WORKSHOP PROCEEDINGS

Inviting Public Participation in Clinical Research: Building Trust through Partnerships October 26–27, 2004

A Workshop Sponsored by the National Institutes of Health Director's Council of Public Representatives (COPR)

- Coordinated in Partnership with the NIH Public Trust Initiative -

The National Institutes of Health
The Nation's Medical Research Agency

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ACKNOWLEDGEMENTS

The COPR would like to take this opportunity to thank each and every person who contributed to the success of this workshop on public trust in clinical research. We particularly wish to recognize the participants who traveled from various parts of the country to the NIH campus in Bethesda to share your experiences, your perspectives, and your ideas. We know that many of you took personal leave from your positions to spend the day with us. Your input led directly to the recommendations found in this report. In addition, we are grateful for the guidance provided by NIH leadership, particularly Raynard Kington, M.D., Ph.D., Deputy Director of the NIH; Patricia A. Grady, Ph.D., R.N., FAAN, Director, National Institute of Nursing Research (NINR), Co-Chair, NIH Public Trust Initiative; Yvonne T. Maddox, Ph.D., Deputy Director, National Institute of Child Health and Human Development (NICHD), Co-Chair, NIH Public Trust Initiative; Dushanka Kleinman, D.D.S., M.Sc.D., Associate Director, Roadmap Coordination, Office of the Director (OD), NIH; and, of course, Jennifer Gorman Vetter, COPR Executive Secretary and NIH Public Liaison Officer, without whom we would not have been able to achieve our goal of holding this workshop in 2004. Thanks go also to the NIH Public Liaison Officers who so graciously volunteered to facilitate the breakout sessions: George Gaines, NICHD; James Hadley, National Cancer Institute (NCI); Elisabeth Handley, NCI; Jean Horrigan, National Eye Institute (NEI); Lisa Kaeser, NICHD; Cindy Palace, National Heart, Lung, and Blood Institute (NHLBI); and Shelly Pollard, OD, NIH, who also contributed to the planning of the workshop. Finally and most importantly, we wish to thank the NIH Director, Elias A. Zerhouni, M.D., who has shared his vision with us and has invited our input on this most important of issues in medical research: public trust.

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EXECUTIVE SUMMARY

The NIH Director's Council of Public Representatives (COPR) held a workshop, *Inviting Public Participation in Clinical Research: Building Trust through Partnerships*, on October 26, 2004, at the Natcher Conference Center on the NIH campus in Bethesda, Maryland. At the workshop, more than 80 participants, representing the various communities who are involved or have an interest in clinical research, met to discuss issues related to public participation and trust. In a full day of interactive sessions, the attendees discussed the public's perception of medical research and explored both the barriers to and opportunities for enhancing public participation and trust in clinical research within the context of partnerships. The communities represented at the workshop included former and/or current clinical trial participants, health care professionals, researchers, research administrators, constituency group leaders, community health and outreach experts, and members of the media. The information that was shared represented diverse ethnic, racial, cultural, and geographic perspectives.

COPR members Rafael Gonzalez-Amezcua, M.D., and Ruth Browne, Sc.D., served as co-chairs of the COPR Public Trust Workshop Work Group. COPR members Debra Hall, Ph.D., and Rafael Gonzalez-Amezcua, M.D., served as the workshop moderators.

The workshop goals were to:

- Identify guiding principles that all involved communities can use to build trust and enhance participation in clinical research.
- Develop recommendations for the Director, NIH, and partnering organizations.

The workshop objectives were to:

- Provide an overview of the current status of public participation and trust in clinical research.
- Learn about past interrelationships and some proven strategies to build partnerships and engender trust.
- Explore, in highly interactive sessions, the barriers to and opportunities for building trust and enhancing public participation.

Workshop events included:

- Opening remarks by Raynard Kington, M.D., Ph.D., Deputy Director, NIH.
- An introduction and explanation of how the workshop evolved by COPR members Drs. Gonzalez-Amezcua and Hall.
- An overview of the NIH Public Trust Initiative by co-chairs Patricia Grady, Ph.D., R.N., FAAN, Director, National Institute of Nursing Research, and Yvonne Maddox, Ph.D., Deputy Director, National Institute of Child Health and Human Development.
- Three keynote speakers and a question and answer period.
    - Claudia Baquet, M.D., M.P.H., Associate Dean for Policy and Planning, Associate Professor of Epidemiology and Preventive Medicine, University of Maryland School of Medicine and the Greenebaum Cancer Center.
    - Robert Beall, Ph.D., President and CEO, Cystic Fibrosis Foundation.
    - Neil Calman, M.D., President and CEO, Institute for Urban and Family Health.

- A series of breakout sessions in which workshop attendees actively discussed challenges and questions related to the workshop topic.
    - Session One: Expectations for collaboration:
        - What do patients and other study participants want from scientists?
        - What do scientists want from patients and other study participants?
        - Under what circumstances do partnerships build trust?
    - Session Two: Information and education:
        - What kinds of information and education have the potential to build trust?
    - Session Three: The experience of participation in clinical research:
        - How can research design (the experience of participation) and the use of research results have a positive or a negative impact on the potential to build trust or mistrust?
- A closing session with all participants led by workshop facilitator Rob Williams, Ph.D.
- Closing remarks by Dr. Kington.

On Wednesday morning, October 27, 2004, COPR members convened as a working group and reviewed the information derived from the previous day's discussions. During this review, COPR drafted a set of preliminary recommendations, which they presented to the NIH Director at the COPR public meeting that afternoon.

The final recommendations resulting from the COPR workshop are as follows.

Introduction
The basic premise that evolved from the workshop and COPR's related research into the issue of public trust in clinical research is the following:

> **To improve and enhance the state of clinical research in this country, it is essential to build trust and relationships among all stakeholders.**

Thus, the recommendations fall into the following areas which refer to the various stakeholders in the clinical research process:

- Building trust through community partnerships
- Building relationships with patients
- Building partnerships with community providers
- Building trust in scientists
- Building trust in the NIH and scientific research

Building trust through community partnerships

Recommendation 1: Incorporate into the NIH mission and philosophy that it values the involvement of the community in research and create language that expresses this value.

Recommendation 2: Encourage change in the culture of the scientific community to ensure that medical research is viewed in the context of a long-term commitment to the community, not a one-time research study.

Recommendation 3: Investigate ways to provide mechanisms that allow for follow-up health care when a clinical trial or treatment ends.

Building relationships with patients. True partnerships with patients may not be possible, but bidirectional relationships must be enhanced.

Recommendation 4: Educate and reorient the current research community to the importance of treating the public as a partner in the research process.

Recommendation 5: Set the expectation across the entire research community, NIH-funded research and beyond that study results and outcomes should be shared with research participants and the larger community promptly and consistently. This will ensure that the research conducted in communities promotes translational research.

Building partnerships with community providers

Recommendation 6: Take action to interest community providers in clinical research and maintain their involvement.

Recommendation 7: Provide incentives (not just financial) for primary health care providers and community specialists to play a role in clinical trials.

Building trust in scientists

Recommendation 8: Engage researchers, educators, and academic institutions in incorporating the public's perspective consistently at every level of training and in both the conduct of clinical research and the publication of findings from that research.

Recommendation 9: Focus on educational strategies to help patients and communities better understand clinical research. This will help scientists because educating the public will empower and prepare individuals to be informed partners in the clinical research process. An informed and trusting public will enhance research participation.

Building trust in the NIH and scientific research

Recommendation 10: Continue to develop and fund efforts to build a national identity for the NIH based on what NIH does best—research and education—as a basis for enhancing public trust in clinical research.

Recommendation 11: Review the role and impact of Institutional Review Boards and other patient protections in the clinical research process because the public views these protections as less effective than they should be.

Recommendation 12: Document and publish "best practices" from efforts to reengineer the clinical research enterprise as soon as the NIH begins to see results, so that progress in improving public trust in medical research grows rapidly and steadily.

