Exploring the Ethics of Clinical Research in an Urban Community

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Objectives. We consulted with representatives of an urban community in Washington, DC, about the ethics of clinical research involving residents of the community with limited access to health care.

Methods. A semistructured community consultation was conducted with core members of the Health Partnership Program of the National Institute of Arthritis and Musculoskeletal and Skin Diseases. Three research case examples were discussed; questions and probes (a predetermined question or series of questions used to further investigate or follow-up a response) guided the discussion.

Results. The community representatives who took part in the consultation were supportive of research and appreciated the opportunity to be heard. They noted the importance of respecting the circumstances, values, needs, and welfare of research participants; supported widely representative recruitment strategies; and cited the positive benefits of providing care or treatment to participants. Monitoring participants' welfare and ensuring care at a study's end were emphasized. Trust was a central theme; participants suggested several trust-enhancing strategies, including full disclosure of information and the involvement of advocates, physicians, and trusted church members.

Conclusions. Several important strategies emerged for conducting ethical research in urban communities whose residents have limited access to health care. (*Am J Public Health.* 2006;96:1996–2001. doi:10.2105/AJPH.2005.071233)

There is widespread concern about minimizing exploitation and protecting vulnerable people who take part in research studies.[1–3] Vulnerability is often understood, in the context of research, as an inability on the part of study participants to protect their own interests and is frequently associated with a compromised capacity to provide informed or voluntary consent.[3,4]

Because their limited options may compromise their ability to freely choose whether or not to take part in a particular study, uninsured individuals and others with limited access to health care are sometimes considered vulnerable to exploitation in research.[5,6] Additionally, in comparison with other less vulnerable populations, uninsured individuals often have lower incomes, are younger and less educated, and are more likely to be members of minority groups.[7,8] Some ethicists, researchers, and community leaders share a concern that, regardless of the risks involved, those with limited access to health care will enroll in research studies to obtain the basic health care services that would otherwise be unavailable to them.[9,10]

Federal regulations include safeguards protecting the rights and welfare of research participants who are "likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons or educationally or economically disadvantaged persons."[11] To the extent that individuals with limited access to health care are vulnerable to exploitation, undue influence, or lack of understanding when asked to participate in research, special protections should be put into place. Conversely, it has been noted that "protecting" people with limited health care options from participating in research may serve only to deprive them of an opportunity to benefit from and contribute to clinical research.[8,9,12] Little is known about the perspectives or concerns held by people with limited access to health care about participation in research.

In 2000, as part of its effort to facilitate research on health disparities in rheumatic diseases, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) of the National Institutes of Health (NIH) established a community partnership, the Health Partnership Program (HPP). The HPP involves approximately 68 community partners representing various sectors of the African American and Hispanic/Latino communities of Washington, DC. HPP development emerged from a series of meetings and discussions with community members in which both NIAMS and the community identified 5 areas of priority: (1) access to medical care, (2) health disparities research and access to clinical investigations, (3) health education, (4) career development in the biomedical sciences, and (5) community relations.[13]

The HPP has several guiding principles: openness regarding its plans and actions, inclusiveness of all constituents in the partnership's activities, and responsiveness to community needs and concerns as well as those of NIH. Extensive community involvement in program development and the research agenda continues to be a distinct and important component of the HPP. A core group of community partners meets regularly with HPP staff to provide initial reviews of and advice on community-based outreach, research, and health education activities. This 22-member group also meets to review research proposals before they are submitted to the institutional review board.

Initial preparation of the HPP core group for community proposal reviews included an introduction to the principles and practices of ethical clinical research and focused discussions of the rationale and details of proposed investigations. The contributions and comments of this core group have led to substantive changes in NIAMS research protocols.

A major element of the HPP was the establishment of the NIAMS Community Health Center (CHC) at the Upper Cardozo Clinic in

Washington, DC. The CHC serves as a venue for community-based research on clinical aspects of rheumatic diseases in urban populations, provides a community base for health education programs, and offers training opportunities for health professionals. The CHC is located in the Shaw/Cardozo community, straddling a historically African American neighborhood and an area populated by many recent immigrants from Central America. The center is housed within a neighborhood health center operated by Unity Health Care Inc, a nonprofit organization that provides health care to uninsured and underinsured residents of the District of Columbia.

