Background Paper on Issues of Group, Community or First Nation Consent in Health Research

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This Working Paper Commissioned by the Aboriginal Ethics Policy Development Project and supported as a joint undertaking of the Canadian Institutes of Health Research -Ethics Office and Institute for Aboriginal Peoples Health.
Contract No.: 270-03-0042 (Group Consent)

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November 2004

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Executive Summary

This working paper summarizes a cross-section of the growing international literature on research ethics and Indigenous communities. We have extensively utilized literature and research policy documents developed by Indigenous and non-Indigenous researchers, organizations and governmental bodies involved in research ethics policy. The paper incorporates insights from our own experiences in research and ethical review; however, we recognize that our own perspectives are those of non-Aboriginal academic researchers, ethics policy advisors and research ethics board members. Although we share a commitment to research policy development by Aboriginal communities, organizations and governments, we also acknowledge that our perspective cannot reflect the lived experiences of Aboriginal research participants, researchers or their communities.

The four primary sections of this background paper include:

1. An analysis of current and historical literature and case materials applying frameworks for group, community or First Nation consent.
2. A review of international policy documents applicable to Indigenous research ethics and other literature relevant to the concept and application of community consent in Canada, the United States, New Zealand and Australia.
3. An examination of the issues to be addressed by external Research Ethics Boards [REBs] and Indigenous advisory committees in order to ensure an appropriate evaluation of frameworks for individual and group consent.
4. A description of current and emerging research ethics policies; identifying and evaluating alternative approaches to negotiating community consent.

The paper concludes with several key recommendations:

1. Require REBs to develop and apply informed definitions of community, including who/what constitutes a community and how to determine who legitimately speaks for that community.
2. The role of the REB in the review and development of guidelines for community-based research must be re-examined and articulated.
3. Development of any new policies should include Aboriginal community representation and membership on external REBs as well as implementation and input from community advisory committees or regional REB reviews.
4. In tandem with a review of the research proposed for Aboriginal communities, REB members should familiarize themselves with the following issues:
    a. local community knowledge
    b. participatory and consensus-oriented decision-making processes;
    c. history of research relationships with Aboriginal communities;
5. Consultation and educational forums should be developed to inform Aboriginal communities and policy makers of the historical, cultural, scientific and ethical frameworks of REBs.
6. A formal agreement between the community authority and the investigators should be established at an early phase of the project. Comprehensive agreements should negotiate and detail issues including data ownership, interpretation/analysis and publication. Such agreements are intended to protect both researchers and participating communities from unreasonable restrictions on access to data or the right to publish findings.

Preface

This working paper explores a number of initiatives to respect Aboriginal communities through the application of frameworks for informed decision-making and consent to participate in research by Aboriginal groups or First Nations. It is intended to provide conceptual, historical and international policy background to support consultation, initiated by Aboriginal Ethics Project, on behalf of the Canadian Institutes for Health Research, with relevant representatives of primary stakeholder communities.

Objectives

The objectives reflected in the four primary sections of the Background Paper include:

1. To analyze current literature and case materials applying frameworks for group, community or First Nation consent; identifying the impact of cultural and historical context and prospects for consensus and divergence.
2. To review international policy documents and other relevant literature on the concept and application of community consent in Indigenous research ethics policy in Canada, Australia, the United States and New Zealand.
3. To examine issues to be addressed by external Research Ethics Boards [REBs] and Indigenous advisory committees in evaluating appropriate frameworks for individual and group consent.
4. To describe current and emerging research ethics policy frameworks identifying the advantages and disadvantages of alternative approaches to negotiating community consent.

The Author's Perspectives

This working paper summarizes a cross-section of the growing international literature on research ethics and Indigenous communities. The analytic perspective is based on the authors' experience with research and research ethics in Canada and the United States. We have extensively utilized the growing body of literature and research policy documents developed by Indigenous and non-Indigenous researchers, organizations and governmental bodies involved in research ethics policy. Although we have incorporated insights from our own experience in research and ethical review, we recognize that our own perspectives are those of non-Aboriginal academic researchers, ethics policy advisors and Research Ethics Board members. Although we share commitment to research policy development by Aboriginal communities, organizations and governments, we also recognize that our perspective cannot reflect the lived experiences of Aboriginal research participants, researchers or their communities. The perspectives presented in this working paper consequently reflect our individual interpretations.

SECTION I:

ISSUES OF GROUP, COMMUNITY OR FIRST NATIONS CONSENT IN HEALTH RESEARCH ETHICS

The Interagency Advisory Panel on Research Ethics (PRE) has been charged with revising or redeveloping Section 6 of the Tri-Council Policy Statement (TCPS) in collaboration with multiple partners including the Canadian Institutes for Health Research. As part of this process, the Institute for Aboriginal Peoples' Health's ACADRE network plan to consult with stakeholders through a series of invitational workshops to be held in the fall of 2004 involving Aboriginal research, policy, ethics, and research participant communities. The focus of the consultation process is on the development of health specific research ethics guidelines that will contribute to the development of a revised Section 6 with a specific commitment to honouring the values, cultural, and policy perspectives of Aboriginal and First Nations peoples in Canada.

This report is designed to provide background information from an academic and Research Ethics Board perspective on the conceptual basis of group consent and protection of communities for knowledge translation and stakeholder consultation in these workshops. As background material, this paper provides detailed information on frameworks, processes and the historical context of Aboriginal research ethics in the experience of Australia, New Zealand, and the United States, based to a large extent on materials from Aboriginal communities in those areas. The primary focus is how these guidelines and review processes have engaged the concept of group consent and protection of communities and therefore, summarizes some of the models that have been adopted to insure the rights of communities are incorporated into the

research ethics review process. The document will also review the experience of indigenous, research and science policy communities in Canada, New Zealand, Australia and the US in relation to the implementation of these guidelines.

The document is designed to guide discussions and facilitate development of guidelines and strategies through a dialogue involving individual and First Nation research communities.

Individual Consent and the Role of Autonomy in Research Ethics

The emphasis placed on individual autonomy and the ability to be self-determining comes to North Americans from basic western liberal democratic political traditions now embedded in both legal and ethical principles as well as in the law itself. The law protects the individual, making it illegal to touch a person or to divulge confidential information without his or her consent. The doctrine of consent to treatment has a long history in Anglo American jurisprudence, with the emphasis on informed consent developing in the 1970s and 1980s. While precedence setting legal cases defining the need for informed consent did not deal with research situations, the notion of personal autonomy and the importance of the right of self-determination have influenced regulations and guidelines in both Canada and the United States. A highly individualistic decision-making process in medical practice and research has developed around the principle of autonomous choice. The basic premise underlying this process is that the best protection for patients or research subjects lies in their ability to make autonomous, informed choices (Greely, 1997; Burgess & Brunger, 2000). In the words of Burgess and Brunger:

> Informed consent is typically considered an ethically adequate model to manage effects on individuals because the risks and benefits evaluated are specifically the direct effects of research on the individual. Disclosure…grants full control over exposure to risks and benefits (Burgess & Brunger, 2000: 120).

Individual informed consent is also part of the international research background (Greely, 1997). As an expression of autonomous choice, it is seen as a crucial component of research participation. The promulgation of the Nuremberg Code raised awareness about the importance of voluntary consent to participate in research, which is deemed "absolutely essential" (U.S. Government, 1949). It detailed the requirements for consent to participate in research in the following terms:

> This means that the person involved should have legal capacity to give consent; should be situated as to be able to exercise free power of choice, without the interference of any elements of force, fraud, deceit, duress, over-reaching or any other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment (U.S. Government, 1949).

The principles of Nuremberg were influential in drafting of the World Medical Association's Helsinki Declaration. The Declaration has underscored the importance of individual rights and informed consent since its first version in 1969. The most recent version states the following:

> In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, and possible conflicts of interests, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it might entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should obtain the subject's freely given informed consent, preferably in writing (World Medical Association, 2002: 2).

In America, the predominant framework for evaluating ethical issues in clinical research is found in the Belmont Report (National Commission, 1979). This report identifies three ethical principles to govern research involving humans: respect for persons, beneficence and justice. The first principle described, that of respect for persons, requires protection of individual

autonomy. The emphasis on individual rights was not surprising at this time given the fight against physician paternalism and the concern for individual rights at the core of the American consumerism movement in America in the early 1970s (Levine, 1988). The Report forms the basis for the US Code of Federal Regulations governing research as well as other national and international policies for the ethical conduct of research, including the 1987 guidelines of the Medical Research Council of Canada [MRC] and the current Tri-Council Policy Statement [TCPS] adopted in 1998 (TCPS, 1998).

