

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

MEETING MINUTES

October 31, 2008

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

CONTENTS

Executive Summary

Welcome and Introductions

Elias A. Zerhouni, M.D.

NIH Director's Update

Elias A. Zerhouni, M.D.

Agenda Workgroup Presentation

James H. Wendorf, M.A.

Elmer R. Freeman, M.S.W.

Role of the Public in Research Workgroup Presentation

Syed M. Ahmed, M.D., Dr.P.H., M.P.H., and Ann-Gel S. Palermo, M.P.H.

Communications Workgroup Presentation

Anne Muñoz-Furlong

The Science of Genomics

Alan E. Guttmacher, M.D.

Charting the Future of NIH Communications: Update

John T. Burklow

Genomics in the Public Domain

Vence Bonham, J.D.

John T. Burklow

Public Trust Initiative: Update on Partners in Research Award Program

Patricia Grady, Ph.D., R.N., FAAN

Yvonne Maddox, Ph.D.

Public Comment

ACD Liaison Report

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

Elizabeth Furlong, J.D., Ph.D., R.N.

Closing

Adjournment

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 110th Congress has shown substantial interest in NIH, introducing more than 200 bills of interest to the agency. The President has signed the Breast Cancer and Environmental Research Act of 2008 into law, and NIH is implementing Title VIII of the Food and Drug Administration Amendments Act of 2007.

On September 30, 2008, the President signed a fiscal year 2009 stopgap continuing resolution to fund most of the government until March 6, 2009. The 2009 House and Senate budgets call for an increase in the NIH budget.

Additional announcements were:

- NIH supports an increase in the number of young investigators through a new policy.
- The Human Microbiome Project will support the comprehensive characterization of the human microbiome.
- The Roadmap Epigenomics Program will support research on how the genome is regulated.
- The NIH Director's Pioneer Award supports creative scientists who propose exceptionally innovative approaches that could have substantial impact on biomedical and behavioral science.

- 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 Research, 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 Spirit Lake Dakota Nation, and Lora M. Church, a member of the Navajo Nation. Dr. Zerhouni and Dr. Kington expressed gratitude for these kind mementos.

As the first item of COPR business, Syed M. Ahmed, M.D., Dr.P.H., M.P.H., and Ann-Gel S. Palermo, M.P.H., reported that the Role of the Public in Research Work Group completed three deliverables: definitions and operating principles of "community engagement" and "public participation," guidelines for educating researchers and the lay public on community engagement, and guidance for peer-review panels in gauging community engagement. Dr. Kington proposed that NIH form an internal NIH working group to develop strategies for implementing the framework.

Anne Muñoz-Furlong reported that the Communications Work Group will support NIH's strategic planning activities to enhance the agency's health communications efforts by issuing a request for information (RFI) on health information-seeking behaviors. The work group

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 manages media outreach and communicates health information through a number of channels, including a monthly consumer newsletter; an electronic research update; and web-based strategies, including Web sites, podcasts, vodcasts, RSS feeds, and the NIH YouTube channels. As part of NIH's effort to enhance collaborative communications efforts across the agency, OCPL hosted a workshop with outside experts and communication directors representing the NIH Institutes and Centers on September 9, 2008. Outcomes include plans for working groups to address such areas as new media, shared resources, and capacity building in science communications among researchers.

In a special presentation, Vence Bonham, J.D., described the National Human Genome Research Institute's efforts to disseminate information about genetics and genomics to the public. Dozens of companies now provide genetic testing directly to consumers. NIH is determining its role in providing accurate and appropriate information about these services to the public and health professionals.

Patricia Grady, Ph.D., R.N., FAAN, and Yvonne Maddox, Ph.D., reported that the NIH Partners in Research program is the newest NIH Public Trust Initiative program. Research partnerships between community leaders and NIH-supported scientists will study methods to engage and

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.
Director, National Institutes of Health

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., welcomed the COPR members and presenters. Dr. Zerhouni welcomed Elmer R. Freeman, M.S.W., as the new Agenda Work Group Co-Chair.

