POLICY FORUM: ETHICS

Protecting Communities in Biomedical Research

C. Weijer* and E. J. Emanuel

Geneticists and other scientists have increasingly targeted communities for biomedical research into the etiology, especially the genetic determinants, of common diseases and have met with some well-known successes. For example, particular mutations predisposing to breast, ovarian, and colon cancer have been identified through studies of Ashkenazi Jews (*1, 2*). Although these discoveries will undoubtedly have important implications for cancer prevention and treatment, the community has expressed concern that they may become the target of discrimination, and there is growing public concern that added protections for communities in biomedical research are required (*3*).

Protections for communities in biomedical research have been developed in limited circumstances. The U.S. Food and Drug Administration has issued regulations allowing for a waiver of informed consent in certain emergency room research, provided there is public disclosure of the research plans and consultation with community representatives (*4*). Guidelines on consulting communities involved in research on HIV/AIDS have been proposed and implemented (*5*). The most developed protections for communities in biomedical research are found in guidelines for research involving aboriginal communities, exemplified by those of the Australia National Health and Medical Research Council (*6*).

C. Weijer is at the Department of Bioethics, Dalhousie University, Halifax, Nova Scotia, B3H 4H7, Canada. E. J. Emanuel is at the Department of Clinical Bioethics, Warren G. Magnuson Clinical Center, Building 10, Room 1C118, National Institutes of Health, Bethesda, MD 20892–1156, USA.

*To whom correspondence should be addressed. E-mail: charles.weijer@dal.ca The views expressed are those of the authors and do not necessarily reflect the policies of the NIH or U. S. Department of Health and Human Services.

Attempts to generalize these approaches by extending them from one community to another have been problematic (*7*). For example, a 1996 draft of the new Canadian research guidelines (the Tri-Council policy statement) applied guidelines for the protection of aboriginal communities in biomedical research to a wide variety of other communities, including Ashkenazi Jews and families (*8, 9*). This effort was curtailed as it soon became apparent that many of the specific protections could not be applied to these other communities.

Rather than simply applying existing guidelines, a rational strategy for the development of protections for communities in biomedical research must entail a series of steps. In discussing this strategy, we will describe characteristics and types of communities; these are not meant to be exhaustive lists, but to be the ones relevant to medical research.

Community Characteristics

The term community delineates a wide variety of human associations, from tribes to municipalities to religious adherents. A single set of regulations to fit all types of communities is doomed to failure. What is needed are morally relevant criteria that distinguish communities. Characteristics of particular importance or relevance to communities in biomedical research can be identified and used to delineate seven types of communities [Table 1; for definitions see Web table 1 (*10*)].

Communities may be arrayed along a spectrum of cohesiveness, from those that have all the characteristics to those that have only a few. At one end of the spectrum, a cohesive aboriginal community often (or nearly always) has all of the characteristics listed. Conversely, a less-cohesive occupational community embodies only two of the characteristics: common culture and a communications network.

CHARACTERISTICS OF TYPES OF COMMUNITIES

Community characteristic	Type of community						
	Aboriginal	Geographic/ Political	Religious	Disease	Ethnic/ Racial	Occupational	Virtual
Common culture and traditions, cannon of knowledge, and shared history	++	+	++	+/–	+	++	+
Comprehensiveness of culture	++	+/-	++	–	+	+/–	–
Health-related common culture	++	+	++	++	+	+/–	–
Legitimate political authority	++	++	+/–	–	–	+/–	–
Representative group/individuals	++	++	++	+	+	+/–	+/–
Mechanism for priority setting in health care	+	+	+/–	+	+/–	+/–	–
Geographic localization	+	++	+/–	+/–	+/–	–	–
Common economy/shared resources	++	++	+/–	+/–	+/–	–	–
Communication network	++	+	+	+/–	+/–	+	++
Self-identification as community	++	++	++	+/–	+	+/–	+

++ The community nearly always or always possesses the characteristic. +The community often possesses the characteristic. +/- The community occasionally or rarely possesses the characteristic. –The community very rarely or never possesses the characteristic.

