

NATIONAL INSTITUTES OF HEALTH
DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES (COPR)

MEETING MINUTES

April 18, 2008

**NATIONAL INSTITUTES OF HEALTH (NIH)
OFFICE OF THE DIRECTOR
DIRECTOR'S COUNCIL OF PUBLIC REPRESENTATIVES**

**Spring 2008 Meeting
Building 31, C-Wing, Conference Room 6, NIH Campus
Bethesda, Maryland**

April 18, 2008

NIH Participants

Elias A. Zerhouni, M.D., Director, NIH
Raynard S. Kington, M.D., Ph.D., Deputy Director, NIH
John T. Burklow, Director for Communications and Public Liaison, Office of the
Director, NIH
Kelli L. Carrington, M.A., Executive Secretary, COPR, and Public Liaison Officer,
Office of Communications and Public Liaison, Office of the Director, NIH

COPR Members Attending

Christina L. Clark, M.A., M.B.A.
Naomi Cottoms, M.S.
Linda Crew, M.B.A., R.N.
Elmer R. Freeman, M.S.W.
Elizabeth Furlong, R.N., Ph.D., J.D.
Brent M. Jaquet
Nicole Johnson, M.A., M.P.H.
Cynthia A. Lindquist, Ph.D., M.P.A.
Marjorie K. Mau, M.D., M.S.
Ann-Gel S. Palermo, M.P.H.
James H. Wendorf, M.A.

COPR Members Not Present

Syed M. Ahmed, M.D., Dr. P.H., M.P.H.
Valda Boyd Ford, M.P.H., M.S., R.N.
Anne Muñoz-Furlong
Matthew Margo, LL.M.

2008 COPR Appointees Present

Micah L. Berman, J.D.
Lora M. Church
Eileen Naughton, J.D.

Carlos A.O. Pavão, M.P.A.
John W. Walsh
James S. Wong, Ph.D.

ACD Liaison

John C. Nelson, M.D., M.P.H, FACOG, FACPM

Speakers

Jeremy M. Berg, Ph.D., Director, National Institute of General Medical Sciences, NIH
Michael M. Gottesman, M.D., Deputy Director for Intramural Research, NIH
Melanie Modlin, Public Affairs Specialist, National Library of Medicine, NIH
Elizabeth G. Nabel, M.D., Director, National Heart, Lung, and Blood Institute, NIH

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EXECUTIVE SUMMARY

The 19th meeting of the National Institutes of Health (NIH) Director's Council of Public Representatives (COPR) was held on April 18, 2008. Elias A. Zerhouni, M.D., NIH Director, welcomed the COPR members and guests.

Dr. Zerhouni recognized the new COPR appointees: Micah M. Berman, J.D., Columbus, Ohio; Lora M. Church, Albuquerque, New Mexico; Representative Eileen Naughton, J.D., Providence, Rhode Island; Carlos A.O. Pavão, M.P.A., Chamblee, Georgia; John W. Walsh, Miami, Florida; and James S. Wong, Ph.D., San Jose, California.

Dr. Zerhouni recognized the two new Advisory Committee to the Director (ACD)-COPR liaisons: John C. Nelson, M.D., M.P.H., FACOG, FACPM, from the ACD, and Elizabeth Furlong, R.N., Ph.D., J.D., from the COPR.

Dr. Zerhouni congratulated Marjorie Mau, M.D., M.S., and COPR alumnus Douglass Yee, M.B.A., on their article about the importance of public participation in research that was published in the January 2008 issue of *Hawai'i Medical Journal*.

Dr. Zerhouni thanked the COPR members serving on other working groups and councils: Dr. Mau and Syed Ahmed, M.D., Dr.P.H, M.P.H., on the ACD Working Group on Peer Review, Dr. Mau on the NIH Council of Councils, and Cynthia Lindquist, Ph.D., M.P.A, on the ACD Working Group on Participant and Data Protection for the Genetic Association Information Network and Genome-Wide Association Studies.

Dr. Zerhouni also thanked COPR members Valda Boyd Ford, M.P.H., M.S., R.N., Brent Jaquet, Anne Muñoz-Furlong, and James Wendorf, M.A., as well as COPR alumnus Michael Manganiello, M.P.A., for participating on the Public Review Working Group for

the Research, Condition, and Disease Categorization system.

Dr. Zerhouni announced that Ann-Gel Palermo, M.P.H., and Dr. Mau would be participating on a review panel for the newly established Partners in Research Awards Program.

Dr. Zerhouni provided updates in a number of areas. The fiscal year (FY) 2008 Budget for NIH remains flat; however, NIH directors continue working hard to maintain their priorities and look to Congress to sustain biomedical research given the enormous discoveries that are occurring at a very fast pace.

Two priority areas for NIH directors are to: 1) continue support of 9,700 investigator-initiated research projects, which is the same number as in FY 2007, and 2) continue investment in more than 1,500 early-stage investigators, the average of the past five years.

A comprehensive peer review analysis has been conducted with input from the public, and a preliminary report with recommendations has been presented to the Director.

The NIH Public Access Policy, which ensures that the public has access to published results of NIH -funded research, has been implemented.

Two initiatives that are part of the NIH Roadmap for Medical Research and critical to scientific progress and discovery are being launched: the Human Microbiome Project and the Epigenomics Program.

Dr. Zerhouni discussed the growing concern about the increasing number of attacks on researchers who use animals in research, which he described as a form of terrorism. He

further noted that this act of violence threatens the dedicated scientists working to improve serious health problems facing this country.

Josephine Briggs, M.D., has been appointed Director of the National Center for Complementary and Alternative Medicine. Samuel Wilson, M.D., has been appointed Acting Director of the National Institute of Environmental Health Services. Christine A. Bachrach, Ph.D., is serving as the Acting Associate Director for Behavioral and Social Sciences Research and Acting Director of the Office of Behavioral and Social Sciences Research.

The National Institute of Child Health and Human Development (NICHD) has been renamed the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development. The ceremony on March 3, 2008, commemorated Mrs. Shriver's role in the establishment of the NICHD and her work with and founding of the Special Olympics. NICHD also has renamed its Mental Retardation and Developmental Disabilities Research Centers Program in honor of Mrs. Shriver. The program is now known as the Eunice Kennedy Shriver Intellectual and Developmental Disabilities Research Centers Program.

Francis S. Collins, M.D., Ph.D., Director of the National Human Genome Research Institute, received the Presidential Medal of Freedom from President George W. Bush.

Vivian Pinn, M.D., Associate Director for Research on Women's Health, received the Silver Plain Language Award for her "Pinn Point on Women's Health" podcast series.

