences with scientific research. Results from focus groups have revealed differences in willingness to participate, concerns, and goals. Methodologies for pilot projects will need to consider these differences.

- Private companies might be reluctant to partner with the NIH because it would involve review of their methodologies. At the citizen science workshop, a number of companies were very open to sharing their methods, but they might not be as willing to share such information in grant applications or method development efforts.

- The issue of informed consent will need to be considered for participants. There are models for variable levels of consent for different conditions that can be adapted for specific pilot projects. Ownership affordability of patient data will be a key issue in citizen science. The issue of patient-directed data has become especially prominent with the increasing use of electronic records.

- It will be important to communicate about NIH's citizen science initiative with nonprofit groups, such as those that work with patients with chronic illnesses, so that their constituents can understand, participate, and benefit from the results. Advocacy organizations and overarching groups can assist in communicating with the community. Initial outreach will be via pilot projects. A Council member questioned, however, whether the NIH has the capacity to manage such interactions.

- The goals for the citizen science initiative are very broad.

- It is important that participation in citizen science not deter patients from participating in traditional research.

- Citizen science differs from focus or advisory groups comprised of citizens because citizens are involved directly in the research, including contributing and analyzing data.

C. The Three-Dimensional Nucleome

Dr. Philip Smith, Deputy Director, Division of Diabetes, Endocrinology, and Metabolic Diseases, NIDDK, provided an update on the Three-Dimensional (3D) Nucleome Program. Sequencing of the human genome has provided a foundation for understanding human physiology and disease, but although the coding regions are well understood, the function of the rest of the genome is not. Genome-wide association studies (GWAS) have established links between mutations and diseases, and 93 percent of

disease-associated variants have been found in noncoding regions. Biomedical researchers have sought to understand the function of noncoding regions of the genome but have not considered the 3D structure of the genome. DNA is arranged in a nonrandom way within the nucleus, however, and there is mounting evidence that the third dimension of genome organization, which will be addressed by the 3D Nucleome Program, is important in genome function as well.

Dr. Smith described innovations that provide new opportunities for today's researchers to learn about genomic architecture and the effects of chromosomal structure on genome function. New methods have been developed to map interactions among chromosomes (i.e., chromosome conformation capture methodologies). High-resolution mapping of the functional organization of the genome is needed to interrogate disease pathways. Predictive models can be developed to describe domain interactions. Combining models with tools such as Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) to perturb particular areas of the genome will lead to a better understanding of the functional relationships between different parts of the genome.

A CF program is needed for this effort for several reasons. Understanding the 3D nucleome will be critical to interpreting genomic data and developing effective therapeutics for diseases across the spectrum of the ICs. Development of 3D nucleome tools will require a synergistic effort, and metrics and standards will need to be developed by a community of investigators rather than individuals. The 3D Nucleome Working Group developed a draft timeline, taking a two-phase approach that would involve evaluating the success of the program's initial activities, including imaging and computational tool development, as well as pilot mapping of the 3D nucleome, after 4 years. In the second phase, proposed activities include evaluating the predictive capabilities of models and developing tools to observe processes over time, which would allow exploration of cell differentiation, cancer development, environmental signaling, and other processes. The Program will link to the Roadmap Epigenomics Program and the Encyclopedia of DNA Elements (ENCODE Project), leveraging these investments. The ultimate goal is to apply the data and analysis tools to better understand human disease mechanisms through an exploration of the structure-function relationships of the genome.

Discussion Highlights

- In the mapping phase, the pilot projects will focus on the areas that are the most biologically interesting as recommended by the scientific community, for example, laminopathies or particular translocation loci. After developing tools, integrating the consideration of disease-relevance with mapping will accelerate the process of discovery.

- Modeling structure-function relationships early in the discovery process would allow model-driven experimentation that would iteratively refine models rather than focus on validating them. Tools for performing iterative testing of models will need to be developed very early. Machine learning techniques might be used to guide the selection of which experiments would be the most informative.

- A Council member commented that the initiative merits increased funding to accelerate discovery. Dr. Smith responded that a pilot period is required because significant technology development needs to occur before useful mapping information can be obtained.

- A member suggested that there might be an opportunity to partner with Google in developing computational tools.