Table 1. Characteristics of types of communities in biomedical research. Examples are aboriginal, Kahnawake; geographic/political, Jackson, MI, and Iceland; religious, Amish; disease, HIV; ethnic/racial, Ashkenazim; occupational, nurses; and virtual, e-mail discussion group.

Potential Protections

Potential community protections extend from the genesis of the research project to the publication of the results (*7*).

Consultation in protocol development. The researcher must show respect for the community's culture, seek community input on protocol development, ensure research is useful to the community, and respect the community's knowledge and experience.

Information disclosure and informed consent. Disclosure to the community should be nontechnical, and appropriate face-to-face meetings are encouraged. The community ought to have adequate time for review, the researcher must obtain the consent of the community, and community consent is required for protocol changes.

Involvement in research conduct. The researcher should ensure that skills and research expertise are transferred to members of the community, employment is offered to mem-

bers of the community, the community is reimbursed for research costs, and the community is informed about research progress.

Access to data and samples. The researcher must seek community consent for further use of samples, and storage of data should be negotiated.

Dissemination and publication of results. The researcher should involve the community in manuscript preparation, transmit a draft report to the community for comment, acknowledge community contributions, seek consent to identify the community, provide a final report to the community, and obtain community consent for media interviews. The researcher must report compliance with guidelines to the Institutional Review Board (IRB) and the publication.

Connecting Guideline Requirements to Community Characteristics

It is possible to identify particular characteristics of communities that are necessary for the implementation of specific protections. In this way, each of the identified community characteristics is linked to one or more of the protections (Table 2).

For example, if the community is to have input on the protocol, the community must have representatives who can provide this input on behalf of the community. Similarly, if community consent is to be sought before individuals are approached for study participation, the community must have a legitimate political authority that is empowered to speak authoritatively for, and make binding decisions on behalf of the community; more than mere representation is required. In addition, if the community is to be reimbursed for research costs, the community must have a common economy or shared resources. Furthermore, community consent for further use of samples requires not only that the community have a legitimate political authority but also that they have a health-related common culture. Unless there are shared ideas about health, the disposition of samples is likely to be of little or no relevance to the community as a whole, although particular individuals within it may have strong feelings. Finally, if a draft report for comment is to be provided meaningfully to the community, a communication network must be in place so that the report can be distributed to community members.

Synthesizing Appropriate Protections

Three general regimes of protection can be delineated, based on the specific protections appropriate to the distinct types of communities: (i) community consent and consultation, (ii) community consultation alone, and (iii) no added protections. [See Web table 2 (*10*).]

Community consent is only possible if the community has a legitimate political authority, which could be a legislative assembly, mayor, or tribal council that has the authority to make binding decisions on behalf of its members. For instance, the Ashkenazim have no legitimate political authority, and hence, suggesting that community consent be sought from them is neither morally nor pragmatically justifiable. However, this does not undermine the importance of respect for communities or the possibility that community consent is appropriate for some.

Not surprisingly, communities that have legitimate political authorities are among the most cohesive communities and have all or most of the characteristics relevant to the implementation of guidelines requirements (Table 1). Thus, protections for aboriginal and geographic or political communities in research include the full list of guideline requirements; in other words, community consent and consultation are required (Table 2).

Even though community consent is not possible for the Ashkenazi Jewish community, other protections that may be characterized as "community consultation" are appropriate. Community consultation encompasses the involvement of community representatives to a limited degree in study planning, informing the community as a whole of the study at its start and as progress is made, consulting with community representatives regarding the disposition of data, and providing them with a draft report on which to comment. Communities that share a religion, a disease, ethnicity, or race may be relatively cohesive and share many, although not all, of the characteristics required for the implementation of guideline requirements. Reflecting the intermediate degree of cohesiveness, the list of potential protections listed is roughly half that for aboriginal and geographical or political communities (Table 2).