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OPENING REMARKS

Welcome and Workshop Overview
Raynard Kington, M.D., Ph.D., Deputy Director, NIH

Rafael Gonzalez-Amezcua, M.D., Co-Chair, Public Trust Workshop Work Group and Workshop Moderator, COPR
Debra Hall, Ph.D., Member, Public Trust Workshop Work Group and Workshop Moderator, COPR

Dr. Kington opened the workshop by welcoming participants and providing a brief overview of the NIH Director's two advisory groups, the Advisory Committee to the Director (ACD) and the Director's Council of Public Representatives (COPR). He briefly described two major NIH initiatives that have direct relevance to the workshop topic: the NIH Roadmap for Medical Research and the Public Trust Initiative.

Drs. Gonzalez-Amezcua and Hall made brief introductory remarks about COPR, reviewed the workshop agenda, and emphasized the day's goal of exchanging information, building on collective experiences, and allowing all who have a stake in the future of medical research to speak and be heard.

WORKSHOP PRESENTATIONS AND CHARGE

NIH Public Trust Initiative

Patricia A. Grady, Ph.D., R.N., FAAN, Director, National Institute of Nursing Research, and Co-Chair, NIH Public Trust Initiative
Yvonne T. Maddox, Ph.D., Deputy Director, National Institute of Child Health and Human Development, and Co-Chair, NIH Public Trust Initiative

The NIH Public Trust Initiative aims to improve the public's health by promoting public trust in biomedical and behavioral research. In this endeavor, the NIH defines the "public" as individuals, patients, families, and communities, and it defines "trust" as confidence placed by the people in an institution or process. While the NIH recognizes that it cannot control the public's perceptions in the area of research, NIH researchers do have the ability to improve how they communicate and interact with the public.

The NIH Public Trust Initiative includes representatives from all Institutes and Centers (ICs) and addresses perspectives from publics including patient advocates, special populations, international groups, communicators, educators, and clinical researchers. These representatives address five categories of public trust:

- Involving and protecting human participants in clinical research.
- Including the public in IC business.
- Promoting the visibility of NIH.
- Teaching and developing course materials for science and education.
- Education and outreach programs for extramural and intramural clinical research communities.

An inventory of existing NIH activities is in progress, as well as a national survey of the public to discover issues regarding public trust and the research enterprise. Results from these activities will be used to develop specific NIH initiatives. The NIH Public Trust Initiative launched a Web site (http://publictrust.nih.gov) to coincide with the workshop date, October 26, to further emphasize its dedication and interest in improving public trust.

Speaker Presentations

Avoidable Disparities in Clinical Research Participation: Building Trust and Partnerships for Overcoming Health Professional and Community Barriers

Claudia R. Baquet, M.D., M.P.H., Associate Dean for Policy and Planning, Associate Professor of Epidemiology and Preventive Medicine, University of Maryland School of Medicine; Director, Cancer Disparities and Intervention Research Program, University of Maryland Greenebaum Cancer Center

Minority, uninsured, poor, and rural communities have lower participation rates in clinical research. Assuring diversity in clinical research participation is therefore a national priority. These communities also experience poorer health outcomes and increased health disparities. Barriers to participation include insufficient, less effective, or ineffective physician-patient interactions, community infrastructure, lack of community outreach, distrust of academic institutions, historical factors, and the lack of knowledge of the importance of clinical research in improving public health.

The University of Maryland School of Medicine has developed partnerships with community health professionals, faith and community-based organizations, local health departments, community hospitals, and policymakers. The school also has received a Health and Human Services (HHS) Best Practice Award for its work to increase the availability of community-based cancer clinical trials in Maryland's rural eastern shore. This model addresses several barriers by including essential components of successful partnerships, such as:

- Strong leadership by a local community physician.
- Shared benefits and commitment to the partnership.
- Ongoing grant support by federal, state, and private funds.
- An on-site nurse community educator and a nurse data manager.
- Investment in clinical trial/research infrastructure.
- Intensive and ongoing health professional continuing education and community education.
- Extensive outreach.

This partnership has taken an inventory of barriers, sources of disparities, and sources of information, and has evaluated what physicians think about clinical research. The partnership also has conducted focus groups to discuss strategies that foster community trust in academia. In addition, it is critical to train the research workforce about how to talk to potential participants and to clearly explain research protocols, randomization and dissemination of trial results.

Cystic Fibrosis Foundation
Robert J. Beall, Ph.D., President and CEO, Cystic Fibrosis Foundation

The Cystic Fibrosis Foundation has formed partnerships with the patient community and with the pharmaceutical industry to develop and enhance a pipeline of new therapies for cystic fibrosis. However, it is difficult to convince the pharmaceutical industry to develop drugs for a disease that affects only 30,000 patients in the United States and 70,000 patients worldwide. To address this barrier, the Cystic Fibrosis Foundation formed the Therapeutics Development Program. This program encourages researchers to become involved in cystic fibrosis research and builds on the knowledge already gained about the basic defect and processes of cystic fibrosis. The program also works to minimize career risks for researchers entering the field of cystic fibrosis, and it builds partnerships with the business community by offering financial support as well as needed infrastructure.

The Therapeutics Development Program takes advantage of a nationwide care center network already established by the Cystic Fibrosis Foundation. The program therefore has access to potential clinical research participants. Several specialized therapeutics development centers have been established across the United States.

The Therapeutics Development Program works at all stages of drug development, including discovery, evaluation, and distribution. The Cystic Fibrosis Foundation has developed strong partnerships with several pharmaceutical and biotechnology companies to assist in these efforts, such as a funding mechanism to support the discovery and evaluation of promising therapies. A non-profit clinical trials network, the CF Therapeutics Development Network~~,~~ plans and conducts early-phase clinical trials of potential new therapies. The alliances developed within the Therapeutics Development Program allow the Cystic Fibrosis Foundation to oversee research and, if a therapy receives FDA approval, to recoup its financial investment. On the other hand, if development activities are suspended, the Cystic Fibrosis Foundation has the right to develop the product, with an agreement to pay royalties to the original partner. By establishing this innovative and far-reaching program, the Cystic Fibrosis Foundation has created a sense of hope for cystic fibrosis patients.

Building Trust the Old-Fashioned Way: By Earning It
Neil Calman, M.D., President and CEO, The Institute for Urban and Family Health

The environment for building trust in clinical research could not be more difficult. The public's trust in the health care system is at an all time low, having been eroded by reports of racial and ethnic disparities, medical errors, gaps in quality of care, drugs being pulled off the market, and shortages in flu vaccine. The public cannot distinguish between the research enterprise and the health care system as a whole. Public trust in clinical research must be built by addressing some of the inequities in the health care system rather than replicating them, especially in minority or low-income communities where the health care system has neglected patients' needs. Academic research institutions exist in these communities, but often the institution does not have connections to its surrounding community. Clinical researchers can only build public trust by earning it, i.e., connecting to the community, its leaders and its needs and helping the community to understand and remedy some of the health care problems they face.

Bronx Health REACH is a community consortium of 40 organizations, including health care providers and faith-based organizations. This consortium has received funding from the Centers for Disease Control and Prevention (CDC). Bronx Health REACH engaged the community in researching issues related to health disparities—not just to learn more about them, but to help the community change some of the many factors it has identified which create disparate health outcomes for people of color in New York City. It has focused its resources on fixing those problems it has delineated, and it has hired community residents and trained them to assist in both the research and the interventions the research findings indicate as most critical. It has conducted focus groups where moderators have presented the results of health disparities research, converted to plain language, and asked community residents to comment. This has fostered ongoing partnerships in the community that Bronx Health REACH serves.

BREAKOUT SESSIONS—AN OVERVIEW

Three distinct breakout sessions focused on a challenge or question related to building public trust in clinical research. The participants were asked to report on the state of clinical research from their perspectives. Several cross-cutting themes emerged from these discussions. A number of participants noted instances whereby investigators come into a community only to conduct their research, stay long enough to achieve their research agenda, and then leave immediately after the grant has ended. The community is left with a sense of abandonment. This practice is especially problematic in low-income communities, where clinical studies might be seen as the only way to obtain good health care. Workshop participants agreed that funding mechanisms should be revised so that partnerships between researchers and the communities in which they work are encouraged or even required. The participants also suggested educating research peer reviewers so that they not only will understand the importance of researchers establishing relationships with the community, but also would require researchers to address this issue in their research planning.

Workshop participants also suggested educating local physicians and other community members about research design. This step would allow the community to play a role in designing research and being an integral part of the process. They emphasized the need to increase the amount and types of community-based research and research that is not community-based, but that should involve community members when it is being planned and conducted.