- A concern was raised about the ability to distinguish causality between two-dimensional (2D) structural effects at the level of the DNA sequence and 3D effects. Although 90 percent of the

genome does not contain protein-coding genes, the noncoding regions code for RNAs. There is a need, therefore, to develop tools that perturb the 3D structure and are not sequence-based. RNA expression, as well as gene expression, will need to be considered.

D. Physical Activity Benefit Mechanisms

Dr. Joan McGowan, Director, Division of Musculoskeletal Diseases, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), provided an update on the CF initiative on Physical Activity Benefit Mechanisms (PABM). The Centers for Disease Control and Prevention (CDC) defines PA as any bodily movement produced by contraction of skeletal muscle that increases energy expenditure above a basal level. The mechanisms of the health benefits from PA are the molecules and cellular pathways that mediate physiologic, metabolic, behavioral, and cognitive changes in response to acute or chronic PA. The current mechanistic model for PA-induced actions involves the interaction of skeletal muscle and brown adipose tissue with white adipose tissue.

To explore unresolved questions regarding the PABM initiative, the Coordinating Committee members from the three lead ICs—NIAMS, NIA, and NIDDK—selected Working Group members, considering feedback from the three IC Directors. The planning process involved investigating questions about current NIH investment; scientific gaps, needs, and opportunities; obstacles and barriers to research; anticipated accomplishments in 5 to 10 years of a PABM CF initiative; and potential contribution to U.S. health. To answer these questions, the Working Group conducted a portfolio analysis, which revealed that approximately 1,000 NIH grants distributed across 13 ICs currently involve the study of PA and that 163 (0.5%) are mechanistic. The Working Group also issued a request for information that received approximately 80 responses. In addition, the Working Group held discussions with the research community, which included a lunch with researchers at the Geroscience Summit in October 2013, as well as two teleconferences. The Working Group determined that the current time is ideal for supporting mechanistic PA research because of a variety of factors. These included intense public and scientific interest, advances in the understanding of the role of myokines in metabolic health and the effects of PA on the brain, the limited current investment in mechanistic PA research, the need for greater interaction between exercise physiologists and biomedical researchers, and the lack of tools and standardized models to add rigor to the research.

The Working Group developed proposed goals, deliverables, strategies, and long-term outcomes for the PABM program. The long-term goal of the initiative would be to inform effective use of PA as an intervention by clinicians by providing the following deliverables:

- Discovery of pathways and molecules involved in transmitting the benefits of PA to tissues and organs.
- Identification of molecular targets for drug development.
- Standardization of PA protocols.
- Identification of animal models.
- Training of a future workforce.

The proposed strategy would begin with a planning workshop in 2014, and then supplement existing grants to include the study of PABMs in 2015. The long-term outcomes of the program would be to achieve multifaceted goals: in science, elucidating the beneficial mechanisms of PA; in the research environment, establishing an interdisciplinary research climate; in the clinic, providing basic knowledge for personalized PA "doses" and novel therapeutics as adjuncts for PA; and in sustainability, partnering with the private sector.

Discussion Highlights

- The study of the effects of PA is well-suited to the citizen science approach (e.g., the interplay of PA, diet, and obesity in schoolchildren).

- The PABM initiative is hoping to engender a holistic approach to studying the effects of PA. Current research has focused on single outcomes.

- Possible collaborative opportunities external to NIH-funded projects include the Olympic Training Center, which has an extensive research effort; gyms and performance centers; and the American College of Sports Medicine.

- Behavior change is a major issue in realizing public health benefits from PA, considering that the benefits of PA already are well-known. One approach might be to partner with nonscientists who are widely respected; for example, there is a major effort by the National Football League (NFL) to induce children to play for an hour each day. The "Let's Move!" campaign developed by First Lady Michelle Obama is another example of an outreach effort to encourage PA in children. The Office of Disease Prevention has been addressing the socio-psychological, behavioral, and environmental aspects of encouraging exercise. The study of mechanisms through the PABM initiative would address a different aspect of the problem, however, because the ability to "prescribe" exercise is hampered by the lack of understanding of "dose"—which requires an understanding of PABMs.

