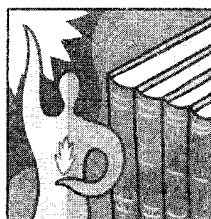


HEALTH POLICY AND ETHICS



Ethical Goals of Community Consultation in Research

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In response to the traditional emphasis on the rights, interests, and well-being of individual research subjects, there has been growing attention focused on the importance of involving communities in research development and approval.

Community consultation is a particularly common method of involving communities. However, the fundamental ethical goals of community consultation have not been delineated, which makes it difficult for investigators, sponsors, and institutional review boards to design and evaluate consultation efforts.

Community consultation must be tailored to the communities in which it is conducted, but the purposes of consultation—the ethical goals it is designed to achieve—should be universal. We propose 4 ethical goals that give investigators, sponsors, institutional review boards, and communities a framework for evaluating community consultation processes. (*Am J Public Health*. 2005;95:1123–1127. doi: 10.2105/AJPH.2004.058933)

ALTHOUGH ETHICAL

considerations of human subjects research have historically focused on protecting the rights, interests, and well-being of individual subjects, growing attention has been given to the importance of involving communities in research development and approval. Activists who represent “disease communities,” particu-

larly AIDS and breast cancer communities, during the 1980s lobbied for access to experimental treatments and for a larger role in the development of research agendas, study designs, and drug approval processes.^{1–4} Research in population genetics raised awareness about the risks for stigmatization and discrimination,^{5–7} and studies of indigenous communities raised concerns about threats to communal identity and social structure.^{7–10} International collaborative research includes working with societies that have radically different structures and norms,^{11–14} and researchers in emergency settings, where obtaining participant or surrogate consent is impractical, must conduct community consultation during project development and approval.^{15,16} Finally, forms of community-based research, such as participatory action research, include communities throughout the research process.^{17–20} Despite an increasing sense of need for community input, difficult questions persist about how best to involve communities as partners in research.

Efforts to expand attention to community perspectives, beyond representation on institutional review boards,^{21–23} have ranged from advocating a principle of respect for community to establishing guidelines that require community disclosure, consultation, and consent.^{12,24–30} Additionally, general principles have

been developed for guiding different types of community-based research.^{10,20,30} Among the methods for involving the community in research, community consultation is particularly common. Formal community consultation is required by Food and Drug Administration regulations before research is allowed to be conducted without informed consent in emergency settings.³¹ Similarly, proposed and actual guidelines for research that involves aboriginal communities,^{27,28,30} population genetics and epidemiologic research,^{29,32} international research,^{12,29} and HIV-related research^{25,26,33} recommend consulting communities when planning and implementing research.⁸

Despite such endorsements, the general ethical goals of community consultation remain unclear, which makes designing and evaluating consultation efforts a challenge for investigators, sponsors, and institutional review boards. Because of the heterogeneity of communities and research projects, the methods of community consultation must be context specific. However, the purposes of community consultation—the fundamental ethical goals that consultation is designed to achieve—should be universal. We propose a set of general goals for community consultation that will provide a framework for investigators, sponsors, institutional review

boards, and communities to evaluate community consultation processes. We in no way intend to detract from the need to consider the particularities of any given research project and community; careful understanding of particular contexts is indispensable for understanding and achieving the goals we recommend.

DISTINGUISHING COMMUNITY CONSULTATION AND CONSENT

Community consultation should not be mistaken for community consent, although the 2 are not mutually exclusive. To consult is “to seek advice or information.”³⁴ Consulting with a community includes eliciting feedback, criticism, and suggestions; it does not include asking for approval or permission. Community consultation is designed to recognize and accommodate the relevant particularities of a given community for a specific project. For example, community consultation for HIV-related trials may include consulting with HIV advocacy groups, people who are HIV-infected, and potential participants.^{1,35} Conducting genetics research in an aboriginal community may necessitate discussing studies with existing political authorities and community members.^{9,30}

Rather than soliciting input, community consent involves so-

liciting approval or permission to conduct a study within a community. Community consent may occur after community consultation and does not obviate the need for individual consent.^{36,37} Rather, the community decides whether to permit investigators to solicit participation from community members. For community consent to be valid, there must be a legitimate political system in place, with representatives properly empowered to make such decisions on behalf of the community.^{37,38} In many aboriginal communities, such legitimate systems exist. However, disease-based communities and many social groups typically lack a political structure, which makes community consent inappropriate.^{37,38}

Although conceptually distinct, the line between community consultation and community consent is inevitably blurred in practice. It would be disingenuous to enter into a consulting arrangement where the consulting party does not intend, *ex ante*, to take the consultants' advice. If relevant consultants have strong negative reactions or endorse particular modifications, those reactions or modifications have significant moral force and warrant respect and careful consideration, even though investigators may sometimes justifiably act contrary to such opinions. Otherwise, community consultation is merely symbolic.³⁹ Despite the clear conceptual distinction between consent and consultation, the degree to which consultants' support is necessary represents a persistent challenge.^{15,16,29}

