



DIRECTOR'S COUNCIL

COPR Alumni

CLASS OF 2008

- [Craig T. Beam](#) (California)
- [Wendy Chaite](#) (New York)
- [Nicolas Linares-Orama](#) (Puerto Rico)
- [Michael Manganiello](#) (Washington, DC)

Craig T. Beam

Term: 2004-2008



Mr. Craig T. Beam, a partner with the health care development firm Hammes Company, oversees the development and management of real estate, especially health care and institutional projects. He is a member and former chairman of the American Heart Association (2002-2003) and serves on the boards of Riverside Community Hospital in California and AllHealth, a company sponsored by the Hospital Council of Southern California.

Mr. Beam's interest in the American Heart Association stems from his family's health history, and he strongly supports national efforts on behalf of health care research in general. His active participation in health care issues and his professional experience have given him insight into the dynamic changes occurring in the industry. He has been a board member for several health care firms and chairman of Martin Luther Hospital in Anaheim, California. He has also served in governance capacities at hospitals in New Jersey and California.

Mr. Beam's understanding of health care trends has brought him major clients, including several health care systems. He has worked with several hospitals and major medical groups such as Harriman Jones, San Jose Medical Group, St. Joseph Medical Foundation, and Buenaventura Medical Group.

Mr. Beam graduated from California State University, Fullerton, with a degree in business administration and started his real estate career in 1977 as chief financial officer of Concordia Development. In 1983 he became president of Beam & Associates, with responsibility for the firm's consulting, development, leasing, and brokerage divisions. The firm merged with Hammes Company in 1999 to form the largest U.S. health care development firm. Mr. Beam has received numerous professional and volunteer awards, including the 2003 American Heart Association Distinguished Leadership Award, and was appointed an Endowed Fellow by the National Health Foundation in 1998. He resides with his family in Orange County, California, where his ancestors settled in the late 1800s.

Wendy Chaite

Term: 2004-2008



Ms. Wendy Chaite serves as the COPR Liaison to the NIH Advisory Committee to the Director. Ms. Chaite, whose daughter was born with systemic visceral and peripheral lymphatic disease and lymphedema, left her professional career in July 1998 to found the Lymphatic Research Foundation (LRF). LRF is a not-for-profit organization dedicated to promoting and supporting lymphatic research and to fostering an interdisciplinary field of research. Ms. Chaite played a central role in establishing a trans-NIH Coordinating Committee for lymphatic research and disease, an international peer-reviewed scientific journal, a prestigious Gordon Research Conference series devoted to lymphatic research and biology, and the creation of the first ever Endowed Chair in Lymphatic Research and Medicine at Stanford University School of Medicine, among other achievements. She is a Board Member Emeritus of Research!America, the nation's cy o1(en5(a)7

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

MEETING MINUTES

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

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

October 31, 2008

NIH Participants

Elias A. Zerhouni, M.D., Director, NIH
Raynard S. Kington, M.D., Ph.D., Deputy Director, NIH
John T. Burklow, Associate Director for Communications and Public Liaison, Office of the Director, NIH
Marin Allen, Ph.D., Deputy Associate 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

Syed M. Ahmed, M.D., Dr.P.H., M.P.H.
Micah Berman, J.D.
Lora M. Church
Christina L. Clark, M.A., M.B.A.
Naomi Cottoms, M.S.
Linda Crew, M.B.A., R.N.
Valda Boyd Ford, M.P.H., M.S., R.N.
Elmer R. Freeman, M.S.W.
Elizabeth Furlong, Ph.D., J.D., R.N.
Nicole Johnson, M.A., M.P.H.
Cynthia A. Lindquist, Ph.D., M.P.A.
Matthew Margo, LL.M.*
Anne Muñoz-Furlong
Eileen Naughton, J.D.
Ann-Gel S. Palermo, M.P.H.
Carlos Pavão, M.P.A.
John Walsh
James H. Wendorf, M.A.
James Wong, Ph.D.

*Participated by telephone

COPR Members Not Present

Brent M. Jaquet
Marjorie K. Mau, M.D., M.S.

