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
July 1, 2010
Via Teleconference

Meeting Minutes

I. WELCOME

Francis S. Collins, M.D., Ph.D., Director, NIH, opened the teleconference at 3:00 p.m. and welcomed participants, NIH staff members, and members of the public to the fifth meeting of the Council of Councils (CoC). He asked the group to consider each of the concepts before them and ask whether they will have a significant impact on science. In addition, he asked the Council to assess whether the goals of each concept are consistent with what the Council wants to see accomplished through the Common Fund.

A. Attendance

1) Council Members Present

Chair: LAWRENCE A. TABAK, D.D.S., Ph.D., Acting Director, DPCPSI, OD, NIH
Executive Secretary: ROBIN KAWAZOE, DPCPSI, OD, NIH
RONALD L. ARENSON, M.D., University of California, San Francisco
STEPHEN L. BARNES, Ph.D., University of Alabama at Birmingham
DONNA BATES BOUCHER, Bates Group, Inc., Denver, Colorado
JORDAN COHEN, M.D., George Washington University, Washington, D.C.*
ELIZABETH B. CONCORDIA, M.A.S., University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania
DAVID W. CRABB, M.D., Indiana University School of Medicine
CECILE A. FELDMAN, D.M.D., M.B.A., University of Medicine and Dentistry of New Jersey, Newark, New Jersey
EDWIN FLORES, Ph.D., J.D., Chalker Flores, LLP, Dallas, Texas
MAE O. GORDON, Ph.D., Washington University School of Medicine, St. Louis, Missouri
JOSEPH H. GRAZIANO, PH.D., Columbia University, New York, New York
MARY J.C. HENDRIX, Ph.D., Northwestern University Feinberg School of Medicine Chicago, Illinois
ARTHUR M. KLEINMAN, M.D., M.A., Harvard University Medical School, Cambridge, Massachusetts
JOSEPH LOSCALZO, M.D., Ph.D., Harvard University Medical School, Cambridge, Massachusetts
JEAN MCSWEENEY, Ph.D., R.N., F.A.H.A., F.A.A.N., University of Arkansas Medical Science College of Nursing, Little Rock, Arkansas

JUANITA L. MERCHANT, M.D., Ph.D., University of Michigan, Ann Arbor.
DARIA MOCHLY-ROSEN, Ph.D. Stanford University School of Medicine, Palo Alto, California
ORIEN REID, M.S.W., Consumer Connection, Laverock, Pennsylvania
MARTIN ROSENBERG, Ph.D., Promega Corporation, Madison, Wisconsin
GARY L. WESTBROOK, M.D., Oregon Health and Science University, Portland, Oregon
LUTHER WILLIAMS, Ph.D., Tuskegee University, Tuskegee, Alabama
MARINA E. WOLF, Ph.D. Rosalind Franklin University of Medicine and Science, North Chicago, Illinois

2) Council Members Absent
ENRIQUETA C. BOND, Ph.D., Burroughs-Wellcome Fund, Marshall, VA
DANIEL H. GESCHWIND, M.D., Ph.D., University of California, Los Angeles
BEVRA H. HAHN, M.D., University of California, Los Angeles
RICHARD A. RUDICK, M.D., Cleveland Clinic Foundation, Cleveland, Ohio
DAVID VALLE, M.D. Johns Hopkins University School of Medicine, Institute of Genetic Medicine, Baltimore, Maryland
JOHN WALSH, Alpha-1 Foundation, Miami, Florida

3) Presenters in Attendance
ELIZABETH G. WILDER, Ph.D., DPCPSI
ROBERT CROYLE, Ph.D., National Cancer Institute
RICHARD HODES, M.D., National Institute on Aging
STORY LANDIS, Ph.D., National Institute of Neurological Diseases and Stroke

4) NIH Staff and Guests
In addition to Council members and presenters, others in attendance included NIH staff and interested members of the public.

*Pending Member

B. Introductions and Plans for the Meeting

Lawrence Tabak, D.D.S., Ph.D., CoC Chair, reminded the attendees that the meeting is open to the public.

Robin Kawazoe, Executive Secretary, took a roll call, and reviewed the following:

- Each Council participant has completed and submitted a conflict of interest statement as a Federal requirement for membership on individual IC advisory councils.
- Time has been allotted for discussion between each presentation. Meeting materials are available to the public via the DPCPSI website, as are overviews of the concept review process. The public is invited to submit comments after the meeting.
- A meeting summary will be posted on the DPCPSI website.