CHALLENGES OF COMMUNITY CONSULTATION

Potential difficulties exist at each stage of community consultation. At the outset, it can be hard to identify communities and stakeholders that have legitimate and relevant interests. Common elements exist among conceptions of community,⁴⁰ but delineating and identifying particular communities for consultation can be challenging. Identifying the community at risk for HIV, for example, can be problematic, because at-risk individuals may not believe they are a part of any such community.⁴¹ Identifying representatives also can be difficult. Helpful procedures for identifying representatives have been suggested by The National Institute for General Medical Science,³² but important conceptual and practical challenges remain. For example, no clear representative exists for persons who may suffer from traumatic brain injury or cardiac arrest.^{42,43}

Closely related to the challenge of identifying communities is deciding when communities should be consulted (assuming they can be identified). In certain cases, there are regulatory requirements for community consultation.³¹ Similarly, when research poses real risks for social stigma to well-defined communities, such as certain genetics studies in native communities, the need for community consultation is evident.⁴⁴ Yet, requiring community consultation in all research projects is unwarranted. Relevant factors to consider

when deciding whether to conduct community consultation include the particular community under consideration, the nature of the research, and the likely impact of the research on that community. Further analysis is needed; however, we hope that articulating the goals of community consultation will at least be a helpful step in determining when consultation is warranted.

The type of community being considered for consultation is an important factor when determining the way in which community input is solicited. Common solicitation methods include open public forums, meetings with community advisory board members, presentations at meetings of religious or civic organizations, and radio and television call-in shows.^{1,17,44-49} Devising successful methods for generating public input can be challenging, particularly in communities that lack a well-defined structure or are geographically disparate.^{37,50} In many cases, multiple modalities of interaction must be employed.⁴⁴ It can also be difficult to determine when consultation efforts have been sufficient. Although insufficient consultation can be ineffective, requiring overly extensive consultation may hamper important work.

Finally, incorporating consultants' input into research plans can be challenging. Although it is undesirable to override or dismiss community objections or concerns, failure to conduct important research on the basis of objections by groups who are nonrepresentative or who have not carefully considered the issues at hand is also problematic.

ETHICAL GOALS FOR COMMUNITY CONSULTATION

A clear set of ethical goals will help investigators, sponsors, institutional review boards, and regulators plan and assess community consultation methods. Additionally, such a framework will provide endpoints for measuring the adequacy of consultation methods. We propose four ethical goals of community consultation: (1) enhanced protection, (2) enhanced benefits, (3) legitimacy, and (4) shared responsibility (Table 1).

Enhanced Protection

Enhancing the protection of research participants' interests and welfare is grounded in the researchers' duty to minimize risks for research subjects. Consultation efforts should be designed and conducted to help identify risks or hazards for individuals and communities and to identify additional protections to ensure the safety of research participants.

Some risks, particularly social risks, may not be apparent at the outset to investigators, sponsors, and institutional review boards. Members of cancer advocacy groups, for example, may serve as important consultants when designing informational materials or calling attention to concerns about adverse treatment effects that may not be obvious to researchers conducting a cancer trial.⁵¹ When research is conducted in emergency settings, community consultation may generate discussion that

TABLE 1—Ethical Goals of Community Consultation

Ethical Goal	Definition
Enhanced protection	Enhance protections for subjects and communities by identifying risks or hazards that were not previously appreciated and by suggesting or identifying potential protections
Enhanced benefits	Enhance benefits to participants in the study, the population for which the research is designed, or the community in which the study is conducted
Legitimacy	Confer ethical/political legitimacy by giving those parties with an interest or stake in the proposed research the opportunity to express their views and concerns at a time when changes can be made to the research protocol
Shared responsibility	Consulted communities may bear some degree of moral responsibility for the research project and may take on some responsibilities for conducting the study

helps to identify groups who are likely to want to opt out of specific studies and that suggests strategies to facilitate the identification of those groups during the study. In this sense, community consultation may be a particularly effective way for investigators to identify individuals or subgroups with particular needs or vulnerabilities that individuals outside the community may not recognize.

Community consultation also may enhance nonparticipant protections by identifying risks for community members who are not enrolled in the study. For example, studies of cancer susceptibility that were conducted among Ashkenazi Jews were opposed by some community members who were concerned that research findings might be used for eugenics or might jeopardize health coverage.⁵ Although all risks are not preventable, making them explicit and minimizing them are essential goals.