The workshop participants strongly agreed that communication was of central importance. They stated that researchers should strive to be honest, forthcoming, and culturally sensitive, and should always use plain language. The participants further suggested that researchers might use patient advocates, constituency groups and/ or community members to help them communicate with the communities in which they work. Likewise, they suggested that liaisons between individual researchers and their patients, as well as between research institutions and the community, be established. These liaisons could help researchers stay in touch with the community, help community members identify clinical studies in which to participate, and help community members find their way through the enrollment and informed consent process.

Researchers also should communicate with and involve local physicians in their research design, thus alleviating any fears among physicians that clinical researchers intend to "steal" their patients.

Workshop participants noted that not enough people outside the Washington, D.C., area know the NIH and its work. A number of participants suggested that the NIH work to enhance on-going and proactive relationships with the media and partner with outside organizations to educate people about the NIH and its mission. They suggested that the NIH find more ways to present the agency in a light that will serve to enhance confidence in the nation's medical research efforts. Furthermore, they suggested that the NIH use different and creative routes to communicate with the public, including television, radio, flyers, faith-based organizations, and print materials, and rely less on the Internet.

While recognizing that NIH's primary purpose is research on disease processes and treatment, several workshop participants suggested that NIH look at the way that the Centers for Disease Control and Prevention (CDC) has a presence in the community. The NIH does not have the same roots at the community level, and establishing those roots would help to build trust in medical research. Because CDC already has a network of community connections, the participants strongly encouraged interagency partnerships between the NIH and the CDC, as well as partnerships between the NIH and other federal agencies, to enhance NIH's community-level involvement.

Breakout Session One: Expectations for Collaboration

What do patients and other study participants want from scientists?

Many workshop participants acknowledged that patients and study participants often want to understand the science behind the study. They would like to know how the research affects them personally and how it might affect their community at large. Other motivations for participating in clinical research include monetary compensation, a sense of helping the greater good, the possibility of obtaining cutting-edge treatment, having access to otherwise unaffordable treatment, and learning how to better manage chronic disease.

Workshop attendees strongly emphasized the importance of the relationship between study participant and researcher. Several workshop participants noted that study participants need to feel as if they are "more than a number." In addition to wanting the researchers to be technically skilled, study participants would like researchers to communicate empathy toward them—to understand and care about their illness or condition. Others noted that patients and other study participants are concerned about safety and want a sense that someone (the researcher and reviewers) is "looking out" for them.

In addition, some participants expressed concern that clinical trials are sometimes presented as "the next big breakthrough," rather than as an opportunity to learn more about a treatment, disease, or condition. Thus, study participants who feel desperate about their illness or their lack of access to other medical care enter a clinical trial more because they feel they have no options other than agreeing to participate in the possibly risky clinical trial.

Public perception about clinical trials led to considerable discussion. For example, the participants stated common misperceptions that some researchers merely "do the work for drug companies to make more money," or are conducting the research for personal benefit, among other problems. The workshop participants emphasized through a number of different statements the importance of researcher communication, honesty, and transparency, and of using language that reflects respect for study participants.

What do scientists want from patients and other study participants?

The researchers in the workshop agreed that they want better communication with patients and better interactions with the communities in which they work. They also noted that they want to see better coverage of research than the often-negative press they see in the mainstream news. They further noted that they would like to hear back from the patients and the community regarding how the study affected them. Several agreed that if a study was worthwhile, then patients or study participants should be compensated for their time. Researchers further noted that they would like to see improved compliance with and adherence to study protocols, and they pointed to retention as an overwhelming problem in clinical research.

Workshop participants suggested that researchers tailor their messages to reflect partnerships between the researcher and the study participants. Others suggested that researchers educate physicians, involve them in conducting research, and address their fear that research scientists will "steal" their patients.

Under what circumstances do partnerships build trust?

Workshop participants agreed that funding strategies could ensure a balance of power among partners in clinical research. They noted that the researchers are funded, but that they rely upon members of the community to recruit participants and to participate, and only the researchers benefit in any notable way from the grant funding.

Workshop participants also strongly agreed that partnerships between the researchers and the community should be built to last beyond the completion of the grant and/or study. They emphasized that trust will be promoted when the research-community partnerships are viewed as other than short-term or temporary. Workshop participants also noted that successful partnerships involve mutual respect and give all partners a sense of ownership, which includes involving the community in research design and implementation.

Several workshop participants noted that partnerships between researchers and the community should be established long before the grant is in place, and that researchers will find the most successful partnerships with organizations that residents already know and trust. Workshop participants specifically suggested that researchers conduct their studies in local medical facilities with which residents are already familiar. Several instances were noted in which individuals decided not to participate in a clinical trial because the trial facility was too far away, unknown, did not offer parking (or parking was too difficult), or because the layout of the medical center was too confusing. Convenience and familiarity were important factors encouraging participation in clinical trials.

Breakout Session Two: Information and Education

What kinds of information and education have the potential to build trust? Does the type of information and education needed to build trust vary depending on which specific audience is being addressed?

Many workshop participants emphasized that trust, information, and education must be two-way. Information and education should be focused on teaching communities about the various components of research, including research design, the importance of participation by healthy volunteers, and the role of placebo groups. Researchers, on the other hand, should be trained to interact with community residents in a manner that is respectful and sensitive to the communities' needs.

Most workshop participants agreed that information should be culturally sensitive and should be disseminated by various means, including television, radio, church pulpits, community advocates, and even door-to-door discussion. Communicating in plain language rather than scientific terms is critical. Some workshop participants suggested providing materials that are written in simpler terms than those commonly found today. Others suggested creating a glossary of common scientific terms for use by community residents. However, some participants cautioned against oversimplifying information to the point of making it inaccurate.

Several discussions focused on the attitudes of both researchers and study participants. It was noted that study participants rely too heavily on expecting someone to "take care of them." They seem unwilling to take control of their own decision making. On the other hand, academic researchers are perceived as unwilling to truly engage with community residents because they believe that the communities "have nothing to teach them." Several models of successful interactions between the medical or research community and the public were described.

When asked about current information, workshop participants noted that the NIH relies more than it should on the Internet. They mentioned the "digital divide" and reminded colleagues that not everyone has access to the Web.

Workshop participants seemed to agree on the need to significantly improve informed consent documents. They noted that these documents are too long. They suggested that such lengthy documents sometimes raise suspicion; others noted that the length discourages people from reading them. They noted that many patients simply put these documents aside, or ask their physician to explain the research to them. There was considerable discussion regarding the perceived purpose of consent documents. A number of participants stated that informed consent forms are often viewed as documents to protect the researchers or the research facility from litigation. Ironically, they said, the documents are supposed to be for the participants and yet the forms do not effectively communicate the purpose of the study and what to expect in a way that participants can actually understand. Workshop participants suggested that this problem could be remedied if researchers involved the lay public in the review of informed consent documents as part of the development process.

The breakout session attendees also discussed physician involvement. Although local physicians are the most trusted source of health information, participants noted that local physicians often are "out of the loop" when it comes to clinical research. The participants told a number of anecdotes about physicians who actually counseled their patients not to participate in clinical research because they knew nothing about the research or had reservations that they might lose their patients. In other stories, a physician referred a patient to a research center that provided impersonal care. The patients then switched physicians because they felt that their original provider did not have their best interests at heart. Other participants mentioned the impact of the Tuskegee Syphilis Study and the Health Insurance Portability and Accountability Act (HIPAA) as barriers to participation in clinical research. Workshop participants suggested that the research community needs to find ways to include physicians in clinical research and to make sure that local physicians have routine access to clinical research being conducted in their local communities. It was also suggested that NIH establish or endorse providing incentives for physicians to refer patients to clinical trials, although it was recognized that this idea presents an added opportunity for potential conflict of interest.

Other suggestions included streamlining the recruitment process to make it less burdensome for physicians to refer patients to clinical trials, and to find ways to involve physicians while keeping in mind their busy schedules.

Breakout Session Three: The Experience of Participation

How can research design (the experience of participation) and the use of research results have a positive or negative impact on the potential to build trust or mistrust?