The requirement of individual informed consent for research has been widely adopted across the world. Although many nations do not agree with all aspects of American models of informed consent, particularly their stress on "…written, legalistic documents", the concept is widespread, though as Greely points out, "…not entirely uncontroversial" (Greely, 1997: 1397).

The notion of individual rights has affected the way in which academics, including scientists, are treated as well. Academic freedom for the individual professor has always been highly prized. In the sciences, "freedom of scientific inquiry" has been a "watchword" of scientific endeavours. In the case of researchers, those who might inhibit the freedom not only of inquiry but also of publication might be governments, employers, such as universities, or research sponsors, both public and private.

The Emerging Concept of Group in Community Consent

The emphasis on individual rights in contemporary research ethics and its codes, regulations and guidelines has been criticized for failing to take into account important relationships such as family or community (Weijer, 1999a; Kaufert et al., 1999).

Weijer suggests that we should adopt a separate principle of "respect for communities" that could be added on to the principles protecting individual rights found in the Belmont Report (Weijer et al., 1999a). He bases this approach on his analysis with colleagues of codes of research ethics developed by indigenous communities and organizations. He proposes that "[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" (Weijer et al., 1999a: 275). This is required because when research involves communities, new issues arise. "Autonomous communities have their own politics, beliefs and values and research may affect any of these elements" (Weijer, 1999c: 505). Weijer's emphasis is on the community's interests, which he argues are separable from individual interests.

Greeley, who writes in the context of genetics research, argues that because genetic research is not about individuals, but about groups, the notion of individual autonomy is "artificial". "It is the group's collective autonomy that is challenged if researchers, with the informed consent of only a few individuals in the group, can probe for information about the whole group" (Greely, 1997: 1431). Groups have reputations which, defined broadly, can be harmed. As a result, Greely argues that consent should be sought from:

[C]ulturally appropriate authorities within the community, where such exist, or through consensus of the entire community, where there are no relevant authorities (or where a consensus is the culturally appropriate authority) (Greeley, 1997: 1431).

Defining Groups, Communities, First Nations and Tribes

Attempts to define 'community' and 'community consent' have been plagued by conceptual and operational problems, but this debate over terminology also reflects a general and continuing lack of consensus over their meaning. The risks of not having some form of agreement became evident during the work of the Tri-Council Working Group, when different interpretations of the concept of collectivities and communities contributed significantly to the interpretation of the 1998 version of the Tri-Council Guidelines (TCPS, 1998). In this section, we first review some of the work that has been done by ethicists and others who tried to bring theoretical and conceptual order to the debate over terminology. We then discuss the implications of their conclusions when applied to First Nations, Inuit and Métis peoples. As part of this discussion, we reflect on what is distinctive about their communities relative to other forms of collectivities, particularly the implications of claims to legal status and political sovereignty for the definition and implementation of 'community consent'.

Fern Brunger and Michael Burgess (2000) and Charles Weijer (1999a; 1999b; 1999c) have been major contributors to the scholarly work on conceptualizing the meaning of community. Brunger and Burgess (2000) argued against defining community by a single characteristic and are in favour of a continuum based on the use of multiple criteria; they re-introduced a new word and concept into the debate, the notion of 'collectivity'. In their view, the notion of collectivities

had been used in earlier drafts of the Tri-Council Policy Statement, but deleted from the Tri-Council Policy Statement approved in 1998 because legal consultants felt the concept was ambiguous and not enforceable.

> Collectivities are constituted by webs of moral relations and networks of social obligations. However, the importance or strength of these relations and obligations will vary depending on the strength of cohesiveness of the collective (Burgess & Brunger 2000: 126).

By the terms of this definition, a population aggregate defined by a single characteristic (such as gender), or any other grouping made up of individuals with only a very weak common identity or sense of mutual obligation, is not a collectivity. In their submission to the Law Commission of Canada, Burgess and Brunger (2000) emphasized the critical importance of social cohesion which they described as the product of several different characteristics, such as a common history, a geographical location, a shared culture and lifestyle, shared values, well established social obligations and a strong sense of common identity. None of these characteristics were proposed as definitive criteria, but were recognized as having variable influence and requiring application of multiple dimensions.

Burgess and Brunger (2000) were interested in the transformation of population aggregates into collectivities, particularly when the initial population was first identified on the basis of a common illness or genetic trait (such as HIV/AIDS or Huntington's disease). Factors involved in the transition process included the recognition of sharing experience, the willingness to combine in order to achieve some mutual objective (such as more money for research or access to new drugs) and the decision to take collective action to achieve these goals. In the case of HIV/AIDS and the breast cancer movements, a high level of frustration with the slow pace of research were critical drivers, although Brunger and Burgess (2000) use examples in which

research was a key factor in encouraging the transformation of a study population into a new community. They write:

> …the research process can lead an aggregate to have collective interests. Most obviously, this would happen if the research process focuses attention on the disease; and over time, the individuals identify themselves as a collective, organizing as a group, appointing media spokespeople, lobbying for increased research funding and gaining a sense of themselves as a collective (Burgess and Brunger, 2000: 127).

Disease based collectivities may create an organisational structure, capable of collecting and distributing money (often to researchers) and lobbying government and other financial institutions for increased funding. They do not have a geographical base and neither do they have legal or political status.

First Nations: Communities and Collectivities

First Nations communities have land, legal, political and constitutional status as well as many of the other criteria listed by Burgess and Brunger (2000). Weijer (1999a; 1999b; 1999c) listed a number of characteristics that are either unique to First Nations communities, or more common in these communities. They include geographic isolation, common histories and traditions that are distinct from the dominant culture and political sovereignty. Weijer et al. (2000) note that most types of communities, with the exception of Aboriginal and First Nation communities, lack characteristics crucial for ensuring both a fair and representative process of informed community consent. In their view, the combination of strong community ties, a recognised leadership structure and established methods of determining the views of the larger group, suggests that it would be possible to develop a meaningful process for eliciting community consent including setting up community review boards (Burgess & Brunger, 2000; Weijer et al., 2000; Weijer, 1999a; 1999b; 1999c).

The idea of community review boards has generated considerable debate, particularly in relation to genetic research (Foster et al.1999). Proponents of these boards in the United States endorse the need for community review in population specific genetic studies and support the authority of existing health governance structures or community based research ethics boards (Greely, 1997; Foster et al., 1999). Canadian guidelines governing health research remain silent on the issue of community consent and consequently, some First Nations such as the Mohawk of Kahnawake and the Mi'kmaq, have begun developing research guidelines acceptable to their specific community (Brant-Castellano, 2004). Such guidelines tend to emphasize the uniqueness of each community and hence, the need for approval of research studies that could have implications for the community as a whole.

Critics argue that community or tribal review may confuse social and biological categories of community oversight (Juengst, 1998a). They also suggest that in large culturally heterogeneous and geographically dispersed populations (such as urban indigenous communities) community review may be impractical (Juengst, 1998b). Some critics have even described the idea of community review as "paternalistic" and "inherently demeaning" (Reilly, 1998: 684) and argue that it gives special consideration to particular stakeholder groups.

A related issue is how researchers and communities decide when a project involves a community and thus, requires permission. Community review processes may also need to establish mechanisms for determining whether decisions of community leaders are ethically appropriate,

even if legally recognized. (Weijer, 2000; Clayton, 2002). Foster et al. (1999) quote the views of the Committee on Human Genome Diversity:

> Of special concern to critics of community review is whether researchers should be required- as a matter of regulatory policy- to consult with communities before beginning their research and whether communities should have authority to veto a research proposal….Critics suggest that, although researchers might be commended for seeking community approval, regulatory requirements that they always do so are too extreme (Foster et al 1999: 1720).

Other arguments are based on the rights of individuals to participate in research that may identify personal illnesses or genetic risk factors, facilitate treatment and develop preventive strategies within kinship networks and populations. Individuals or groups sharing these traits may oppose the right of a community review board to refuse a research project or to insist that a project must be reviewed and its risks and benefits be evaluated, not just for the individual, but for the community as a whole (Juengst, 1998b).