Enhanced Benefits

Enhancing benefits through community consultation is consistent with researchers' general duty of beneficence toward research subjects.⁵² Early HIV research illustrates how community consultation enhances benefits to individual subjects. For example, 1 community advisory board recommended that a clinical trial incorporate referral programs for participants to gain access to available ancillary services.³⁵ Based on this recommendation, investigators chose to incorporate such programs into their studies.

Community consultation may also enhance benefits to the community of individuals who have the condition being studied or to the larger communities to which study subjects belong. In the international setting, a common benefit of research involvement is the improvement of the research or health care delivery infrastructure. By consulting with

host country researchers and others in the host community, the areas of infrastructure that need improvement can be identified.¹⁴ Similarly, a central notion in community-based participatory research is that communities should be involved in identifying research questions and planning studies that benefit the particular communities involved.²⁰ In short, community consultation may enhance direct, indirect, and aspirational benefits.⁵³ Investigators are by no means required to provide all benefits that could conceivably be offered to participants or communities, but enhancing benefits to ensure that research efforts are mutually beneficial is an important goal.

Legitimacy

Community consultation can help to confer ethical and political legitimacy on a research project by engaging in a process in which stakeholders (those people, institutions, and groups that have an interest in the proposed research) may express their views and concerns. The opportunity to speak has significant justificatory power for imposing research risks, especially when individuals are unable to provide consent and surrogate decision makers are unavailable. In such cases, community consultation may be the only chance investigators have to assess the likely preferences of the study population. Similarly, when a study poses significant risks for a community, such as genetics research that could have potentially negative implications on the insurabil-

ity of an entire population, community consultation seems essential for legitimacy.

The challenges to achieving this goal are well-known. What counts as a community? Who counts as a representative? What level of community support is needed to legitimize a particular study? These are deep, conceptual questions for which we do not have well-developed answers; however, it is important to note that the goal of legitimacy refers to the process of community consultation and not the political legitimacy of consulted bodies.³⁷ Suggestions or concerns that are expressed during community consultations are significant, even when consultants lack the authority to provide consent on behalf of the community.

Shared Responsibility

As partners in the research process, community members may share responsibility in 2 ways. First, community consultants may assume active roles in conducting research. Community advisory board members, for example, may become involved in recruiting subjects for studies^{40,48,54} and thus bear some responsibility for the success of research efforts. Second, by acknowledging the stake that community members have in the conduct of research, and by soliciting their assistance and input through a legitimate process, community consultation confers on communities a degree of moral responsibility for the research.²⁶

Shared responsibility is particularly evident with cases involv-

ing HIV advocacy groups, where the advocacy groups have taken on the role of actually conducting studies,¹ and with cases involving participatory-action research or community-based participatory research, where communities are involved at every stage.¹⁷⁻¹⁹ It is important to clarify that sharing responsibility does not constitute a shifting of blame or removal of responsibility from investigators, sponsors, and institutional review boards. On the contrary, community consultation places additional responsibility on investigators to attend to important community concerns. The degree to which responsibility can be shared is limited by the degree to which investigators and sponsors are sensitive to and accommodate those concerns.

CONCLUSIONS

As the need for identifying and incorporating community input into the design, planning, and conduct of research has become clearer, it is critical to identify the ethical goals of community consultation. Attention to the 4 ethical goals of enhancing protection, enhancing benefits, creating legitimacy, and sharing responsibility should allow for more effective assessment by communities, investigators, institutional review boards, and sponsors of particular consultation efforts. We also hope that these goals can be developed into metrics by which methods of community consultation may be systematically assessed. For example, enhanced protections can

be measured by observing whether a particular consultation effort identifies additional risks previously unknown to investigators or whether it proposes new solutions for minimizing risk. There are currently few empirical data on the effectiveness of consultation strategies.⁵⁴ By identifying the goals of the process, this framework should facilitate attempts to assess different types of consultation efforts in different settings and enhance understanding of which consultation methods are appropriate in varying types of communities and types of research.

Finally, this framework draws attention to 2 important lingering issues that are beyond the scope of this article. First, an account is needed for determining when investigators may justifiably override or dismiss community concerns. Such an account must be particularly sensitive to the nature of disagreements.⁵⁵ Second, further research is needed to determine what types of studies require community consultation and what types of consultation are needed for particular research projects. In the meantime, careful attention to the 4 ethical goals we have identified should facilitate the proper incorporation of community views into research and its oversight.

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This article was accepted February 15, 2005.

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J. Sugarman originated the idea for this article; both authors developed ideas and reviewed each draft of the article.

Acknowledgments

We are extremely grateful for the helpful comments we received while developing this article. In particular, we would like to thank Ezekiel Emanuel, Christine Grady, Kate MacQueen, Holly Taylor, and Myron Weisfeldt. We also thank the reviewers for their very thoughtful and instructive suggestions.

Financial Disclosures

No protocol approval was needed for this project.

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