Participants stated that a major barrier to trust and participation in clinical research is the legacy of previous trials inappropriately conducted with children, women, and some minority groups. Another barrier is the amount of time and paperwork, involved in enrolling in a trial. Strict eligibility criteria are yet another. Attendees again emphasized problems inherent in the current informed consent process. They noted that researchers tended to provide too much information in the consent form, but to spend too little time with potential study participants explaining the study and what to expect. It is too difficult for study participants to make an informed decision.

Others observed in this session as well that the language in consent forms is often too technical and therefore difficult to read. Suggestions for the informed consent process included using patient advocates to assist potential study participants, setting standards to develop informed consent documents at a sixth-grade reading level, and providing a mechanism to obtain ongoing informed consent so that participants have the option to remove themselves from a study at any time. Other suggestions for increasing recruitment included raising greater awareness about NIH and its work and mission, increasing physicians' roles in recruitment, and relaxing eligibility criteria. Reimbursing physicians was another suggestion.

What should NIH consider if mistrust arises?

Participants noted that mistrust might arise because of differences in expectations between researchers and study participants. For example, the announcement for a study on Duchenne muscular dystrophy read like an advertisement: "From the Bench to the Badminton Court."

This approach created a false expectation. Researchers can address this problem by changing the way they present information about a pending study.

In addition, researchers too often convey that they have all the answers, when realistically knowledge evolves with each new finding. Others noted that the timing of the release of information may contribute to mistrust. For example, the Arthritis Foundation learned that Vioxx was to be removed from the market only two hours before the news was made public. Although the Foundation has established lines of communication, it did not have time to plan a response for the many calls and the correspondence received about this development.

Workshop participants also noted that "bad news travels quickly," i.e., the media seem to focus on negative study results much more than on the positive ones. For example, one participant mentioned the *Time* magazine cover that featured a woman in a cage with the caption, "Guinea pigs advance science." Some participants expressed the opinion that the research community should have responded to that cover so that the public heard about the positive side to research efforts as well.

When asked how the NIH should respond when mistrust arises, most participants agreed that the NIH should be honest, forthcoming, and transparent, even with negative information. They stated that the public can understand science and that they want health information, even when the news is not always good.

Should all patients be notified of their research results and the implications of those results, and if so, how?

Workshop participants agreed that research results should be communicated to patients. Study participants should, at a minimum, receive a thank you letter and a summary of study results, where the results will be published, and whom to contact if the participant wanted more information. Others suggested that even if the results were not directly helpful to participants, their family members might benefit from the knowledge. Researchers also complained about the lack of feedback, particularly for trials sponsored by pharmaceutical companies. Some mentioned reading in the media about a study they had participated in and never heard directly from the sponsor. Workshop participants stated that there were several models for successfully disseminating research findings to the study participants and to the public, including ways to convey how the results applied to different populations.

Some workshop participants noted that researchers might be required by law or regulations to keep some information confidential, such as the results of genetic tests. Attendees suggested that in such cases, investigators should state the constraints at the beginning. Others cautioned that a balance needed to be found between conveying interim research results versus final results, because interim results could create expectations that might prove false by the study's end. They also stressed the importance of communicating negative information to the community that participated in the study before it is released to the general public.

Others noted the problem created when researchers share breakthroughs from which certain communities will not be able to benefit. For example, if an expensive drug turns out to be lifesaving, the information means nothing if the community members cannot afford the drug.

What differences exist among groups that inform how NIH can approach them (e.g., groups that are focused on communities more than on individuals)? How can NIH tailor approaches for building trust for each type of group?

Communication, spreading the word about NIH, and building partnerships were the primary themes in the responses to these questions. Communication included the need to convey honest expectations to the community, informing research participants and the community of research results, and approaching potential study participants in a sensitive manner (for example, focusing on "healthy weight" rather than "obesity"). Workshop participants suggested the need for researchers to understand the community's perspective. For example, educational outreach should teach community members about the scientific process and explain, for example, what a placebo is and why one might be used.

Several workshop participants admitted that they or others in their community did not know what NIH is and does. The importance of building stronger relationships between the NIH and the media was stressed. This discussion included the importance of increasing the education of the media about the NIH to reduce the tendency to "bash" clinical research. Other suggestions included creating public information shows for radio and television, developing media programs that air "every day like weather or sports," and tailoring messages to various communities.

The culture at NIH was discussed in great detail. The discussion focused on the need to encourage research that involves the community and to ensure that all parties—from those who review the research, to those who approve/fund the research, to those who actually do the research at the community level—understand the importance of involving the community throughout the process.

CLOSING SESSION

All Workshop Participants with Dr. Rob Williams, Workshop Facilitator

Workshop participants reconvened in an afternoon session to discuss their impressions of the overarching themes that arose in the breakout discussions. The balance (or imbalance) between research that is conducted with the community and research that is conducted by a research institution "on" the community was one such theme. Participants noted that the current system does not foster research that is conducted in partnership with the community, and they expressed uncertainty about whether researchers are willing, in the present paradigm, to support increased research with the community as a partner in the process. They agreed that academic research should continue, but that research involving the community should be developed further.

The discussion during this closing session echoed the breakout sessions. Specifically, the participants emphasized the importance of providing study participants with results from the studies in which they participated, increasing the education of communities about the NIH and the importance of clinical research, involving community members in developing research

questions, and building sustainable relationships between researchers and community residents and health care professionals. Workshop participants also noted that receiving a copy of the report stemming from this workshop would be a good starting point. They requested feedback on their ideas, even the ones the NIH chooses not to address directly.

The development of community-involved research also should address and seek to reverse the perception by some that the relationship between physicians and patients can never be a true partnership. Workshop participants cited changes in NIH funding mechanisms as one way to promote community-involved research. An international participant stated that other nations were highly familiar with the NIH and based their research agendas on what the NIH did.

Workshop participants noted that passion and science both have a place in policy, and that it must be a 50-50 partnership. One scientist observed that scientists are very passionate. However, the community might not see the scientist's passion because scientists are trained to behave objectively. Other workshop participants noted the disservice done to research by designating it either "academic" or "community-based." They stated that all research was academic and should be weighted equally. Communication, as well as integration of community passion and scientific merit, would address the perceived chasm between academia and the community.

Workshop participants reiterated the opportunity for partnership between the CDC and the NIH. Research Applied to National Needs (RANN), which was developed by the National Science Foundation to promote community partnerships, was cited as a model for NIH funding mechanisms. One participant noted a bill recently passed by Congress to establish sickle cell anemia treatment centers across the country. This bill mandated that these centers must conduct community-based research. Finally, workshop participants re-stated the suggestion that academic centers not serving their communities should be held accountable. They also emphasized that the NIH should develop stronger partnerships with the media as a conduit for educating the public about the importance of clinical research and the role that the NIH plays in the nation's health.

CLOSING REMARKS

Raynard Kington, M.D., Ph.D., Deputy Director, NIH

Dr. Kington noted that most of the suggestions he had heard during the day fell into the following categories:

- Changing NIH practices, policies, and procedures.
- Using the power of the NIH to encourage researchers to "do the right thing."
- Changing several cultures, including the NIH, the extramural research community, and relationships among researchers, patients, and communities.

He assured workshop participants that the NIH wanted to change the way it does business and noted the number of senior NIH leaders at the workshop as a good sign. Dr. Kington ended the meeting by promising that workshop participants would hear from the NIH as it synthesized the

information from this workshop. He also assured participants that the NIH would inform them of policy changes resulting from the day's discussions.

COPR DELIBERATIONS AND PUBLIC MEETING

On Wednesday morning, October 27, 2004, COPR members met to review and analyze the information derived from the previous day's discussions. During this preliminary review, COPR drafted a set of preliminary recommendations and prioritized them.

COPR's 12th meeting began at 3:00 p.m. in the Natcher Conference Center. Dr. Debra Hall, the workshop moderator, and Dr. Rafael Gonzalez-Amezcua, co-chair of the COPR Public Trust Work Group, presented the preliminary recommendations developed by COPR in the morning session. These initial recommendations were divided into the following broad categories:

- Clear Communication of Intent Leads to Trust.
- Community Partnerships Help To Build Capacity.
- Public Trust and Communications Are a Shared Responsibility.