ACD Liaison

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

Speakers

Vence Bonham, J.D., Senior Advisor to the Director on Societal Implications of Genomics and Chief, Education and Community Involvement Branch, National Human Genome Research Institute, NIH

Patricia Grady, Ph.D., R.N., FAAN, Director, National Institute of Nursing Research, NIH

Alan E. Guttmacher, M.D., Acting Director, National Human Genome Research Institute, NIH

Yvonne Maddox, Ph.D., Deputy Director, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, NIH

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EXECUTIVE SUMMARY

The 20th meeting of the National Institutes of Health (NIH) Director's Council of Public Representatives (COPR) took place on October 31, 2008.

NIH Director Elias A. Zerhouni, M.D., expressed his appreciation to the COPR for its guidance over his six and a half years as NIH Director. He also recognized and thanked the six retiring COPR members: Christina L. Clark, M.A., M.B.A.; Valda Boyd Ford, M.P.H., M.S., R.N.; Nicole Johnson, M.A., M.P.H.; Cynthia A. Lindquist, Ph.D., M.P.A.; Marjorie K. Mau, M.D., M.S.; and James H. Wendorf, M.A.

Dr. Zerhouni reported that the 110

The Transformative R01 program supports innovative, high-risk, original, and unconventional research with the potential to create new or challenge existing scientific paradigms.

NIH has issued a total of 38 Clinical and Translational Science Awards.

NIH has increased access to information on research funding by creating the Condition, and Disease Categorization system.

The NIH process to make critical changes and improvements in its peer-review system is now in the implementation phase.

Mr. Wendorf and Elmer R. Freeman, M.S.W., co-chairs of the COPR Agenda Work Group, began the COPR reports with acknowledgments to Dr. Zerhouni for his years of service to NIH. They noted Dr. Zerhouni's commitment to and support of the COPR. Four presentations were made to recognize Dr. Zerhouni, including presentations of a replica of the new COPR fact sheet signed by the COPR members; a Rhode Island House of Representatives Resolution and Citation from Eileen Naughton, J.D.; a spirited solo verse by Ms. Ford; and a Native American special presentation and blessing for Dr. Zerhouni and Raynard S. Kington, M.D., Ph.D., respectively, by Dr. Lindquist, a member of the

recommended that COPR members introduce the RFI in plain language and disseminate it to constituents by e-mail, mail, and telephone.

Alan E. Guttmacher, M.D., described the accomplishments of the Human Genome Project. The project produced the human genome sequence; spurred new technologies; helped spawn the new field of genomics; and provides new knowledge, technologies, and approaches for understanding health and changing health care. He discussed the International HapMap Project, which is mapping variations in the human genome across various populations around the world. He also cited several examples of current genomic research under way.

John T. Burklow described the ways in which NIH disseminates health and science information to the public. Through the Office of Communications and Public Liaison (OCPL), the agency

inform the public about health science, improve public understanding of the benefits of publicly funded research, and increase scientists' understanding of and outreach to the public.

The COPR heard public comments from Leo Hallan of Yankton, South Dakota, and Margo Michaels, Executive Director of the Education Network to Advance Cancer Clinical Trials.

John C. Nelson, M.D., M.P.H., FACOG, FACPM, summarized the presentations and discussions at the last meeting of the Advisory Committee to the Director.

Dr. Kington closed the meeting, thanking the COPR members for their support for Dr. Zerhouni, who only speaks of the COPR using superlatives.

WELCOME AND INTRODUCTIONS

Elias A. Zerhouni, M.D.

diseases, including expansion of research on tuberculosis, pain, muscular dystrophy, arthritis, breast cancer and the environment, pulmonary hypertension, and pediatric cancer.

Legislation is pending to renew the Small Business Innovation Research and Small Business Technology Transfer programs. The President signed the Breast Cancer and Environmental Research Act of 2008 into law on October 8. This act requires the Secretary of Health and Human Services to establish an Interagency Breast Cancer and Environmental Research Coordinating Committee to organize research, develop a strategy to solicit proposals, summarize breast cancer research advances, and recommend improvements to the NIH research portfolio.

