Public Confidence and Involvement in Clinical Research: Symposium Summary, Clinical Roundtable, September 2000

Board on Health Sciences Policy

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Douglas A. Boenning, Senior Program Officer
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INSTITUTE OF MEDICINE

Washington, D.C.

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"Knowing is not enough; we must apply.
Willing is not enough; we must do."
—Goethe

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The report was reviewed by individuals chosen for their diverse perspectives and technical expertise in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments to assist the authors and the Institute of Medicine in making the published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The content of the review comments and the draft manuscript remain confidential to protect the integrity of the deliberative process. The committee wishes to thank the following individuals for their participation in the report review process:

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While the individuals listed above provided many constructive comments and suggestions, responsibility for the final content of the report rests solely with the authoring committee and the Institute of Medicine.

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Abstract. The Clinical Research Roundtable (CRR) of the National Academies held its second meeting in September 2000 in Washington, DC. An information-gathering symposium on Public Confidence and Involvement in Clinical Research was open to the public. It included speakers who have collected data on the public's perception of clinical research; speakers who are experienced researchers and have collected information on the barriers and incentives that influence recruitment and retention of research participants; speakers who represent different patient groups; and speakers who have experience integrating clinical research into a community-based clinical practice. Repeated themes from the meeting suggest that the American public is very supportive of clinical research, that collaborative models where researchers and participants work together tend to be more successful, and that research participants needs must be explicitly address in order to improve recruitment and retention.

The Clinical Research Roundtable (CRR) of the National Academies held its second meeting on September 25-26, 2000, at the National Academy of Sciences building in Washington, D.C. The CRR, chaired by Dr. William Gerberding, President Emeritus of the University of Washington, consists of individuals from the academic health community, federal agencies sponsoring and regulating clinical research, private-sector sponsors of clinical research, foundations, public-sector and private-sector insurance programs, health plans and insurance companies, corporate purchasers of health care, and representatives of patient interests. The roundtable meets quarterly to discuss the challenges facing clinical research and ways to create a more supportive environment for the conduct of a broad agenda of high-quality clinical research. The roundtable provides a forum for discussions about approaches to resolving both acute and long-term issues affecting clinical research and will sponsor workshops on these issues. The roundtable aims to enhance mutual understanding of clinical research within the scientific community and the general public, and to increase public participation in clinical studies. The charge to the group

from IOM also calls on the CRR to be attentive to the ethical underpinnings of clinical research as it considers a broad range of workforce and infrastructure-related issues that span the full spectrum of clinical research.

During its second meeting, the CRR held a symposium on Public Confidence and Involvement in Clinical Research chaired by Mary Woolley, President of Research!America and liaison to the CRR from the IOM's Health Sciences Policy Board. This report summarizes the presentations given at the three panel sessions of the symposium.

Data-based Studies on Public Opinion

The first panel explored what we know about the public's opinion of clinical research. Mary Woolley opened the discussion with findings from Research!America commissioned polls of the general public. The main message from this research is that Americans take great pride in the fact that the U.S. leads the world in medical research. Americans also continue to support basic research, as they have for the past 20 years, even if it brings no immediate clinical benefit. They support research on health disparities and prevention. Furthermore, there is strong public support for increasing the federal research budget and for furthering research in the private sector. These data challenge the idea that Americans are skeptical and suspicious about the research enterprise.

Kenneth Getz, member of the CRR and President and Publisher of CenterWatch, which provides information services used by patients, pharmaceutical, biotechnology and medical device companies, CROs and research centers involved in clinical research around the world, presented data on industry-sponsored research. According to his data, approximately 675,000 U.S. residents participated in industry-sponsored clinical research in 1999; however, 6.5 million people had to be contacted in order to recruit those 675,000 participants. According to data collected through an on-line survey of approximately1050 former research participants, people chose to be research participants primarily to find relief from a medical condition. One-third reported they were motivated by the opportunity to advance science. Less than 10 percent of those surveyed said they participated for the stipend or because they could not afford care. Concerns of research participants include fear of receiving a placebo, concern about side effects, and fear of losing access to an effective treatment at the conclusion of the trial. Overall, most research participants were satisfied with the research experience, saw the researchers as professionals, felt well informed about the risks of participating, and would be willing to participate again. One area participants would like to see improve is better follow-up after the study, both follow-up care and information about the outcome of the trial. Additional information, including a database of industry-sponsored and NIH-sponsored clinical trials and a publication that summarizes findings from this survey, are available through CenterWatch.

Robert Comis, President of the Coalition of National Cancer Cooperative Groups, Inc. (CNCCG), an organization designed to ensure that patients have access to clinical research, presented [Harris internet and telephone poll data] on various stakeholders' perceptions about clinical research (1000 random individuals, 6,000 cancer patients, 200 primary care physicians, 225 oncologists, 200 nurses, and 100 journalists). Of the cancer patients surveyed, only 15 percent were aware that they could participate in clinical research as part of their care. Of that

15 percent, only 25 percent (or 4 percent of all eligible patients) actually did. Barriers to participation included concern that the standard treatment was better than an untested treatment, that they would receive a placebo, that they might be treated like "guinea pigs," that travel would be a burden, and that there would be additional expenses not covered by their insurance. In spite of these concerns, former participants reported having very positive experiences. Because the data indicate that oncologists may report more negative responses to clinical research than patients, Dr. Comis discussed a number of ways of recruiting patients directly. Others suggested this was an area for targeted education about the benefits of clinical research.