Following this presentation, Drs. Hall and Gonzalez-Amezcua invited meeting attendees to discuss first impressions, what was missing, suggestions for improving these draft recommendations, perspectives and opinions, areas of disagreement, the preferred format for the refined recommendations, and the strongest possibilities for improving trust.

POST-WORKSHOP NOTE

In the days following the workshop, COPR conducted a careful analysis of the input from the workshop participants (which are only summarized in this report) and refined the recommendations. This report provides a context for those final recommendations, as well as ideas for actions that the NIH could consider. The COPR acknowledged that the NIH has already made notable progress in some of the areas contained in this report as part of the NIH Public Trust Initiative and the NIH Roadmap for Medical Research. COPR's hope is that this report will reinforce those efforts and stimulate additional, complementary actions that will further the goal of enhancing public trust in the clinical research enterprise.

REPORT AND RECOMMENDATIONS ON PUBLIC TRUST IN CLINICAL RESEARCH

NIH Director's Council of Public Representatives (COPR)

Introduction

The basic premise that evolved from the workshop and COPR's related research into the issue of public trust in clinical research is the following:

> **To improve and enhance the state of clinical research in this country, it is essential to build trust and relationships among all stakeholders.**

Thus, the recommendations fall into the following areas which refer to the various stakeholders in the clinical research process:

- Building trust through community partnerships
- Building relationships with patients
- Building partnerships with community providers
- Building trust in scientists
- Building trust in the NIH and scientific research

The term community is used throughout this report. For purposes of this report, COPR defines "community" as an association of people who gather together to share a common interest and/or relevancy during a period of time. The term community is seen as dynamic depending on the reference and context. For example, different contexts and references for the term community that arose during the workshop included references to communities that were geographic, cultural, interest-based, and organizational in nature.

Building trust through community partnerships

Concept: The public has a perception that researchers conducting clinical trials tend to disregard the perspective of the community and the public at large. It is important to change this perception. The workshop participants suggested that researchers should look at each community as if it were their own, and then ask the question: What should the research look like? At least part of the answer is that the community members would want a well-designed study in which the issues were ethical, family and neighbors were treated respectfully and with equality, and that there was benefit to the community.

Community participation can be enhanced and public trust in medical research can be improved by addressing these factors. Rather than having researchers enter communities with a predefined definition of what the research should be, they should ask the local community "What makes people healthy?" and/or "What does your community need?" Then they should design the study around the preferences of the local people rather than around an agenda unrelated to the needs of the community. They should also include an economic benefit to the neighborhood by investing in the community to support the trial.

Recommendation 1: Incorporate into the NIH mission and philosophy that it values the involvement of the community in research and create language that expresses this value.

Action Items:

- Establish grant criteria that require community involvement in the clinical trial. Where appropriate, require researchers to demonstrate active involvement with the community in issues it considers important.
- Assign a task force to identify barriers in the funding mechanisms for research that involves communities. One example of a barrier is a lack of researchers with expertise in this type of research who can serve on peer review groups.
- Formally broaden the definition of "NIH-funded research" to embrace the concept of research that involves communities as a viable and legitimate method of research.
- Require a fair distribution of grant funding so that community collaborators share in the financial support awarded to the research institution or entity.

- Establish a category of grants that funds series of community studies rather than one study at a time.
- Encourage Institute and Center Directors to include in their annual strategic plans ways to enhance public trust in clinical research.
- Reward NIH employees and NIH grantees for outstanding, replicable efforts related to enhancing public trust and/or improved communications in communities (e.g., Director's Awards).

This recommendation and the action items correspond to the NIH Roadmap for Medical Research, particularly the section, Re-engineering the Clinical Research Enterprise. Many of these initiatives are already in the planning stages.

Recommendation 2: Encourage change in the culture of the scientific community to ensure that medical research is viewed in the context of a long-term commitment to the community, not a one-time research study.

Action Items:

- Provide funding to sustain community-based groups over time so that they become "evergreen" sources for participants; focus on building these groups as ongoing relationships rather than transactional partners.
- Build on the NIH Clinical Research Associates program planning efforts, part of the Roadmap for Medical Research, to enhance networks and infrastructure that will promote community research that *involves* communities.
- Reward and fund researchers who have established ongoing relationships/partnerships in the community and have active community involvement. Centers that currently conduct research within communities may not be conducting research that *involves* the community.
- Provide funding mechanisms and training to assist communities in developing their own research projects (community-initiated research). Communities frequently have needs that are not identified by outside agencies or are not a priority of those agencies, but would make a difference in the health of community members.
- Partner with community-sanctioned organizations, such as voluntary and professional organizations (cystic fibrosis model), women's health groups, faith-based groups, housing organizations, etc. Communities are more trusting of entities that have a community presence and longevity, and that provide continued benefits to the community once the research has ended.
- Partner with sister agencies (e.g., Centers for Disease Control (CDC), Health Resources and Services Administration (HRSA) to create bidirectional channels for communication between communities and the NIH to enhance the growth of research that involves communities [and to address different aspects of the same problem—particularly for communities that are underserved or that do not usually participate in clinical research]. This may include engaging existing *Centers of Excellence* in helping to build community capacity and local research opportunities, or it may mean relying on CDC's established community networks to connect the NIH and its funded research institutions with local clinics.

This recommendation ties in with the part of the NIH Roadmap for Medical Research titled "National Clinical Research Associates Program."

Recommendation 3: Investigate ways to provide mechanisms that allow for follow-up health care when a clinical trial or treatment ends.

Action Items:

- Encourage research institutions to look for new partnerships and other ways to bridge the gap between clinical trial treatment and options for additional treatment in the local health care system beyond the clinical trial.
- Partner/work with appropriate Federal agencies (e.g., Centers for Medicare and Medicaid Services [CMS], HRSA) to address the insurance issues that are barriers to participants agreeing to sign up for trials.
- Create an inter-governmental task force to study the depth and breadth of the problem of continuity of health care when a clinical trial ends, and suggest remedies and/or find ways to integrate medical research into the primary health care delivery system. This solves several problems—including patient recruitment, dealing with access issues (such as participants finding and negotiating their way to and from unfamiliar research facilities) vesting practicing physicians, relying on known community leaders and partners, developing partnerships within the community to help with continuity of care, managing dropouts, and so on.

Building relationships with patients. (True partnerships with patients may not be possible, but bidirectional [two-way] relationships must be enhanced.)

Concept: Besides a cure, what do patients want?

- Honesty about the study (true benefits/risks).
- To know the relevance of the study to themselves and/or their community.
- To know that their own health is important and will be considered.
- To be treated with empathy (as a person, not a case number).
- To be invited, not coerced.
- To know they are protected (Data Safety Monitoring Board [DSMB] or other monitoring boards).
- To know that the researcher has fully disclosed any inherent conflicts of interest related to the study and to know that these conflicts of interest have been managed in an open and appropriate way.
- To have their privacy/confidentiality protected.
- To have their participation facilitated where possible, i.e., remove roadblocks such as inconvenience, long waits, no parking.
- To receive interim information about the study progress.
- Advice about patients' post-study options for medical care.
- To hear about the study results.

Recommendation 4: Educate and reorient the current research community to the importance of treating the public as a partner in the research process.

Action Items:

- Recommend that clinical researchers who are providing a treatment include in the study the services of a paid liaison or ombudsman—a person who bridges the communications gap between the researcher and the patient—or demonstrate how this will be accomplished by the researcher. An ombudsman would be responsible for such areas as:
  - Explaining the research in plain language.
  - Identifying and providing options for post-study care.
  - Sharing the study results with the patient and community.
- Give weight to grant criteria that ensure researchers will treat participants as partners in the process, e.g., with respect, with sensitivity to local culture, with attention to communication and information needs, and so on.
- Develop training programs for researchers that include addressing the many issues to consider when working with communities. For example, the training should address being genuine with people, sensitive to their culture, honest, understanding that "desperate patients" are poor listeners and may not understand the trial, and insist on an increased willingness to share responsibility for the research process with community participants. The researcher/staff-participant interface matters and should be an integral part of the training programs.
- Require researchers to include a feedback loop in their study designs.
- Require researchers to acknowledge (thank) participants for participating in the study.

This recommendation ties in with the part of the NIH Roadmap for Medical Research titled "Clinical Research Workforce Training."