Raynard Kington, M.D., Ph.D., announced that on April 10, 2008, French President Nicolas Sarkozy presented Dr. Zerhouni with France's highest honor, the French National Order of the Legion of Honor, at the Elysée Palace in Paris.

Dr. Zerhouni presented data showing that investigators are being funded at later ages and stages of their careers, and he discussed the long-term implications of flat budgets that increase the difficulty of sustaining established investigators and of funding early-stage investigators who have vigorous new ideas that will transform health and medicine.

Michael M. Gottesman, M.D., Deputy Director for Intramural Research, discussed the NIH Intramural research program and outlined new trans-NIH initiatives.

Jeremy M. Berg, Ph.D., Director of the National Institute of General Medical Sciences, presented an update on the Peer Review Enhancement Initiative.

Melanie Modlin, Public Affairs Specialist at the National Library of Medicine (NLM), presented on the library's outreach program, including NLM's work with the National Network of Libraries of Medicine.

Elizabeth G. Nabel, M.D., Director of the National Heart, Lung, and Blood Institute, presented an update on the Genome-Wide Association Studies Policy, which promotes data sharing to identify common genetic factors that influence health and disease. More information is available at <http://grants.nih.gov/grants/gwas.index.htm>.

Christina Clark, M.A., M.B.A., and Mr. Wendorf, co-chairs of the COPR Agenda Work Group, provided an overview of the COPR's Work Group Day.

Ms. Palermo, co-chair of the COPR Role of the Public in Research Work Group, reported on the initiatives of the Work Group and action items discussed during the sessions the

previous day.

Mr. Jaquet, co-chair of the COPR Communications Work Group, reported on the recommendations discussed during the Work Group sessions on the previous day.

COPR members received updates from Dr. Nelson, the ACD liaison to COPR. Public comments were presented by Taylor Werner, who spoke on behalf of patients with Traumatic Brain Injury, and submitted by Diane Bargonetti, N.D., of New York and B. Sachau of New Jersey.

WELCOME AND INTRODUCTIONS

Elias A. Zerhouni, M.D.

Director, National Institutes of Health

The 19th meeting of the National Institutes of Health (NIH) Director's Council of Public Representatives (COPR) was held on April 18, 2008. NIH Director Elias A. Zerhouni, M.D., welcomed the COPR members and presenters.

Dr. Zerhouni recognized the new COPR appointees: Micah L. Berman, J.D., Executive Director and Visiting Professor of Law, Tobacco Public Policy Center of the Capital University Law School, Columbus, Ohio; Lora M. Church, Senior Program Manager, Acoma-Canoncito-Laguna Teen Centers, University of New Mexico, Albuquerque; Representative Eileen Naughton, J.D., State Representative of Rhode Island, Providence; Carlos A.O. Pavão, M.P.A., Community Administrator, DeKalb County Board of Health, Chamblee, Georgia; John W. Walsh, President and Chief Executive Officer, Alpha-1 Foundation, Miami, Florida; and James S. Wong, Ph.D., Senior Advisor, Strategy and Product Planning, Hitachi Global Storage Technologies, San Jose, California.

Dr. Zerhouni also recognized the two new Advisory Committee to the Director (ACD)-COPR liaisons: John C. Nelson, M.D., M.P.H., FACOG, FACPM, from the ACD, and Elizabeth Furlong, R.N., Ph.D., J.D., from the COPR.

Citing the important contributions that the COPR has made since last October, Dr. Zerhouni congratulated Marjorie Mau, M.D., M.S., and COPR alumnus Douglass Yee, M.B.A., for publishing an article on the importance of public participation in research on behalf of the COPR in the January 2008 issue of *Hawai'i Medical Journal*.

Dr. Zerhouni thanked COPR members who have joined ACD working groups: Dr. Mau and Syed Ahmed, M.D., Dr.P.H., M.P.H., members of the ACD Working Group on Peer Review, and Cynthia Lindquist, Ph.D., M.P.A., a member of the ACD Working Group on Participant and Data Protection for the Genetic Association Information Network and Genome-Wide Association Studies. He noted the importance of the COPR in bringing the public's perspective to the important process of privacy and protection that these working groups are addressing.

Dr. Zerhouni also recognized COPR members Valda Boyd Ford, M.P.H., M.S., R.N., Brent Jaquet, Anne Muñoz-Furlong, and James Wendorf, M.A., as well as COPR alumnus Michael Manganiello, M.P.A., for participating on the Public Review Working Group for the Research, Condition, and Disease Categorization system.

Dr. Zerhouni announced that Dr. Mau has been appointed to the newly instituted NIH Council of Councils, which was established under the 2006 NIH Reform Act and advises the NIH Director on cutting-edge trans-NIH priorities and matters related to the policies and activities of the Division of Program Coordination, Planning, and Strategic Initiatives.

Dr. Zerhouni noted that directly following the COPR meeting, Ann-Gel S. Palermo, M.P.H., and Dr. Mau would be participating on review panels for the newly established Partners in Research Awards Program, which is a part of the NIH Public Trust Initiative supported by the COPR and co-led by Patricia Grady, R.N., Ph.D., FAAN, Director of the National Institute of Nursing Research, and Yvonne Maddox, Ph.D., Deputy Director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development. The initiative's goals are to increase public trust in and understanding of NIH research and to foster a new paradigm for the future of medical and behavioral research. NIH has committed \$3 million to the program in fiscal year (FY) 2008 to

support two small pilot grant and feasibility studies.

Dr. Zerhouni thanked the COPR for its contributions and participation in this phase of the program. He also recognized and thanked all COPR members for their personal outreach efforts on behalf of NIH.

Dr. Zerhouni welcomed two former COPR members in the audience, Nicolas Linares-Orama, Ph.D., from Puerto Rico, and Ted Mala, M.D., M.P.H., from Alaska.

NIH DIRECTOR'S UPDATE

Elias A. Zerhouni, M.D.

Director, NIH

Dr. Zerhouni presented the status of the FY 2008 budget for NIH, noting that the budget remains flat with no real increase planned and inflation continuing. NIH directors continue working hard to maintain their priorities and look to Congress to sustain biomedical research given the enormous discoveries that are occurring at a very fast pace.

Two priority areas for NIH directors are to: 1) continue support of 9,700 investigator-initiated research projects, which is the same number as in FY 2007, and 2) continue investment in more than 1,500 early-stage investigators, the average of the past five years.

The intent is to organize priorities to meet the budget crisis and allow for flexibility of immediate scientific investments, which will determine long-term competitiveness.

Enhancing Peer Review

Dr. Zerhouni noted that one of the most important issues for NIH is the effort to enhance the Agency's peer -review system. the key question: How do we adapt Peer Review to

the changing landscape of science in changing times and ensure the highest quality review with the lowest administrative burden to both the investigators and NIH?

