Report and Recommendations on

Public Trust in Clinical Research

for the NIH Director
from the Director's Council of
Public Representatives (COPR)

Presented to the Advisory Committee to the Director, December 2, 2004
Revised and approved by the COPR based on ACD Discussion – January 14, 2005

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

The Department of Health and Human Services, USA

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NIH Director's Council of Public Representatives (COPR)

Preface

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.

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.

In the days following the workshop, COPR conducted a careful analysis of the input from the workshop participants 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.

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, Reengineering 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., CDC, 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., Medicare, 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 (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 the research participants and the larger community promptly and consistently. This will ensure 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 M.D.s 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 sub-section, "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 healthcare 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 healthcare 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.

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