Recommendation 5: Set the expectation across the entire research community, NIH-funded research and beyond that study results and outcomes should be shared with research participants and the larger community promptly and consistently. This will ensure that the research conducted in communities promotes translational research.

Action Items:

- Require NIH researchers and urge all researchers to identify in their grant proposals how they will ensure full disclosure of the outcomes of clinical trials to participants and the public in general.
- Encourage researchers to communicate regularly with participants and community representatives during the study; for example, sharing information about the nature and process of the study.
- Train researchers to translate the research results into how they benefit the community (short-term and/or long term).

This recommendation ties in with the parts of the NIH Roadmap for Medical Research titled "Clinical Research Workforce Training" and "Regional Translational Research Centers."

Building partnerships with community providers

Concept: Practicing health care providers are a critical factor in patient trust related to medical research. Workshop participants reported that, in their experience, community providers are not currently involved in clinical research but they should be. The public looks to their physicians and other providers for advice about clinical research and are often counseled not to become involved. Studies indicate that many practicing physicians do not initiate discussions about clinical trials or other research with their patients. Maryland surveys indicate that reasons include the physicians' lack of understanding of potential benefits and risks, concern about reimbursement, and, sometimes, concern that researchers would "steal" patients.

Recommendation 6: Take action to interest community providers in clinical research and maintain their involvement.

Action Items:

- Survey local physicians and nurses regarding the reasons that they are not active participants in the clinical trial arena—what are the barriers to their participation?
- Assign a trans-NIH work group to find ways to address the barriers to involving community providers in clinical research.
- Start engaging community providers through the top 5 or 10 leading research institutions. One approach would be to train their associate volunteer clinical faculty about the value of clinical research and how they can both contribute and benefit from becoming involved. (Most research institutions have numerous associate volunteer clinical faculty members; begin with them and others will follow.)
- Enlist teaching hospitals in the effort to educate practicing physicians across the country about the value of clinical research. Grand rounds offer opportunities to introduce and reinforce messages about the value of clinical trials, and the local physician's role in medical research.
- Fund research that will identify time-efficient ways for health care providers to fit the time it takes to access information about available, local clinical trials into their busy schedules.
- Collaborate with professional organizations to educate primary care/community physicians and nurses about the value of clinical trials and their potential role in medical research initiatives.

This recommendation ties in with the part of the NIH Roadmap for Medical Research titled "Clinical Research Workforce Training" and the "National Clinical Research Associates Program."

Recommendation 7: Provide incentives (not just financial) for primary health care providers and community specialists to play a role in clinical trials.

Action Items:

- When approving grants for clinical research that involves communities, provide additional funding for ways to make participation in clinical trials easier for local providers who could refer patients into the trials.
- Consider funding the development of software that local providers could access so that when a patient is visiting and presents with symptoms, the providers could check to see if the person meets criteria for local clinical trials. This would help providers with limited time refer patients to appropriate trials if desired. NIH could also educate providers about accessing www.clinicaltrials.gov.
- Require researchers to include input from community health care providers in the trial design.
- Create safeguards to preserve relationships between primary care providers and patients/participants.
- Share the data from the patient's clinical trial with community health care providers.
- Ask the Institutes and Centers or research institutions to publish a grid (quarterly or semi-annually) of the research that is in process in local communities and send it to physicians.

Building trust in scientists

Concept: An increasing portion of the public perceives scientists as not having the training and perspective that they need to build public trust in clinical research. Current training for scientists doesn't seem to address issues related to considering community participants as partners in the research process. This makes it difficult to expect scientists to view community health in the same way as the community itself views local health issues. Also, scientists are trained to act as authority figures at the same time that they encounter patients who do not understand clinical research and who are expecting the "authority figure" to protect them, tell them what to do, and cure them. Improvements in the status quo and/or in these perceptions are needed if clinical research is to be enhanced at the community level.

Recommendation 8: Engage researchers, educators, and academic institutions in incorporating the public's perspective consistently at every level of training and in both the conduct of clinical research and the publication of findings from that research.

Action Items:

- Explore ways to collaborate with schools, professional societies, and organizations to help train the diverse professionals involved in clinical research, from M.D.s and Ph.D.s to R.N.s, C.R.N.s, M.P.H.s, social workers and others. Specific ideas could be:
    - Hold a conference for the deans of medical schools and educate them on the importance of training their students about the value of research that involves communities.

    - Make presentations to professional groups, such as the American College of Physicians.
    - Create fellowship programs, such as a fellowship in public trust.
    - Educate students about the value of translational research and how it will benefit their patients in the future.
- Look to models from professional schools that tend to include more training on community relationships, for example, dental, nursing, and public health schools.
- Establish a certification for research that involves the community.

This recommendation ties in with the part of the NIH Roadmap for Medical Research titled "Multidisciplinary Clinical Research Career Development Programs," a sub-section under Clinical Research Workforce Training."

Recommendation 9: Focus on educational strategies to help patients and communities better understand clinical research. This will help scientists because educating the public will empower and prepare individuals to be informed partners in the clinical research process. An informed and trusting public will enhance research participation.

Action Items:

- Enhance relationships with the media and find opportunities to broadcast information about clinical research (e.g., create one-minute radio programs about health, similar to *Our Ocean World* from the National Oceanic and Atmospheric Administration, and *Star Date* from the McDonald Observatory).
- Take note of how the service industry reaches its public with messages and duplicate the successes; keep the message simple but fill the information void—people are hungry for medical research information.
- Create through public service announcements a "sense of pride" associated with participating in a clinical trial—it is a form of service to the country. People who participate in clinical trials could wear pins (badges of honor). (Dispel the notion of "guinea pig" and replace it with the notion of "contributor" to the nation's health.)
- Communicate the importance of normal, healthy people also contributing to the nation's health through clinical trials.
- Educate the public (particularly research participants) about the changing and evolving nature of research findings and why findings are sometimes in conflict. Educate the public about as to why this happens.
- Engage elected officials to educate the public about research.
- Recognize that lay people can understand and are interested in science (examples include Howard Hughes' journal and *Science* magazine).
- Encourage disease-specific magazines (e.g., on diabetes, heart disease) to publish information about clinical trials (e.g., what constitutes good clinical research; research results, negative as well as positive, and contact information—how to get involved).
- Communicate frequently and in plain language.

Building trust in the NIH and scientific research

Concept: Even though the NIH is the premier medical research agency in the nation, the NIH needs a much stronger community presence. Many participants spoke to the fact that the NIH is not as well known as it should be; what it stands for and what it does are a mystery not only to the public, but also to many providers and health professionals. COPR heartily endorses what the NIH is already doing to improve public awareness of the NIH. Continued efforts at two-way communication between the NIH and the public are important.

Recommendation 10: Continue to develop and fund efforts to build a national identity for the NIH based on what the NIH does best—research and education—as a basis for enhancing public trust in clinical research.

Action Items:

- Continue and expand the outreach projects that the NIH has initiated which bring NIH into the community.
- Continue to create opportunities to educate journalists about the NIH and its relationships to research institutions and researchers in communities.
- Continue to support a network of health and science journalists, and host a conference once a year during which the NIH is clearly explained, that year's medical advances are showcased, and promising areas of "science to watch" are identified.

Recommendation 11: Review the role and impact of Institutional Review Boards and other patient protections in the clinical research process because the public views these protections as less effective than they should be.

Action Items:

- Educate IRB members about research that involves communities. These researchers experience barriers from IRBs due to a lack of knowledge about their research, its development, and the community ties necessary to conduct it.
- Provide clear guidelines for more public participation in IRBs. IRBs need more public participation to represent the concerns and needs of various communities.
- Survey researchers about any barriers they encounter due to IRB regulations and address the barriers. One example is the IRB regulation that requires the researcher to destroy tapes of community meetings because the project is ending. This requirement destroys some community history and would be useful in later projects.
- Change the language and focus of consent forms. Current consent forms are perceived by the public as protections for the researcher/institution. Convert consent forms into plain language documents that explain the research in an honest, straightforward way that protects both parties equally.

This recommendation ties in with the part of the NIH Roadmap for Medical Research titled "Clinical Research Policy Analysis and Coordination (CRpac) Program."

Recommendation 12: Document and publish "best practices" from efforts to reengineer the clinical research enterprise as soon as the NIH begins to see results, so that progress in improving public trust in medical research grows rapidly and steadily.

