

Protecting communities in research: current guidelines and limits of extrapolation

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As genetic research increasingly focuses on communities, there have been calls for extending research protections to them. We critically examine guidelines developed to protect aboriginal communities and consider their applicability to other communities. These guidelines are based on a model of researcher-community partnership and span the phases of a research project, from protocol development to publication. The complete list of 23 protections may apply to those few non-aboriginal communities, such as the Amish, that are highly cohesive. Although some protections may be applicable to less-cohesive communities, such as Ashkenazi Jews, analysis suggests substantial problems in extending these guidelines *in toto* beyond the aboriginal communities for which they were developed.

Recent cancer genetics studies documented a high prevalence of particular genetic mutations predisposing Ashkenazi Jews to breast, ovarian and colon cancers^{1,2}. In response, an editorial expressed concern that “anyone with a Jewish-sounding name could face discrimination in insurance and employment as companies struggle to keep down health-care costs,”³ and some Jewish leaders in the United States have called for the development of guidelines to protect the Ashkenazi community. Developing protections for communities in research is complicated by several fundamental issues, including ambiguity as to what constitutes a community in need of protection, disagreements about multiculturalism and uncertainty as to what these protections should be. Codifying protections for communities in research is a dialectical process that will require addressing these issues by proposing and refining potential safeguards based on conceptual reflection and practical experience.

To begin the process of determining whether protections for communities are appropriate and what their substance should be, we critically examine well-established guidelines protecting aboriginal communities participating in biomedical research. These guidelines make a logical starting point for our enquiry for two reasons. First, while protections for communities in research are controversial and remain open to question, there is at least general agreement that aboriginal communities are distinct communities with common interests in need of protection. Second, the highly cohesive nature of these communities makes it likely that the requirements articulated represent the most extensive set of possible protections for a community in research. Accordingly, two fundamental questions need addressing. What is the scope of protections for aboriginal communities? To what extent can such protections extend to other types of communities?

Limitations of current regulations

The predominant framework for analysing ethical issues in clinical research is articulated in *The Belmont Report*⁴. It identifies three ethical principles to govern research on human beings:

respect for persons, beneficence and justice. Although widely cited, *The Belmont Report* has been criticized for overemphasizing individual rights and failing to take into account important human relationships found in the family and the community⁵. Indeed, the word ‘community’ is not mentioned once in *The Belmont Report*. This lack of attention to community is reflected in the *Common Rule* (45 CFR 46), which focuses only on individual research subjects and vulnerable groups, such as the mentally ill and educationally disadvantaged people, insofar as they might be wrongfully included in or excluded from research participation⁶. To remedy this situation, some have argued for the adoption of a new ethical principle of respect for communities^{7–9}. A reasonable formulation of the principle of respect for communities confers on the researcher an obligation to respect the values and interests of the community in research and, wherever possible, to protect the community from harm.

Indeed, some official bodies have begun studying and proposing protections for communities. Recent Food and Drug Administration (FDA) regulations permitting the waiver of consent in certain emergency research requires investigators to consult with the community before a study is initiated¹⁰. The National Bioethics Advisory Commission (NBAC) now recommends that research involving stored tissue and DNA samples that poses risks to a particular community requires consultation with that group¹¹. Similarly, in Canada, part of the 1996 draft national guidelines developed by the Tri-Council Working Group on Ethics for research involving human subjects set out standards for research involving collectivities, including aboriginal groups and people infected with HIV (refs 12,13).