- Members suggested that PABMs are a very broad topic, involving many factors. Focus will be very important for the success of the initiative. There needs to be more scientist engagement in determining the focus. Studying the role of exercise in inflammation represents a unique opportunity in understanding PABMs.

- Sustainability is an issue for encouraging PA. There is a need to induce medical organizations to treat exercise as they do prescriptions for drugs.

VII. REPORT FROM THE SCIENCE OF BEHAVIOR CHANGE PROGRAM

Introduction

Dr. Wilder provided an introduction to the report from the Science of Behavior Change (SOBC) Program. She indicated that the SOBC Program is developing a proposal for a second phase of support from the CF. As part of this proposal, the group is evaluating the Program's achievements to date and new requirements for the future. Dr. Wilder stated that Dr. Richard J. Hodes, Director, NIA, would give an overview of the SOBC Program. Following Dr. Hodes' presentation, there would be an update from one of the Program's awardees.

Report

Dr. Hodes emphasized the importance of behavioral change. He reminded the CoC members that poor health behaviors are fatal: behavioral patterns account for 40 percent of premature deaths, and fully 50 percent of deaths are attributable to behavioral risk factors. The Diabetes Prevention Program trial showed that lifestyle intervention (i.e., a modest reduction in body mass and increase in physical activity) was more effective than metformin treatment or placebo in preventing diabetes. In addition, the metformin treatment became less effective in preventing diabetes in older age groups, but the lifestyle

intervention remained effective. Lifestyle interventions had persistent positive effects on health and diabetes incidence years afterwards.

The CF initiative for behavioral change was created because behavioral sciences were balkanized into different subdisciplines, with limited interaction among the sciences in understanding the basis for behavioral change. The goal of the SOBC Program is to capitalize on emerging basic science to accelerate investigation of common mechanisms of behavior change. To accomplish this goal, the program established milestones of supporting laboratory and clinical studies of behavior change mechanisms, and conducted two workshops, one on integrating mechanistic approaches with clinical treatments in ongoing clinical research, and the other on identifying neurobiological targets for behavioral change interventions. Major funding supported a request for applications (RFA) on identifying mechanisms of behavior change in the laboratory and the field. A smaller program announcement was issued in the area of use-oriented basic research, focusing on mechanisms of behavioral and social interventions. The SOBC Program's budget for meetings and grants during the past 5 years has been approximately $4 to $5 million per year.

From the outcomes of the two sponsored meetings, key targets for behavior change were identified, including environmental and social factors; stress and stress reactivity, given that decision making is compromised under stress; cognitive processes (e.g., manipulating the focus of attention); and emotional processes. Two examples of research supported by the SOBC Program investigated the following:

- Evolution of emotion regulation in teenagers: A major finding was that older teenagers are better able to regulate their emotions in response to negative emotional stimuli, and these improvements are correlated to attention-related activation in the left inferior frontal cortex.

- Use of Attentional Bias Training (ABT) to decrease attention to negative stimuli and increase attention to positive stimuli: This study revealed a potential neurobiological biomarker of the change in behavior.

Dr. Hodes emphasized that it is important to understand mechanisms to achieve goals of behavior change. He introduced a parallel to the medical model for studying causal mechanisms and behavior change, which included a putative target and the measurement of the engagement and validity of the target. The experimental medicine approach to behavior change is to first identify and isolate the most promising intervention targets, develop assays to measure target engagement, identify individual differences in treatment response via *a priori* validated assays, and improve behavioral trial designs to incorporate verification of target engagement.

The next steps in the SOBC Program are to implement the experimental medicine approach to behavior change, with deliverables of isolating targets for interventions, developing assays to measure engagement, and validating targets in the laboratory and in clinical studies through use-inspired research. The long-term goal of the program is to reshape the NIH's approach to behavior change interventions by building a unified science of behavior change.

A. Emotions and Choice: Mechanisms of Behavior Change

Dr. Elizabeth A. Phelps, Silver Professor of Psychology and Neural Science, New York University, presented an overview of research on the effects of emotions and decision making, focusing on the mechanisms of behavior change. Dr. Phelps noted that historically, emotions and the intellect have been considered competing processes. The discipline of affective neuroscience has provided insights revealing that there are no separate brain systems of emotion and reason.