Conclusion

The National Institutes of Health, as the most prestigious medical research agency in the world, has already taken many positive steps toward addressing the issues related to public trust and public participation in clinical research. In the broader context, the NIH is also making strides in improving public confidence in medical research in general. The NIH Roadmap for Medical Research and the Public Trust Initiative are two significant and major efforts that are leading toward enhancements and innovations in the conduct of clinical trials. We hope COPR's recommendations will complement and inform NIH's ongoing work in these areas.

Within that context, we also wish to note that these recommendations represent major shifts in the culture and perspective of the medical research community that falls under the purview of the NIH. The Director and the top level of NIH leadership might benefit from engaging experts in change management to help make the transitions that these recommendations indicate. We anticipate that there may be strong institutional resistance throughout the clinical research community, as there always is when change is in the wind. COPR understands this difficulty and encourages the NIH to anticipate and take steps to overcome resistance, because in the long run, every citizen in the nation will benefit from successfully addressing the issue of public trust in clinical research.

Summary of Recommendations

Building trust through community partnerships

Recommendation 1: Incorporate into the NIH mission and philosophy that it values the involvement of the community in research and create language that expresses this value.

Recommendation 2: Encourage change in the culture of the scientific community to ensure that medical research is viewed in the context of a long-term commitment to the community, not a one-time research study.

Recommendation 3: Investigate ways to provide mechanisms that allow for follow-up health care when a clinical trial or treatment ends.

Building relationships with patients. True partnerships with patients may not be possible, but bidirectional relationships must be enhanced.

Recommendation 4: Educate and reorient the current research community to the importance of treating the public as a partner in the research process.

Recommendation 5: Set the expectation across the entire research community, NIH-funded research and beyond that study results and outcomes should be shared with research participants and the larger community promptly and consistently. This will ensure that the research conducted in communities promotes translational research.

Building partnerships with community providers

Recommendation 6: Take action to interest community providers in clinical research and maintain their involvement.

Recommendation 7: Provide incentives (not just financial) for primary health care providers and community specialists to play a role in clinical trials.

Building trust in scientists

Recommendation 8: Engage researchers, educators, and academic institutions in incorporating the public's perspective consistently at every level of training and in both the conduct of clinical research and the publication of findings from that research.

Recommendation 9: Focus on educational strategies to help patients and communities better understand clinical research. This will help scientists because educating the public will empower and prepare individuals to be informed partners in the clinical research process. An informed and trusting public will enhance research participation.

Building trust in the NIH and scientific research

Recommendation 10: Continue to develop and fund efforts to build a national identity for the NIH based on what NIH does best—research and education—as a basis for enhancing public trust in clinical research.

Recommendation 11: Review the role and impact of Institutional Review Boards and other patient protections in the clinical research process because the public views these protections as less effective than they should be.

Recommendation 12: Document and publish "best practices" from efforts to reengineer the clinical research enterprise as soon as the NIH begins to see results, so that progress in improving public trust in medical research grows rapidly and steadily.

APPENDIX A

Director's Council of Public Representatives (COPR) Workshop

Inviting Public Participation in Clinical Research:
Building Trust through Partnerships

Tuesday, October 26, 2004
Lower Level, Natcher Conference Center, NIH Campus, Bethesda, MD

AGENDA

8:00 a.m. – 8:30 a.m.	**Breakfast and Registration**
8:30 a.m. – 8:40 a.m.	**NIH Director's Welcome** *Dr. Raynard S. Kington, Deputy Director, NIH*
8:40 a.m. – 8:55 a.m.	**COPR Overview of Workshop Presentation** *Dr. Ruth Browne, Co-Chair, Public Trust Workshop Work Group, COPR* *Dr. Rafael Gonzalez-Amezcua, Co-Chair, Public Trust Workshop Work Group, COPR*
8:55 a.m. – 9:10 a.m.	**NIH Public Trust Initiative Presentation** *Dr. Patricia A. Grady, Co-Chair, NIH Public Trust Initiative; Director, National Institute of Nursing Research* *Dr. Yvonne T. Maddox, Co-Chair, NIH Public Trust Initiative; Deputy Director, National Institute of Child Health and Human Development*
9:10 a.m. – 10:25 a.m.	**Speaker Presentations** **Avoidable Disparities in Clinical Research Participation: Building Trust and Partnerships for Overcoming Health Professional and Community Barriers** *Dr. Claudia Baquet, Associate Dean for Policy and Planning, Associate Professor of Epidemiology and Preventive Medicine, University of Maryland School of Medicine;* *Director, Cancer Disparities and Intervention Research Program, University of Maryland Greenebaum Cancer Center* **Cystic Fibrosis Foundation** *Dr. Robert Beall, President and CEO, Cystic Fibrosis Foundation* **Building Trust the Old Fashioned Way: *By Earning It***

	Dr. Neil Calman, President and CEO, The Institute for Urban Family Health
	Question and Answer Session
10:25 a.m. – 10:40 a.m.	**Description and Explanation of Breakout Sessions** ***Dr. Rob Williams, Facilitator***
10:40 a.m. – 11:00 a.m.	**Break**
11:00 a.m. – 12:00 p.m.	**Breakout Session One** *All Participants*
12:00 p.m. – 1:30 p.m.	**Lunch Break**
1:30 p.m. – 2:30 p.m.	**Breakout Session Two** ***All Participants***
2:30 p.m. – 2:40 p.m.	**Transition to Breakout Session Three**
2:40 p.m. – 3:40 p.m.	**Breakout Session Three** *All Participants*
3:40 p.m. – 4:15 p.m.	**Break**
4:15 p.m. – 5:00 p.m.	**Closing Session** ***Interactive—All Participants*** ***Dr. Rob Williams, Facilitator***
5:00 p.m. – 5:30 p.m.	**Closing Remarks** *Dr. Raynard S. Kington, Deputy Director, NIH*
5:30 p.m.	**Meeting Adjourns**

APPENDIX B

Director's Council of Public Representatives (COPR) Meeting

Wednesday, October 27, 2004
Conference Room D, Natcher Conference Center, NIH Campus, Bethesda, MD

AGENDA

3:00 p.m. – 3: 15 p.m.	**NIH Director's Welcome** *Dr. Elias A. Zerhouni, Director, NIH*
3:15 p.m. – 3:45 p.m.	**COPR Presentation of Workshop Findings from Community Dialogue on *Inviting Public Participation in Clinical Research: Building Trust through Partnerships*** *Dr. Ruth Browne, Co-Chair, Public Trust Workshop Work Group, COPR* *Dr. Rafael Gonzalez-Amezcua, Co-Chair, Public Trust Workshop Work Group, COPR*
3:45 p.m. – 4:45 p.m.	**Question, Answer, and Discussion Session** *NIH COPR Members, NIH Leadership, and Participating Public Members*
4:45 p.m. – 5:00 p.m.	**Closing Remarks** *Dr. Elias A. Zerhouni, Director, NIH and NIH Leadership*
5:00 p.m.	**Meeting Adjourns**

APPENDIX C

Director's Council of Public Representatives (COPR) Workshop
Inviting Public Participation in Clinical Research:
Building Trust through Partnerships

Challenges and Questions for the Three Small Group Breakout Sessions

Breakout Session One: Expectations of Collaboration

Challenges and Questions for Small Group Discussion

- **What do patients and other study participants want from scientists?**
- **What do scientists want from patients and other study participants?**
- **Under what circumstances do partnerships build trust?**

Additional Questions to Consider:

- How do prior experiences with health care affect public trust in clinical research?
- What role do non-scientists play in strengthening public trust (policymakers and other opinion leaders)? How can NIH work with these leaders more effectively?

Possible assumptions underlying these questions include:

a. Partnerships build trust and participation in medical research.

b. Partnerships between the NIH, academic health centers, hospitals, clinics and health systems, researchers, and communities will engender trust when authority and decision-making are shared, resources are shared, there are balanced power relationships, and credit for discovery is shared.

c. Public trust and participation in research increase as researchers and health professionals build personal ties to communities and seek to identify and serve long-term health needs.

d. Trust and participation increase as researchers and health professionals demonstrate sensitivity to race, culture, gender, ethnicity, and other forms of diversity and how those differences affect medical research.