Many CHC patients receive primary care services in Unity Health Care clinics and are referred by the organization's providers across the city. Patients are also referred by other clinics, private physicians, or HPP partner organizations or individuals, or they sometimes enroll in the program without a referral. The neighborhood surrounding the center is composed of approximately 70% Latino and 30% African American residents. Initially, the composition of CHC's patient population reflected the neighborhood's demographic characteristics; however, as a result of referrals from other neighborhoods, the number of Latino and African American patients is roughly equal. Since the CHC opened in July 2001, more than 1000 patients have been enrolled in a NIAMS natural history study of rheumatic diseases in minority communities.

Establishment of the CHC has provided a unique collaborative opportunity for investigators in the NIH Department of Clinical Bioethics and NIAMS to learn more about the views of the center's research participants and community members regarding the ethics of research. In September 2004, a consultation was held with representative members of the community to explore the ethics of clinical research and identify possible safeguards and areas for further study.

METHODS

Members of the core group of HPP community partners were invited to a meeting to discuss clinical research ethics. They were informed that the purpose of the meeting was to explore issues related to the development of a research program investigating exploitation and protection of research participants, especially those with limited access to health care. The meeting was held at the Upper Cardozo Clinic.

Ten HPP partners representing various community organizations participated in the discussion. Participants were program directors and managers from a local government human services agency, a senior center, a child development program, a community development program, a community health center, a church-based wellness program, a faith-based nurses program, and a minority health resource center. Several participants were involved in additional community initiatives, including civic and neighborhood associations and related programs. Several of the participating partners, along with holding professional or volunteer positions with community organizations, were members of the communities in which they worked. Thus, their comments were informed by both personal and organizational knowledge and experience.

After introductions, the purpose of the meeting was described. All of the participants were encouraged to be candid about their views. It was acknowledged that some of the topics to be discussed, including exploitation, were potentially sensitive. For this reason and to encourage frank discussion, the meeting was not audiotaped, and participants were assured that their ideas and comments would not be attributed to them individually.

The discussion was led by 2 moderators, one representing NIAMS and associated with the HPP since its inception and the other representing the NIH Department of Clinical Bioethics. The moderators used a guide that included preselected hypothetical case studies (Table 1), questions, and probes. In addition, 5 facilitators assisted with the meeting but did not participate in the discussion. These individuals took notes, made observations, and managed logistics, including participant recruitment, room set-up, and provision of refreshments and handouts.

Of the 10 HPP participants, 6 were African American, 3 were Hispanic, and 1 was Asian; of the 7 NIH participants, 4 were White, 1 was African American, and 2 were Hispanic. Most of the participants (14 of 17) were women. Given that individual characteristics of moderators and facilitators can either inhibit or prompt openness during focused discussions,[14,15] we included some facilitators whose racial/ethnic and linguistic backgrounds were similar to those of the community partner participants. The meeting was approximately 2 hours in duration.

The discussion was contemporaneously transcribed. Relying heavily on focus group methodology, the analysis plan included identifying the main themes arising from the discussion, considering the meaning of the participants' words, and evaluating consistency of responses throughout the discussion. Transcripts were prepared, and a debriefing session was held with 5 moderators and facilitators.

Transcript-based data analysis has been shown to be the most rigorous method of analyzing information generated during focus groups.[16] Here each member of the research

TABLE 1—Hypothetical Case Examples and Descriptions

Case No.	Description
Case 1	A randomized placebo-controlled trial of chronic nighttime propanolol in individuals with mild to moderate hypertension. The primary outcome was reduction in morning blood pressure measured at 8 weeks. The study, advertised in the *Washington Post*, recruited individuals 18 years or older with mild to moderate hypertension and otherwise reasonable medical status. The study required 5 visits and offered $25 per visit.
Case 2	An open label treatment trial evaluating a combination of 5 or 6 chemotherapy medicines for lymphoma. Adults or children recently diagnosed with lymphoma but not yet treated were eligible. Participants were asked to have a research biopsy of their tumor. The study required 1 hospitalization and regular clinic visits.
Case 3	Investigation of serum markers predictive of disease severity or response to treatment. The study required 1 tube of blood and clinical information from patients being treated by their primary doctors for kidney disease. Patients were asked for written consent. The researchers did not plan to provide information on results to patients because the significance of their findings might not be known for years.

team independently analyzed transcripts, identifying themes that emerged from the discussion. After independent thematic analyses had been conducted, the team met to establish consensus regarding major themes. All of the participants reviewed and commented on a draft of the final document and verified that the thematic interpretation represented what they had intended to convey. In addition, all participants gave permission for their contribution to be acknowledged.