As part of NIH's longstanding commitment to supporting promising and meritorious biomedical and behavioral research using diverse approaches, strategies, and mechanisms, the agency has begun a comprehensive analysis of the Peer -Review Process lead by Lawrence Tabak, D.D.S., Ph.D., Director of the National Institute of Dental and Craniofacial Research, and Jeremy Berg, Ph.D., Director of the National Institute of General Medical Sciences (NIGMS). A preliminary report with recommendations has been presented to the Director, and the COPR will be briefed on the priorities of the new program as decisions are finalized.

Public Access Policy

The NIH Revised Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research went into effect January 11, 2008. Dr. Zerhouni noted that the policy represents a fundamental shift in the way scientific and public health information is distributed and used to enhance the research process. NIH is currently working to implement the policy from voluntary to mandatory status. As of April 7, 2008, all final peer-reviewed manuscripts arising from NIH funds must be submitted to PubMed Central upon acceptance for publication. It is a phased-in approach, allowing authors time to learn the new process. Public comments were being sought from March 31 to May 31, 2008. Dr. Zerhouni recognized Betsy Humphreys, M.L.S., Deputy Director of the National Library of Medicine (NLM), for her leadership on this effort and COPR members for promoting the public input opportunities.

Scientific Projects Initiated Through the Roadmap and the Common Fund

Two initiatives that are part of the NIH Roadmap for Medical Research and critical to scientific progress and discovery are being launched: the Human Microbiome Project,

which will use genomic technologies to explore the role of microbes in human health and disease, and the Epigenomics Program, which will accelerate understanding of how the genomic code is regulated. A small portion of the budget, about 1.7%, is set aside for projects such as these, which are seen to be critical to scientific progress. More information on the Microbiome Project is available at <://nihroadmap.nih.gov/hmp> and information on the Epigenomics Program is available at <://nihroadmap.nih.gov/epigenomics/initiatives.asp>.

Use of Animals in Research

Dr. Zerhouni cited growing concern about the increasing number of attacks on researchers who use animals in research. NIH treats animals in research with respect, even as every effort is being made to reduce the use of animals. Dr. Zerhouni pointed out that 85% of all treatments for animal diseases come from research using animals. These attacks on scientists, which are a form of terrorism, are not in the public interest or in the interest of the animals themselves.

Leadership Update

Dr. Zerhouni introduced Josephine Briggs, M.D., the new Director of the National Center for Complementary and Alternative Medicine (NCCAM), calling her an accomplished researcher and physician who brings a focus on translational research to the study of complementary and alternative medicine. In 1997, Dr. Briggs served as Director of the Division of Kidney, Urologic, and Hematologic Diseases in the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

Dr. Briggs described the two-fold mission of NCCAM as (1) bringing the rigor of science to the evaluation of the safety and efficacy of widely used interventions for health and (2)

serving as a public information resource. She invited the COPR's input and advice.

Dr. Zerhouni thanked John (Jack) Killen, M.D., for his contributions to NCCAM and Ruth Kirschstein, M.D., who was the Acting Director of NCCAM and who remains a senior advisor to the NIH Director.

Samuel Wilson, M.D., was appointed Acting Director of the National Institute of Environmental Health Sciences (NIEHS) and the National Toxicology Program. Dr. Wilson joined NIEHS in 1996 as Deputy Director and Chief of the DNA Repair and Nucleic Acid Enzymology Group in the Intramural Division. He will oversee a proactive analysis of the institute.

Dr. Zerhouni noted that Christine A. Bachrach, Ph.D., is the Acting Director of the Office of Behavioral and Social Science Research and Acting Associate Director of Behavioral and Social Science Research at NIH.

Dr. Zerhouni announced the renaming of the National Institute of Child Health and Human Development (NICHD) to the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development in a ceremony on March 3, 2008, to honor Mrs. Shriver's role in the establishment of the NICHD and her work in and founding of the Special Olympics.

NICHD also has renamed its Mental Retardation and Developmental Disabilities Research Centers Program in honor of Mrs. Shriver. The name change acknowledges the contribution of Mrs. Shriver and replaces the outmoded term "mental retardation" with "intellectual disabilities." The program is now known as the Eunice Kennedy Shriver Intellectual and Developmental Disabilities Research Centers Program.

Duane F. Alexander, M.D., NICHD Director, addressed the Council, noting that other than the John E. Fogarty International Center, NICHD is the first institute at NIH to have the name of a person associated with it in its title. He recalled Mrs. Shriver's advocacy for an institute at the NIH focusing on maternal and child health and human development, lobbying both her brother, President John F. Kennedy, and the Congress until NICHD was established. Mrs. Shriver was also inducted into the Institute's Hall of Honor, which recognizes outstanding individuals who have made major contributions to the Institute and public health. In addition, the Mental Retardation and Developmental Disabilities Research Centers were renamed in her honor and are now the Eunice Kennedy Shriver Intellectual and Developmental Disabilities Research Centers.

Guests of the event included Mrs. Shriver's brother, Senator Edward Kennedy, her sister, Jean Kennedy Smith, her daughter Maria and her husband, Governor Arnold Schwarzenegger, members of Congress, federal officials, as well as extended family and friends.

NIH Directors Receive Awards

Francis S. Collins, M.D., Ph.D., Director of the National Human Genome Research Institute, received the Presidential Medal of Freedom from President George W. Bush at a White House ceremony on November 5, 2007, in honor of his leadership in revolutionizing genetic research.

Vivian Pinn, M.D., Associate Director for Research on Women's Health, received the Silver Plain Language Award for her very successful "Pinn Point on Women's Health" podcast series, which provides the latest news in women's health research and includes conversations with expert guests on a variety of subjects. Podcasts are located on the Office of Research on Women's Health web site at

[://orwh.od.nih.gov/podcast/podcast_archive.html](http://orwh.od.nih.gov/podcast/podcast_archive.html) .

Dr. Zerhouni Discusses Grants to Young Scientists

Dr. Zerhouni noted his concern about the long-term effect of not encouraging and supporting talented young scientists early in their careers. Through a series of slides, he illustrated that the average age for receiving independent grants has risen from early 30 years to early 40 years. Dr. Zerhouni expressed concern that as a result of lengthening training periods, compounded by the demographic impact of the baby boom generation, today more scientists are in late-stage than early-stage careers, a trend that is expected to continue over the next decade.

Tight budget times penalize new investigators more than established investigators, and there has been a significant decrease in first-time Research Project Grants (RO1s) from a high of more than 1,600 as the budget has gone flat. The NIH directors have instituted successful policies to maintain the number of new investigators at about 1,500 in the face of falling budgets. But the long-term risk of these flat budgets is the difficulty of sustaining the established investigators and still funding early-stage investigators who have vigorous new ideas that will transform health and medicine.