Existing guidelines for protecting communities

So far, most guidelines for the protection of communities in research have been written for research involving aboriginal communities and peoples. We use the term ‘aboriginal peoples’ to apply to American Indians, Alaska Natives, Canadian First Nations and Inuit Peoples, Australian Aborigines, Torres Strait

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Table 1 • Guidelines from Australia, Canada, US and international fora designed for the protection of aboriginal communities in research

	Australia			Canada			United States			International					
	Year	Guideline	Country	Year	Guideline	Country	Year	Guideline	Country	Year	Guideline				
Target community ^a	1989	AHRECSA ¹⁵	A	1982	ACUNS ¹⁹	NC	1971	CAAA ²²	AA	1995	IARPC ²⁵	NC	1991	CIOMS ²⁸	E
Community representation on committee drafting guidelines	1989	MSHR ¹⁶	A	1993	RCAP ²⁰	A	1996	KSDPP ²¹	A	1994	AIRC ²⁴	A	1997	AAA ²⁶	AA
Guideline requirements	1989	AHRECSA ¹⁵	A	1993	RCAP ²⁰	A	1996	KSDPP ²¹	A	1994	AIRC ²⁴	A	1997	AAA ²⁶	AA
Consultation in protocol development	1989	AHRECSA ¹⁵	A	1982	ACUNS ¹⁹	NC	1996	KSDPP ²¹	A	1994	AIRC ²⁴	A	1997	AAA ²⁶	AA
Respect for culture	1989	MSHR ¹⁶	A	1993	RCAP ²⁰	A	1996	KSDPP ²¹	A	1994	AIRC ²⁴	A	1997	AAA ²⁶	AA
Input on protocol	1989	MSHR ¹⁶	A	1993	RCAP ²⁰	A	1996	KSDPP ²¹	A	1994	AIRC ²⁴	A	1997	AAA ²⁶	AA
Research useful	1989	MSHR ¹⁶	A	1993	RCAP ²⁰	A	1996	KSDPP ²¹	A	1994	AIRC ²⁴	A	1997	AAA ²⁶	AA
Respect for knowledge and experience	1989	MSHR ¹⁶	A	1993	RCAP ²⁰	A	1996	KSDPP ²¹	A	1994	AIRC ²⁴	A	1997	AAA ²⁶	AA
Consent process and informed consent	1989	MSHR ¹⁶	A	1993	RCAP ²⁰	A	1996	KSDPP ²¹	A	1994	AIRC ²⁴	A	1997	AAA ²⁶	AA
Non-technical and appropriate disclosure	1989	MSHR ¹⁶	A	1993	RCAP ²⁰	A	1996	KSDPP ²¹	A	1994	AIRC ²⁴	A	1997	AAA ²⁶	AA
Face-to-face meetings	1989	MSHR ¹⁶	A	1993	RCAP ²⁰	A	1996	KSDPP ²¹	A	1994	AIRC ²⁴	A	1997	AAA ²⁶	AA
Adequate time for review	1989	MSHR ¹⁶	A	1993	RCAP ²⁰	A	1996	KSDPP ²¹	A	1994	AIRC ²⁴	A	1997	AAA ²⁶	AA