RESULTS

Participants uniformly expressed support for such a community discussion and appreciation for having their views solicited and disseminated. They expressed both agreement and disagreement with the comments of other participants and the moderators, and the discussion was as much among participants as between the moderators and the participants.

After each case study had been read, participants were asked for their reaction with the open-ended question "What do you think about this study?" The discussion was free flowing and not tightly directed. Interrelated themes were elicited, and specific questions had been designed to probe particular issues of interest for each case. Common themes emerged relevant to respecting and not exploiting research participants, including the following: attentiveness to issues associated with inclusion or broad representativeness of participants, recognizing pervasive distrust and using various strategies to enhance trust, incorporating adequate plans for monitoring participants' welfare and ensuring appropriate follow-up, and involving trusted advocates in the research process. More specific case-related concerns were also raised.

Discussion about the first case focused primarily on recruitment, inclusion, monetary compensation, the importance of accurate and complete communication of information, and careful clinical monitoring. The second case elicited additional concerns about referrals, advocacy, and the need for follow-up at the conclusion of a study. The third case raised the most concern about exploitation, appropriate gathering and use of information about participants, and the importance of honest disclosure about research purposes. In the following, we describe themes that emerged from the discussion; illustrative quotations are presented in Table 2.

Although, overall, participants seemed to perceive clinical research as valuable, some were more positive and others more negative in their views. They emphasized the importance of ensuring wide access to research studies, for example by avoiding advertisement and recruitment strategies likely to yield only 1 kind of participant group. Participants did not suggest restricting research or excluding individuals because of limited health care access. Rather, participants overwhelmingly embraced the idea of including such individuals in research as long as attention was focused on respecting these individuals' rights and welfare and building trust.

Trust was a central theme in the discussion. Some of the partners described a common and pervasive distrust of research and researchers on the part of members of minority communities, as documented elsewhere.[17–23] Particularly in the African American community, this distrust is based on a history of abuse and exploitation in many areas and not simply on the "Tuskegee" legacy,[24] which was nevertheless referenced by several of the participants. Participants suggested several viable strategies that they believed would help to build trust within their communities so that clinical research could be successful and meet the needs of those who take part in it.

One suggestion was to ensure that research teams include individuals who can relate to the participants, have similar backgrounds, understand the participants' experiences, and speak their language. The group believed that those conducting clinical research in minority communities should strive to ensure that research teams include individuals with the same cultural, racial/ethnic, and language backgrounds as prospective research participants. Yet, mere racial or ethnic concordance was not perceived as sufficient (Table 2). Familiarity with particular community customs, patterns, and values was also deemed crucial.

Several participants emphasized the need for full and honest disclosure of information before a study begins. Accurate disclosure of information to prospective participants as part of the informed consent process is a widely accepted tenet of ethical research. The practice of obtaining informed consent is based on the principle of respect for individuals and their ability to make decisions about their lives, including whether or not to participate in research. The group members suggested another key reason for informed consent: to help build a relationship of trust between researcher and participant. This, again, requires that researchers speak the same language as participants and understand the cultural idioms and circumstances of the community and its members.

At the same time, some of the group members expressed the belief that information disclosed by researchers cannot always be trusted and therefore recommended the use of advocates. This practice might entail encouraging participants to bring a family member or trusted friend to advocate for them during their research visits or having on-site advocates available to help participants understand the details of a proposed study. A variation on this suggestion was to have a medical team separate from the investigator's team explain the study and its risks and to advocate for participants.

In addition to research team concordance and use of advocates, group members suggested involving respected members of the community as another way to enhance trust. For example, members stated that referrals from known and respected doctors who believe that the study is beneficial would promote trust in the study and the researchers. Along with recommendations or referrals to a study, support from a primary care physician favoring ongoing participation might also increase the likelihood of trust among potential participants. According to one of the group members, "Walls come down when a physician refers. Credibility increases exponentially."

Similarly, meeting participants suggested enlisting the support or recommendation of pastors or church leaders as a means of enhancing the recruitment of church members to a study. Partnerships with such individuals, who are already trusted and respected members of the community and occupy positions of authority, may be helpful in terms of establishing trust in the community at large.