NIH is also implementing Title VIII of the F

this new policy to level the playing field, allowing new investigators to achieve success rates comparable to those of established scientists submitting new grant applications. Achievement of a comparable success rate should permit NIH to support 1,650 or more new investigators across all Institutes and Centers in FY 2009, a number equivalent to that achieved in FY 2008.

New Initiatives

Two new Roadmap projects that will support biological research could have a substantial impact on the understanding of how diseases develop. Th

an initiative on rare and neglected diseases to create and make available resources for scientists conducting related research.

Transparency and Accessibility

NIH is working to improve transparency and access to information on research funding through creation of the Research, Condition, and Disease Categorization (RCDC) computer-based system, which will sort and report the amount of funding NIH provided in each of 215 historically reported categories of disease, condition, or research area. RCDC provides consistent and transparent information to the public about NIH-funded research. For the first time, a complete list of all NIH-funded projects related to each category will be available. COPR members have been connected with this effort since its conception, providing perspectives on usability and communication with the public. NIH's first RCDC reports will be a part of the release of the President's 2010 budget request. The RCDC system will generate Web-based summary tables that the public can view and download.

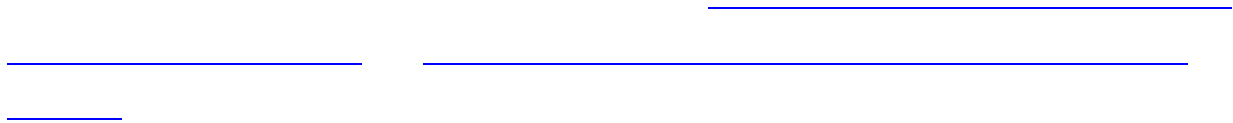
Peer Review Reform

NIH's process to make critical changes and improvements in its peer-review system is now in the implementation stage. The new plan calls for an increased commitment to investigator-initiated high-risk, high-impact research to prevent a slowdown of transformative research in spite of the difficult budgetary situation.

Dr. Zerhouni thanked the COPR members for their contributions to this effort, including Dr. Mau and Syed M. Ahmed, M.D., Dr.P.H., M.P.H., for their participation in the Advisory Committee to the Director Working Group on Peer Review. He also thanked Ann-Gel S. Palermo, M.P.H., for her testimony at an NIH regional consultation meeting and the other COPR members who asked their constituents to provide feedback during the request for information (RFI) process.

New NIH Policy on Application Resubmission

NIH recently announced a new policy that will speed up the funding of meritorious science. Starting in January with applications being considered for funding in FY 2010, investigators will be able to resubmit grant applications only once. Under the previous policy, which allowed



their health. To support this transformation, the public needs to understand that NIH funding is an important public investment—possibly the most important investment in this century.

Mr. Wendorf asked Dr. Zerhouni to comment on the future of behavioral research. Dr. Zerhouni explained that behavioral research is related to the preemptive and personalized components of the NIH strategic vision. Behavioral and social sciences will play a major role, but they need to become an intrinsic part of all biomedical research. Integrated approaches to research are the key to success.

Ms. Palermo asked Dr. Zerhouni for his thoughts on the COPR's future over the next decade. Dr. Zerhouni asked the COPR to continue to deepen its activities. He also asked the COPR to distinguish between its advisory role and the NIH staff implementation role. Advisory bodies, such as the COPR, focus on guiding policy and shaping the agency's thought processes, whereas staff has operational responsibility for implementing policies.

John C. Nelson, M.D., M.P.H., FACOG, FACPM, asked how the COPR might best help the new Director understand the Council's role and take on his or her new responsibilities. Dr. Zerhouni suggested that the COPR brief the new Director on the COPR and how it can assist him or her.

Several COPR members made presentations to Dr. Zerhouni to thank him for all of his work as NIH Director. On behalf of the COPR, Mr. Wendorf and Mr. Freeman presented Dr. Zerhouni with a copy of the new COPR fact sheet surrounded by signatures of the COPR members. The fact sheet serves as a co

The definition of “community engagement” was modified in response to Dr. Zerhouni’s comments to better express how the term is operationalized. Below is the definition as presented.