Dr. Zerhouni explained that this was his last day in office. He expressed his appreciation to the COPR for its guidance on many important issues over his six and a half years as NIH Director. In particular, the COPR has made major contributions to NIH's communications, public access policy, and efforts to involve the public in research. He noted that the COPR can also take credit for the addition of the fourth "P," for "participatory," to the original three "Ps" (for "predictive," "personalized," and "preemptive" medicine) in the NIH strategic vision. Dr. Zerhouni said he valued the COPR's commitment to analyzing problems before identifying solutions. He expressed his appreciation for the COPR's thoughtful approach to the many issues it has addressed.

Dr. Zerhouni 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. He noted that in addition to their individual contributions, all of these members had participated in the NIH Roadmap consultation meetings and the NIH Public Trust Initiative.

NIH DIRECTOR'S UPDATE

Elias A. Zerhouni, M.D.
Director, NIH

Legislative Update

Dr. Zerhouni reported that the 110th Congress has shown substantial interest in NIH, introducing more than 200 bills of interest to the agency. These bills have addressed a range of issues and

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 Food and Drug Administration Amendments Act of 2007, which mandates a significant expansion of the ClinicalTrials.gov database, expanding the number of trials required to be registered. It will also require the inclusion of some results information about trials for approved drugs and devices.

NIH Budget

On September 30, 2008, the President signed a fiscal year (FY) 2009 stopgap continuing resolution to fund most of the government until March 6, 2009. The continuing resolution provides \$29 billion in funding for NIH, at the same rate and under the same terms and conditions as in 2008. The 2009 House and Senate budgets call for an increase in the NIH budget of 3.9 and 3.5 percent, respectively. If Congress enacts this legislation, NIH funding will keep pace with the biomedical inflation rate for the first time in six years. This legislation would also increase funding for the National Children's Study.

Support for Young Investigators

NIH has a new policy that establishes a minimum number of new investigators who will receive NIH funding. In FY 2009, the goal is to award grants to approximately 1,650 new investigators. This policy will help ensure that more young people enter the biomedical research field. NIH is hopeful that this new policy will nurture a new cadre of promising scientists and provide the continued expertise needed to foster the next generation of biomedical research. NIH expects

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. The Human Microbiome Project will support the comprehensive characterization of the human microbiome, which is the full collection of microbes—bacteria, fungi, viruses, etc.—that exist naturally in the human body. Scientists believe that these microbes have a profound influence on many biological processes. The Roadmap Epigenomics Program will support research on epigenetic changes, which control normal growth and development across many genes in a cell or entire organism. This program is based on the hypothesis that health and susceptibility to disease are, in part, due to epigenetic regulation of the genetic blueprint.

Two more new programs support high-risk, high-reward approaches to major biomedical questions. The NIH Director's Pioneer Award supports creative scientists who propose exceptionally innovative approaches that could have substantial impact on biomedical and behavioral science. The Transformative R01 program supports exceptionally innovative, high-risk, original, and unconventional research with the potential to create new or challenge existing scientific paradigms.

NIH has now issued 38 Clinical and Translational Science Awards (CTSAs). The CTSA program is an effort to create a new paradigm in how clinical research is conducted, including creating partnerships with patient groups. The program is training a new generation of clinical investigators, enhancing the clinical research enterprise, developing more effective translational research methods, and establishing linkages through bioinformatics systems.

NIH has made a point to focus on rare and neglected diseases in the new budget. Recognizing the lack of financial incentive for industry to focus on this area of research, NIH has advocated for

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 investigators to resubmit their applications twice, many meritorious applications did not receive fundable scores during the first submission, perhaps because reviewers knew that the investigators would have one more opportunity to resubmit and improve their applications. As a result, funding for many meritorious applications was delayed by one or even two years. The new policy will increase the number of high-quality applications funded after the initial submission process. The guide notices are available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-016.html> and <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-003.html>.