Occupational and virtual communities are the least cohesive of the communities in the typology (Table 1). Generally, they have few of the morally relevant commu-

COMMUNITY CHARACTERISTICS REQUIRED FOR PARTICULAR PROTECTIONS

Proposed protections	Community characteristics							
	H	LPA	Rep.	PS	GL	CE/SR	CN	SI
Consultation in protocol development								
Respect for culture	✓							
Input on protocol			✓					
Research useful				✓				
Respect for knowledge and experience	✓							
Process of providing information and obtaining informed consent								
Nontechnical and appropriate disclosure			✓				✓	
Face-to-face meetings			✓		✓			
Adequate time for review			✓					
Consent		✓						
Consent required for protocol changes		✓		✓				
May withdraw consent		✓						
Involvement in research conduct								
Transfer of skills and expertise						✓		
Employment						✓		
Reimbursement for research costs						✓		
Informed about research progress			✓				✓	
Access to data and samples								
Consent for further use of samples	✓	✓						
Storage of data negotiated			✓					
Dissemination and publication								
Involvement in manuscript preparation			✓					
Draft report for comment							✓	
Acknowledgment								✓
Consent to identify		✓						
Final report			✓				✓	
Consent for researcher media interview		✓						

H, health-related common culture; LPA, legitimate political authority; Rep., representative group or individuals; PS, mechanism for priority setting in health care; GL, geographic localization; CE/SR, common economy or shared resources; CN, communication network; SI, self-identification as a community.

Table 2. Appropriate protections for communities depend on their characteristics. Italics indicate community protections that require consent; nonitalics, protections that require only community consultation.

nity characteristics, and accordingly, no added protections are required for research involving them.

However, there may be exceptions to these guidelines. Actual communities are diverse and can deviate from the ideal types. For instance, for historical and social reasons, farm workers or coal miners with strong union representation, geographic localization, union-based health insurance, and other social security programs may be more cohesive than typical occupational communities. Their cohesiveness may be so extensive that they have all or most of the characteristics legitimizing the additional protections of community consent and consultation.

Furthermore, it is important to recognize that human associations are not static but dynamic; bonds within a group may strengthen over time, and novel social structures may emerge as a new community develops, necessitating reconsideration of the level of protections. For example, it is not meaningful to speak of many disease groups, such as asthmatics, as communities. However, at some time in the future they may come together for support and to advocate for more research funding and a voice in setting research agenda. In this evolution, such a group accrues these same morally relevant characteristics that confer the ability and obligation to enact protections when the community is targeted for research. Similarly, a relatively cohesive community may experience disagreements, rupture, and disintegration over time, losing characteristics and thereby losing attendant protections.

Possible Questions

How do community protections relate to individual informed consent? Ultimately, no person can be enrolled in research without his or her individual consent. Properly understood, community consent is an additional protection; a study may not proceed without informed consent from both the community and the individual research subject. However, protections for communities are asymmetric: If the community consents to research participation, individuals may still refuse to participate; if the community does not consent, then individuals who are identified because they are members of the community should not be approached for study enrollment. Conflicts may arise when individual and community interests conflict. For example, what if the community withdraws consent for study participation when individual research subjects seem to be deriving medical benefit and wish to continue participating? Inevitably, the answer to such conflicts will depend on the circumstances.

Is it more appropriate to conceive of a community as a vulnerable group protected by current regulations? Research ethics and protections have largely been shaped in reaction to instances of unethical and exploitative research on prisoners, children, the elderly, the poor, and racial or ethnic minorities (*11*). Vulnerable groups are socially, economically, and otherwise disadvantaged and, therefore, are more susceptible to exploitation or harm. Regulations protecting such groups include added consent requirements and limits on the nontherapeutic research risk to which they may be exposed (*12*). Conversely, the driving issue for protections for communities is not vulnerability, but rather, that communities have interests that are entitled to respect and protection (*13*). Respecting and protecting the interests of a community call for a partnership between community and researcher. This is a fundamentally different relation than with vulnerable groups, for which there is more of a protective guardianship (*14*). Consequently, the protections typically afforded vulnerable groups, such as limits upon risk, would be inappropriate for communities in research.