**COPR ROLE OF THE PUBLIC IN RESEARCH WORK GROUP
PRESENTED TO NIH DIRECTOR, OCTOBER 31, 2008**

I. DEFINITION OF “PUBLIC PARTICIPATION”

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 for Public Participation. (2007). *IAP2 Core Values*. [On-line], Available: <http://www.iap2.org/> .

Creighton & Creighton, Inc. (2008). *What is Public Participation?* [On-line], Available: <http://www.creightonandcreighton.com>.

II. DEFINITION OF “COMMUNITY ENGAGEMENT”

Community engagement is a dimension of Public Participation. In research, community engagement 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.

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

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 partnerships for community health and development. *Am J Community Psychol* 1995;23:677–697

Ms. Palermo presented the work group's second deliverable, describing it as a template for developing educational guidelines for researchers. The template includes values, strategies, and outcomes for investigators who want to engage the community in their research. The 13 values are grounded in the experience presented and discussed during meetings with experts and in published and unpublished literature. The full template is available at <http://copr.nih.gov/reports.asp>.

Dr. Ahmed presented the work group's third deliverable, guidance for peer-review panels assessing community engagement. The template outlines 2 criteria for reviewers and 10 for grant applications. Dr. Ahmed explained the importance of having peer reviewers understand what community engagement means and how to evaluate public input as part of the researchers' community engagement design. The full template is available at <http://copr.nih.gov/reports.asp>.

Following the Role of the Public in Research Work Group's presentation, the co-chairs sought approval, requested guidance/response on implementation for the recommendations, and offered support from the Council where needed. The co-chairs also reported on plans to prepare manuscripts on the frameworks for publication in peer-reviewed literature.

Discussion (COPR Members)

Dr. Kington said that he was delighted to accept the work group's recommendations and suggested that NIH consider them through the formation of an internal NIH working group, modeled after the implementation process used for the Peer Review Enhancement Initiative. This process seems more appropriate than a new COPR work group, as the Council suggested, because the COPR is not involved in implementation of NIH operations, as Dr. Zerhouni noted earlier in the day. He proposed that the Office of Communications and Public Liaison (OCPL), directed by John T. Burklow, take responsibility for forming a working group.

Dr. Nelson expressed concern about how his colleagues on the Advisory Committee to the Director (ACD) might respond to the work group's frameworks. Dr. Kington said that his staff could discuss the frameworks at a future ACD meeting; COPR members could also be invited to present and explain the frameworks.

COMMUNICATIONS WORK GROUP PRESENTATION

Anne Muñoz-Furlong

Anne Muñoz-Furlong reported on the activities of the Communications Work Group. She began by noting that in April, the work group suggested a communications roadmap, modeled after the NIH research-focused roadmap, which ultimately led to the COPR's proposal for an integrated, unified communications and Web strategy across the agency. Over the summer, Ms. Muñoz-Furlong explained, the NIH communications staff began a study of health communications to look at new media usage and health information-seeking behaviors.

During the Work Group Day, the Communications Work Group discussed how the COPR could support a broader public input effort using an RFI to gain insight on how the public wants to obtain information about health and research from NIH. Although the work group members appreciate the constraints that NIH is under to conduct mass public input activities, such as surveys, they noted several issues with the use of an RFI geared toward general public response.

Target audiences for the RFI are unlikely to read the *Federal Register*, responses are more likely to come from organizations than individuals, and RFIs are not consumer friendly. The work group therefore recommended that the COPR and COPR alumni:

Introduce the RFI in plain language to make it more consumer friendly.

Disseminate the RFI to constituents by e-mail, mail, and telephone.

This approach will ensure that the questions quickly reach a wide and diverse group of health consumers and stakeholders. The work group also considered that conducting this type of communication study annually could become a core COPR responsibility.

Additional strategies for overall communications efforts were:

Communicate through a variety of methods directly to health consumers and consumer and advocacy groups.

Encourage NIH to develop a formal communications network that any non-advocacy group can join to receive information for its constituents.

Partner with groups that interact with large numbers of health consumers (such as the American Medical Association and pharmacy and nursing organizations).

Partner with state groups that set health policy and legislation.

Communicate through establishments that exist in every community (e.g., pharmacies, grocery stores, and barbershops), and tailor communication vehicles to target audiences (e.g., places of worship and small or ethnic newspapers).