Supporters of community review argue that community consent would add extra protections to vulnerable communities in situations when the results of a research projects may have implications for everyone in a community and not just those individuals who participated in the research as subjects (Foster et al., 1999). The objective of community review is to require a dialogue between researchers and community members to allow both sides to identify risks and define ways of managing risks from inside the Tribe or First Nation. This type of collective risk might not be considered if a community review were not in place. The extra step would help ensure that it was identified and understood (Burgess & Brunger, 2000; Juengst, 1998b).

The most obvious risk to a community is that a research project will produce data emphasizing the negative health outcomes that may have serious implications either for the community as a

whole or for certain members of its subgroups. When community members are intricately connected to one another by kinship and others ties, the impact of negative research results can have severe implications. There may be reluctance to marry into a family identified as carrying some form of hereditary disease, such as chronic arthritis or early onset diabetes. Behavioural genetics is developing slowly, but researchers are hunting for genetic mutations that will make an individual more vulnerable to depression or addictions involving smoking, substance dependence or gambling. Fear of stigmatisation is understandable given the history of many First Nations and their awareness of the dangers of negative stereotyping.

Other risks of genetic research are less obvious, but may be of very real concern. Genetic research may call into question the origin of particular kinship groups, possibly challenging their rights to Treaty Status or to settlements in relation to Land Claims. The risk may be historical and cultural as researchers use genetic data to explore the origin of a group and produce evidence that contradicts traditional stories of origin and questions fundamental values defining the basis for a collective sense of identity.

Foster et al. (1999), suggest that many opponents of community review ultimately justify their opposition on what they believe are potentially problematic areas of the review process, but without having actual experience of working in collaborative consultation with tribal communities (Foster et al., 1999). Their own position, arguing in favour of community review is based on case studies of two Native American Tribes and their experience of a community consultation involving genetic research projects. In both cases, the review process included a careful assessment of cultural and collective risks of concern to each community. The fears of

critics that collective decision-making would conflict with or erode individual autonomy were not realized. Both case studies showed that it was possible to balance community concerns with the choices of individual research participants. They also demonstrated the strength of local values supporting the collective decision of the community to make decisions. They also found in both communities a general acceptance of the subordination of individual rights of community members to the collective judgment of the community as a whole.

Foster et al. recognize the problems of generalizing their observations to larger geographically dispersed communities. They acknowledged that in the two communities described in their case studies:

> …consensus was reached within private social units, not through political organizations or established moral leaders. In this way, a number of private social units and their members were involved in reviewing the implications of genetic research. This broader engagement of community members is preferable to reliance on a small number of leaders who may have individual agendas that fail to reflect the full range of community concerns. When political organizations and their leaders were involved, their role was to formally ratify the consensus reached by the private social units, not to shape it. Thus our experiences suggest that community review can take place in populations lacking established, inclusive political organizations and readily identifiable leaders (Foster et al., 1999: 1722).

Community review and collective consent to participate in research may be complicated in communities where populations are nested within other populations, and sub-communities may be either over or under-represented in the community leadership (Juengst, 1998a). The interests of small sub-communities in having a research project go forward may conflict with the interests of the wider population and agenda of elected leaders. These leaders may be more concerned with the risks of research for discrimination, stigmatization or fair transfer of benefits of research to the overall community. Foster et al. (1999) propose their own solution for dealing with plural

agendas and nested populations. Their proposal involves forums to assess the various risks presented at different levels of social identity:

> The form that community review should take will vary between populations, depending on the pre-existing collective decision-making processes that are already in place. Thus, community review is a spectrum of different activities, including holding informal discussions with members of a community, involving community members in the planning stages of research, asking the community to participate in the evaluation of human subjects' protections, and negotiating formal agreement with the community. Clearly, not all these activities are appropriate for every population (Foster et al., 1999: 1723).

Brunger and Burgess (2000) also discussed the problem of overlapping ties and identities, competing stakeholder groups and leadership factions, but still supported the principle of community review and community consent.

Conclusion

Writing on the Canadian situation, Burgess and Brunger (2000) and Weijer et al. (2000) recognise that First Nation and Aboriginal groups are quite distinct from most other types of communities. They also advocate some system of establishing protections for Aboriginal communities in the area of health research. The last point is particularly poignant, for it is important to recognize that even if some Aboriginal communities may not meet all the criteria on the cohesiveness and/or homogeneity continuum, such communities still have distinct legal and constitutional rights and thus, have political legitimacy to make decisions about issues, including health research projects, which directly affect the community. Aboriginal leaders might argue, however, that their rights to community consent are inherent in the legal, political and constitutional rights as Aboriginal people that ground their authority to and that is for their communities to make decisions about issues which they see as likely to affect the community as a whole. In this sense, they are not dependent on whether or not they satisfy the criteria of being

a community as defined by an external body or on whether or not a research ethics board rules in favour or against community consent.

SECTION II:

FIRST NATIONS, COMMUNITY CONSENT AND HEALTH RESEARCH: INTERNATIONAL, NATIONAL AND LOCAL FRAMEWORKS FOR DETERMINING CONSENT

This section reviews the different interpretations of the meaning of the term "community consent" in the context of health research. The primary focus is on how the principle of community consent has evolved in relation to research undertaken in Inuit, Métis and First Nations communities in Canada and, we have included materials on community consent from the United States of America, Australia, and New Zealand, plus international and pan-Indigenous forums. This report is not intended as a comprehensive review of policy in relation to research on the health of Indigenous people or of the control over this research exercised through the research ethics review process. Rather its purpose is to explore how different jurisdictions have dealt with the rights of communities to be informed and with their rights to give or withhold consent to research.

Policies in relation to research ethics vary from country to country and between different institutions and communities even within the same country. We have organized our analysis by national and regional levels of government and by national, regional, and local levels of Indigenous organizations (see **Figure 1**):

1. Codes, regulations and documents relating to the governance of scientific research issued by national government agencies;
2. Policy documents and statements on ethics issued by non-governmental agencies representing Indigenous peoples at a national or international level;

3. The management and implementation of research ethics review by research ethics boards operated at the local and regional level by Indigenous and Non-Indigenous governmental or non-governmental agencies (such as universities);
4. The management and control over research access exercised at the local and community level by Indigenous organization (such as Band councils, First Nations and Tribal Organization);
5. Defining community consent, or determining how it is best implemented, has been an issue for the organizations that operate at each of these different levels.

Once national governments decided to claim responsibility for the ethics and regulation of all scientific research involving human subjects, their initial interest was in the development of multidisciplinary codes based on "universal" principles. These codes usually included sections on the protection of children or the intellectually impaired, but disregarded most other forms of differentiation. More recently, some governments have responded to demands from their Indigenous communities for a separate framework, which would recognize Indigenous values and their rights to determine access for research in their own communities. Governments in Australia, for example, have included specific statements on the ethical values and that should govern research within Indigenous communities.

Indigenous organizations operating at the national level (such as the American Indian Law Center in the United States) have challenged the notion of universal principles and have developed guidelines for scientific research based on Indigenous values, particularly the moral significance of the community as distinct from the individual and, recognizing the importance of

having the community consent to research as well as the assent of the individual. Examples include the Model Tribal Research Code developed by the American Indian Law Center (1994), the National Aboriginal Health Organization [NAHO], Ethics Tool Kit (2003) and First Nations Longitudinal Regional Health Survey: Code of Research Ethics (NAHO 2004). Both these last examples are Canadian and assume the legitimacy and sovereignty of First Nations, Inuit or Tribal communities to control research within their boundaries (Brant-Castellano, 2004).

While general statements on ethical principles and codes of practice are the responsibility of national or international level Indigenous organizations, the application of these principles and regulations is often worked out by organizational structures at the state, province or regional level. Examples include the regional Institutional Review Boards (IRBS) within the US Indian Health Service (Freeman, 2003) and the Regional Aboriginal and Torres Strait Islander Boards (National Health and Medical Research Council [NHMRC], 2003) in Australia. Some of these regional level organizations have published their own guidelines on the requirements that must be satisfied by researchers wishing to work within their jurisdictional area. Canadian examples include the Participatory Research Process for Dene/ Métis Communities (Masuzumi, Quirk & Denedeh, 1993) and The Model Agreement (Inuit Tapirisat of Canada [ITC], 1993) put out by the Inuit Tapirisat.

Responsibility for the implementation of these guidelines is usually passed to the local level and given to advisory boards, Band or Tribal councils or locally appointed research ethics committees. Some guidelines, however, have been developed at the local, rather than the national or regional level and often in relation to a specific project. The Kahnawake Schools

Diabetes Prevention Project Code (Macaulay, Delormier, et al., 1998), for example, was developed by the Kahnawake First Nation to govern relationships between diabetes researchers, community advisory structures and individual participants. This code then became the model for other research projects in the same community. Consequently, a number of agreements have emerged out of this type of "bottom up" approach for creating an ethical framework.