Consent ^b	1989	MSHR ¹⁶	W	1993	RCAP ²⁰	W	1996	KSDPP ²¹	W	1994	AIRC ²⁴	CS	1997	AAA ²⁶	AA
Consent required for protocol changes	1989	MSHR ¹⁶	W	1993	RCAP ²⁰	W	1996	KSDPP ²¹	W	1994	AIRC ²⁴	CS	1997	AAA ²⁶	AA
May withdraw consent	1989	MSHR ¹⁶	?	1993	RCAP ²⁰	?	1996	KSDPP ²¹	?	1994	AIRC ²⁴	CS	1997	AAA ²⁶	AA
Involvement in research conduct	1989	MSHR ¹⁶	?	1993	RCAP ²⁰	?	1996	KSDPP ²¹	?	1994	AIRC ²⁴	CS	1997	AAA ²⁶	AA
Transfer of skills and research expertise	1989	MSHR ¹⁶	?	1993	RCAP ²⁰	?	1996	KSDPP ²¹	?	1994	AIRC ²⁴	CS	1997	AAA ²⁶	AA
Employment	1989	MSHR ¹⁶	?	1993	RCAP ²⁰	?	1996	KSDPP ²¹	?	1994	AIRC ²⁴	CS	1997	AAA ²⁶	AA
Reimbursement for research costs	1989	MSHR ¹⁶	?	1993	RCAP ²⁰	?	1996	KSDPP ²¹	?	1994	AIRC ²⁴	CS	1997	AAA ²⁶	AA
Informed about research progress	1989	MSHR ¹⁶	?	1993	RCAP ²⁰	?	1996	KSDPP ²¹	?	1994	AIRC ²⁴	CS	1997	AAA ²⁶	AA
Access to data and samples	1989	MSHR ¹⁶	?	1993	RCAP ²⁰	?	1996	KSDPP ²¹	?	1994	AIRC ²⁴	CS	1997	AAA ²⁶	AA
Consent for further use of samples	1989	MSHR ¹⁶	?	1993	RCAP ²⁰	?	1996	KSDPP ²¹	?	1994	AIRC ²⁴	CS	1997	AAA ²⁶	AA
Storage of data negotiated	1989	MSHR ¹⁶	?	1993	RCAP ²⁰	?	1996	KSDPP ²¹	?	1994	AIRC ²⁴	CS	1997	AAA ²⁶	AA
Dissemination and publication	1989	MSHR ¹⁶	?	1993	RCAP ²⁰	?	1996	KSDPP ²¹	?	1994	AIRC ²⁴	CS	1997	AAA ²⁶	AA
Involvement in manuscript preparation	1989	MSHR ¹⁶	?	1993	RCAP ²⁰	?	1996	KSDPP ²¹	?	1994	AIRC ²⁴	CS	1997	AAA ²⁶	AA
Draft report for comment	1989	MSHR ¹⁶	?	1993	RCAP ²⁰	?	1996	KSDPP ²¹	?	1994	AIRC ²⁴	CS	1997	AAA ²⁶	AA
Acknowledgement	1989	MSHR ¹⁶	?	1993	RCAP ²⁰	?	1996	KSDPP ²¹	?	1994	AIRC ²⁴	CS	1997	AAA ²⁶	AA
Consent to identify	1989	MSHR ¹⁶	?	1993	RCAP ²⁰	?	1996	KSDPP ²¹	?	1994	AIRC ²⁴	CS	1997	AAA ²⁶	AA
Report compliance with guidelines	1989	MSHR ¹⁶	?	1993	RCAP ²⁰	?	1996	KSDPP ²¹	?	1994	AIRC ²⁴	CS	1997	AAA ²⁶	AA
Final report	1989	MSHR ¹⁶	?	1993	RCAP ²⁰	?	1996	KSDPP ²¹	?	1994	AIRC ²⁴	CS	1997	AAA ²⁶	AA
Consent for researcher media interview	1989	MSHR ¹⁶	?	1993	RCAP ²⁰	?	1996	KSDPP ²¹	?	1994	AIRC ²⁴	CS	1997	AAA ²⁶	AA