Link the NIH Awareness Month campaign to high-powered television exposure, such as arranging for the NIH Director to appear on *The Oprah Winfrey Show*.

Provide lapel pins to COPR members, COPR alumni, physicians, health care providers, advocacy groups, and others that say "Ask me about NIH." These pins will encourage frequent and informal dialogues about the agency.

Create a group on Facebook or MySpace to attract interest and encourage dialogue.

Discussion (COPR Members)

Dr. Nelson expressed concern that the RFI could miss groups of people not usually reached using this public input mechanism.

Marin Allen, Ph.D., explained that NIH has used RFIs successfully in the past. She hoped that the COPR would disseminate the questions beyond the general NIH constituent contacts and databases to ensure a broad-based public input opportunity. This will ensure an equal opportunity to express interest and ideas.

Dr. Kington explained that NIH could use evaluation funds to determine the mechanism's effectiveness. The agency could also use focus groups and other strategies to collect the

information, especially if it identifies gaps in the information collected. John Walsh reported that some voluntary organizations can support the costs of focus groups.

THE SCIENCE OF GENOMICS

Alan E. Guttmacher, M.D.

Alan E. Guttmacher, M.D., described the accomplishments of the Human Genome Project,

NIH is investigating the interest of healthy young adults in genetic susceptibility testing for eight common conditions.

The Cancer Genome Atlas, sponsored by NCI and the National Human Genome Research Institute (NHGRI), is identifying unique genomic alternations in cancer samples.

The Electronic Medical Records and Genomics (eMERGE) Network is developing, disseminating, and applying approaches to research that combine DNA biobanks with electronic medical record systems for research.

The 1,000 Genomes Project will produce a detailed catalog of human variants for different populations around the world.

Dr. Guttmacher reported that after 13 years of debate, Congress passed the Genetic Information Nondiscrimination Act and the President signed it into law.

Discussion (COPR Members)

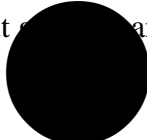
In response to a question from Ms. Ford, Dr. Guttmacher explained that several genes are involved in obesity, although behavioral factors also play a role. Understanding the biology of obesity can help scientists find ways to interfere with the pathways that lead to obesity.


Ms. Church asked about NIH efforts to communicate with communities that do not have access to the Internet. Mr. Burklow replied that NIH does not plan to abandon the traditional communications vehicles or even word-of-mouth communications.


Linda Crew, M.B.A., R.N., asked about the health resource information kiosk in Jackson, Mississippi. Yvonne Maddox, Ph.D., reported that this center provides publications and brochures from all 27 Institutes and Centers describing the research supported by NIH. The center is located in the Jackson Medical Mall, a former shopping center that now houses physician offices and care facilities.

GENOMICS IN THE PUBLIC DOMAIN

Vence Bonham, J.D.

Vence Bonham, J.D., described NHGRI's efforts to disseminate information about  and genomics to the public. These programs include:

Developing Community Based Models for Education and Utilization of Family Health History Information: A Demonstration Project in Urban Appalachian Communities, a model program to educate urban Appalachian women about the collection  their family health histories.

The Brigham and Women's Hospital Family History Project, which provides  organize health history information.

The National Council of La Raza, which uses lay health care workers to communicate to people with low literacy levels about the importance of family health history.

Dozens of companies now provide genetic testing directly to consumers, and several companies are marketing genetic ancestry tests. NIH is determining its role in providing accurate and appropriate information to the public and health professionals about these services.

Mr. Burklow reported that Dr. Zerhouni has emphasized the need to educate the public about genomics and direct-to-consumer genetic testing. In response, a new trans-NIH committee has been formed to determine what information the agency should present to the public and how to

present this information. The committee is conducting a literature review, focus groups, and an environmental analysis to determine what information is available and what studies have been or are being conducted. The committee will also create a Web site for the public.

PUBLIC TRUST INITIATIVE: UPDATE ON PARTNERS IN RESEARCH AWARD PROGRAM

Patricia Grady, Ph.D., R.N., FAAN, and Yvonne Maddox, Ph.D. , R.N3(4 T12 3.0001 Twd scientists. Th

that the workshop would address project sustainability. Dr. Maddox added that Institute and Center program staff will help partners develop applications for funding through regular NIH grant mechanisms after the PIR grants end.