Dr. Zerhouni Honored by the President of France

Raynard Kington, M.D., Ph.D., announced that on April 10, 2008, Dr. Zerhouni received France's highest honor in a ceremony at the Elysée Palace in Paris. French President Nicolas Sarkozy made him a Knight of the National Order of the Legion of Honor "in recognition of his brilliant professional career and his remarkable contribution to Franco-American exchanges in life sciences research."

Discussion (COPR Members)

Mr. Wendorf thanked Dr. Zerhouni and Dr. Kington for their comments.

Dr. Nelson asked whether any specific demographic explained why certain laboratories did not receive bridge awards. Dr. Zerhouni said that because it takes about \$300,000–\$400,000 to fund a lab for a year, the institutes focused on helping labs that had less than that and would have to close without a bridge award. He offered to provide information about the areas of research that needed these awards.

Christina Clark, M.A., M.B.A., asked Dr. Zerhouni to comment about careers in knowledge management and the strategic thinking process that would transition into 21st century opportunities. Dr. Zerhouni replied that the complexity of analyzing new information involves knowledge management, an evolving field of science. He noted Dr. Kington's view that more must be done to understand not only the knowledge management but also the social and behavioral aspects involved. Alan Krensky, M.D., Director of the Office of Portfolio Analysis and Strategic Initiatives (OPASI), added that OPASI is focusing on this issue both in the knowledge management of portfolio analysis and the lesser-known "science of science." A workshop with a wide range of experts is being scheduled to discuss these issues, particularly the role of NIH in knowledge generation for public health. Ms. Humphreys observed that knowledge management is considered a core activity within the general discipline of biomedical informatics. She noted that NLM, which has been supporting academic research training in biomedical informatics for more than 30 years, currently has programs funded at 18 universities across the country.

Mr. Pavão asked whether the gender gap has closed in the past 25 years and what strategies are planned for the future. Dr. Zerhouni stated that the numbers are going in the right direction, with 25%–30% of chairs and top science positions held by women. The gap is closing, but not fast enough, and more needs to be done.

Mr. Jaquet, referring to violence against scientists, asked whether grants include a requirement that universities must protect scientists. Dr. Zerhouni said that policies and support mechanisms are being developed to ensure that the public understands the

problem and that universities support their scientists. There is also outreach to mainline animal rights organizations. Dr. Kington added that the Office of Extramural Research is developing toolkits and a Web site to help universities respond to threats.

Dr. Mau asked whether NIH had a mentorship program for young scientists. Dr. Zerhouni said that although NIH does not provide direct mentoring, it supports and provides indirect mentoring through the peer -review process and fellowship awards. He noted that this area is best addressed by medical schools.

THE NIH INTRAMURAL RESEARCH PROGRAM: NEW TRANS-NIH INITIATIVES

Michael M. Gottesman, M.D.

Dr. Gottesman, Deputy Director for Intramural Research, explained that the mission of the intramural Research program is to conduct distinctive, high-risk, high-impact laboratory, clinical, and population-based research in a unique and fostering environment and to train a diverse population of outstanding young researchers. The intramural budget is slightly less than 10% of the overall NIH budget.

The majority of institutes and centers have intramural programs that involve more than 8,000 scientists and students. The main focus of the intramural training activity is the postdoctoral fellowship program. Although most intramural research is conducted on the NIH campus, there also is an NIH intramural presence in other states, including North Carolina, Montana, Arizona, Michigan, and other areas in Maryland.

Several factors make the NIH intramural Research program distinct:

- A high degree of intellectual freedom that supports the ability to do high-risk, high-impact research with a predominantly retrospective review system.
- Stable resources and funding for new technology and long-term projects.
- A critical mass of talent.
- Leadership that recognizes and preserves the unique features of the program.

- The Clinical Center, which is the largest hospital in the world dedicated to research.

Dr. Gottesman stated that trans-NIH initiatives are being undertaken to encourage researchers to interact in a more cooperative process that transcends the individual institutes and centers and takes advantage of the special features of the intramural research program in new and creative ways. These initiatives include:

- Center for Human Immunology, Autoimmunity, and Inflammation—This program, headed by Neil S. Young, M.D., of the National Heart, Lung, and Blood Institute (NHLBI), is designed to tap the talent of the 400 (out of 1,200) intramural principal investigators (PIs) who work primarily with immunologic systems. It will bring clinical investigators together with the basic immunology community to advance the study of human immunology in a major way that could become a model for NIH translational research.
- Imaging Initiative—This project will combine all the various imaging initiatives across NIH to foster the development of new probes and chemistry that will provide scientists with access to cutting-edge technology.
- Systems Biology Initiative—This initiative will support a comprehensive integration of basic biological and quantitative information with the goal of creating a computer-based model that is predictive about how cells respond to various stimuli.
- Various other initiatives, which include funding opportunities for collaboration between the laboratory and the clinic, a new obesity center, and the use of adult stem cells in research in clinical practice.

Discussion (COPR members)

Mr. Walsh noted the positive impact of the NIH intramural Research program, especially on rarer diseases. He asked about the possibility of “connecting the dots” between the Systems Biology Initiative and the Chemical Genomics Center. Dr. Gottesman agreed that the Genomics program would be useful in developing chemical probes for use in

systems biology studies. He added that the immunology studies would also use the Chemical Genomics Center and stated that the Center would continue to be funded after its Roadmap funding expired.

Mr. Wendorf asked what plans were being made to communicate the results of these initiatives for maximum impact both within NIH and to the public. Dr. Gottesman cited the *Catalyst*, an NIH-based magazine published from his office and read by intramural scientists, and the technology that allows him to access investigators quickly with messages. The public will learn about some results through the normal process of publication, but Dr. Gottesman asked for the COPR's help in disseminating information that is especially important to the public. Dr. Gottesman agreed that more work needs to be done to educate the public about the work being done at NIH, both intramurally and extramurally.

Naomi Cottoms, M.S., asked about the ranking of the obesity initiative in light of the flat budget. Dr. Gottesman said that it is ranked at the highest priority because the obesity center, containing state-of-the-art equipment such as the metabolic chamber, has been completed and research has already begun. He invited COPR members to tour the new facility (new members toured the facility as part of orientation on April 16). Dr. Zerhouni added that the obesity research budget has tripled, and he referred to a strategic research plan on obesity that was developed in 2003 that could be shared with the COPR. He noted the difficulty of obesity research and the need to undertake it in a highly sophisticated facility, such as that at NIH.

UPDATE ON ENHANCING PEER REVIEW AT NIH

Jeremy M. Berg, Ph.D.