Recognition for NIH Leadership

Three NIH employees received Presidential Rank Awards on September 30 for their outstanding and longtime service to the federal government. Colleen Barros, Deputy Director for Management, received the Distinguished Executive Award. Don Christoferson, Associate Director for Administrative Management at the National Heart, Lung, and Blood Institute, and Maureen Gormley, Clinical Center Chief Operating Officer, received the Meritorious Executive Award. In addition, Anthony S. Fauci, M.D., Director of the National Institute of Allergy and Infectious Diseases, received the Presidential Medal of Freedom.

Discussion (COPR Members)

Dr. Ahmed praised Dr. Zerhouni for his leadership during the past six and a half years and asked him to comment on one of the greatest challenges he faced as NIH Director and how he addressed the challenge. Dr. Zerhouni replied that the greatest challenge today is the tremendous burden of disease; the high cost of providing care to prevent and treat disease is endangering the nation's economy. Medicine must be transformed to produce much more effective ways of preventing and preempting disease, delivering care to the public, and helping people maintain

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 communications tool for the Council to use as part of its outreach activities. Ms. Ford sang a verse from a rhythm and blues song. Eileen Naughton, J.D., presented a proclamation from the State of Rhode Island recognizing Dr. Zerhouni's accomplishments, a picture of a lighthouse, and a certificate. Dr. Lindquist, a member of the Spirit Lake Dakota Nation, presented Dr. Zerhouni with a remembrance quilt made by the Dakota people, and Lora M. Church, a member of the Navajo Nation, gave a blessing to Dr. Zerhouni for his journey into his next role. Ms. Church also blessed Raynard S. Kington, M.D., Ph.D., as he assumes the responsibilities of NIH Acting Director.

AGENDA WORK GROUP PRESENTATION

James H. Wendorf, M.A., and Elmer R. Freeman, M.S.W.

Mr. Freeman described recent activities of COPR members, including giving presentations on the COPR and NIH at scientific meetings, participating in peer-review panels, and taking part in NIH panels and meetings.

Participants viewed a public service announcement (PSA) developed by Matthew Margo, LL.M., for CBS Cares. The PSA, which first aired during the show *60 Minutes* on July 27, 2008, promotes prostate cancer screening and publicizes the National Cancer Institute's (NCI's) toll-free information hotline.

ROLE OF THE PUBLIC IN RESEARCH WORK GROUP PRESENTATION

Syed M. Ahmed, M.D., Dr.P.H., M.P.H., and Ann-Gel S. Palermo, M.P.H.

Ms. Palermo and Dr. Ahmed reported that the Role of the Public in Research Work Group ended with this meeting. The work group has completed three deliverables:

1. Definitions and operating principles of “community engagement” and “public participation.”
2. Guidance for educating researchers and the lay public about community engagement.
3. Criteria and/or guidance that peer-review panels can use to gauge community engagement.

These deliverables were based on the work group's charge to identify ways to encourage researchers to involve the public in research, with emphasis on community engagement. The impetus for the work group stemmed from five key items: limited opportunity for community involvement in research beyond recruitment in clinical trials; limited research competency for community engagement in research; lack of incentives for community engagement in research; limited guidance available for peer-review panels to evaluate proposals involving community engagement; and the need to identify how to operationalize the fourth “P” (participatory research), which is part of the NIH strategic vision.

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 research team, thereby creating a unique working and learning environment before, during, and after the research.

OPERATING PRINCIPLE FOR COMMUNITY ENGAGEMENT

Community engagement 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.

Sources:

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 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 to consumer and advocacy groups.
- Encourage NIH to develop a formal communications network that any nonprofit or 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 stimulate 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, which 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.

The International HapMap Project is mapping variations in human genomes across various populations around the world. This project provides the information necessary to enable the selection of optimal sets of approximately 500,000 gene variants to make genome-wide association studies (GWAS) possible. Genotyping now costs less than 1/12 of a cent, so the total cost of studying 1 billion genotypes is now often less than \$800,000 per disease.

One HapMap-based study examined age-related macular degeneration, one of the leading causes of major vision loss. The researchers found two genes involved in this disease, which many had not previously even considered to be heavily genetic in its etiology. These two genes account for approximately half of a person's risk of developing the disease and—because they are both involved in the complement pathway—also suggest that this may be an inflammatory disease, an important new insight into the biology of the disease process. This study demonstrates the power of GWAS. However, GWAS do not yet explain most of heritability, which will require more research using current tools and the development of new scientific approaches.