Participants were generally troubled by the offer of $25 as part of the hypertension case

TABLE 2—Themes Emerging From the Discussion

Theme	Illustrative Quotations
Research and researchers	• Researchers are concerned with benefits to the masses . . . by higher risk to a limited number. It's about looking at the entire picture and looking outside the box. • I have a friend who underwent [a] kidney transplant. . . . There is a bond and a desire to expand scientific knowledge, a core group with common interests to do it for those who are coming after.
Inclusion/broad representativeness	• People in research need to look like all the people in the community. • Everyone has a different makeup; you can't lump them in a big pot.
Recruitment	• Advertising in the *Post* means there are assumptions they are buying the *Post*. There are other people who don't read it . . . maybe they watch TV . . . speak other languages. You are defining a population, this is problematic. • Seniors may not read the *Post*. You need to go where seniors congregate . . . churches, senior centers.
Trust/distrust	• My church, where there are a lot of homeless people and people from the projects . . . they are very suspect of research from . . . before. . . . African Americans from a long history, they don't trust . . . what has been done to them in the past . . . no trust. Over [the] years, Tuskegee stuff to Vietnam War, world wars . . . Black men are still suffering today. It is hard to trust with a long history . . . even before World War II there was exploitation with slaves . . . history of mistrust. Working with them . . . it takes a long time to build up trust in new people. • If they don't trust you, they are not going to come. It isn't the money, it is the trust.
Concordance of research team members/ familiarity with community	• Who will they have confidence in? [Researchers] need to be in the community where they are . . . with people they have faith in . . . have confidence in. In Black culture, we have lived with high blood pressure for many years and they have lived with it so they don't see the value in experiments. You need people they trust, to know that the people [researchers] have lived your experience . . . that they understand where you're coming from. • We'll be suspect of exploitation and have to be comfortable and trust people giving the information. • If the pastor and session approve, then they would agree [to participate in a research study]. • If they know their doctors are working closely with you . . . another trust thing.
Information disclosure	• It goes back to communication. The person needs to know everything that is going on. • I'm not saying they are going to lie, but not hone in on the risks. But say I have money to do this study and it is going on my [curriculum vitae]; I will focus on benefits, not the risks. • What people [scientists] understand, the average person doesn't understand, they say what they want people to know. They aren't going to tell you everything, otherwise people wouldn't do it. • What I said in the beginning, be clear in the beginning.
Referrals	• If my pastor got up and said do this study—people would do it. • Who is doing the referrals? Walls come down when a physician refers. Credibility increases exponentially. • If they are referred by their doctor, they won't feel exploited. . . . If your doctor explains everything and explains about a study at [the National Institutes of Health]. . . .
Advocates	• Clearly explain to the patient, let them take time to think about it, and then come back with a sister or mother. It goes back to communication. The person needs to know everything that is going on. You are not alone with an advocate. • If they are allowed to bring an advocate, that makes the process better. My father is 74 years old, and I go with him everywhere.
Payment or compensation for research participation	• It is reasonable to pay someone for work, if you gain. How much are you gaining? Telling someone their community is gaining is a stretch. How much . . . will it take out of their time? Their cost? Time is money. Money for medicine? What is the value of their time for a person in the study?

Continued

example. The concern among those most vocal was that $25 was not sufficient to truly compensate individuals for their time and effort. Some of the group members suggested that a fair amount would be based on a more accurate sense of participants' transportation and time costs, especially given that researchers are well compensated for their work. Although 1 member acknowledged concern about the possibility of a study attracting individuals seeking to obtain money to use in purchasing drugs or alcohol, overall participants agreed that other considerations would be more important to most individuals considering involvement in a research project. One stated that the focus should be on providing needed care and not on monetary compensation.

Provision of care during the course of a study was also identified as a sign of respect for research participants. Group members described providing treatments and care to participants, especially treatments known to be expensive and potentially unaffordable, as a positive benefit, even if the treatments were under investigation in the research (as in the second case example). Provision of care was also seen as an appropriate means of responding to particular community needs.

The group members noted that attention to research participants' clinical welfare both during and after a study is critical to respectful research. In response to the hypertension case example, for instance, group members were adamant that there be an adequate plan for monitoring the participants and taking appropriate action when blood pressure increased or when no response to experimental therapy was observed.