Seen from a global perspective, the ethical guidelines specific to health research within Indigenous communities, whether formulated at the national, regional or local level, are very similar in character. There are variations reflecting differences in the history of research ethics within each country and also on the political and other relationships between the government, Indigenous peoples and the scientific research community. Some points of similarity may result from the interchange of reports and discussion papers between those working on the development codes and guidelines for research in Indigenous communities. A more important factor is that these codes are based on values and principles that are held in common across many Indigenous peoples. Regardless of the level (national, regional, or local) these codes focus on the quality of the relationships between the researcher, the community and the individuals who participate in research. They emphasize the importance of trust, reciprocity, and respect for local knowledge in these relationships. The frameworks proposed by the First Nations and Inuit Regional Health Survey Project (Code of Research Ethics, 1997), for example, stress mutual commitment to the principles defined as OCAP (Ownership, Control, Access and Possession) as the basis for self-determination in research (Snarch, 2004). They often require that research should focus on locally relevant problems, or that there be a commitment to community-based capacity building and the generation of local knowledge. In their determination to ensure that

research represents interests of the community, local guidelines may insist that their rights extend to an evaluation of the methodology to determine whether a project is culturally appropriate, and examine plans to analyze data and disseminate results in a form useful to the community.

The core principle running through all these codes and ethical guidelines is that the community, not just the individual, must give consent to research. In the States, national governments with a significant Indigenous population have been under increasing pressure to include a statement of this principle in their national codes governing scientific research in Indigenous communities; the problem for these governments lies in determining what is meant by community, as distinct from individual, consent. This review goes through the answers and ideas implemented by Indigenous communities to help answer this question. It is organized on a country-by-country basis, starting with Canada.

Canada

The Canadian Federal Government set up the Tri-Council Working Group on Ethics for Research Involving Human Subjects in 1995 as part of a larger initiative directed at the transformation of scientific research in Canada. The mandate of the Council was to develop an over-arching, multidisciplinary framework that would lead to the creation of a unified ethics code acceptable for research in all disciplines, whereas previously each of the three councils responsible for funding research in Canada (MRC, NSERC and SSHRC) had their own codes of ethics. These codes varied from council to council depending on the ethical concerns of different disciplines. Health research was largely (although not exclusively) funded by the Medical Research Council (MRC). Its code of ethics focused almost exclusively on protecting the

confidentiality and autonomy of the individual patient and their rights to informed consent. Health research by social scientists was usually funded by the Social Sciences and Humanities Research Council (SSHRC). Its guidelines advised researchers that they should consult with community leaders if working in an Indigenous community, but the Council did not demand formal evidence of community consent. While social scientists often did consult the leadership of the local community in which they were doing research, they often presumed that community access depended on the relationships they had established with the local members of the local community. Many were hostile towards any suggestion that their right of access should depend on the oversight of an external organization, such as a funding council or an Indigenous authority at a territorial or regional level.

One of the tasks of the Tri-Council was to reconcile the differences between the very narrow medical interpretation of ethics in research favored by the MRC code and the more flexible codes used by the social sciences and humanities. The first draft of the new guideline, circulated by the Tri-Council in 1996, generated strong criticism from the research community, who felt that particular methodological concerns had been neither understood nor acknowledged. Consequently, two more drafts were circulated between 1996 and 1998, but the same criticisms remained and in addition, there were concerns that the rewriting process had been neither transparent nor democratic.

Attempted revisions of the Tri-Council Policy Statement to produce the new code also occurred within a timeframe when groups outside the research community were demanding a stronger voice. Groups such as people with HIV/AIDS and women with breast cancer demanded more

say in how research money was spent and how research was conducted. Other demands for greater control over the content and process of research were expressed by Indigenous organizations and were based on claims that their communities not only had physical boundaries but also political status.

In response to concerns expressed by various groups, the Tri-Council working group considered whether or not there should be a separate consent process for research projects that targeted groups represented by some form of community structure or organization. Reflection on the topic ultimately resulted in a second draft of the guidelines, which included a section on the difference between individual and group consent. Struggling with how best to define what they meant by group or community consent, the second draft adopted the term 'collectivity'; however, this term was defined so broadly that it included not only Indigenous communities, but also ethno-cultural groups (such as the Ashkenazi Jewish population), groups based on a common illness or genetic risk (people living with HIV/AIDS or at risk of Huntington's disease). The ambiguity of the concept was challenged by lawyers and by Indigenous organizations on the premise that it did not differentiate between these other groups and communities such as the First Nations, which asserted their own clear political identity and had legitimate, well-established authority structures.

When the third draft of the Tri-Council Policy Statement was distributed in 1998, the section on collectivities had been replaced by section 6 on research in Indigenous communities (Tri-Council Policy Statement [TCPS], 1998):

> The present document refers to the rights of communities and there is growing recognition that some research involving Aboriginal individuals may also involve the communities or

> groups to which they belong. The Councils affirm that in developing ethical standards and practices, Aboriginal peoples have rights and interests which deserve recognition and respect by the research community (TCPS, 1998: 1.1).

Section 6 does not offer much detail nor does it discuss the rights of communities to block research that they deem irrelevant, harmful or involving unacceptable risk, but it does challenge the freedom of the researcher to pursue projects which could result in a negative characterization of Aboriginal communities. The Tri-Council Policy Statement reads:

> A general principle is that the obligation to respect human dignity in research involving Aboriginal groups gives rise to both special considerations and to basic ethical duties regarding ethics review, informed consent, confidentiality, conflict of interest and inclusion (see sections 1-5) This principle is not intended to preclude critical inquiry and research, or research that may come to negative conclusions; it seeks to advance accurate, informed and ethical research (TCPS, 1998: 6.2).

Section 6 was prefaced by a statement acknowledging that insufficient consultation had taken place with Aboriginal communities or with their regional and national organizations.

> During the drafting of this Policy Statement, suggestions were made to create a Section dealing with research involving Aboriginal peoples. The Councils, however have not held sufficient discussions with representatives of the affected peoples or groups, or with the various organizations or researchers involved. The Councils have therefore decided that it is not yet appropriate to establish policies in this area (TCPS, 1998: 6.1-6.4).

Typically, if research involves Aboriginal communities or tribes, researchers and REBs should consider the interests of the aboriginal group whenever:

1. property or private information belonging to the group as a whole is studied or used.
2. leaders of the group are involved in the identification of potential participants.
3. the research is designed to analyze or describe the characteristics of the group.
4. individuals are selected to speak on behalf of, or otherwise represent the group (TCPS, 1998: 6.2).

Although it does not refer directly to participatory models, there is an acknowledgement that Aboriginal organizations wanted a larger role in the planning, conduct, analysis and dissemination of research results. Section 6 advises researchers to include community expertise in their consultation process. It also recommended that the community should have rights to oversee and monitor the research process.

Lastly, section 6 also suggests that researchers and research ethics boards involved with Aboriginal communities should familiarize themselves with the "good practices" put fourth by the Working Group. Included in the concept of “good research practices” is the notion that researchers should respect culture, traditions and knowledge of Aboriginal communities, consult with local experts, conduct research in partnership with the community, involve the community in the design of the project and shape the research, so as to address the needs and concerns of the community (TCPS, 1998: 6.2). However, in contrast to the strong directives defining ethical practice in other sections of the document, these practices are phrased as suggestions or recommendations rather than as requirements.

The commitment to consult with Aboriginal communities was important, although the mechanism for implementing consultation still is not well defined nor comprehensively informed. It will be undertaken by the CIHR Institute for Aboriginal People’s Health working with ACADRE centers to consult with stakeholders in First Nations, Métis, urban Aboriginal, and Inuit communities. This broader consultation and consensus formation process will identify values, principles and alternative frameworks.

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Indigenous Initiatives at the National Level

The influence and relevance of Aboriginal codes and working papers on research ethics were partially acknowledged at the time the Tri-Council Policy Statement was adopted in 1998; however, there was no suggestion that alternative Indigenous guidelines or value statements should in any way replace the ethical codes imposed by national research councils. Rather, the Working Group emphasized the guidelines developed by Indigenous communities should merely be treated as a set of additional requirements whose purpose it is to ensure that the rights and interests of the community as a whole are respected (TCPS, 1998: 6.1).

