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The Role of Community Advisory Boards: Involving Communities in the Informed Consent Process

Ethical research involving human subjects mandates that individual informed consent be obtained from research participants or from surrogates when participants are not able to consent for themselves. The existing requirements for informed consent assume that all study participants have personal autonomy, fully comprehend the purpose, risks, and benefits of the research; and volunteer for projects that disclose all relevant information. Yet contemporary examples of lapses in the individual informed consent process have been reported.

The authors propose the use of community advisory boards, which can facilitate research by providing advice about the informed consent process and the design and implementation of research protocols. These activities could help reduce the number of individual informed consent lapses, benefiting study participants and the scientific integrity of the research in question. (*Am J Public Health*. 2001;91: 1938-1943)

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INDIVIDUAL INFORMED consent has traditionally been understood as a substantive ethical requirement, an agreement between the researcher and the research subject concerning the roles and obligations of each party in a study. The researcher seeks to enroll fully informed, consenting, individual subjects in a study. When informed consent is not obtained, or when subjects are not fully informed, research abuses can occur. Community activists, joined by some scientists, have publicized the limitations of individual informed consent and have argued for the incorporation of community perspectives or "voices" during informed consent and throughout the research process.¹⁻⁴ Community involvement has been part of international research in developing countries for some time. Issues of culture and individual autonomy, however, must be dealt with to create partnerships

between researchers, study participants, and communities that will protect participants.

Here we review examples of situations in which the required process of individual informed consent failed to ensure that study participants were fully aware of the implications of their involvement. In response to this problem, we propose that individual informed consent be augmented by community advisory boards (CABs), which can facilitate research by advising about the informed consent process and the design and implementation of a study.

BACKGROUND ON INDIVIDUAL INFORMED CONSENT

Since the Nuremberg Code of 1947,⁵ several organizations have worked to provide a set of ethical guidelines for the conduct of research involving human subjects; these guidelines

include specific references to obtaining informed consent. The Council for International Organizations of Medical Sciences and the World Medical Association, which focus on international research, and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which focuses on research conducted nationally, are responsible for setting and amending the guidelines that govern research on human subjects.

The Council for International Organizations of Medical Sciences has formulated 15 guidelines, 9 of which, in its most recent document, address issues of informed consent. These issues include those that may occur in vulnerable populations (e.g., women, the mentally challenged, minors) where individual informed consent would be difficult, if not impossible, to achieve.⁶ The World Medical Association has recently

amended the Declaration of Helsinki, positing 7 principles for obtaining informed consent that not only address consent involving vulnerable populations but also include practical guidance on obtaining consent in situations where medical research is combined with medical care.⁷

Finally, the Belmont Report,⁸ developed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, establishes 3 fundamental ethical principles that are relevant to informed consent—*respect for persons, beneficence, and justice*. These principles require that sufficient information about the study in question (e.g., risks and benefits) be disclosed to study subjects, that the information

be conveyed to subjects in an easily comprehensible manner, and that subjects endorse statements indicating that their participation is voluntary—that is, free of coercion and undue influence. Researchers have an ethical and legal obligation to ensure that these 3 elements of informed consent are honored when individuals agree to participate in research.⁹

RESEARCH LAPSES RELATING TO INDIVIDUAL INFORMED CONSENT

Although informed consent requirements were established specifically for the purpose of providing protection for human subjects, these requirements are insufficient. Recent examples exist, in both industrial

and developing countries, in which informed consent has failed to ensure that participants recognized that their participation was voluntary, understood the research in question (including study terminology and all potential benefits and risks), and were sufficiently informed to make an educated decision regarding their participation.

The examples listed in Table 1 illustrate that the requirements of informed consent—voluntariness, full disclosure, and comprehension—do not always protect or sufficiently inform human research subjects.^{11–27} Furthermore, over 90% of the cases in which research abuses have taken place are associated with lapses in informed consent.²⁸ Indeed, in 2 studies

where research abuses were reported,^{19,21} the federal Office for Protection From Research Risks (now the Office of Human Research Protections) of the US Department of Health and Human Services cited the manner in which research subjects or parents of research subjects were informed about the studies. Given that the target populations in these studies were vulnerable (children and poor, HIV-seropositive Haitians), greater efforts are necessary to ensure that the rights of all human subjects are protected. We believe that protecting and fully informing human research subjects requires supplementing the current methods of obtaining informed consent with increased involvement and advocacy at the community level.