Dr. Berg, Director of NIGMS, described the peer -review process as advancing Dr. Zerhouni's directive to "fund the best science, by the best scientists, with the least administrative burden."

The diagnostic phase of the review, which included outreach to the public and scientific community to identify the challenges of the current peer -review process and potential solutions, is complete. Some of the recommendations include:

- Reducing the administrative burden on applicants, reviewers, and staff who are inundated with too many applications and submission rounds. Solutions include adding a “Not recommended for resubmission” category and eliminating the special status of amended applications.
- Enhancing the rating system for usefulness and consistency by adding more early interaction between reviewers and applicants, rating multiple criteria to provide better-defined feedback instead of using a single overall score, and shortening and restructuring the applications and the reviews.
- Enhancing review quality, with more emphasis on the broad impact of the research, and the use of editorial board models and electronic reviews.
- Enhancing reviewer quality through training of study section chairs and scientific review officers, building in more flexibility, and linking board service to NIH awards to help attract top-quality reviewers.
- Optimizing support at different career stages by funding early-career investigators and giving established investigators longer periods of support.
- Optimizing support for different approaches to science by setting aside a percentage of funding for transformative (high risk/high reward) research, piloting use of patients or their advocates to review clinical research, and enhancing support for interdisciplinary research.
- Reducing stress on the support system by requiring a minimum percentage (20%) of effort by PIs, and analyzing the incentives in the funding system.
- Meeting the need for continuous review of peer review by identifying what is working and what might cause unintended consequences.

Dr. Berg stated that a report has been sent to Dr. Zerhouni about the feasibility of implementing these various ideas. When Dr. Zerhouni has made a final decision, phased implementation of selected actions will begin.

Discussion (COPR members)

Ms. Palermo asked whether the goals of the Peer -Review process to reduce the administrative burden and focus on the merit of the science would exclude community engagement and participation. She also asked for Dr. Berg's thoughts as the COPR begins to develop guidance for peer -review panels to help them evaluate community engagement. Dr. Berg stated that institutes should, and do, consider community participation for funding projects that depend critically on community involvement. Dr. Berg noted that some institutes have piloted the use of public members in the first level of peer review, and he emphasized the importance of public representatives having adequate training. He asked the COPR to consider the type and structure of training that would be helpful.

Ms. Palermo suggested that the transparency of the process from a community perspective appeared to be missing from the goals of the peer -review process and asked that this be included as a goal. Dr. Berg agreed that the process must be as transparent as possible to avoid misunderstandings about how projects are funded. Dr. Zerhouni emphasized that peer review at the first level is a technical review; funding decisions are made at the advisory level, at which one-third of the members are public members, thereby giving the public a tremendous impact on these decisions.

Linda Crew, M.B.A., R.N., asked for a clarification of the "editorial board model." Dr. Berg explained that there are many variations, but the basic concept is to have a large number of people independently involved in the first level of review with their input going to an editorial board that integrates the various input and compiles a final list of ratings, which go to the advisory councils for the next level of review.

Dr. Mau asked for comment about peer review for applications that are looking at community engagement and translation, such as the Clinical and Translational Science Awards or the partners in research Awards. She also inquired about the scientific expertise required for those kinds of applications. Dr. Berg said that this had not been

discussed because the focus was on scientific initiatives. He noted that institutes and centers have their own review offices in addition to the peer review conducted by the Center for Scientific Review, and he suggested that there is a need to find people with expertise in how to engage appropriate communities effectively in the research.

Ms. Church asked about the timeline for assessing the new review process and wondered about recruiting more community members to serve on review panels. Dr. Berg said that the timeline and evaluation plans are linked to specific actions. Some, such as providing scores to reviewers, are easy to implement and can be assessed quickly. Others, like changing the structure of the application, are complicated and will take considerable time to implement. The biggest challenge will be measuring whether better science is being funded, which is hard to do in a reasonable time scale. With respect to recruiting public members, Dr. Berg welcomed input from the COPR.

Ms. Clark cautioned against having too narrow a focus on the appropriate roles for the public and thus failing to involve the public in basic biomedical protocols from the start. She asked whether Dr. Berg thought it valuable to revisit where the public belongs in the peer review continuum in light of what may be artificial distinctions between basic and clinical research. Dr. Berg replied that the reviews of basic research are stronger when there is a broad review panel and that it is tremendously helpful to have sufficient breadth to counteract the more narrowly focused study sections.

NATIONAL LIBRARY OF MEDICINE OUTREACH INITIATIVES

Melanie Modlin

Ms. Modlin, Public Affairs Specialist for NLM, gave an overview of the outreach services available from NLM, the world's largest medical library, with resources in 150 languages. She noted that in a typical two-day period, NLM users download the equivalent of an entire Library of Congress of data. Providing this level of information is one way that NLM magnifies the positive impact of NIH's investment in scientific and clinical research.

The main NLM outreach tools include:

- MedlinePlus—An online resource, in English and Spanish, that links consumers to reliable, up-to-date, easy-to-read public and private health information.
- *NIH MedlinePlus* magazine—a quarterly publication designed to provide the public with the gold standard of consumer health information from NIH. NLM distributes 300,000 copies free of charge to doctor's offices, libraries, community health centers, and other locations. Ms. Modlin invited the COPR's suggestions about topics for articles and celebrities to feature on the cover. There will also be a bilingual version of the magazine, in Spanish and English.
- National Network of Libraries of Medicine—This is an effort to provide all U.S. health professionals with equal access to biomedical information and improve the public's access to information that will enable consumers to make informed decisions about their health. The network is comprised of eight regional libraries (hubs), 159 resource libraries located primarily at medical schools, and 4,700 primary access libraries.
- ClinicalTrials.gov—A centralized, comprehensive database for clinical trials that includes 54,000 trials in the United States and 154 nations.

Smaller outreach initiatives include:

- DeBakey Science Events—A program of reaching out to high school students to encourage medical careers.
- Pow Wows—An outreach to Native American populations.
- Exhibitions—The current exhibition is *Against the Odds: Making a Difference in Global Health*. A previous exhibition, *Changing the Face of Medicine*, on America's women physicians, is traveling throughout the country until 2010. There are also Web sites associated with the exhibits, which include detailed teaching and lesson plans.

Discussion (COPR members)

Dr. Lindquist recounted how her small tribal college in North Dakota, with the help of the NLM outreach program, created a section in the school public library dedicated to various diseases and health issues that affect the community. NLM also helped provide the technology and computers to track usage. Dr. Lindquist noted the tremendous impact this network can make at small, more remote venues.