Similarly, members believed that it was essential to have a clear plan for what occurs at the end of the study; participants may feel used or exploited after a study has been completed if plans are not in place for follow-up care or referral. This was a special concern in the second case example, given that participants would clearly need ongoing care. Although group members believed that referral back to a primary care physician was adequate in some cases, they stressed that those who did not already have a primary care doctor or did not have access to care should be referred to a place where they would receive

TABLE 2—*Continued*

	• [People should be reimbursed] fair market value for time . . . value of the study to the researchers. They are getting millions of dollars for research. We are talking about people's lives. The amount of money is disgusting if [someone is] putting life on the line. . . .
	• Reconcile it. If you know who you want you are paying for a service that costs that much; $25 can look like $100 . . . $100 can look like a million. Worry about if they make the criteria. If you think someone is only doing it for the money, you can make it a challenge and make them come here.
	• Druggies and alcoholics may do it for the money. . . .
Provision of care	• If you come and you have high blood pressure, we will give you good care for a year. That says we care about you. Get rid of the money altogether and just give good medicine—give them a year of medical care and follow-up—that's good care.
	• I like this study because I was told it would be more than $1000 [to pay for treatment] if you have this [disease/condition]. . . . If you have limited access [or] no access, this would fit the bill, especially in African Americans.
Clinical monitoring	• Are these people [research participants] being monitored? If their pressure gets worse, are they going to pull them from the study? As long as there are stopping rules. . . . Physiology is different for different groups. . . . Especially the elderly can be on 20 medications affecting each other.
	• I'm not so sure if they come off [their meds]. . . . [They] need close monitoring. You may have people not able to or not competent to take their blood pressure. You're playing with their lives. Will they take them off their medications?
Poststudy follow-up	• But the person with no insurance, where do they go when the study is over? There has to be a responsibility of the researcher to these people when the research is over. Is there a clinic then set up where they can go? They're concerned: "The research is over . . . where do I go?"
	• How long is this going to last when the study is done? Is the person going to be thrown away?
	• The biggest thing is the follow-up. Social workers, patient advocates. . . . When the study is over, that is when they feel used.
Use of data/anonymity	• Data collected in databases can be used against you, [you] can't get insurance, loans. What is it being used for? How is it being used?
	• Where is the information going? How is personal information [insurance, Social Security number, address] being used? Who is getting this information? The information is going to a database and people can pull it up.
	• Clear exploitation. What are they going to use it [blood samples] for? No way.

needed care, otherwise, the research team should continue to care for them.

Group members were most troubled by the third case example, which involved collecting specimens for use in examining predictors of disease severity. Distrust of the researchers' motives and concern regarding how the participants' data would be used (and could be misused) were reasons that the members found this case the most potentially exploitive. According to some members, this study might be acceptable if the purpose of the research were clearly explained and safeguards to protect data confidentiality were in place. Others were of the strong opinion that such a study is unacceptable.

DISCUSSION

Researchers conducting clinical studies in urban communities whose residents have limited access to health care can gain several valuable lessons from the consultation described here. For example, open discussions of concerns about research and ideas for building trust are one indication to community members that researchers value their perspectives. Sincere partnering with the community in an effort to develop programs that are attentive to residents' perspectives is critical in establishing trust and conducting research responsive to the community's needs. This process of community building is also likely to enhance the investment of all parties involved and, as a result, the success of the research subsequently undertaken.

Benefits of community consultation have been described in HIV/AIDS research, genetics research, and international research.[25,26] The meeting described here took place against a backdrop of discussions and HPP partnership development. Because it was intended to be an open discussion with diverse representation, and because it was meant to be a convenient forum for the participants, the meeting may have contributed to fostering trust among community members. At the same time, the openness with which group participants spoke was an indication that some trust in the HPP was already in place.

Themes that emerged demonstrated support for clinical research. Participants underscored the necessity in research of treating people fairly and with respect for their cultural and life circumstances, as well as monitoring their clinical well-being both during and after their study involvement. Although these are perhaps familiar themes, the group members described them as inextricable to the task of establishing and maintaining the trust needed for successful research projects. At the same time, participants were clear that lack of trust remains one of the principal challenges to successful research, especially studies involving minority communities. Several useful strategies that might enhance trust in research and researchers were suggested, and these strategies warrant further exploration and evaluation.

Because they are based on a single group discussion in a single urban community, the findings presented here are limited and therefore may not be generalizable to other urban communities in the United States. In addition, although all of the group members were residents of the community, participants also represented community organizations, and some were in leadership positions. Future research is planned with a broader sample of the community's residents.

Nonetheless, the views of this extremely articulate group were compelling regarding research involving members of minority groups and individuals with limited access to health care. The goal of a qualitative analysis such as the one reported here is illumination

of issues rather than causal determination, prediction, or generalization.[27] The open and frank discussion of research ethics detailed in this article illuminates critical issues that merit further study and analysis. ■

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Contributors

C. Grady originated the study and was responsible for design and implementation, analysis of data, and initial writing and revisions of the article. L.A. Hampson, G.R. Wallen, M.V. Rivera-Goba, K.L. Carrington, and B.B. Mittleman contributed to the conceptualization, design, and implementation of the study; analysis of data; and critical review of the article.