Emotion has a modulatory role on cognition, attention, memory, and perception. To conceptualize the relationship between emotion and choices, the researchers used the tools of affective neuroscience and

neuroeconomics. The researchers also used the tools of affective science to change emotion and change choice. In affective science, emotion is defined as a discrete response to an internal or external event, and stress is defined as a response to a real or imagined threat resulting in relatively prolonged physiological and neuroendocrine changes. From economic theory, three variables were identified as components of decisions: loss aversion, risk sensitivity, and temporal discount rate.

In the experiments on emotion and decision making, subjects were presented with tests to measure loss aversion, risk sensitivity, and temporal discount rate. Two measures of emotion used were skin conductance and pupil dilation, both indicators of emotional arousal. An elevated cortisol level, resulting from activation of the hypothalamic-pituitary axis (HPA), was used as an indicator of stress. Two approaches were used to change emotion. The subjects' arousal response was blunted pharmaceutically with the beta-adrenergic receptor antagonist propranolol. In addition, cognitive emotion regulation (re-appraisal) was taught to subjects to reduce the arousal response to threat perception.

Dr. Phelps summarized the results from studies of the effects of emotions on loss aversion, risk sensitivity, and temporal discount rate, as well as the effects of techniques to alter emotion on decision making, identifying the neural circuitry involved in such effects. Results included:

- Loss aversion was correlated with physiological arousal. There was no correlation, however, between risk sensitivity and arousal.

- Propranolol reduced loss aversion only for low body mass index (BMI) participants, suggesting a dose-dependent effect. Cognitive emotion regulation (re-appraisal) decreased loss aversion by decreasing arousal. Blunting the arousal response pharmaceutically or through cognitive emotion regulation did not affect risk sensitivity.

- Non-specific stress reduced sensitivity to risk but had no effect on loss aversion.

- Stress diminished the effectiveness of cognitive emotion regulation techniques.

- Loss aversion, but not risk sensitivity, was correlated with amygdala activity.

- In the study of temporal discounting and arousal, contrary to the researcher's hypothesis, the greater arousal at choice, the more patient the subjects were.

- By introducing greater variability into the levels of reward and delay, researchers found that arousal and discount rate (i.e., the rate at which subjects discount future awards) were reference-dependent. These results contradicted the predominant theory of emotion in temporal discounting, and introduced a new view of the way in which emotion links to discounting future rewards.

Dr. Phelps concluded her presentation by stating that results on the mechanisms of behavior change indicate that if emotions can be changed, choice can be changed. Characterizing the relation between affective factors and decision factors informs the understanding of choice behavior, and suggests new approaches for behavior change.

Discussion Highlights

Council members discussed the SOBC Program with Drs. Hodes, Phelps, and Jonathan King, Program Director, Cognitive Aging and Human Factors, Division of Behavioral and Social Research, NIA.

- The SOBC Program includes a study of the genetic and environmental components of the proclivity to engage in PA from childhood through adulthood. Preliminary results have shown

that factors vary across the lifespan from the predominance of the influence of the family environment in younger children to the emergence of genetic factors in school age, when organized sports becomes important, to the decrease of the importance of genetic factors in adulthood. This work is being used to design interventions. It is likely that interventions will need to be individualized.

- In research with children, it should be remembered that there is a correlation between educational attainment and health status. This link might provide an incentive for engaging schools.

- A Council member suggested that given the potential for major transformational effects on public health, the proposed funding levels of $30 million over a 5-year period might not be sufficient. For sustainability, there also is a need to develop mechanisms for funding this research through the ICs. The work is pertinent to the missions of multiple ICs. Funding of clinical trials might be more appropriate through mission-relevant ICs rather than the CF. Another option is to fund clinical trials through UH2 or UH3 cooperative agreements. Supplementing ongoing empirical trials with measurement of underlying mechanisms is another funding approach (e.g., intentional bias training).

- Creating a template for developing behavioral change targets that parallels the development pipeline for therapeutics (i.e., isolating targets, developing assays, validating targets, and so forth) is an important paradigm shift. Study sections have been resistant to this type of research because of the lack of therapeutic implications.