Dr. Grady commented that almost half of the reviewers were community members. Perhaps some lessons learned could be developed in collaboration with the Center for Scientific Review.

PUBLIC COMMENT

Mr. Wendorf reminded the COPR that the topics brought forward during the public comment period are for information only. These comments are not presented for deliberation or action by the Council.

Leo Hallan of Yankton, South Dakota, sent a letter to the COPR in support of the Christopher and Dana Reeve Paralysis Act. Margo Michaels, Executive Director of the Education Network to Advance Cancer Clinical Trials (ENACCT), described a new report (*Communities as Partners in Cancer Clinical Trials: Changing Research, Practice, and Policy*) issued by ENACCT and Community-Campus Partnerships for Health.

ACD LIAISON REPORT

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

Dr. Nelson explained that the ACD is one of four advisory committees to the NIH Director. At its last meeting, the ACD heard about the NIH Blue Ribbon Panel to advise the Director on risk assessment for the Boston University National Emerging Infectious Diseases Laboratories. The ACD plans to make recommendations to the NIH Director based on an upcoming report at its December 5 meeting.

The ACD has also discussed NIH's efforts to enhance peer review. The ACD is part interested in four core priorities:

Engaging the best reviewers.

Improving the quality and transparency of reviews.

Ensuring balanced and fair reviews across scientific fields and scientific careers and reducing the burden on applicants.

Developing a permanent process for continuous review of peer review.

The ACD has also discussed the following programs:

The Public-Private Partnerships Program, which sponsors partnerships to promote public health.

The Foundation for NIH, which develops public-private partnerships that build on existing NIH programs to take advantage of new scientific opportunities, enables private partners to expand the number of funded NIH grants, and develops partnerships for clinical and public health studies to collect data in support of improved prevention or interventions for childhood diseases.

The National Center for Research Resources, whose mission is to accelerate research from basic discovery to improved patient care.

Dr. Nelson believes that the ACD would support some of the strategies proposed by the Role of the Public in Research Work Group. He will discuss the work group's recommendations with the ACD.

CLOSING

As outgoing co-chair for the Agenda Work Group, and speaking on behalf of the six retiring members, Mr. Wendorf described his service on the COPR as an honor. Dr. Kington thanked the COPR members for their support for Dr. Zerhouni, who only speaks of the COPR using superlatives. Dr. Kington asked for the COPR's assistance in delivering an agency in top form to the next NIH Director.

ADJOURNMENT

Dr. Kington adjourned the meeting.

LIST OF ABBREVIATIONS AND ACRONYMS

ACD	Advisory Committee to the Director
COPR	Council of Public Representatives
CTSA	Clinical and Translational Science Award
eMERGE	Electronic Medical Records and Genomics
ENACCT	Education Network to Advance Cancer Clinical Trials
ENCODE	Encyclopedia of DNA Elements
FY	

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.
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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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Melanie Modlin

Genome-Wide Association Study Policy: An Update

Elizabeth G. Nabel, M.D.

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Update: Role of the Public in Research

Ann-Gel S. Palermo, M.P.H.

Update: Communications Work Group

Brent M. Jaquet

Public Comment

ACD Liaison Report

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

further noted that this act of violence threatens the dedicated scientists working to improve serious health care services of vulnerable populations of the world.

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.

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

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

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

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

[://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. 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

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 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:

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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

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.

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.,



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

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 of
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 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,

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)

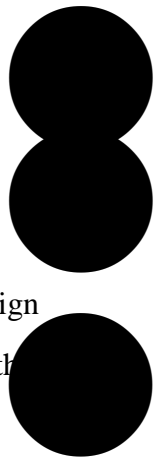
As Agenda Work Group Co-Chair, Mr. Wendorf presented the definitions of community engagement and public participation that represent the consensus of the COPR to Dr. Zerhouni for approval.

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 committee should be responsible for

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.



Mr. Pavão asked whether other federal agencies, such as the Centers for Disease Control

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