TABLE 1—Examples of Research Lapses Relating to Individual Informed Consent

Lapse	Explanation	Examples
Lack of voluntariness	Potential coercion to influence participation has occurred	Conflict of interest: Investigator is the subject's physician ¹⁰ Subjects are asked to participate when under considerable duress ^{11–13} Subjects are asked to participate when they have few or no options (e.g., placebo-controlled surgical trials) ^{14–16}
Incomplete disclosure	Subjects are misinformed or not fully informed about the intent of the research in question, potential risks associated with the research, or previous pertinent research	In a multisite breast cancer prevention trial of the drug tamoxifen, pertinent information about side effects was omitted or minimized in consent forms ^{17–18} In a New York study, parents were not informed that their children with attention deficit-hyperactivity disorder were taken off their medication and subjected to brain chemistry tests ¹⁹ In a study of serodiscordant couples in Haiti, subjects were not told that the purpose of the study was to observe couples in which 1 partner was HIV-seropositive ^{20–21} In a zidovudine (AZT) trial in Cote d'Ivoire, 1 female subject was not told that the experimental treatment had been proven to reduce vertical transmission of HIV in a US trial ^{13,22–23} In a trial of isoniazid (INH) for tuberculosis in Uganda, HIV-positive subjects were not told that INH is routinely used in the United States to prevent tuberculosis ^{24–25} In a study conducted in Los Angeles, researchers did not properly inform parents providing consent for their children about previously reported adverse side effects of an investigational measles vaccine ^{26–27}
Confusion about study terminology	Subjects do not fully understand the scientific terminology or the study's purpose as presented to them	Parents of critically ill babies were confused about the words <i>random</i> and <i>placebo</i> ; they perceived random assignment to mean either acceptance or rejection of their babies as subjects in a UK study ¹¹ One female subject in an AZT trial in Cote d'Ivoire perceived that participating would help her child and ease her childbirth ¹³ HIV-positive subjects in a trial of INH for tuberculosis in Uganda were told that they would be assigned to one of the treatment groups, with one of the groups being "treatment with a placebo drug" ^{24–25} Subjects may not have understood that placebo-controlled surgical trials in the United States were risk-free ^{14–16}

PROMOTING EFFECTIVE INDIVIDUAL INFORMED CONSENT

A Proposal to Implement Greater CAB Involvement

The lapses of the individual informed consent process demonstrate that participants may not be autonomous in their ability to make decisions about research participation and that researchers may not always respect the interests of human subjects while pursuing the goals of research. Traditionally, informed consent focuses on the relationship between the researcher and

the participant. Using the principles of community consultation and participatory research,^{4,29} we recommend enhancing this process by developing a partnership between researchers and the community.

A CAB is composed of community members who share a common identity, history, symbols and language, and culture.³⁰ For example, gay activists and gay HIV-affected individuals could serve on a CAB for an AIDS clinical trials group interested in recruiting participants from the gay community. Representatives from the African

American community (e.g., young women, faith leaders) could serve on a CAB that is linked to a community-based study testing a comprehensive prenatal program for high-risk minority pregnant women.

Using CABs to facilitate the informed consent process fundamentally changes how researchers relate to participants. Table 2 illustrates how this might work; the elements of informed consent developed by Beauchamp and Childress³¹ are used as the basis for defining the functions and responsibilities of the study participants,

the CAB, and the investigators. It is assumed that participants have a high degree of personal autonomy and therefore fulfill their functions and responsibilities for each of the informed consent elements listed. Similarly, investigators are expected to fulfill their roles in protecting and fully informing participants by adhering to their functions and responsibilities.

The CAB, since its members come from the same community as the participants, serves as a liaison between participants and researchers. In this role, the CAB can help in the development of

TABLE 2—Functions of Study Participants, Community Advisory Boards, and Investigators in the Research Process

Elements	Functions and Responsibilities		
	Participant	Community Advisory Board	Investigators
Threshold elements			
Competence—The capacity to understand and reasonably decide about participants' rights and the process of research participation	Is legally competent to decide about research participation	Is competent to sponsor research and to act in an accountable manner to represent community perceptions of research	Are obligated to maximize participants' ability to make decisions; are obligated to follow ethical guidelines of informed consent; are scientifically competent to produce and disseminate valid research findings
Voluntariness—The exercise of free choice in making a decision about research participation; the absence of coercion in research participation	Exercises individual free choice in deciding about research participation	Expresses the community's desire to participate in research; conveys to participants their right to refuse	Are obligated to construct a situation that ensures voluntary participation
Informational elements			
Disclosure—The process of making known relevant risks, benefits, conflicts of interests, and research issues to those directly or indirectly affected or involved in research	Is honest when enrolling in research by revealing information needed by researchers	Elicits from researchers information that the community needs to have; disseminates necessary information to participants, researchers, and community members	Are obligated to fully reveal relevant information and ramifications of research to institutional review board, community advisory board, and participants
Understanding—The ability to evaluate information and recommendations	Is able to evaluate whether to give consent for a specific research study	Evaluates and communicates risks and benefits of research	Anticipate and provide information needed by communities and participants to evaluate research
Consent elements			
Decision to act—The process of agreeing or disagreeing with a research plan	Determines whether to give consent for enrollment in a specific research study	Formulates recommendations to potential participants, community members, and researchers; includes decision to proceed with and monitor or to withdraw support from a specific research study	Are able to accommodate to community and individual concerns about the design or conduct of a specific research study
Authorization—Legal sanctioning of participation in a chosen research plan	Legally and formally agrees to enroll in a specific research study	Facilitates autonomous decision making and authorization by participants	Are obligated not to initiate research on a subject without legal authorization
Note. Threshold, informational, and consent elements were adapted from Beauchamp and Childress. ³¹			