Dr. Wong asked whether the information on the NLM Web site or through links on that site is available at a variety of technical levels that can take patients from a first cursory look at a disease to more detailed research. Ms. Modlin stated that people could start with the basics on MedlinePlus, then move on to both PubMed, which offers biomedical knowledge, and PubMed Central, which includes 1.7 million printed medical articles. In addition, there is a toll-free line on the Web site, and the NLM staff is available and happy to answer questions. Ms. Modlin noted that NLM has about 75 databases, so there is a wealth of information available at various levels.

Ms. Church noted that she has found PubMed invaluable in her graduate work. She asked for NLM publications that she could distribute at the various Native American events. Ms. Church offered to open a COPR meeting with Native American culture and traditions to celebrate the diversity of public representation on the Council.

Dr. Furlong complimented her Nebraska area network representative that operates the listserv informing the public of so many resources. She wondered about getting NIH to become a top tourist attraction in Washington, D.C.

Ms. Palermo, noting that she works in East Harlem, suggested creating a program to help develop the capacity of community librarians to navigate these databases and help community residents access them. Ms. Palermo also suggested a partnership between NLM and the National Area Health Education Centers to facilitate the establishment of mini National Libraries of Medicine around the country in disadvantaged areas.

Mr. Jaquet asked about the scope of ClinicalTrials.gov. Ms. Modlin replied that it has become such a successful recruiting tool that private pharmaceutical companies have started posting trials. Elliot R. Siegel, Ph.D., Associate Director, NLM Health Information Program Development, added that as a condition of publication, many journals now require the registration of clinical trials in clinicaltrials.gov. NLM is also working with international organizations to acquire their trials through a partnership similar to that of the genomics community. Dr. Siegel announced that the next NLM exhibition, opening in 2010, would feature Native American concepts of health and illness.

Ms. Crew recalled that NLM had helped fund a project called The Health Connector Program that she implemented to bring reliable health information to rural communities. Her organization bought a computer, paid for the Internet connection, and trained a person from the community to show community residents how to access health information. Ms. Modlin expressed interest in the program, saying that it might fit into Ms. Palermo's suggestion about training librarians.

Mr. Berman asked for interdisciplinary outreach efforts to departments at schools and universities. Ms. Modlin agreed that outreach to nontraditional departments could help identify important areas that have been overlooked.

GENOME-WIDE ASSOCIATION STUDIES POLICY: AN UPDATE

Elizabeth G. Nabel, M.D.

Elizabeth G. Nabel, M.D., Director of NHLBI, discussed the new policy, across all 27 institutes and centers, to coordinate sharing of data obtained in NIH-supported or -conducted genome-wide association studies (GWAS). More information is available at <http://grants.nih.gov/grants/gwas.index.htm>.

Dr. Nabel described how variations in genetic codes can predispose individuals to certain diseases. Genomics research takes advantage of new technology to isolate DNA to compare individuals who are affected with a certain variation that has caused a disease with those unaffected. These genetic studies are designed to determine how common the variance is in the population and its importance in causing disease.

This new technology can be applied to previous studies, such as the Framingham Heart Study, which NIH has funded since 1948. The 10,000 participants in that study agreed to have their DNA analyzed. The more than 5.5 billion pieces of genetic data (genotype), along with their clinical data (phenotype), are now contained in a database called Database Genotype and Phenotype (dbGaP), which allows researchers to conduct more than five trillion tests of association between genetic variation and clinical parameters.

Other institutes are assembling similar rich datasets for diabetes, cancer, and mental illness. Realizing the importance of sharing these data, especially with the proliferation of applications to do genome-wide associations, NIH drafted a policy for data sharing.

Dr. Nabel outlined the components of the policy. Submitting investigators gather information on participants, de-identify it, and submit this dataset for inclusion in the NIH central data repository, dbGaP. This process includes privacy safeguards and institutional review board (IRB) input about confidentiality issues. The NLM Web site, which is the homepage for dbGaP, lists the studies that are contained within the repository.

Investigators wishing to use dbGaP datasets (recipient investigators) apply and must be approved by a data access committee (DAC). Each institute has a DAC that consists of federal staff with expertise in science, bioethics, and privacy/confidentiality issues. The recipient investigator and the institution must agree to strict requirements about the use of

the data before receiving the dataset, which is sent in an encrypted manner.

The recipient investigator has a 12-month period of exclusivity for publication. NIH urges that genotype-phenotype associations remain available to all investigators, unencumbered by intellectual property claims.

For any grant to do GWAS that is funded after a submission date of January 25, 2008, the investigator must submit a data sharing plan that is consistent with the GWAS policy prior to receiving notice of the grant award. This ensures that the data from the grant will be added to dbGaP.

To provide adequate oversight for the implementation of this policy, a comprehensive trans-NIH governance structure has been established that includes technological protection for the information itself and confidentiality protection for human subjects.

Dr. Nabel noted the role of Dr. Lindquist, who is the liaison to the ACD Working Group on Participant and Data Protection for the Genetic Association Information Network and Genome-Wide Association Studies. She concluded by acknowledging the role of the participating institutes and centers.

Discussion (COPR members)

Mr. Walsh commended Dr. Nabel on the NHLBI chronic obstructive pulmonary disease (COPD) public awareness campaign, *Learn More, Breathe Better*. He added that as an individual affected by alpha-1 –related genetic COPD, he hoped for a reconsideration of the GWAS confidentiality policy to allow individuals in studies to be notified of a finding of a genetic predisposition to a disease. Mr. Walsh congratulated Dr. Nabel for her leadership on the COPD Genetic Epidemiology Study, which includes a GWAS with

more than 10,000 study subjects. Dr. Nabel stated that the issue of notification of individuals is a very complex one, involving the need for strong privacy safeguards to prevent misuse of the information. Currently, notification is being handled at the PI and IRB level.

Dr. Furlong asked what other limitations participants request, besides not wanting their information used in a proprietary way. Dr. Nabel replied that the other major limitation requested was to limit the type of studies for which the information could be used, such as for heart research but not mental illness studies.

Ms. Palermo asked how GWAS are initiated and what the implications are for participants in terms of understanding the scope of these studies and thus being less likely to put limitations on the use of information. She also asked about plans to disseminate the information from the studies to the community. Dr. Nabel explained that GWAS are initiated by institutes, as with the Framingham example, and by investigators who have datasets that could be enhanced by adding a genomic component. An important aspect is instilling pride in participants that they are furthering medical research that benefits others. In terms of disseminating information to the community, this education piece will be the subject of upcoming meetings. A public update component to the dbGaP web site is also being considered.

Dr. Nelson asked whether there is a “chilling effect,” both because of the project’s complexity and the possibility that it will raise the cost of research and actually reduce the amount of research being done. Dr. Nabel acknowledged that it is difficult to find the right balance between making the data available to foster creative research and yet still have enough privacy safeguards in place. At least in these early stages, there is probably a trend toward erring on the side of caution to avoid an incident that could jeopardize the entire program.