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This study was deemed exempt from institutional review.

References

1. World Medical Association. Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA.* 2000;284:3043–3045.

2. Macklin R. Bioethics, vulnerability, and protection. *Bioethics.* 2003;4:44–49.

3. Levine C, Faden R, Grady C, Hammerschmidt D, Eckenwiler L, Sugarman J. The limitations of "vulnerability" as a protection for human research participants. *Am J Bioethics.* 2004;4(3):44–49.

4. Kipnis K. Vulnerability in research subjects: a bioethical taxonomy. In: *Ethical and Policy Issues in Research Involving Human Participants.* Vol. 2. Bethesda, Md: National Bioethics Advisory Commission; 2001:G1–G13.

5. 45 CFR 46 (2005).

6. Pace C, Miller F, Danis M. Enrolling the uninsured in clinical trials: an ethical perspective. *Crit Care Med.* 2003;31(suppl 3):S121–S125.

7. Alliance for Health Reform. Health care coverage in America. Available at: http://www.covertheuninsured.org/materials. Accessed July 23, 2006.

8. American College of Physicians. Racial and ethnic disparities in health care: a position paper of the American College of Physicians. *Ann Intern Med.* 2004;141:226–232.

9. Noah BA. The participation of underrepresented minorities in clinical research. *Am J Law Med.* 2003;29:221–245.

10. Stone TH. The invisible vulnerable: the economically and educationally disadvantaged subjects of clinical research. *J Law Med Ethics.* 2003;31:148–153.

11. 45 CFR 46.111(b) (2005).

12. Berg J, Appelbaum P, Lidz C, Parker L. *Informed Consent: Legal Theory and Clinical Practice.* 2nd ed. New York, NY: Oxford University Press Inc; 2001:271–272.

13. NIAMS Local Health Partnership Program. Available at: http://www.niams.nih.gov/hi/outreach/hppplan.htm. Accessed August 3, 2006.

14. Huer MB, Saenz TI. Challenges and strategies for conducting survey and focus group research with culturally diverse groups. *Am J Speech Lang Pathol.* 2003;12:209–220.

15. Dreachslin JL. Conducting effective focus groups in the context of diversity: theoretical underpinnings and practical considerations. *Qualitative Health Res.* 1998;8:813–820.

16. Krueger RA. *Analyzing and Reporting Focus Groups.* Thousand Oaks, Calif: Sage Publications; 1998.

17. Bonner GJ, Miles TP. Participation of African Americans in clinical research. *Neuroepidemiology.* 1997;16:281–284.

18. Corbie-Smith G, Thomas SB, St. George D. Distrust, race, and research. *Arch Intern Med.* 2002;162:2458–2463.

19. Corbie-Smith G, Viscoli CM, Kernan WN, et al. Influence of race, clinical, and other socio-demographic features on trial participation. *J Clin Epidemiol.* 2003;56:304–309.

20. Gamble VN. A legacy of distrust: African Americans and medical research. *Am J Prev Med.* 1993;9:35–38.

21. Harris Y, Gorelick PB, Samuels P, Bempong I. Why African Americans may not be participating in clinical trials. *J Natl Med Assoc.* 1996;88:630–634.

22. Shavers VL, Lynch CF, Burmeister LF. Knowledge of the Tuskegee study and its impact on the willingness to participate in medical research studies. *J Natl Med Assoc.* 2000;92:563–572.

23. Shavers VL, Lynch CF, Burmeister LF. Factors that influence African-Americans' willingness to participate in medical research studies. *Cancer.* 2001;91(suppl 1):233–236.

24. Corbie-Smith G, Thomas SB, Williams MV, Moody-Ayers S. Attitudes and beliefs of African-Americans towards participation in medical research. *J Gen Intern Med.* 1999;14:537–546.

25. Godard B, Marshall J, Laberge C, Knoppers BM. Strategies for consulting with the community: the cases of four large-scale genetic databases. *Sci Eng Ethics.* 2004;10:457–477.

26. Morin SF, Maiorana A, Koester KA, Sheon NM, Richards TA. Community consultation in HIV prevention research: a study of community advisory boards at 6 research sites. *J Acquir Immune Defic Syndr.* 2003;33:513–520.

27. Patton MQ. *Qualitative Evaluation and Research Methods.* 3rd ed. Newbury Park, Calif: Sage Publications; 2002.