Documents are listed by country of origin and chronologically. Guideline requirements are grouped under five main themes: (i) consultation in protocol development; (ii) consent process and informed consent; (iii) involvement in research conduct; (iv) access to data and samples; and (v) dissemination and publication of research results. ^aA, aboriginal peoples; NC, northern communities and peoples; E, people studied by epidemiologists; AA, people studied by anthropologists; C, collectivities (national, cultural groups, indigenous communities, neighbourhood groups, families). ^bW, written consent; ✓, consent required, ambiguous as to written or oral; NIC, only if it is not possible to obtain individual consent; CS, if research involves areas of cultural sensitivity.

Islanders and other indigenous peoples¹⁴. Guidelines for the protection of aboriginal peoples emanate from Australia^{15–18}, Canada^{12,13,19–21}, United States^{22–26} and an international forum²⁷. These are motivated by three considerations. First, aboriginal communities are often geographically isolated and possess histories, cultures and traditions distinct from the dominant culture. Second, there is an evolving political consciousness and aspiration to self-determination in aboriginal communities. Third, aboriginal peoples are increasingly concerned that research may adversely affect them and their values. All of these factors support our belief that guidelines for the protection of aboriginal communities in research are prototypical and probably the most extensive elaboration of protections available.

Recently, guidelines to protect communities beyond aboriginal peoples have been proposed, including the Council for International Organizations of Medical Sciences (CIOMS) guidelines for epidemiological research²⁸, and Canada's Tri-Council Working Group on Ethics draft document¹² and a later 'final' document¹³, which articulate guidelines to protect a variety of 'collectivities'.

Another set of guidelines addresses the involvement of another type of community in addition to aboriginal peoples in research, people with HIV (ref. 29).

Historically and conceptually, the guidelines of Australia's National Health and Medical Research Council (NHMRC) are paradigmatic. Distilling from the NHMRC guidelines and 16 other documents (one 'HIV' document is considered separately), we identified 23 specific requirements for the protection of communities in research that are organized into five broad themes (Table 1). The protections are arranged chronologically, beginning with the issues pertaining to consultation with the community on research design and ending with issues arising from the dissemination and publication of research findings. The order is as follows: consultation in protocol development, consent process and informed consent, involvement in research conduct, access to data and samples, and dissemination and publication of research results. A critical evaluation of these specific requirements provides an opportunity to conceptualize how a principle of respect for communities in research could be put into operation.

Community representation in the drafting of guidelines

Before considering the substantive requirements of the guidelines, it is important to identify a morally salient procedural requirement used in the Australian NHMRC and a few other guidelines. As a matter of democratic legitimacy, guidelines written to govern research involving a particular community should include community members in the guideline-writing committee. Community representation adds legitimacy to the final product because it provides an opportunity for a community to help formulate and thereby consent to the ethical ground rules under which research involving the community may proceed. Furthermore, involving community representatives helps to ensure that guidelines are comprehensive and cover all the concerns that arise from the traditions and values unique to and constitutive of the community. Indeed, failing to document community representation may diminish the validity of a set of guidelines.

Even with community involvement in the guideline-writing committee, it is important to recognize that any vibrant community will have multiple and even conflicting interpretations of its own traditions and values. Selected representatives may not be able to speak adequately for the diversity of viewpoints of com-

munity members. In addition to including aboriginal members on committees, other procedures, such as open meetings, need to be developed to elicit broad-based community consultation.

Substance and content of the guidelines

All the documents surveyed envisioned the relationship between the community and researchers as a partnership. There was substantial consistency with the need to address all five themes, although there was significant variation with regard to the specific requirements within the guidelines.

Consultation in protocol development. Almost all the guidelines require that researchers respect the culture of the community (Table 1). The fact that each of the four of the specific requirements in this theme is mentioned in half or more of the guidelines surveyed suggests widespread agreement about the need for consultation early in the research development process. It is this early involvement of the community that lays the groundwork for the partnership between community and researcher.

All but three of the documents require that the community be consulted in the actual development of the study protocol. Consultation on research design is a necessary prerequisite to ensuring that the research itself is useful to the community and respects aboriginal knowledge. The major requirement stipulates that the research itself must be what Freedman has termed being of *value* to the community³⁰. This guideline requires researchers to acknowledge and be responsive to community priorities in health and other areas pertinent to research. The research protocol, or even the study questions themselves, may have to be reassessed to meet the needs of the community as well as those of the researcher.

Another specific requirement of many guidelines is to recognize that aboriginal peoples may have epistemologies—that is, ways of knowing—that differ from the Western scientific method. Projects need to take account of the fact that oral tradition is considered an important source of knowledge in many aboriginal communities. The guidelines indicate that researchers ought to collaborate with the community to define how the research problem might be approached and, where relevant, oral tradition and other sources of communal knowledge ought to be used in a respectful manner.

Consent process and informed consent. The guidelines view community consultation and consent as supplementary to but not a replacement of individual consent. All but one of the documents assume and require that informed consent must be obtained from individual research subjects. The CIOMS guidelines for epidemiological research allow a narrow exception to this rule: "When it is not possible to request informed consent from every individual to be studied, the agreement of a representative of a community or group may be sought..."²⁸. The guidelines then go further and require that researchers consult with and obtain consent from the community before the research project may proceed.