The current process of community consultation being undertaken by the CIHR Institute of Aboriginal Peoples Health with a wide range of stakeholder communities through the [ACADRE Centers], builds on a series of initiatives by First Nations and Aboriginal bodies at a national level. In 1998, the Steering Committee of the First Nations Regional Longitudinal Health Survey articulated the (OCAP) principles which continue to have significant implication for self-determination in research and community ethical oversight. The principles emphasize "(1) collective ownership of group information; (2) First Nations control over research and information; (3) First Nations management of access to their data; (4) physical possession of

data" (Schnarch, 2004: 80). These principles have been widely discussed as a framework for assessing and controlling research, monitoring/surveillance of survey research and documentation of cultural knowledge.

The projected benefits of implementing the OCAP principles as the basis for First Nation or Community research relationships include re-establishment of trust relationships, improvement in research quality, emphasis on local relevance, decreasing bias, development of community capacity and general empowerment. (Schnarch, 2004) A significant challenge in the community consultation process will be obtaining input from both First Nations and research communities about how the principles can be operationalized and implemented within both the existing academic research ethics review system and within Community/First Nation review of protocols.

Another more recent Aboriginal initiative has been the development and broad distribution of the National Aboriginal Health Organization's *Ethics Tool Kit* (NAHO, 2003). The *Tool Kit* is designed to be a resource for First Nations communities planning their own research and also provides guidance for communities to evaluate the ethical dimension of research proposed by external investigators. Due to its accessible format and clear expression of First Nations Confederacy/National Aboriginal Health Organization Policy, the *Tool Kit* may provide an example in stakeholder consultations involving the ACADRE Centers.

Indigenous Initiatives at the Regional Level

National level initiatives by First Nations and Aboriginal organizations to decolonize research processes and improve community ethical oversight were preceded by several innovative models developed by regional organizations in Canada.

Barney Masuzumi has described a number of initiatives by regional Aboriginal organizations to increase the involvement of their communities in the ethical review process (Masuzumi et al, 1993). Several of the most widely referenced frameworks developed by First Nations communities and national or regional Aboriginal organizations in Canada and Australia have used the participatory action research framework.

The conventional model for health research is one in which the investigators maintain exclusive control over the research process throughout all of its phases, including the presentation of its results; the participatory action research model is very different. Participatory action research aims to involve and empower individuals and communities and enable them to assume ownership of the research process. Typically, this framework requires researchers to engage in consultations with key stakeholders and communicate with the whole membership. This process of consultation precedes community approval, but is maintained through all phases of the research. The purpose of these consultations is to ensure that the research question is locally relevant and that the research methods are both culturally appropriate and reflective of local knowledge. Examples of frameworks developed by regional Aboriginal organizations include: *The Inuit Tapirisat Background Paper on Negotiating Research Relationships in the North* (Inuit Tapirisat of Canada [ITC], 1993) and *Dene Tracking: A Participatory Research Process for Dene/Métis Communities* (Masuzumi et al, 1993).

The *Inuit Tapirisat Background Paper* and the *Dene Tracking* paper were drafted as discussion papers or proposals for an alternative process of ethical review and community collaboration for

the research process. Such papers include a template for community consent in the form of a mutual agreement between the researcher and the community, outlining their reciprocal obligations and the conditions of community access. As an alternative to the conventional model whereby consent is sought only at the start of a research project, the participatory action model treats research as a continuing process requiring continual monitoring and renegotiating of the consent agreement.

The ITC working paper advocated the development of mechanisms of enforcement which went beyond the "moral authority" of existing codes of research ethics. It states:

> The new legal regimes affecting research do not supplant or replace ethical guidelines, but they do place them in a different context. Where power, authority, and knowledge are clearly unequal, ethical guidelines seek to place limits on the exercise of power by the powerful-chiefly by moral persuasion. Guidelines are usually stated as principles, without much implementing detail and they are normally voluntary. The claims provisions empower the representative bodies of the Inuit to exercise some control and authority over some types of research; ethical research guidelines continue to apply to the participation of both individuals and communities in research. But the general trend is for voluntary compliance to be supplemented by, if not replaced by, binding negotiated arrangements which are in some cases mandated by law (ITC, 1993: 2).

At the time the paper was written, the Inuit Tapirisat already recognized the future power of Inuit governments to enforce binding, legally mandated agreements and to demand equitable research participation. Indeed the paper laid the groundwork for the current initiatives by the Nunavut government as it becomes increasingly active in review of research and the enforcement of ethical principles. The report laid out some of the key components of this new type of research model:

1. The development of culturally and linguistically accessible informed consent agreements at both community and individual levels;

2. Protection of community and individual rights to suspend research;
3. Guidelines for maintaining anonymity and confidentiality;
4. Agreements on the process to be followed in the interpretation of research findings including criteria for arbitration in cases of disagreement;
5. Agreements on the dissemination of results and ownership of data.

The ITC paper also dealt with the difficult question of, "…what constitutes research, emphasizing the perspective of individual participants and northern communities" (ITC, 1993:2). The document made clear the distinction between "research" and "surveillance". Research activities were subject to ethical review and evaluation, but the routine collection of administrative or clinical data generated by surveillance activities is not. Recent legislation protecting personal health information and regulating secondary use of aggregate data is continuing to generate problems in terms of local, provincial, and federal interpretation of data protection guidelines. The ITC paper proposed community-based ethics review of all research that was to be based on information collected in the community even if it had originally been collected for administrative reasons.

The ITC working paper offers a framework for developing agreements between the researchers, sponsoring institutions and Inuit communities defining mutual obligations, rather than emphasizing principles or detailed guidelines for monitoring and enforcement. The model extends to include all parties involved in the research project by having each specify their understanding of the research plan and mutual obligation at every stage of the research program. The process includes the agreement and understanding of: scope and purpose; methods;

provisions for community participation and skill transfer; data ownership and access to research results; confidentiality; dissemination strategy and media relations, and commitment to disclose all sources of support. Furthermore, community participation throughout the duration of the project may involve re-negotiation of objectives and modification of methods to insure that the final research product is useful for the community or First Nation sponsoring the work.

Community, First Nation or Tribal Level Frameworks and Review Boards

A significant influence in the development of Aboriginal research guidelines in Canada has been the development of guidelines at the local level. This "bottom up" process may provide a model for local community consultation on draft principles and guidelines in consultation with stakeholders in regional ACADRE Centers. A widely used model has been the *Kahnawake Code of Research Ethics* which was developed at the community level to deal with specific relationships in a participatory research program with the objective of preventing non-insulin-dependent diabetes.

Like most other indigenous codes or documents, the development of the *Kahnawake Code* was informed by surveying a wide range of indigenous ethics documents. The code defines a relationship between the communities of Kahnawake, community based researchers, and academic researchers at McGill University. As the case study of the multidimensional diabetes program presented here emphasized, the process of developing the *Kahnawake Code* has been as important as the formal document. Researchers met with the Advisory Board and successive drafts of the agreement were developed and circulated between researchers and board members over an eight-month period (Macaulay, Delormier, McComber, et al, 1998).

The final version of the code began with a policy statement that identified primary Mohawk community values and validated the sovereignty of the First Nation:

> The sovereignty of the Kanien'ke ha: ka (the people) of Kahnawake to make decisions about research in Kahnawake is recognized and respected. The benefits to the community as a whole and to individual volunteers should be maximized by the researchers. Research should empower the community to support community goals of health and wellness, to promote healthy lifestyles, improve self-esteem and fulfill its traditional responsibility of caring for the Seventh Generation (In Mohawk tradition, the Seventh Generation represents those as yet unborn) (Code of Research Ethics, 1997: 1-2).

In contrast to codes like the Tri-Council Policy Statement, which were developed to guide all research from a variety of disciplines, the *Kahnawake Code* makes explicit the wishes, perspectives, and values of a specific Mohawk community. It specifies the focus of the research on the problem of diabetes prevention and the commitment to the principles of participatory research.

The case study of the *Kahnawake School Diabetes Prevention Project* described at these meetings illustrates the development and continuing application of a code of research ethics developed at the community level defining alternative research relationships. Although they assert the generalizability of their experience and the resultant code, the developers also recognized that their recommendations "…should not be imposed on all research; rather that these ideas be discussed and individualized for each project" (Macaulay et al, 1998). This statement emphasized the value of the process, rather than the product as a generalizable code. In redeveloping the section dealing with community consent, the new versions of the Tri-Council need to be informed by, and be able to accommodate the frameworks defined by local frameworks.