Breakout Session Two: Information and Education

Challenges and Questions for Small Group Discussion

- **What kinds of information and education have the potential to build trust?**

Additional Questions to Consider:

- Does the type of information and education needed to build trust vary depending on which specific audience is being addressed?

- What is your reaction to NIH's information materials on clinical research (e.g., informed consent process)?

Possible assumptions underlying this question include:

- Public trust and participation in medical research increase as additional amounts of relevant information and education are made available to possible participants.
- There are specific methods for increasing patient understanding that will enhance trust, if practiced by researchers and health professionals.
- Educating future researchers and health professionals in their academic programs about strategies that build public trust will improve research participation in the future.
- The media can improve public trust and participation in research by expanding their coverage of science and medicine and improving the quality and accuracy of reports on research-related problems and results.
- Web sites and the communications of patient advocacy groups, disease- or condition-specific organizations (for example, American Heart Association), and health professional associations (for example, American Society of Clinical Oncology) can increase trust and participation by providing information about research.
- Increasing understanding about the impact of the drug or procedure on patients and their health status will improve trust and participation.

Breakout Session Three: The Experience of Participation

Challenges and Questions for Small Group Discussion

- **How can research design (the experience of participation) and the use of research results have a positive or a negative impact on the potential to build trust or mistrust?**

Additional Questions to Consider:

- What should NIH consider if mistrust arises?

- Should all patients be notified of their research results, and the implications of those results, and if so, how?

- What differences exist among groups that inform how NIH can best approach them (e.g., groups that are focused on communities more than on individuals)? How can NIH tailor approaches to building trust for each type of group?

- How can the NIH be helpful to the media in improving public trust?

Possible assumptions underlying this question include:

a. During the research development and design stage, specific steps (for example, determining eligibility criteria, prioritizing data analysis, coordinating with similar trials, and incorporating patient-communication mechanisms) can be taken to increase participation and trust.

b. NIH plays a role in shaping the attitudes, beliefs, and behaviors of researchers.

c. How research is translated into practice will influence public trust and participation in the future.

d. Communicating how the research results may benefit the participant directly, the participant's immediate family or community, or society in general, helps build trust and increase participation in clinical research.

NIH Roadmap for Medical Research

Overview

Soon after becoming the Director of the National Institutes of Health (NIH), in May 2002, Elias A. Zerhouni, M.D., convened a series of meetings to chart a "roadmap" for medical research in the 21st century. The purpose was to identify major opportunities and gaps in biomedical research that no single Institute at NIH could tackle alone, but that the agency as a whole must address to make the biggest impact on the progress of medical research.

Developed with input from meetings with more than 300 nationally recognized leaders in academia, industry, government, and the public, the NIH Roadmap provides a framework of the priorities NIH as a whole must address in order to optimize its entire research portfolio. It lays out a vision for a more efficient and productive system of medical research. The NIH Roadmap identifies the most compelling opportunities in three main areas: new pathways to discovery, research teams of the future, and re-engineering the clinical research enterprise.

The implementation of the NIH Roadmap vision—including the initiatives under the Re-engineering the Clinical Research Enterprise theme—relies on strong partnerships between researchers, health and medical professionals, and the public.

Re-engineering the Clinical Research Enterprise

Clinical research is the linchpin of the nation's biomedical research enterprise. Before a therapy is approved for general use, it must be studied carefully in the laboratory to understand how the treatment works, how effective it is, and what potential risks may exist. The safety and benefits of the therapy for humans must then be proven through an orderly series of tests in people. Over the years, medical research has succeeded in converting many diseases once considered uniformly lethal into more chronic, treatable conditions. Yet clinical research has become increasingly difficult to do and it has become clear to the scientific community that the United States must recast its entire system of clinical research if such efforts are to remain as successful as they have been in the past.

To accelerate and strengthen the clinical research process, a set of NIH Roadmap initiatives will work toward improving the clinical research enterprise by adopting a systematic infrastructure that will better serve the evolving field of scientific discovery. This effort, which complements the other initiatives encompassed by the NIH Roadmap, will provide the necessary foundation for advancing basic and clinical research. With the NIH Roadmap in action, investigators will be

better poised to translate basic discoveries into the reality of better health for our nation. Several initiatives are in place to carry forward this goal:

- Clinical Research Networks and NECTAR.
- Clinical Research Policy Analysis and Coordination.
- Clinical Research Workforce Training.
- Dynamic Assessment of Patient-Reported Chronic Disease Outcomes.
- Translational Research.

The speed at which exciting basic science discoveries emerge from laboratories demands that clinical research continue and even expand, while at the same time be more efficient and better inform basic science efforts. This is undoubtedly the most difficult but most important challenge identified by the NIH Roadmap process.

At the core of this vision is the concept that clinical research needs to develop new partnerships among organized patient communities, community-based health care providers, and academic researchers. In the past, all research for a clinical trial could be conducted in one academic center; that is unlikely to be true in the future. In the Re-engineering the Clinical Research Enterprise Roadmap initiatives, NIH will promote the creation of better integrated networks of academic centers that work jointly on clinical trials and that include community-based health care providers who care for sufficiently large groups of well-characterized patients. Implementing this vision will require new ways to organize the manner in which clinical research information is recorded, new standards for clinical research protocols, modern information technology, new models of cooperation between NIH and patient advocacy alliances, and new strategies to strengthen the clinical research workforce.

The NIH Roadmap for Medical Research is a series of far-reaching initiatives designed to transform the Nation's medical research capabilities and speed the movement of scientific discoveries from the bench to the bedside. It provides a framework of the priorities the NIH must address in order to optimize its entire research portfolio and lays out a vision for a more efficient and productive system of medical research. Additional information about the NIH Roadmap can be found at http://nihroadmap.nih.gov.

The National Institutes of Health (NIH), an agency of the U.S. Department of Health and Human Services, is the primary Federal agency for conducting and supporting basic, clinical, and translational medical research. NIH comprises 27 institutes and centers and investigates the causes, treatments, and cures for both common and rare diseases. For more information on the NIH, please visit the NIH Web site at http://www.nih.gov.

NIH BACKGROUNDER

National Institutes of Health

NIH Public Trust Initiative

In the spring of 2004, Elias A. Zerhouni, M.D., Director of the National Institutes of Health (NIH), announced the establishment of the NIH Public Trust Initiative. In doing so, he stated that his goal is to "improve the public's health through promotion of activities and attitudes that will instill confidence in what we do as a premier biomedical and behavioral research enterprise." As envisioned by Dr. Zerhouni, this initiative is an important component of the NIH Roadmap for Medical Research, but it extends beyond the Roadmap as well.

To carry out the Public Trust effort, Dr. Zerhouni appointed Drs. Patricia Grady, Director of the National Institute for Nursing Research, and Yvonne Maddox, Deputy Director, National Institute of Child Health and Human Development. Working with representatives from each of the 27 Institutes and Centers, Drs. Grady and Maddox have been compiling an extensive inventory of activities aimed at enhancing the public's trust that are already being conducted throughout the NIH, and hope to publish a summary in the near future. The Public Trust Steering Committee, comprising some of the most experienced leadership within NIH, are reviewing this compilation to see whether some of the most successful activities might be replicated by other Institutes and Centers.

Through the Director's Council of Public Representatives (COPR), the co-chairs are seeking advice from the public on strategies for increasing the public's trust, with particular emphasis on participation in clinical trials. In October 2004, the COPR is sponsoring, with Dr. Zerhouni's support and working closely with the Public Trust co-chairs, a workshop to examine this issue and to provide recommendations to the NIH. Those recommendations will help to form the underpinning for a five-year plan for the initiative to enhance and maintain the public's trust in the work of NIH.

In addition, the NIH Public Trust Web site is being established, so that NIH's various "publics" will have an easily identifiable place to begin when seeking information about these efforts, to ask questions, and to provide needed input. Numerous other activities, including the identification and addressing of gaps in our efforts, are also under discussion.

Gaining and enhancing the public's trust is a top priority for all of NIH, one that will require a long-term commitment and partnerships with each of NIH's publics. How and why the NIH conducts and supports research, and the outcomes of that research, should be conveyed in such a manner that everyone can understand and use the information to achieve better health.