The delineation of the specific requirements by the guidelines emphasizes that adequate consent—whether from a community or an individual—requires an emphasis on process rather than mere agreement or signing a document³¹. Almost all of the documents recognize the need to communicate in a clear and intelligible manner, such as using local languages where necessary. The most comprehensive of the guidelines suggest face-to-face meeting between community and researcher and adequate time for review and consideration of the protocol by the com-

"early involvement of the community . . . lays the groundwork for the partnership between community and researcher."

Table 2 • A comparison of guidelines for research on people with HIV with NHMRC guidelines for research on aboriginal peoples

	NHMRC ¹⁷ 1991	HIV ²⁹ 1991
Target community	aboriginal	HIV/AIDS
Community representation on committee drafting guidelines	✓	✓
Consultation in protocol development Input on protocol	✓	✓
Consent process and informed consent		
Non-technical and appropriate disclosure	✓	
Face-to-face meetings	✓	
Adequate time for review	✓	
Consent	✓	
Consent required for protocol changes	✓	
May withdraw consent	?	
Additional elements		
Community advisory committee	✓	✓
Community representatives on IRB	?	✓
Researcher holds primary responsibility for consultation	✓	✓

munity's leaders. Unfortunately, not all of the guidelines specify in sufficient detail the process of obtaining informed consent from the community and, despite the fact that written consent is the standard for individual research participants, only six of the documents require community consent to be obtained in writing (Table 1).

Little attention is paid also to the issue of consent for changes in study design. If consent is required for the research study to proceed, then it would seem logical that major changes in the agreed-upon protocol should also be consented to by the community. Only four documents explicitly require such consent. Similarly the issue of withdrawal of consent by the community is rarely mentioned. Individual research subjects have the right to withdraw from study participation at any time. Do communities have the same right? Three documents clearly indicate that they do. There is potential for inciting conflict between the community leadership and individual study participants. What if the community withdraws consent but individual participants wish to continue in the study or are receiving medical benefits by their participation? These important issues are not thoroughly considered by the existing guidelines and need more deliberation informed by experience.

In some circumstances it may be unclear who speaks for a particular aboriginal community. Some aboriginal communities may have multiple representatives. For example, a traditional band council as well as an elected municipal government. Who is the researcher to approach for consultation and consent regarding the study? What if the two bodies give conflicting pronouncements regarding the wishes and interests of the community? None of the guidelines discuss how to resolve conflicts between legitimate authoritative bodies.

Involvement in research conduct. For the community to be a true partner in research, involvement cannot end with informed consent. The community as partner ought to be meaningfully involved in the actual conduct of the research project. Several guidelines illustrate the various ways in which participation in research can benefit the community as a whole. First, community members can be trained to help conduct the research, thereby transferring research skills and expertise. Second, individual members of the community may be given employment on the research project—an economic benefit to the community. Surprisingly, while most of the guidelines suggest that community members be fairly paid for their work, only two documents add that the community should be reimbursed for any costs it incurs

through its participation, such as accommodation for researchers, or water, power or materials used during the conduct of the study. Informing the community of ongoing developments in the research, required by most guidelines, is another instantiation of the community-researcher partnership.

Access to data and samples. The need for community consent to future use of data and, in particular, tissue samples, is the result of historical factors and aboriginal beliefs. First, the history of exploitation of aboriginal peoples engenders suspicion as to the disposition of data and samples. As a result, some aboriginal people view research materials as yet another resource at risk of wrongful expropriation. Second, many aboriginal peoples espouse a belief in natural harmony, a doctrine that does not allow certain types of samples to be taken and forbids particular uses of samples by researchers, such as the creation of immortalized cell lines. The requirement of consent for further uses of data or samples, as a few of the guidelines suggest, promotes trust between the community and the researcher and protects the community from unwanted uses of such materials.