Might a community use added protections for research to legitimize the oppression of groups within the community? For example, a community with a male-dominated leadership may silence the voices of women within the community. Such a community may be reluctant to permit research into the prevalence and causes of spousal abuse, because it may reflect poorly on the community. Careful reflection is needed to ensure that the desire to protect the community in research does not perpetuate oppression. All the relevant values, including respect for persons, beneficence, justice, and respect for communities, must be used in the assessment of potential oppression. Viewed in isolation, any of the ethical principles articulated in the "Belmont report" (*15*) may be used to justify unethical ends. One formulation of justice requires that the burdens and benefits of research participation be distributed equitably; another aspect of justice calls for the elimination of domination (*16*, *17*). Thus, a community that seeks to perpetuate oppression might be legitimately criticized on grounds of justice; community safeguards used to perpetuate such oppression have no moral force.

Who counts as the community leader? In some communities, a multiplicity of legitimate leaders may make it difficult to discern with whom researchers ought to interact; an aboriginal community may have both a tribal council and an elected mayor. The decision will depend on the values and traditions of particular communities and whose authority encompasses the questions raised. For instance, political leaders may be appropriate for interaction regarding reimbursement for use of resources, whereas religious leaders have a stake in cases involving the disposition of tissue samples.

What if the community wants to suppress adverse or undesirable research findings? This problem is not restricted to research with communities but also exists in relation to research funded by pharmaceutical companies, managed care and other health care institutions, or other research organizations (*18*). Experience in research with the aboriginal community provides a useful guide to the negotiation of disparate interests. Researchers and the Kahnawake community have negotiated a mechanism in which consensus between the researcher and the community on data interpretation is sought (*19*). If consensus cannot be attained within a reasonable amount of time, the competing interpretations of the study will both be published. Further experience may generate other examples of creative and equitable solutions to these problems that are less threatening to academic freedom than many existing agreements between researchers and for-profit companies.

Putting Principle into Practice

Undoubtedly, difficult questions do remain. By providing precision in distinguishing different types of communities in research, their characteristics, and protections appropriate for each, this analysis should make discussion of community consent and consultation more focused. By distinguishing between community consent and community consultation, skepticism as to the feasibility and appropriateness of additional protections for communities in research ought to be allayed.

References and Notes

1. J. P. Streuwing *et al.*, *Nature Genet.* **11**, 198 (1995).
2. S. J. Laken *et al.*, *Nature Genet.* **17**, 79 (1997).
3. S. Lehrman, *Nature* **389**, 322 (1997).
4. 61 Code of Federal Regulations 51497.
5. C. Levine, N. N. Dubler, R. J. Levine, *IRB: Rev. Human Subj. Res.* **13**, 1 (January–April 1991).
6. Australia National Health and Medical Research Council, "Guidelines on ethical matters in aboriginal and Torres Strait islander research" (NHMRC, 1991).
7. C. Weijer, G. Goldsand, E. J. Emanuel, *Nature Genet.* **23**, 275 (1999).
8. Canada Tri-Council Working Group on Ethics, "Code of conduct for research involving humans (draft)" (Minister of Supply and Services, Ottawa, 1996).
9. Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, "Tri-council policy statement: Ethical conduct for research involving humans" (Public Works and Government, Ottawa, 1998).
10. Supplemental material is material is available to *Science* Online subscribers at www.sciencemag.org/feature/data/1050363.shl
11. R. J. Levine, *Ethics and Regulation of Clinical Research* (2nd ed.) (Yale Univ. Press, New Haven, CT, 1988).
12. C. Weijer, *Accountability Res.* **7**, 21 (1999).
13. C. Weijer, *Cambridge Q. Healthcare Ethics* **8**, 501 (1999).
14. B. Freedman, A. Fuks, C. Weijer, *Hastings Center Rep.* **23**, 13 (March–April 1993).
15. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, "Belmont report" (Department of Health, Education, and Welfare, 1979).
16. J. Rawls, *A Theory of Justice* (Harvard Univ. Press, Cambridge, MA, 1971).
17. M. Walzer, *Spheres of Justice* (Basic Books, New York, 1983).
18. D. G. Nathan and D. J. Weatherall, *Lancet* **353**, 771 (1999).
19. A. C. Macaulay *et al.*, *Can. J. Public Health* **89**, 105 (1998).