II. CRITERIA FOR REVIEW OF COMMON FUND PROGRAMS

Elizabeth G. Wilder, Ph.D., DPCPSI, reminded the Council of the criteria for reviewing Common Fund programs. When the Fund was created, the goal was to use it for addressing rising public health challenges or supporting initiatives that would benefit from strategic coordination and planning across two or more Institutes or Centers (ICs).

NIH has operationalized the legislative language to refine the areas of science that could be considered using Common Fund monies, using the following criteria:

1. Is the initiative truly transforming – could it dramatically affect how biomedical and/or behavioral research is conducted over the next decade?
2. Will the outcomes synergistically promote and advance the individual missions of NIH ICs to promote health?
3. Does the initiative require participation from NIH as a whole or does it address an area that does not clearly fall within the mission of one IC?
4. Is the proposed initiative something that no other entity is likely or able to do?

NIH staff has chosen concepts considered to have potential high impact, and have invested considerable time planning for how the programs might be implemented.

III. CONCEPT CLEARANCE: HMO RESEARCH NETWORK COLLABORATORY

Robert Croyle, Ph.D., Director, Division of Cancer Control and Population Sciences, National Cancer Institute, introduced the concept by noting its critical timing. Health care reform legislation includes requirements for comparative effectiveness research, and stimulus dollars were allocated to such studies. There have been ongoing discussions about how NIH can better leverage healthcare systems for research purposes. There are domains where better strategic coordination is merited across NIH, and one is the HMO Research Network (HMORN). Some ICs have been conducting research in the network and others have expressed interest, including other Health and Human Services (HHS) agencies. These events and trends led NIH to look at ways to more systematically enable the HMORN to work with a larger number of NIH investigators across a wide array of disciplines.

The HMORN includes 15 research sites, with a catchment of 12 million covered individuals. The network provides the potential to access comprehensive data resources, including electronic health records, biobanks, and data warehouses (e.g., claims data). HMORN has a history of research involvement, primarily in primary care and health services research, but a growing number of other research efforts have emerged. HHS-wide discussions have focused on health IT and ways to leverage the electronic health record for population-based studies and comparative effectiveness research. There is widespread interest in increasing the efficiency by which investigators can extract electronic health record and claims data to conduct large-scale studies. NIH has not been the only funder—several providers, such as Kaiser Permanente, are also investing in research initiatives using clinical data systems.

There has been an increase in HMORN research accomplishments and a steady growth in NIH-funded projects using the network, e.g., a Cardiovascular Surveillance System; eMERGE and Research Program on Genes, Environment and Health; a vaccine safety study (proof of principle) to collect adverse events data; and a study on racial disparities in colorectal cancer survival. The goal of the proposed Collaboratory is to use pre-existing data to look at outcomes and identify patients who might meet eligibility criteria for trials. There is a need to conduct trials outside the academic health setting to enhance diversity. The HMORN provides the opportunity to create one national research network. NIH has discussed this concept with the Agency for Healthcare Research and Quality (AHRQ). There is agreement that those charged with conducting comparative effectiveness research are struggling to create de novo relationships with providers, which is creating rate-limiting effects. The HMORN Collaboratory has the advantage of building on pre-existing experience and opening access to data up to all ICs and a broader set of investigators.

Dr. Croyle noted that there are some limitations to the networks current usability as a resource for research; however, the timing is right for NIH to make an investment in the network's research infrastructure. Efforts would be focused on infrastructure development and a virtual data warehouse (with anonymized data pulled for large-scale studies using data from multiple healthcare systems). The program would have to make sure that smaller ICs and investigators studying rare diseases are able to participate.

Discussion Highlights:

- This will not duplicate the efforts of the Clinical and Translational Science Awards (CTSAs). Several HMORN sites have pre-existing collaborations with CTSA sites but these are neither consistent nor broad and they cannot reach the full potential of HMORN.

- To facilitate optimal research access to the Collaboratory, workshops could be convened for interested investigators or held in tandem with academic meetings.

- There will have to be a unified governance process for the network to maximize efficiency and minimize confusion or duplication of efforts.

- The network is currently negotiating with additional healthcare systems and bringing in international partners. As such, the patient population is relatively diverse and includes Medicaid patients. Rural representation is increasing.

- Ethical issues concerning patient privacy and confidentiality have been addressed to protect enrollees.

ACTION: Approved by unanimous vote.

IV. CONCEPT CLEARANCE: NIH-SUPPORTED SUMMER RESEARCH PROGRAM FOR HIGH SCHOOL AND COLLEGE STUDENTS AND SCIENCE TEACHERS

Story Landis, Ph.D., Director, National Institute of Neurological Diseases and Stroke, presented the concept for a high-quality science research experience with the potential to:

- enhance science literacy
- offer educational opportunities not available to students at their home schools
- generate interest to consider science as a career
- help prepare undergraduates for the rigors of a research doctorate program
- offer science teachers a research experience to inform their classroom and laboratory teaching.