Australia

The Canadian experience in redrafting initial versions of the Tri-Council Policy Statement, deleting generalized references to the concept of collectivities paralleled developments in Australia.

In both countries resistance from Indigenous communities and researchers resulted in the removal of the generalized reference to collectivities. However, the experiences of the two countries also contrast as the unitary Tri-Council Framework is distinct from the Australian experience of adopting a separate statement of *Draft Values and Ethics in Aboriginal and Torres Strait Islander Health Research* (NHMRC, 2003). However, despite some differences Australia has developed frameworks for research ethics review at the levels of:

1. Federal government;
2. Indigenous organizations at the national level;
3. State, territory or regional level boards; and
4. Community or local government level.

Federal Research Ethics Policy and Indigenous Research Ethics Initiatives at the National Level

In Australia, parallel development of both generalized and differentiated guidelines for research ethics in Indigenous communities has occurred for more than two decades. The need for oversight and a decolonization process in research ethics review involving Indigenous communities was recognized at a series of national and regional conferences in the mid 1980s. The outcome of these conferences, due largely to the demands from Aboriginal communities and

policy makers that Indigenous communities in South Australia take control of their own health and medical research, led to the formation of the Aboriginal Health Research Ethics Committee (Aboriginal Health Research Ethics Committee [AHREC], 1990). This period of development was characterized by external resistance from the research community, as described in the organization's newsletter:

> At the time the Committee experienced a great deal of resistance from the general community of researchers and non-Aboriginal agencies regarding the research requirements that the Committee set down to be followed. This phase was worked through successfully and as researchers began to understand the role of the Committee and its need in the community, gradual acceptance of its function was witnessed in their desire to work with and through the Committee (AHREC, 1990: 1).

Development of Parallel Indigenous Values Statements

In Canada while actions to develop and finalize the TCPS continued until 1998, in Australia, the National Health and Medical Research Council supported both the development and revision of the *Draft Values and Ethics in Aboriginal and Torres Strait Islander Health Research*, as a differentiated framework of Indigenous research ethics, and also supported the revision of an overall research ethics policy.

The Australian Health Ethics Committee formed the initial committee in the 1990s and began to review and revise the generalized framework (NHMRC, 1998), paralleling experiences reviewing and redrafting the Canadian Tri-Council Policy Statement. The Australian Health Ethics Committee also reviewed its general guidelines for health research (*Statement on Human Experimentation*) to produce a revised and expanded *National Statement on Ethical Conduct in Research Involving Humans* (NHMRC, 1999).

The 1991 *Interim Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Research* (NHMRC, 1991) emerged out of three meetings facilitated by the National Aboriginal and Islander Health Organization and the NHMRC, and involved a wide range of stakeholders. The resultant multidisciplinary research policy statement parallels current Canadian initiatives to redevelop the Tri Council Policy Statement in that it represented a national oversight document providing general research ethics governance. Comparable to the Canadian experience, revisions emphasized extended research ethics oversight beyond a health-related framework used by the National Health and Medical Research Council. The interim guidelines applied to the full spectrum of non-medical research supported by other bodies such as the Australian Research Council (the NRC equivalent) and the Academy of Humanities and Social Sciences (the SSHRC equivalent). Unlike the preceding guidelines the expanded multidisciplinary field now required engagement with Aboriginal and Torres Strait Islanders, communities and organizations. The 1991 *Interim Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Research* (Gillam & Pyett, 2003) were also criticized for inadequacies in their capacity to deal with the changes in (a) The social and intellectual context; (b) Growth of the Indigenous community-controlled health sector; (c) Need for increased representation of Aboriginal and Torres Strait Islander researchers and; (d) Associated demand for community control over the health sector and capacity development (Gillam & Pyett, 2003).

The case for separate, specific guidelines was made in the preface to the *Value Statement*:

> It is important to emphasize that separate, specific guidelines on Aboriginal and Torres Strait Islander health research are complementary to the National Statement. Aboriginal and Torres Strait Islander people are entitled to the protections afforded by the guidelines set out to protect individuals in the National statement. As a community with a specific history in Australia, Aboriginal and Torres Strait Islander people are also entitled to recognition of that specific history and its implications. This is why the 1991 Interim Guidelines were developed

> and it is why AHEC has decided to revise them as separate guidelines. But they are still intended as complementary, not alternative guidelines (NHMRC, 2003: 2).

The Australian Health Ethics Research Committee utilized the concept of "collectivities" in the July 1998 Consultation Draft of Ethical Conduct in Research Involving Humans. The Draft applied the concept, using it as an expression to "…distinguish distinct groups from informal community, commercial or social groups" (NHMRC, 1998).

> [It] defined collectivities as groups distinguished by: (a) Common beliefs, values, social structures and identity as a separate group; (b) Customary collective decision making which goes according to tradition and beliefs; (c) Customs or traditions for leaders to express a collective view; and (d) Members of the collectivity being aware of their common activities and common interests of other groups members (NHMRC, 1998).

The Draft for obtaining group consent or approval for research involving the collectivity required community consent in situations including: (a) research where "…property or information private to the group as a whole is studied or used; and (b) research requiring the permission of people occupying positions of authority, whether formal or informal, or involves participation of members acknowledged as representatives" (NHMRC, 1998).

Although the Draft highlighted the need to have the consent or permission of the collectivity, it left the responsibility with the Research Ethics Boards (which in Australia could include both University-based and Indigenous boards) to determine which research involving collectivities should be approved. The Human Research Ethics Committee should apply a core set of criteria to the research protocol and its subsequent review, defining relationships at both an individual and a collective level. Ideally, these requirements were to be applied in (a) situations where, in addition to individual consent, collectivity leaders could be consulted for approval and (b)

situations involving issues of consent, privacy, confidentiality and harms within the collectivity, to either individuals or to the collectivity.

The 1998 *Consultation Draft Statement* identified a number of suggestions to involve collectivities relevant to the issue of group/collective consent, even though the concept of collectivities wasn't ultimately included in the indigenous guidelines. Suggestions included:

1. Need for specification arrangements to address community issues involving a process of respectful negotiation;
2. The manner in which anticipated or actual disagreements between the researcher and the collectivity will be resolved;
3. The provisions defining ownership of data and the rights of publication of research findings and;
4. Need for fair distribution of direct benefits and harms of the research among the affected participants (NHMRC, 1998).

Reaction to the Second Stage Consultation process and efforts of the Statement Working Group of the Australian Health Ethics Committee to develop a multidisciplinary Statement of Ethical Conduct in Research Involving Humans came from Aboriginal and Torres Strait Islander peoples and the wider research community. Reactions came mostly in the form of opposition, specifically applying to the concept of "collectivities" for research involving Indigenous communities and instead, emphasized the need for a separate and revised Values Statement (NHMRC, 2003). In response to this opposition, the Chairperson of the Australian Health Ethics Committee acknowledged that although some submissions had given qualified support to apply

the concept of "collectivities" to Aboriginal and Torres Strait Islander research, the majority of submissions had opposed the proposal. He stated:

> Therefore the Statement Working Group of the Australian Health Ethics Committee (AHEC) acknowledges that the proposal to use the concept of 'collectivities' does not adequately address all ethical matters unique to Aboriginal and Torres Strait Islander peoples…The Working Group has amended the Draft Statement to clarify that the expression 'collectivities' does not apply to Aboriginal and Torres Strait Islander peoples (Chalmers; 1998: 1).

In addition, submissions supported the continuation and updating of a separate Ethical Values statement emphasizing the 1991 document's comprehensiveness, direct focus on Aboriginal and Torres Strait Islander health issues and development through a consultative process;

> The Working Party will recommend that the ethical aspects of health research involving Aboriginal and Torres Strait Islander should continue to be governed by separate and distinct Guidelines (Chalmers, 1998: 1).