Dr. Guttmacher offered some other examples of current genomic research:

- The Encyclopedia of DNA Elements (ENCODE) Project is determining how the entire human genome functions.
- Researchers are using chemical genomics to validate new drug therapy targets more rapidly and to move these targets and compounds into the drug-development pipeline.

- 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 tumor samples.
- The Electronic Medical Records and Genomics (eMERGE) Network is developing, disseminating, and applying approaches to research that combine DNA biorepositories 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.

Mr. Walsh asked whether NIH will continue to support GWAS. Dr. Guttmacher replied that the agency will continue supporting these studies, which are becoming cheaper because the cost of genotyping is dropping. Many NIH Institutes and Centers are using this kind of information to study acute and chronic diseases.

Ms. Clark asked about the role of the pharmaceutical industry in GWAS. Dr. Guttmacher explained that the industry cosponsored the first large collaborative GWAS after several conditions were established for industry participation. For example, pharmaceutical companies received the data at the same time as everyone else and could not select the diseases to be studied. Pharmaceutical companies understand that this type of research could produce new drug targets more quickly and at a lower cost.

CHARTING THE FUTURE OF NIH COMMUNICATIONS: UPDATE

John T. Burklow

Mr. Burklow described the ways in which NIH disseminates health information to the public. OCPL processes more than 3,000 press calls a year and issues many more news releases than any other agency in the Department of Health and Human Services. The office distributes *NIH News in Health*, a monthly consumer health newsletter, and *NIH Research Matters*, which provides brief research summaries. NIH has also launched a network for public information officers at the agency's 3,000 grantee institutions.

OCPL recently hosted a workshop, "Relevance and Credibility in a Changing Environment: Charting the Next Course for NIH Communications" (September 9, 2008), for the communication directors of the NIH Institutes and Centers as part of its strategic planning activities to enhance NIH health communications efforts. A consumer panel including a teen, a Gen-Xer, a health advocate, and a senior citizen discussed the kinds of health information the groups they represent seek and how they obtain that information. The teen described going straight to Google to answer a question and said that her friends on Facebook numbered more than 300. The senior citizen favored the newspaper and spent part of his day on the Internet. He described his role in a close-knit, face-to-face community.

A panel of experts, including the CEO of a major public affairs firm dealing with health; the author of *The Paradox of Choice*, Dr. Barry Schwartz; Pew Foundation Internet expert Susannah Fox; Rick Weiss, a former *Washington Post* science writer who is now with the Podesta firm; and Pere Estupinya, an international media expert experienced in video and blogging with Spanish-language audiences, discussed emerging needs and how to serve those not connected to social media. Some of the key findings from the group included:

- NIH must adapt to the ever-changing media landscape.
- Information overload is leading to confused, overwhelmed consumers.
- E-patients can be both a critical audience and communicators of NIH messages.
- Many health stories are information, not news, in today's 24/7 news cycle.

- Journalists may spend more time developing articles for mainstream media and may feel that they are more complete and better written, but their blog posts may be more influential—or at least seem to generate more interest.
- Content should be customized to the medium and the demographic group.

After the panel discussions, the communication directors met privately to develop recommendations. Among the takeaway action steps was the plan (now under way) to form four working groups on (1) new media; (2) shared resources across the Institutes and Centers; (3) NIH identity; and (4) internal/external communication to make NIH leadership and NIH-based scientists stronger partners in science-based health and science information dissemination to the full spectrum of NIH audiences.

Facebook and MySpace are popular information sources for adolescents and young adults. OCPL is exploring the use of social networking sites and Wikipedia to disseminate its information. In addition, the Institutes and Centers have agreed to a moratorium on developing new logos.