- There has been a division between researchers proposing mechanistic studies and investigators intending to implement findings with clinical trials. The NIDA, however, has implemented a long-term strategy of structuring trials in the planning phase to include mechanistic studies in investigations of new drug treatment plans. Another example is studies of drugs to treat Alzheimer's disease, which routinely include biomarkers to elucidate underlying mechanisms.

- There are opportunities for synergies between the SOBC Program and the BRAIN initiative. Most of the recently issued RFAs for the BRAIN initiative, however, were focused on development tools rather than human studies.

- More technologies are needed to measure the human brain at work and human neural circuitry.

- The goals for the next 5 years of the SOBC Program include identifying candidate targets, and validating that they are associated with behavior mechanisms and changes. There is a need to develop new, straightforward, behavioral tasks that can be used in clinical trials. The tools need to be validated by measurements of nervous system responses. There is a need to develop inexpensive, sustainable interventions, as exemplified in reverse by the Diabetes Prevention Program. Being able to predict who will respond readily to a given treatment also will be important, as has been shown for behavioral treatments in smoking cessation. The behavioral intervention development community has realized that it is not sufficient to determine that an intervention is effective; it is necessary to understand the way in which it works and for whom it is effective. Such understanding will provide an opportunity for each behavioral intervention trial to contribute to a cumulative set of evidence.

Council members also provided specific feedback and discussed Dr. Phelps' presentation.

- In the experiments that used propranolol to blunt arousal, the beta blocker likely was acting on receptors in the amygdala. Previous work with animal models has shown that propranolol

diminishes the amygdala's modulation of arousal response in habit behavior and declarative memory studies. By extrapolation, the same neural circuits are involved in humans.

- The effects of arousal on loss aversion have not been investigated with animal models.

- The subjects in Dr. Phelps' studies had normal brain function. The mechanisms of behavior change are beginning to be investigated in individuals with neurodevelopmental disorders (e.g., schizophrenia, autism spectrum disorder, anxiety disorder, post-traumatic stress disorder).

VIII. UPDATE FROM THE COMMON FUND PLANNING AND MANAGEMENT WORKING GROUP

Drs. Janice E. Clements, The Johns Hopkins University School of Medicine, and K.C. Kent Lloyd, University of California, Davis, Co-Chairs of the Working Group, provided an update on the approach and activities of the CF Planning and Management Working Group. The Working Group was formed to evaluate the processes of managing, implementing, and overseeing the CF on the occasion of its 10th anniversary. The Working Group's goals are assessing whether the planning processes are optimal for identifying programs that meet the CF criteria, and whether the management and/or oversight processes are optimal for achieving program goals. The Working Group has convened biweekly conference calls; reviewed CF documents; developed surveys; and conducted interviews of the IC leadership, members of CF working groups, planning and evaluation officers, budget and grant managers, and others. The Working Group plans to continue interviewing and to distribute the survey to gather more data, and is on schedule to present a report of its recommendations to the CoC in June 2014.

Discussion Highlights

- The Working Group currently plans to survey approximately 1,000 people across the NIH who have been involved with CF initiatives, including as working groups and IC management. The Working Group is considering extending the survey to individuals external to the NIH who have been involved with CF projects. In particular, it would be useful to get broad scientific community input regarding the mechanism for developing new ideas.

- A Council member suggested interviewing individuals who are not being funded by the CF to ensure an unbiased sample. External contacts might be able to provide information about the effectiveness of outreach efforts for initiatives and knowledge regarding the program mechanisms. The purpose of the report is to evaluate the efficiency of the CF processes rather than the scientific content, however, and those external to the program might not be able to provide informed feedback regarding processes and management.

IX. CLOSING REMARKS

Dr. Anderson thanked the Council members and speakers for their contributions at this meeting. The next Council meeting will be held on June 20, 2014. On June 19, there will be a celebratory symposium of the 10th anniversary of the CF. Dr. Anderson looked forward to the Council members' participation and contributions at the June meeting and the 10th anniversary celebration.

X. ADJOURNMENT

Dr. Anderson adjourned the meeting at 4:29 p.m. on January 31, 2014.

CERTIFICATION

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

3-31-14

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

Date

3.31.2014

Franziska B. Grieder, D.V.M., Ph.D.
Executive Secretary, NIH Council of Councils
Director, Office of Research Infrastructure Programs, DPCPSI, OD, NIH

Date