Dr. Zerhouni noted Dr. Nabel's great leadership in crafting a policy that addresses so many complex issues.

OVERVIEW OF THE COPR WORK GROUP DAY AND REPORT FOR THE NIH DIRECTOR

Christina L. Clark, M.A., M.B.A., and James H. Wendorf, M.A., Co-Chairs

Ms. Clark and Mr. Wendorf, co-chairs of the spring 2008 Agenda Work Group, provided Dr. Zerhouni with an overview of the Work Group Day that took place April 17.

Ms. Clark described the purpose of the Agenda Work Group as helping to translate the COPR's recommendations about the broad development of NIH programmatic and research priorities into action. Therefore, the Work Group Day was organized to more effectively carry out the COPR's dual functions of bringing the public's perspectives to NIH and identifying ways to help NIH deliver information to the public.

Ms. Clark noted that since the last meeting, the COPR has:

- Delivered an editorial to raise public awareness, published in Hawai'i Medical Journal.
- Developed definitions of community engagement and public participation.
- Developed recommendations to support trans-NIH communications strategies.
- Supported the strategic initiatives of the Office of the Director as they relate to public interest.

COPR members and alumni have also been active on several fronts. In addition to the activities noted by Dr. Zerhouni during his update to the Council, Ms. Clark reported on the following:

- Wendy Chaite, Esq., former COPR member, has been appointed to the National Advisory Research Resources Council.
- Nicole Johnson, M.A., M.P.H., who interacts with the public through her television show, dLife, recently visited the laboratory of David Harlan, M.D. at NIDDK.

UPDATE: THE ROLE OF THE PUBLIC IN RESEARCH WORK GROUP

Ann-Gel Palermo, M.P.H., Co-Chair

Ms. Palermo reported on activities for the Role of the Public in Research Work Group on behalf of its members and her Co-chair, Syed M. Ahmed, M.D., Dr. P.H., M.P.H., who was unable to attend the meeting. The purpose of the Work Group is to identify ways to encourage researchers to involve the public in research, with an emphasis on community engagement.

During the previous day, the Group held a roundtable session with experts from within and outside NIH to help build a framework for their efforts focused on researcher training and peer -review panels involving community engagement. Roundtable participants included:

- Amy Bany Adams, Ph.D., *Special Assistant to the NIH Director, Office of the Director, NIH*
- David Armstrong, Ph.D., *Chief, Scientific Review Branch, National Institute of Mental Health, NIH*
- Jared Jobe, Ph.D., FABMR, *Program Director, Clinical Applications and Prevention Branch, Division of Prevention and Population Sciences, NHLBI, NIH*
- Loretta Jones, M.A. *Founder and Executive Director, Healthy African American Families II*

- Donna Jo McCloskey, Ph.D., R.N., *Health Scientist Administrator, Division for Clinical Research Resources, National Center for Research Resources, NIH*
- Walter Schaffer, Ph.D., *Senior Advisor, Office of Extramural Research, NIH*
- Vivian Ota Wang, Ph.D., *Executive Office of the President, National Nanotechnology Coordination Office, National Science and Technology Council*

As a result of research undertaken since the last meeting and the valuable input from the roundtable discussion with experts during the Work Group Day, the Role of the Public in Research Work Group has:

- Crafted definitions of community engagement and public participation:
 [DRAFT] *Community engagement in research is a process of inclusive participation that supports mutual respect of values, strategies, and actions for authentic partnership of people affiliated with or self-identified by geographic proximity, special interest, or similar situations to address issues affecting the well-being of the community of focus.*
It is a process that requires power sharing, maintenance of equity, and flexibility in pursuing goals, methods, and time frames to fit the priorities, needs, and capacities within the cultural context of communities. Community engagement in research is often operationalized in the form of partnerships, collaboratives, and coalitions that help mobilize resources and influence systems; change relationships among partners; and serve as catalysts for changing policies, programs, and practices.

Community engagement is a core element of any research effort involving communities. It requires academic members to become part of the community and community members to become part of the research team, thereby creating a unique working and learning environment before, during, and after the research.

Adapted from:

Jones L, Wells K. Strategies for academic and clinician engagement in community-participatory partnered research. *JAMA* 2007;297:407–410. p. 408.

Fawcett SB, Paine-Andrews A, Francisco VT, Schultz JA, Richter KP, Lewis RK, Williams EL, Harris KJ, Berkley JY, Fisher JL, Lopez CM. Using empowerment theory in collaborative partnership for community health and development. *Am J Community Psychol* 1995;23:677–697.

Public participation is based on the belief that those who are affected by a decision have a right to be involved in the decision-making process. Public participation is the process by which an organization consults with interested or affected individuals, organizations, and government entities before making a decision. Public participation is two-way communication and collaborative problem solving with the goal of achieving better and more acceptable decisions

Sources:

International Association of Public Participation. IAP2 Core Values.

<http://www.iap2.org/displaycommon.cfm?an=4>.

Creighton and Creighton, Inc. What is...?

<://www.creightonandcreighton.com/whatis.html#6>.

- Created a template of values, strategies/recommendations, and outcomes to be used for developing guidelines for educating researchers and the public about community engagement.
- Identified a process for developing guidelines that peer-review panels can use to gauge community engagement.

Next steps to be addressed between April 2008 and October 2008:

- Complete the template for use in developing guidelines for educating researchers about community engagement.
- Identify models/best practices for developing guidelines for peer-review panels.

Ms. Palermo asked the COPR to approve the definitions of community engagement and public participation.

Discussion (COPR Members)

As Agenda Work Group Co-Chair, Mr. Wendorf presented the definitions of community engagement and public participation that represent the consensus of the COPR to Dr. Zerhouni for approval.

Dr. Zerhouni thanked Ms. Palermo and the Work Group members for their extensive work. He shared positive impressions on the definitions, but noted that the portion of the community engagement definition that states “It is a process that requires power sharing, maintenance of equity and flexibility...” was more of an operating principle or method of implementation than a definition. Ms. Palermo recognized the work group’s agreement with Dr. Zerhouni’s comments, as they discussed the need to operationalize the definitions as part of their next steps.

Dr. Zerhouni raised the question of whether the text might be considered “characteristics of positive community engagement” rather than a definition. He stated that he is officially in receipt of this text, calling it “terrific work.” He added that it could be implemented at many levels.

Ms. Clark noted that the COPR considers this definition a starting point to be further developed. Dr. Zerhouni characterized it as a definition of “desirable processes.”

UPDATE: COMMUNICATIONS WORK GROUP

Brent M. Jaquet, Co-chair

Mr. Jaquet described the role of the Communications Work Group as:

- Promoting awareness about NIH to the public.
- Acting as a vehicle for communication from the public to NIH.
- Recommending communications strategies that support the work of the COPR.