Many individual research institutions offer summer research programs, and many make efforts to recruit students from diverse populations. However, many applicants are turned away because of insufficient funds.

NIH had the opportunity in 2009 and 2010 to use $45 million in ARRA funds for summer programs such as this, offering programs to 5,000 students and teachers. The proposed initiative would allow NIH to build on the success of the ARRA programs. With reasonable investment of funds in institutional grants 1,200-1,500 students could be funded per year. Institutional awards allow for an integrated, coherent program, where the programs select the students rather than individual laboratories. The initial ARRA program asked institutions to identify students and teachers at the time of the application, but this would not be required in the future. NIH is interested in conducting short-term evaluations for success, e.g., is the experience effective in engaging students and teachers from diverse backgrounds? Other measures might be diversity, entry into college science curricula, teaching enhancement, and changes in how teachers interact with students in their schools.

Dr. Landis said this program is fashioned after several existing IC programs. The reason it is being proposed for the Common Fund is that the anticipated incentive created by Common Fund monies will encourage matching investments by ICs. The estimated cost per student is $10,000 over 10 weeks.

<u>Discussion Highlights:</u>

- The success of the program will rest on the commitment of the participating institutions.

- The $10,000 per participant is realistic. But, it is expected that participating institutions will supplement NIH funds. Funds must cover supplies, laboratory costs, food, and lodging. Institutions also can offer in-kind contributions such as lower dormitory costs. Thus, the cost to NIH could be as low as $5,000-6,000.

- This program differs from those of the National Science Foundation (NSF) and National Institute of General Medical Sciences (NIGMS) in the following ways. The NSF program

covers broad areas of basic science, but not the biomedical focus of this proposal. NIGMS does target basic biomedical science, but the proposed initiative will pull in a broader selection than is possible through the NIGMS program. Nonetheless, some elements of the NSF programs could be productively aligned with this initiative. NIH is working closely with NSF to gain from its extensive experience and long history with related programs.

- NIGMS has a history of evaluating its training efforts, and the indications are that the outcomes are poor, overall. For this initiative, NIH should design measures of improvements in students and teachers. It is recognized that evaluation of teachers is difficult. However, a tangible transfer of the summer experience to the high school curriculum could be an objective outcome.

- NIH could not require that applicants leverage their grant with industry partners, such as biotech and pharmaceutical companies, or find matching funds, but it could be included as an option.

- The criteria for enrolling students should be broad enough to include those with nonscientific backgrounds, including those who express an interest in science relatively late.

- It usually takes more effort to bring a high school student into the laboratory, whereas a college student may already be motivated. Therefore, it would be best to gear this toward the high school student; this would result in a more long-term benefit. In addition, it would be important to make an effort to include students from community colleges. The announcement could state that preference will be given to high school students.

- It is difficult to engage middle school students in these laboratory-based programs because of safety issues. Instead, it would be useful to include middle school teachers.

- Ideally, bring in the high school teachers with their students, so that the connection can continue after the summer.

- The program would include all research opportunities within the NIH mission.

- The NIH Intramural Research Program already has on-campus summer programs. It will not be included in this program—this is an extramural program.

- The initiative is meant to transform the richness of the diversity of the workforce. In addition, it will broaden the experience that participants bring back to their schools. Also, if this were done IC by IC, it would not have the impact, and in fact, might not happen.

ACTION: Approved by unanimous vote.

V. INFORMATION ITEM: RESEARCH IN SUPPORT OF THE WORKFORCE

Dr. Tabak said that this is an information item for the Council and it is not yet at the concept stage. The Common Fund will support a planning activity in this area, soliciting broad input on issues related to research training, diversity of the workforce, and career choices. No action is required at this time.

VI. CONCEPT CLEARANCE: HEALTH ECONOMICS FOR HEALTH CARE REFORM

Richard Hodes, M.D., Director, National Institute on Aging (NIA) provided data on economics research funded by NIH in Fiscal Year 2009, which totaled $194 million, with NIA making the largest investment of $79 million. He said that health care reform provides the opportunity for a natural experiment, as changes in insurance are phased in. A May 10-11, 2010 meeting of economists, Nobel Laureates, and members of the National Academies provided input on the health economics of health care reform that led to this proposal.