materials that explain the study to participants and can represent the participants' concerns to the researchers. The CAB can act as an advocate for the rights of human subjects, for example, by conveying to participants their right to refuse or their right to full disclosure of information about the benefits and risks of the study and about previous relevant research. Finally, the CAB can provide a set of recommendations to help potential participants decide whether or not to participate in a study.

Practical Examples of CABs in the Research Process

This section highlights some of the ways in which CABs can be implemented in research involving human subjects. These examples come from AIDS research, because the history and experience of using CABs in AIDS-related research have been described previously.³²⁻⁴⁰ CAB involvement can, however, be extended to research on other diseases that disproportionately affect communities of color or communities that share a specific identity. These examples also are predominantly from clinical trials research, but CAB involvement can be applied to community-based prevention research (e.g., testing a behavioral intervention) as well.

Formalizing community involvement in research through the use of CABs may greatly improve the informed consent process, study design, and study implementation at different levels of the research. CAB participation has the potential for affecting clinical trials of experimental therapies, particularly those targeting vulnerable populations. Some US federal and state funding agencies have responded to

the call for greater community involvement in research by requiring scientists to incorporate CABs into their research protocols, particularly in randomized placebo-controlled clinical trials of experimental therapies and vaccines in HIV/AIDS research.

By 1990, the National Institute of Allergy and Infectious Diseases (NIAID) had formally integrated community representatives into the AIDS Clinical Trials Group (ACTG), the Center for AIDS Research, and the Community Programs for Clinical Research on AIDS to involve community members who had raised concerns about the conduct of AIDS clinical trials.³² Currently, each of these NIAID-sponsored programs is expected to have a local CAB, with one member of each CAB serving on a national-level advisory board called a Community Constituency Group.

Local CABs can be influential in halting the progress of clinical trials, as shown in the following example. A CAB helped prevent 2 ACTG study protocols from being initiated at the San Francisco, Calif. site, even though both protocols were up and running at the national level. Regarding ACTG 320, which had two arms—AZT/3TC/placebo and AZT/3TC/Crixivan—the San Francisco CAB felt that there were enough data to substantiate the benefits of Crixivan in reducing viral load, and thus having a placebo arm was considered unethical. In ACTG 343, participants were randomized to either a 3-drug, 2-drug, or 1-drug regimen after having been on successful antiretroviral therapy for 6 months. The San Francisco CAB felt that randomizing patients to receive less than the standard of care unnecessarily

exposed participants to risk. The study was closed prematurely by an interim review committee, which determined that the risk of virologic rebound was clearly weighted in the 1- and 2-drug arms. This decision convinced the principal investigator not to implement the protocol at the San Francisco site.

The HIV Network for Prevention Trials (HIVNET) was established in 1993 to conduct domestic and international multicenter trials, with a primary focus on conducting phase I and II clinical trials of HIV vaccines.³³ In the following examples, HIVNET CABs played a role in advocating compensation for trial-related injuries and full disclosure of information explaining the benefits and risks associated with trial participation.

- The national HIVNET CAB convinced both NIAID and 2 pharmaceutical sponsors to guarantee compensation for medical costs incurred by participants in the event of physiological harm caused by the candidate preventive HIV vaccine tested that year in a phase II trial.³⁴ Without CAB input, this issue might have been overlooked by the vaccine trial researchers.

- The national HIVNET CAB was instrumental in creating a participants' bill of rights despite objections from local principal investigators, who believed that the bill of rights simply restated the consent form. The national CAB members thought otherwise, recognizing that individuals need to understand their rights as trial volunteers, given the list of social harms associated with participation, and that such a document would be an important tool for communication in their respective communities.

- The local San Francisco HIVNET CAB wanted to ensure that individuals being enrolled in the commercially sponsored phase III preventive HIV vaccine trial were provided with sufficient information to make a fully educated decision about participation. In particular, CAB members were concerned that potential participants might not fully comprehend the content of the consent forms. Thus, the informed consent process was lengthened into several visits so that these individuals would have time to ask questions and digest the information given to them before making a decision to participate.

The HIV Cost and Services Utilization Study (HCSUS) and the CDC/NIAID-funded Project LinCS (Linking Communities and Scientists) showed that CAB participation has the advantage of forging a true partnership with scientists from the studies' inception.