At the end of 2002, The National Health and Medical Research Council followed through on a commitment to consult and revise a separate indigenous framework, releasing the *Draft Values and Ethics in Aboriginal and Torres Strait Islander Health Research* as a framework replacing the NHMRC's original guidelines from 1991. The document has already precipitated a continuing dialogue of interpretation both of the values framework in actual research practice and issues of implementation and enforcement in the current policy climate in Australia. Gillam and Pyett in a special comparative issue of the *Monash Bioethics Review* believe that *Draft Values* will have significant implications for Aboriginal and Torres Strait Islander peoples, researchers and Human Research Ethics Committees, as it is poised to both provide a review of the issues of interpretation as well as enforce the current framework (Gillam & Pyett, 2003). In terms of the focus of this particular background paper on community consent, the 2002 *Draft Guidelines and Ethics* document dealt less with specific issues of how Indigenous communities

should be involved (e.g. capacity building, data ownership and frameworks for community feedback). Its primary focus was on the six core values relevant to Aboriginal and Torres Strait Islander health research ethics including: reciprocity, respect, equality, survival, protection and responsibility (Gillam & Pyett, 2003). Although the six values do not contradict principles applied in conventional frameworks, they do however represent a fundamental shift in the philosophical basis influencing the guidelines. The six values are "…understood as being bound together over time by spirit and integrity" (Gillam & Pyett, 2003: 12), and emphasize historical continuity in relationships between past, current and future generations. The focus on the six values represents a shift from the traditional focus on the right of autonomy in conventional consent frameworks. Instead the values framework emphasizes integrity as "…behavior which maintains the coherence of Aboriginal and Torres Strait Islander culture" (NHMRC, 2003). The body of the document emphasizes an alternative framework for consent:

> Although The Draft Values and Ethics document mentioned the meaningful consent processes and community agreements around publication, the framework attempts to "move away from sole reliance on the quasi-legal consideration of compliance with rules. It seeks a more flexible approach that encourages research to reposition itself to incorporate alternative perspectives, and exercise nuanced judgment as to its ethical implications (NHMRC, 2003: 7).

Despite the power of an emphasis on values and less dependence on legal frameworks to define and enforce the process, some issues relevant to community consent have been identified by Gillam and Pyett. Particularly, the issue of community consent is problematic for Health Research Ethics Committees (HREC) as it relates to the internal workings of Indigenous communities and specific local or regional issues. They recognize that is it often difficult for an external research ethics review board to gain insight into local issues and develop a sense of the community's inclination to participate. Gillam and Pyett (2003) conclude that Research Ethics

Committees may experience unique problems determining:

1. Whether benefit has been valued by the relevant community;
2. Whether Indigenous representation (in the review and consent process) is appropriate;
3. Whether relevant Indigenous organizations of communities have been consulted;
4. Whether there is evidence of the engagement that communities perceive to be fair and just;
5. How researchers have considered the potential impact of research on the cohesion and social functioning of communities (Gillam & Pyett, 2003: 15).

In order for Health Research Ethics Committees to gain access to information that would genuinely help evaluate the validity of community consent, committees would require its own resources and time, valid information from legitimate leaders speaking from a community's perspective. Gillam and Pyett propose that the *Draft Values and Ethics* document must be supplemented with three additional supporting documents for researchers, health research ethics boards and Indigenous communities. They emphasize the need for research ethics resource materials to be written in an accessible format, noting that the document:

> …needs to be written specifically by and for members of Indigenous communities, in language that is more appropriate for laypersons and community organization. Processes by which Indigenous could assess researchers' intensions and monitor the progress of research could be set, and perhaps some explanation of the wider process of HREC review could be Health Research Ethics Committees could be given. The form and detailed content of such a document would obviously best be developed by Indigenous communities themselves, and it is not appropriate for us to stipulate any further on this matter" (Gillam & Pyett; 2003: 15).

Ultimately, Gillam and Pyett (2003) propose that researchers and research ethics committees use complementary, yet equally focused documents and frameworks to express key differences in values and alternative research processes required for research in Indigenous communities.

A discussion of differences should consider such things as a commitment to a process of explicit exchange of benefits, community inclusion in all phases of research, commitment to capacity building, community perception of benefits and mutual respect.

Regional Level Research Ethics Review

Like the United States and Canada, states and regions have also been the focus of research ethics development in Australia. In 1989, the scope of influence of the Aboriginal Health Research Committee for South Australia was extended to include a broader national field, now designated as the National Health and Medical Research Council Institutional Ethics Committee. The official recognition by the national body gave strength to the Committee to go on promoting research and ethical cultural oversight of work and research with Indigenous communities. The external jurisdiction of the Committee was linked with the development of the Aboriginal Health Council of South Australia and given status within the South Australian Health Commission Act (AHREC, 1990). The initial progress in South Australia provided a model for other States and Territories, leading to the development of parallel regional level research ethics committees and regional as well as local frameworks, extending the drive for national guidelines and value statements in the Northern Territory, Western Australia and geographical areas receiving services based in Darwin.

Local or Community Initiatives in Australia

Indigenous initiatives developed in Australia in order to protect and actively involve communities in the research consent process, like Canada and the United States, may have to be characterized by "bottom-up" initiatives. Largely, it has been individual communities or

regional aggregations of communities that have developed specific guidelines reflecting community or regional perspectives and values. These frameworks may also define reciprocal contractual obligations related to specific research initiatives, such as the *Ethics Code for the Kahnawake Schools Diabetes Project*.

Regional community-initiated frameworks and partnership relationships can be seen in the development of guidelines for non-Indigenous people undertaking research among the Indigenous population of northeast Victoria (Henderson et al., 2002). The framework ensures that researchers work in a non-exploitive, culturally appropriate manner by forming partnerships between Koorie communities and researchers in a regional area encompassing northern Victoria and New South Wales. These partnerships are more comprehensive than previous agreements between researchers and specific Indigenous organizations because they involve ongoing dialogue between the Koorie Health Partnership Committee, including representatives of all Koorie communities, and the Multidisciplinary Department of Rural Health at the University of Melbourne. Ultimately, the framework is intended to insure that the research community is "informed" and is intended to develop trust, reinforce the integrity of the Department of Rural Health and maintain robust relationships with local communities that can withstand some of the difficulties (e.g. funding that only partially meets partnership committee objectives). However, the benefits of the guidelines not only protect Indigenous communities, but they also benefit Non-Indigenous investigators helping to maintain their neutrality (Henderson et al., 2002). Additionally, frameworks are generally compatible with the NHMRC 1991 frameworks *Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research*, on which they are based.

Returning the focus again to the issue of community consent, the partnership framework provides a model of a process to insure that each community is consulted about any research that is proposed within it. Each proposed project must have initial consent from the Board of Directors of the Koorie community organization, and in many projects researchers must hold meetings to explain the proposed research and gain wider community approval. It is in this initial process that the objectives and outcomes relevant to the community are negotiated. The guidelines state:

> Existing projects negotiated outcomes at the start of each project during community consultations, some aiming to improve the health of study participants, some to establish healthcare programs, and others to provide recommendations for existing health care programs (Henderson et al, 2002: 483).

The alternative of using Indigenous organizations or alternative structures to negotiate community consent appears to be recognized in the requirement that "…all research proposals require written documentation of consent and support from the Koorie organizations or community in which the research is to be conducted" (Henderson et al, 2002: 483). Negotiation of community awareness and approval also requires that both community organizations and individual participants are fully aware of the research process and methods or tools to be used. For example, communities would be consulted if data collection strategies involving videotaping were used.

Of particular importance, the guidelines emphasize the notion that individual and community consent reflects relationships involving a continuing process and true reciprocity between research partners, the Koorie and relevant Indigenous organizations. Through the committee and

individual representatives, communities are continuously involved in all phases of the research from design, fieldwork and ownership of the research product. Oversight of the process is maintained through the nomination and community approval of a local community representative who monitors compliance with the guidelines and maintains a continuous liaison with the researchers. Additionally, it is recommended that the ethics review committee approving the research include at least two Koorie people (emphasizing that single community representative on ethics boards may be subject to pressures of tokenism and intimidation). The role of the two Koorie members is to maintain oversight and "…assess the need for referral to a Koorie community group" (Henderson et al, 2002).

The guidelines define a specific framework for data storage and retention emphasizing that Koorie assert their right to own data collected in their communities, mask individual identification, and require that publications include a summary of the terms of the joint research agreement, community context and role of the indigenous community in formulating the agreement.

Finally, the framework for the Koorie Health Partnership Committee recognizes the existing system of academic research ethics review of university based research ethics committees should continue to be the source of external review, and reciprocally, University Ethics Boards agree to several provisions including: community-based steering committees, local capacity building and employment, data storage and approval of the research product. In this manner, although the framework is local or regional, it still allows for generalized relationships that provide an

alternative to the proposal to develop a framework for each research initiative in Koorie communities.