This proposal would support research to assess what can be done to slow the growth in health care costs while expanding access to high-value care. It would support research to answer a series of important questions. For example, although there is mandate to be insured, how will the insured respond, will selection of plans be suited to individual risks and needs, how will the labor force participate, how will insurers use comparative effectiveness data, how will prices respond to demand, how will financial incentives affect technological change and innovation, and how will prevention efforts be affected, etc… The numerous questions that will emerge as a result of health care reform require data infrastructure to enable the research, which would have to be funded in the earliest stages. The components of the program could be phased in over multiple years.

Discussion Highlights:

- The concept lists a series of questions: the plan is to request proposals from investigators as to how best answer the questions. There is confidence in the field that studies can be designed to answer the questions.

- Dr. Hodes will provide a summary of the May meeting for the Council's information.

- The importance of behavior and behavior change will be included, as well as behavioral economics and strategies for decision-making and adherence.

- This research could benefit health care reform efforts by providing evidence and data.

- There will be efforts to link data infrastructure with existing provider databases, including Medicare and Medicaid,, and those at the State level.

ACTION: Approved by unanimous vote.

VII. CONCEPT CLEARANCE: NIH DIRECTOR'S INDEPENDENT FELLOWS PROGRAM

Dr. Tabak identified the issues that are the bases of this proposal: 1) the increasing length of the scientific training period, and 2) the increasing age of investigators reaching scientific independence. There is an opportunity to reduce the length of the training period for exceptional early career scientists by providing a mechanism to skip the post-doctoral experience. A number of successful models already exist in the academic and non-profit sectors, so this is not a new concept.

A May 3, 2010 workshop that included administrator of existing programs, senior investigators from other academic institutions, and current and past fellows of existing programs provided input for this proposal. Under this proposal, institutional awards would support independent fellows. Each institution would recruit its own fellows and would be expected to provide significant support for the fellows (e.g., mentorship, access to resources, dedicated laboratory space, technical support staff, supplies, protected time), with NIH funds off-setting the costs. Dr. Tabak noted that the term "fellow" is used loosely here as it has specific meaning within NIH training programs. The May meeting participants debated whether the awards should be individual or institutional and concluded that institutional support is critical to success; thus, an institional award would be preferred.

Discussion Highlights:

- When asked about the criteria that would be used to select the fellows, Dr. Tabak said each institution might have its own criteria, but that the program would provide guidance. Productivity and independence are central features. Experience available from a number of ongoing programs show a process that uses targeted outreach, references, and even meetings in which all nominees attend together and make presentations.

- These appointments are not intended to be "super postdocs" or tenure track slots.

- Mentorship would be available as with the case of an assistant professor. Therefore, the environment is critical, and the applicant institutions will need to describe mentoring along with facilities.

- Approximately 10 awards would be made in the pilot stage.

- The NIH Intramural program can participate.

- Applicants would not have to be affiliated with the awardee institution. The applicant should describe a robust recruitment plan. The institution's outreach plan will be a key element in the review criteria as well as in the funding selection

- If this is an institutional award, there is a danger of bypassing outstanding individuals who are not currently at the big-name institutions.

- If you are looking to find individuals, why not make this an individual award? Let them take the money to the institution that is the best fit for them.

- Institutional support is essential, including access to facilities and reduced teaching load. The environment is critical. An individual award could result in a mismatch, with a person working in relative isolation.

- An individual award could include a mechanism through which the individuals could network.

- NIH should consider a hybrid model between the individual and institutional models. For example, the application would come from the institution and would include one individual as the institution's first choice.

- This approach is transformative because it differs from the way that most career pathways evolve; it breaks the mold. Admittedly, only a small number of individuals will qualify, but the impact of these exceptional people could be great.

ACTION: Approved by a vote of 19 to 1 (one member opposed on the basis of favoring the individual over institutional award mechanism). A number of individuals who voted in favor of the motion also urged NIH to consider a hybrid approach.

VIII. NEXT STEPS AND CLOSING REMARKS

Dr. Tabak closed the meeting by noting that this was the second time for concept review, and it continues to be a learning experience for all. He thanked the Council for the quality of the discussion and thanked the NIH presenters for their preparatory week. He invited Council members to provide him with input on the process.

The next meeting of the Council will be Tuesday, August 17, 2010 by teleconference. There will be an open session followed by a closed session for second-level review of applications.

Dr. Tabak adjourned the meeting at 5:09 p.m.

IX. CERTIFICATION

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

Robin I. Kawazoe
Executive Secretary, NIH Council of Councils
Deputy Director, Division of Program Coordination,
Planning, and Strategic Initiatives
Office of the Director
National Institutes of Health