The related requirement of storage of data negotiated refers to the need for researchers and communities to discuss where data or samples will be stored, whether or not any will be destroyed, and who ultimately controls them after the completion of the project. The actual recommendations of individual guidelines vary in this category: some require storage in the community, others require that a copy of the data be given to the community and others leave the specifics to be determined by a process of negotiation between community and researcher. Six of the guidelines are completely silent on this potentially contentious issue.

Dissemination and publication. The model of partnership between community and researcher extends even beyond the conduct of the study to its dissemination. Consideration of co-authorship by community members and the circulation of preliminary drafts for comment and criticism allows the community to remain a full partner throughout the research process. In a recent description of research in the aboriginal community of Kahnawake, consensus between community and researcher on data interpretation is sought and, failing this, the competing interpretations will be included in published work³². In research where confidentiality is a particular concern, there is a tension between the requirement for acknowledgement and protecting the identity of the community. In some cases the disclosure of research results may harm the community and yet there seems to be an imperative to acknowledge important contributions.

The requirement to include a statement of compliance with guidelines in publications is an important part of the implementation and enforcement of the guidelines. Not only does it alert readers to the fact that ethical standards were observed in the conduct of the research, it gives journal editors and peer reviewers a role in enforcing guidelines to protect communities in research. Despite the importance of this requirement, only two of the documents require it. The provision of a final report to the community and consent by the community for media interviews are further reflections of the partnership theme.

The challenge of developing guidelines for non-aboriginal communities

This analysis of guidelines for research on aboriginal peoples provides a considerable amount of information on the implementation of the principle of respect for communities in this type of community. But as recent experience with genetic research indicates, aboriginal peoples are neither the only type of community nor the only communities requesting protection. How well, if at all, can these guidelines be extrapolated to other types of community?

So far, there have been only a few attempts to develop or adapt guidelines for non-aboriginal communities. In a prominent example, Levine *et al.*²⁹ put forth guidelines for research involving people with HIV. Like the NHMRC guidelines, these guidelines are dedicated to a community-researcher partnership model. However, because the HIV community is more dispersed and diverse, having fewer shared traditions and lacking politically legitimate institutions, these commentators propose that the community-partnership model be implemented differently, with fewer protections for the community. The safeguards common with those for aboriginal communities include requirements for consultation with the community in the design of the research study and the incorporation of members of the community into existing decision-making structures within health-care institutions, such as Institutional Review Boards (Table 2). The commentators recognize that having no system of legitimate political representation within the HIV community negates the possibility of having informed community consent. As an alternative, they emphasize that researchers must devise creative ways to foster legitimate community representation:

“Even in situations where no formal community-based organizations exist that might plausibly serve to represent potential subjects’ interests, individuals who have long experience in the community can be consulted to identify particular concerns and other knowledgeable people. Through such contacts it should be possible to assemble a credible standing advisory committee. This standing advisory committee can provide advice on how the investigators may accomplish the purposes of community consultation in regard to particular proposed clinical trials”²⁹.

While Levine *et al.*²⁹ articulated fewer protections for the HIV community, Canada’s Tri-Council Working Group on Ethics initially opted for the opposite approach, extending comprehensive protections like those of the NHMRC to almost any association that might be considered a community. Whereas the new Canadian *Tri-Council Policy Statement* no longer includes formal guidelines for communities, the early efforts of the Working Group are instructive³³. In 1994, the Working Group was charged with the task of producing a single set of research guidelines for biomedical and social science research in Canada. Many of the protections for

communities in the Working Group’s document parallel those found in the NHMRC guidelines (Table 1). The Working Group intended these requirements to apply to the broadest possible range of communities, including aboriginal peoples, people with HIV and Ashkenazi Jews. Commentators on the 1996 draft document pointed out that many of the requirements were not widely applicable and, as a result, the final document contains a restricted set of requirements. The *Tri-Council Policy Statement* curtailed the scope of applicability to include only aboriginal communities, but, although included, the section was not approved because there had been no formal consultation with aboriginal communities.