- HCSUS created a 12-member national CAB that functioned as a conduit for ensuring participation of HIV-seropositive individuals and their advocates in the planning and implementation phases of clinical trial research.³⁵⁻³⁶ Among its activities, the HCSUS CAB contributed by identifying research priorities, including a greater emphasis on women-specific issues, and areas of research inquiry that had not been proposed by the researchers before. This CAB was also helpful in the day-to-day operations of the study, for example, by reviewing informed consent forms for content and comprehensibility.

- Project LinCS used CABs to assist in examining community

perceptions about HIV vaccine efficacy trials.³⁷ Three sites (San Francisco, Calif; Philadelphia, Pa, and Durham, NC) formed and worked with local CABs, and these CABs contributed to different aspects of the research, including problem identification, participant recruitment, research monitoring (including retention and follow-up), and dissemination of study findings.³⁸ Had CABs not been used, the ability of Project LinCS to recruit study participants, as well as the quality of the interview data collected, would have been greatly affected. Furthermore, 2 resources have been developed with assistance from Project LinCS CABs. First, a video was developed that discusses the 3 communities' perspectives on participating in phase III preventive HIV vaccine trials.³⁹ Second, the Durham CAB assisted in the development of a brochure that provides a list of questions for potential study participants to ask researchers before deciding whether or not to participate in any given study.⁴⁰

CRITICISMS OF CABS

All research involving human subjects, particularly clinical and behavioral studies, could benefit by having CABs or equivalents to provide advice about informed consent protocols, subject enrollment, research design, and implementation. Yet the use of CABs has not always been seen as conducive to the research process. For example, CABs in clinical trial research are often viewed by researchers as auxiliary, or as "window-dressing."⁴¹ Indeed, it is likely that the dynamic between the principal investigator and the CAB may dictate the extent to which a CAB can influence and

guide research. A principal investigator who is willing to listen to the concerns of the CAB and to obtain feedback from its members may be a requirement for an effective CAB.

Second, the resources allocated to the development and management of CABs tend to be limited and are often the first to be cut from study budgets when research priorities are considered. Indeed, in the first phase III trial of a candidate HIV vaccine, the private financial sponsor did not provide funding for CAB development at its 50 North American trial sites, and a national CAB had not been assembled when the study began.¹

Finally, greater CAB implementation is needed in developing countries, particularly in clinical studies, where there is more at stake in terms of potential risks and social harms. Community involvement sometimes means having trusted local leaders or even family members act as liaisons between scientists and study participants.^{2,41-42} This mechanism, however, has its limitations; replacing the autonomy of the individual with the judgment of a community leader or family member may not be in the best interests of prospective research participants. On the other hand, if developing countries could adopt CABs as a component of clinical research, individual informed consent failures, such as confusion over study terminology (e.g., what it means to receive a placebo) and participants' not being fully informed, could be avoided or at least minimized.

CONCLUSION

In most situations, investigators and potential research subjects expect that the decision

about research enrollment and the authorization of research will be an individual choice. Yet community perceptions of research and of a specific research project may guide individual action. Having a CAB provides a context for researchers and community members to discuss the intent, risks, benefits, and implications of research projects in culturally sensitive terms.

In spite of the increasing use of CABs, there has been only limited investigation into their impact on the design and implementation of research, particularly AIDS research, where their use is most prevalent. Some attention has been given to examining how CABs can enhance recruitment and participation in AIDS clinical trials.³² No studies, however, have systematically evaluated the lessons learned from using CABs and their impact on effecting change in the way in which research is conducted. Indeed, one of the criticisms of CAB participation in the research process has to do with not having enough information about the structure of a CAB and how it works to appreciate and evaluate its ability to guide, speak for, and protect its community.⁴³

We recognize this as a limitation. We call for a greater effort to devise methods of training investigators in the development and maintenance of CABs and in the selection of community advisors who will see that the interests of the target community, as well as the research priorities of the investigators, are considered.

In a climate where formal research safeguards do not always succeed in protecting the rights of human subjects, the need for community-based methods to augment the process of protec-

tion is apparent. CABs reinforce the importance of community involvement in the decision-making process from the inception of a research study, to ensure that consenting human subjects are fully informed about the study in question. We hope that the examples of CAB participation presented here have demonstrated the crucial role communities can play in the ethical conduct of research and how community input may enhance, not detract from, the research process. ■

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R.P. Strauss and S. Sengupta planned and led the writing of this commentary, using the input, ideas, and revisions offered by the other authors. S. Sengupta examined the history of ethical lapses in research. S.C. Quinn and J. Goepfing reviewed the literature and examined the theoretical aspects of informed consent and participatory research. C. Spaulding, S.M. Kegeles, G. Millett, and R.P. Strauss used their experiences in working with community advisory boards to provide historical and practical examples of how communities have been involved in research.

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