During the previous day, the Work Group held a panel session with experts in communications from within and outside NIH to gain insight on effective communications strategies that can be incorporated into the Council’s planning activities surrounding education and outreach efforts. Presentations included:

- *The Heart Truth*TM Campaign —Ann Taubenheim, Ph.D., M.S.N., and Diane Striar, NHLBI; Sarah Temple and Jennifer Wayman, M.H.S., Ogilvy Public Relations Worldwide
- *Nuts and Bolts of Campaign Advertising* —Kate Emanuel, M.P.H., M.A., Ad Council
- *Communications and New Media* —Jeff Gralnick, NBC News
- *NIH YouTube Update* —Jeff Dehoff, Office of Communication and Public Liaison, NIH

Building on previous initiatives, crystallizing the Work Group’s recommendations presented in the March 14, 2008, letter to Dr. Zerhouni, and incorporating the valuable input from the presenters on the Work Group Day, the Communications Work Group recommends implementation of a trans-NIH “Communications Roadmap” that will:

- Present NIH through an integrated, unified communications and Web strategy.

- Require budget and cultural changes and possibly include public/private partnerships.
- Represent the opportunity to devise a dual awareness and branding campaign focused on health consumers that would make NIH widely recognized as the “gold standard” for objective, evidence-based health information.
- Integrate the use and power of “new media” for maximum dissemination of information.

The COPR offered to take a leadership role in helping NIH obtain input about:

1. What the public wants to know.
2. How the public obtains health information.

Possible approaches they suggest include town hall meetings, internet activities, and large public deliberation activities.

Discussion (COPR Members)

Mr. Burklow called this a timely project that would harness the resources of NIH to provide an integrated, valuable communications strategy.

Dr. Nelson complimented Mr. Burklow on his work to date in advancing the NIH communications strategy and endorsed the idea of moving to a new level.

Dr. Zerhouni called the presentation stimulating and timely. He asked whether the focus of the project is strategic distribution. Mr. Jaquet replied that the project’s goal is to raise awareness of NIH as an entity, rather than as many disparate parts, and that strategic distribution of information is a part of the process.

Dr. Zerhouni asked whether the current NIH Web presence and content is insufficient or whether the problem is that NIH is not positioned in a way to get maximum attention from consumers. Mr. Wendorf suggested a look at the consumers' ability to find information from many separate silos, which can be confusing, or if there is benefit in pursuing an integrated, strategic communication network at the NIH level. Mr. Jaquet added that to move from individual silos to an integrated trans-NIH Web site would require a dedication of resources.

Dr. Zerhouni stated that his understanding from the presentation was that both the NIH Web presence and the way NIH distributes information need to move to another level.

Ms. Church cautioned about forgetting the people who do not have access to the technology or resources to get information online. She added that literacy level must also be taken into account. Mr. Jaquet suggested that a fully developed awareness campaign would filter to the community level and include printed or other appropriate materials.

Ms. Johnson suggested having NIH alumni or others who have been associated with NIH write a blog to further disseminate the story of what NIH does.

Dr. Nelson suggested recounting some of the major NIH breakthroughs on the Web site and framed the ultimate goal as having the American public understand that NIH is the gold standard.

Mr. Burklow described new media as one component of an integrated, multipronged strategic approach and said that the communications directors are ready to consider a specific campaign to make information more accessible. He announced plans for a fall meeting of experts, including COPR representation, to discuss this issue.

Mr. Pavão asked whether other federal agencies, such as the Centers for Disease Control and Prevention, have information dissemination practices that could be used by NIH. Mr. Wendorf suggested looking at university models that have integrated communication networks without losing the individuality of their various schools.

Mr. Walsh suggested working with organizations such as the American Cancer Society or American Heart Association, asking them to refer to NIH, which funds much of their research, on their Web sites and in their literature.

PUBLIC COMMENT

Public comments were presented by Taylor Werner, who spoke on behalf of patients with Traumatic Brain Injury, and submitted by Diane Bargonetti, N.D., of New York and B. Sachau of New Jersey.

ACD LIAISON REPORT

John Nelson, M.D., M.P.H., FACOG, FACPM, ACD Liaison to the COPR, and Elizabeth Furlong, R.N., Ph.D., J.D., COPR Liaison to the ACD

Dr. Nelson reported on the December 2007 meeting of the ACD. The ACD members discussed the issue of supporting both established and new investigators and will continue to explore realistic ways within budget constraints to accomplish this issue. The ACD and invited speakers also discussed peer review (Lawrence Tabak, D.D.S., Ph.D., and Keith Yamamoto, Ph.D.), the National Institute of Diabetes and Digestive and Kidney Diseases Director's Report (Griffin Rodgers, M.D.), Participant and Data Protection for Genome-Wide Association Studies (Christine Seidman, M.D.), Roadmap 1.5 (Alan Krensky, M.D.), and the National Children's Study (Duane Alexander, M.D.), which is the largest long-term study of children's health and development ever conducted.

Dr. Zerhouni thanked Dr. Nelson for his work on both the ACD and COPR, and he stated that the input that he gets from the various advisory councils (ACD, COPR, Council of Councils, and the Scientific Management Review Board) is enriching, complementary, and makes a tangible difference to what happens at NIH.

NIH DIRECTOR AND COPR MEMBERS SUMMARY AND NEXT STEPS

Ms. Clark recognized the efforts of Mr. Burklow, Marin Allen, Ph.D., and Kelli Carrington, M.A., in making the meeting a success. Dr. Zerhouni thanked Ms. Clark and Mr. Wendorf for their leadership and thanked the COPR members for the stimulating meeting and proposals.

Ms. Carrington announced that the next meeting of the COPR will take place October 30–31, 2008.

ADJOURNMENT

The meeting was adjourned at 4:15 p.m.

LIST OF ABBREVIATIONS AND ACRONYMS

ACD	Advisory Committee to the Director
COPD	chronic obstructive pulmonary disease
COPR	Council of Public Representatives
DAC	data access committee
dbGaP	Database Genotype and Phenotype
FY	fiscal year
GWAS	genome-wide association studies
IRB	institutional review board
NCCAM	National Center for Complementary and Alternative Medicine
NHLBI	National Heart, Lung, and Blood Institute
NICHD	<i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development
NIDDK	National Institutes of Diabetes and Digestive and Kidney Diseases
NIEHS	National Institute of Environmental Health Sciences
NIGMS	National Institute of General Medical Sciences
NIH	National Institutes of Health
NLM	National Library of Medicine
OPASI	Office of Portfolio Analysis and Strategic Initiatives
PI	principal investigator
RO1	Research Project Grant