The model ethics protocol of the Human Genome Diversity Project (HGDP) provides another example of an attempt to articulate comprehensive protections³⁴. The protocol, based on the CIOMS guidelines for epidemiological research and other international documents, defines ethical procedures for researchers collecting DNA samples and ethnographic information for the HGDP from a wide-variety of communities, for example, Navajo,

Irish Americans and Ashkenazi Jews. The protocol advocates a community-researcher partnership, and community involvement in the design, conduct and publication of the study. It requires that community consent be obtained—be it from community authorities, active community members or community consensus—in all cases.

There are substantial problems with applying protections developed for aboriginal populations to other less cohesive communities, especially ones without legitimate political authorities. First, it is sometimes difficult to clearly delineate a particular community. Aboriginal communities tend to be geographically localized, bound by shared histories, cultural traditions, languages, established community fora and with legitimate political structures. But other communities lack these morally relevant features: they are dispersed, with attenuated cultural traditions, without established forums or modes of communication and may not self-identify as a community.

Second, whereas most aboriginal communities have legitimate political institutions and leaders, many other communities do not. The absence of a system of legitimate political representation in either the Irish-American or Ashkenazi Jewish community seems to make a range of consent requirements—such as consent from the community at the start of the study, community consent for protocol changes, the right for the community to withdraw from the study, consent for further use of samples, consent to identify the community in print and community consent for media interviews—of the researcher difficult if not impossible to fulfil and lacking moral foundation. Similarly, the determination of community-wide needs and priorities in the two communities may be problematic due to the diversity of religious beliefs, political affiliation and organizations within the community.

Further work will require a more nuanced approach and recognize that communities represent a wide variety of human associations, including ethnic, cultural, religious, political, artistic, professional, sexual and disease communities. To define and delineate the substantive, practical protections for the principle of respect for communities, we need to construct a typology of communities matching protection to specific community characteristics. For example, if one is to be able to implement the requirement for community consent or other requirements involving community consent, then the community in question must have a system of legitimate political representation. What

“The related requirement of storage of data negotiated refers to the need for researchers and communities to discuss where data or samples will be stored . . . [some] guidelines are completely silent on this potentially contentious issue.”

constitutes legitimate political representation is itself an issue requiring further analysis. Similarly, to establish health priorities, the community must have a formal organization devoted to its health affairs.

Whereas extending guidelines developed for aboriginal peoples to the HIV community, Irish Americans or Ashkenazi Jews *in toto* is problematic, they may be of more immediate relevance to research with communities that are comparable to aboriginal populations. For example, geneticists have worked with the Amish to determine the aetiology of bipolar affective disorder (C. Francomano, pers. comm.). Amish communities tend to be localized and united by common language, history, values and religious belief. A Bishop, who is chosen by lot, represents individual communities both politically and spiritually. Because the Amish share these morally relevant characteristics with aboriginal communities, the protections found in the most refined guidelines for aboriginal communities, such as the Australian NHMRC guidelines, would be an appropriate template to guide the community-research partnership between the Amish communities and genetic researchers.

Over recent years, there has been concern that current codes and regulations are too individualistic and do not offer sufficient protection for families or communities in research. Whether it is prudent and, if it is, how to develop and implement protections for communities is unclear and controversial. One important line of work will critically examine community boundaries, risks to communities and the legitimacy of existing protections. If such protections are developed, they will evolve

along the same lines as those that protect individuals in research: after a dialectical process of proposing safeguards, considering their moral basis and appropriateness, and evaluating their effectiveness in practice. Reviewing existing guidelines for conducting research in aboriginal communities reveals five major categories of protection that extend chronologically from consultation over research design through community-informed consent to dissemination and publication of research results. Attempts to extrapolate these extensive protections to dispersed, less cohesive communities are problematic. For example, we conclude that extending requirements for community consent to communities with no legitimate political representation is an error. We must delineate carefully the morally relevant features of distinct communities and balance the extent of the protections to the different types of communities.

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