Patient Perspectives on Clinical Research

The second panel explored the patient's perspective on clinical research including the barriers and incentives to volunteer. Panelists discussed a number of creative recruiting and retention techniques. Martha Hill, Director of the Center for Nursing Research (CNR) at the Johns Hopkins University discussed her experience recruiting young, urban, African American males for a study of high blood pressure. There were numerous challenges to recruiting participants, including a lack of response to invitation letters because the potential participants assumed it was a bill, the fact that this population typically does not seek preventive medical care, and the transient nature of this population. To address some of these concerns, she ran focus groups with community members and potential participants to identify successful recruitment methods. She also hired a dedicated staff from the community and trained them. They put extra effort into making the research participant feel valuable and cared for by sending birthday cards, greeting the participants at the door, and even tracking them down when they were incarcerated. Her central message to the CRR was that no population is unreachable if appropriate resources are available and staff is creative and persistent. A list of Dr. Hill's publications on this topic is available.

A national educational campaign to encourage women to participate in clinical research was recently undertaken by the Society for the Advancement of Women's Health Research (SWHR). Sherry Marts, the SWHR Scientific Director, reported on this initiative. The message of the campaign is that women are needed as participants in clinical research and that participation means empowerment for women. The next phase of the Campaign is to develop materials specifically focused on minority populations. Evaluation data of the Campaign should be available soon. One early finding is that visitors to the SWHR web site spend an unusually long amount of time looking at the site an average of 32 minutes. Materials are available free of charge. The Campaign's website also contains links to databases listing clinical research studies currently recruiting women.

Margene Kennedy, Manager and Senior Coordinator of the Clinical Trials Unit at Johns Hopkins University, described the typical research volunteer as a white male, risk taker, between the ages of 55-68, and interested in improving his personal health. College degrees and insurance coverage are also correlated with higher rates of volunteering. She reported that the location of the research site, ease of access and parking, the personality and trustworthiness of the staff, and the flexibility of the schedule are all factors that make a difference in recruiting and retaining research participants. People are motivated to volunteer when they believe the trial will give

them access to better or free care and innovative treatment. Other motives include helping society and financial compensation.

David Barr, Director of the Forum for Collaborative HIV Research at George Washington University, discussed ways of bringing patient groups, activists, and researchers together into collaborative relationships. He outlined positive steps that have been taken within the research community to actively involve AIDS activists and patients in identifying the research priorities, design of trials, and entry and exclusion criteria for trials. The Forum maintains an access-restricted database of HIV/AIDS related clinical trials and studies that are currently in development. See the Forum's web site for more information on current projects.

Perspectives from Other Parts of the Community

Panel three explored the perspectives from two different patient groups and a community physician involved in clinical research. Judith Tsipis, Professor of Biology and Director of the Genetic Counseling Program at Brandeis University, presented a case study of research experiences of families affected with Canavan disease, a rare genetic disorder. She cited a number of incidents that led to the disintegration of trust between the Canavan community and clinical researchers who were developing a Canavan screening test. These included allegations that research was conducted without informed consent and that patent and marketing restrictions imposed by the hospital at which the research was performed kept families affected by Canavan from accessing the screening test once it was developed in spite of the fact that they had financially supported the research and participated as research subjects. Dr. Tsipis described a collaborative model that she believes might prevent many of these problems from occurring in future genetics research. Dr. Tsipis' [written testimony] is available. More information about Canavan disease is available through the National Tay-Sachs and Allied Diseases Association.

Rex Cowdry, Medical Director of the National Alliance for the Mentally Ill (NAMI), began his discussion by explaining that, based on survey results, the community he works with is generally very supportive of clinical research, although a small but vocal minority is highly critical and well informed members have concerns. Dr. Cowdry discussed a number of ways scientists can both address ethical concerns and make clinical research more attractive to people with mental illness, such as including family members on IRBs, providing immediate feedback on study findings, providing continued access to study medication, replacing placebo-controlled studies with a cross-over design, and evaluating the participant's capacity to consent independent of the research study. He noted the defensive response of the research community to criticism and outlined three issues that the Clinical Research Roundtable might address: the overburdened and underfunded IRB system that lacks consistent policies and patient protections; the financial conflicts of interest in clinical research; and the development of ethical alternatives to placebo-controlled studies in serious disorders with established treatments, such as psychoses. The NAMI web site contains both general information about NAMI policies and a guide tto assessing key ethical issues in clinical trial protocols.

Richard Schwartz is a community pediatrician in the Washington, DC area who has made clinical research a vital part of his clinical practice. Dr Schwartz discussed many of the challenges community-based clinicians face in attempting to conduct clinical research. For

instance, it is very difficult for a physician who is not connected with an academic research center or industry to find funding, deal with the complexities of the IRB review and informed consent process, and collaborate with other experts. Often the administrative work of running a clinical trial requires additional staff, which can be expensive. In addition, grants are often written in such a way that the physician has to front all of the funds for the research and wait for many months to be reimbursed. All of these factors inhibit community physicians from participating in clinical research.

Roundtable Discussion

A number of themes emerged from the various speakers, including (1) the fact that there appears to be widespread support for clinical research, but also that those within the research enterprise need to address concerns to ensure that there is no erosion of public trust in the future; (2) there is a need to develop collaborative relationships between researchers and patient groups; (3) there is a need to improve the regulatory system so that it accomplishes the goal of protecting human subjects without creating unnecessary burdens for researchers; and (4) the fact that the Internet is playing an expanding role in how patients and the public are getting information about clinical research. Other issues discussed were ways to create incentives for cross-institutional research, how to effectively involve community-based physicians who wish to participate in clinical research, the importance of creating national guidelines for IRBs, and the pros and cons of placebo-controlled trials.

The next meeting of the CRR will be December 12-13th in Washington DC.