Discussion (COPR Members)

Elizabeth Furlong, Ph.D., J.D., R.N., asked about NIH's interactions with Wikipedia. Dr. Allen explained that OCPL identified the appropriate contact person at Wikipedia. Mr. Margo reported that a new Wikipedia-related Web site targets people in public relations, communications, and the media. Perhaps NIH could create an analogous partnership that focuses on health and health research.

Dr. Furlong mentioned a group of five major health and medical universities developing an online resource with information from credentialed health providers. Dr. Kington noted that some other universities are also involved and this might be an appropriate discussion topic for the COPR's next meeting.

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 genetics 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 and use of their family health histories.
- The Brigham and Women's Hospital Family History Project, which provides tools to 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.

Discussion (COPR Members)

Micah Berman, J.D., asked whether NIH is exploring the ethical, legal, and social implications of GWAS. Mr. Bonham responded that the trans-NIH committee is considering these issues.

Dr. Ahmed asked how NIH communicates with children about genetic issues. Mr. Bonham replied that NHGRI reaches out to teachers and students across the country. On National DNA Day, for example, NIH researchers visit schools across the country to share information and excite students about careers in genetics and genomics.

Dr. Nelson wondered how genetic testing could be of practical use in medicine. Mr. Bonham explained that NHGRI's Genomic Healthcare Branch works with health care organizations to educate practitioners. Researchers are studying how health professionals will use new genetic and genomic information.

Ms. Palermo asked about efforts to educate communities on environmental changes that affect genetics. Mr. Burklow replied that the trans-NIH committee will discuss this issue. The group is establishing a system to disseminate information quickly through its Web site when confusing, controversial, or misleading news is published. Mr. Bonham added that NHGRI is examining the roles of environmental, cultural, social, and genetic issues.

Ms. Church asked about the information that the new Web site will provide to consumers about genetic-testing companies. Mr. Bonham replied that the Web site will list questions to ask these companies, and research is ongoing to determine the utility, validity, and accuracy of the tests. Mr. Burklow noted that the Web site will not provide a "Good Housekeeping Seal of Approval" for any test. Instead, it will provide assistance in making good decisions about testing.

PUBLIC TRUST INITIATIVE: UPDATE ON PARTNERS IN RESEARCH AWARD PROGRAM

Patricia Grady, Ph.D., R.N., FAAN, and Yvonne Maddox, Ph.D.

Patricia Grady, Ph.D., R.N., FAAN, reported that the NIH Partners in Research (PIR) program is the newest NIH Public Trust Initiative program. The program was inspired, in part, by the 2004 COPR workshop on public trust. The PIR program will develop research partnerships between community leaders and NIH-supported scientists. These partners will study methods to engage and 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 PIR program recently awarded 74 grants to 37 partnerships for two years.

Dr. Maddox explained that during its first phase, the program solicited and reviewed applications and awarded grants to successful pairs of applicants. The second phase will include a workshop to provide an update on partner progress and experiences as well as opportunities to network and share ideas about successes and challenges.

Discussion (COPR Members)

Mr. Wendorf commented on the strong shared mission between the COPR and the PIR program. Ms. Palermo served on a peer-review panel for the PIR applications. She suggested that NIH evaluate the peer-review process for the program and that COPR representatives attend the PIR workshop.

Dr. Brady explained that NIH is establishing a steering committee for the workshop and would like the COPR's input. Ms. Palermo offered to provide a COPR overview at the workshop. Carlos Pavão, M.P.A., Mr. Freeman, and Dr. Ahmed also volunteered to join the steering committee.

Mr. Pavão asked about the two-year funding limit. Dr. Maddox explained that this limit is due to the amount of funding available and NIH's desire to fund as many partnerships as possible. Mr. Pavão wondered how to promote a learning community after the grants end. Dr. Grady explained

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 particularly 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 career stages 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 of 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	Fiscal year
GWAS	Genome-wide association studies
ICs	Institutes and Centers
NCI	National Cancer Institute
NHGRI	National Human Genome Research Institute
NIH	National Institutes of Health
OCPL	Office of Communications and Public Liaison
PIR	Partners in Research
RCDC	Research, Condition, and Disease Categorization
RFI	Request for information