The experience of the Partnership Committee is relevant to international Indigenous development of frameworks for community consent. One significant issue identified by Henderson et al. relates to the role of committees and frameworks in dealing with the perspective of sub-communities and families:

> The partnership committee, Koorie Team and researchers can find themselves between conflicting family groups or perceived to favor some families of organizations over others. The challenge for outsiders to understand and address this and for insiders to work between them while living in these communities remains.
> The growth and use of evidence for developing and implementing sustainable interventions to improve Indigenous health is urgently required. Our framework addresses the key concern of undertaking this while respecting history and Indigenous cultures (Henderson et al, 2002: 485).

This statement reflects the profound issue of representation and fairness in community-based review and consent to participate in research.

The Relevance of Australian Initiatives in Indigenous Research Ethics in Canada

Several dimensions of the Australian experience in developing and revising both more generalized research ethics policy statement and a separate statement of Indigenous values are relevant to current policy development in Canada. The experience of developing separate value statements in Australia involved a long-term process of consultation with Aboriginal and Torres Strait Communities and Organizations that is still ongoing. Proposals include future development of specific processes and organizational requirements to insure Indigenous representation in ethics review. At regional and community levels a working system of

community consultation has made community consent a continuing process, rather than a one-time event. On the other hand, current policy developments at a national level have disenfranchised powerful Indigenous committees that had initiated and supported Aboriginal and Torres Strait Islander Community participation in research ethics review.

United States of America

The experience of Governmental and Native American Tribal research ethics review is directly relevant to the application of the concept of group or community consent and may be the most relevant to Aboriginal research ethics policy review in Canada. There has been a continuing interchange at both the federal and regional or community levels where US tribal and Canadian Aboriginal organizations maintain a continuing dialogue centered on shared problems in ethical review and experience with participatory research processes fostering principles of ownership, control and capacity building.

Federal Level Research Ethics Policy and Community Consent

At a national level, one of the most fundamental contrasts in the experience between American Indian and Alaska Native Tribes and communities in the US, and First Nations, Métis, and Inuit communities in Canada, was the early development of a framework of including national, regional and tribal level review of proposed research from both ethics and community perspectives, integrated within the structure of the Indian Health Service. Freeman has stated that the "…USA modified the usual approach to health research intended for its Indigenous population over the past 30+ years" (Freeman, 2003b). This modification has had significant

implications for the application of one form of group or community consent at the level of tribal governments, region and Indian Health Service Policy.

In the 1970s Dr. Emery A. Johnson, the Director of the Indian Health Service, established the policy that the Service, as the primary health service provider to Tribes would only participate or become involved in research collaboration where the research was approved by the relevant tribal government(s) (Freeman, 2003b).

As Freeman observes:

> The general change was to have the research be more directly beneficial to Indigenous communities and people in the research, to have the researcher report the results to the communities, to involve the communities more than they had been involved before and than is customary in 'mainstream' research. The two major rationales early in the process were that the Indigenous communities would more likely accept research and that the quality of the research would improve (Freeman, 2003b: 40).

Freeman dates the principal of community approval or tribal consent:

> The first mention of a community's prior approval of research that I am aware of in any health journal anywhere, , was in 1976 concerning the IHS [Indian Health Service]: 'Permission to conduct this investigation was granted by the Indian Health Service, the Bureau of Indian Affairs and appropriate Navajo tribal authorities including local school boards (Freeman, 2003b: 40).

In contrast to the Canadian Tri-Council Policy statement that did not explicitly acknowledge the status of First Nations as a legitimate focus for ethics review, tribal governments in the United states were however recognized as having both authority and legal jurisdiction over activities within the territory of the tribe or community, including research initiatives, and were accepted as having legal status. The discrepancy is quite significant since if the community or group consent is focused at the level of tribal authority, disapproval of research will mean that legal sanctions can be invoked to bar the researcher from the reservation. This policy has been

reinforced by development of specific processes and policies within the Indian Health Service and also strengthened by its role as the primary health service provider.

In addition to recognizing the right of the tribe as the gatekeepers of community rights, approval is supported by two sets of regulations including enforcement mechanisms which regulate all research funded by the federal government and are reinforced, in some states, by laws defining the ethical conduct of research. Federal regulations support the requirement of ethical review by Institutional Review Boards (IRBs, similar to REBs) in universities and other institutions and companies. The roles of national, regional and tribal Institutional Review Boards within the Indian Health Service are supported by this same requirement for Institutional Review Board approval (American Indian Law Center, 1994). The mission of the Indian Health Service Research Ethics Boards was not limited to the field of research conducted by Indian Health Service researchers, but was mandated to review all research involving the Indian Health Service in any way. That is, the Indian health Service IRBs were mandated to review research by outside researchers, such as from a university, that used IHS facilities or resources (such as using IHS charts or recruiting participants in clinic waiting rooms, even though an IHS employee was not on the research team. In addition, a few universities elected to ask IHS IRBs to review all research involving American Indian people done by those universities, even if IHS was not otherwise involved and if the research was not strictly health related, due to the cultural expertise of the IHS IRBs. In those ways the field of ethical oversight of IHS boards partially represents the kind of board interdisciplinary field that the Canadian TPCS was designed to regulate.

At a national level, the Indian Health Service IRB is responsible for ethical review and protection of communities for research initiatives and it deals with the review of research proposals. The national board was previously composed of more than seventy percent Indigenous members, including Native American health professionals with expertise in both clinical and research areas. Despite major representation of Native American health professionals, Freeman observes from his experience as Chair of the national REB, at least three instances where the board failed to recognize potential harms to communities (Freeman, 2003b). Therefore, even with strong representation of Aboriginal members, there is still the potential for Boards to misinterpret local concerns. Gilliam and Pyett's commentary on implementing the Australian *NHMRC Draft Value Statement* proposed to mandate that lower proportions of REB membership (e.g. 5-10%) be drawn from indigenous communities. However, this proposal was evaluated by Freeman and deemed insufficient to recognize potential harms that indigenous communities may be exposed to (Freeman, 2003b). In terms of community consent, questions as to whether a national oversight body, even with a majority of indigenous representation, can evaluate potential harms and level of community agreement at the local level considering members are not from the community and may be unable to evaluate risks and benefits from an insiders perspective. Thus, there still remains a need for ethical oversight and final consent from individuals and, where collective risks and benefits are involved, from the community itself.

One final point raised by Freeman on the issue of community consent concerns external organizational and time constraints imposed on ethics committees by the research funding and

review system that may constrain meaningful review of community impact and ethics. Freeman writes:

> Both researchers and Indigenous community members have noted that major barriers to truly meaningful community involvement or consultation in research are the policies and practices of funding bodies. Announcing grant applications only 45 days before the application, not paying for or reimbursing the costs of community involvement in CBPR [Community-Based Participatory Research] or of community consultation, are two major barriers. In the past few years, IHS and NIH have worked closely together to reduce major barriers. Several grants by NIH start with a one year "planning grant" for researchers and communities to work together to develop a 4-5 year grant proposal in a specific topic important to Native Americans (Freeman, 2003b: 41).

Research Ethics Review Frameworks

In the United States policy and ethics review systems that were developed through collaboration of Indian Health Service Institutional Review Boards (IRBs) and tribal communities interfaced with national initiatives by Native American organizations and individuals who also proposed national frameworks and collaborated with governmental science bodies in development of initiatives like the Native American Research Centers for Health.

At a national nongovernmental level, the development of interactions of a *Model Tribal Research Code* by the American Law Center in Albuquerque, New Mexico provided a theoretical and legal basis for tribal regulation of research and proposed a checklist for Indian Health Boards. In the early 1990s the Model Codes began providing materials to implement tribal regulation of research. The preface to the model code raised the question of whether tribes should rely on federal or state regulation to protect dignity and communities or, whether they should develop their own tribal regulations. For unfamiliar or contested concepts like community consent, The Model Tribal Code provided a model for researchers, Tribes and

Institutional Review Boards within which expectations of Tribe members would be clearly articulated to potential research partners, funding agencies, and governmental agencies in a manner that ensured compliance could be monitored and enforced (American Indian Law Center, 1994, 1999).

The model agreement clearly recognizes the need for protection of both individuals and tribal communities:

> Unlike the mainstream society which, because of its size, can more easily absorb the impact of research, Indian tribes must consider the impact of research on the life of the community itself, and in particular the impact of social science research, which often may view Indian communities as examples of social pathologies interesting to the mainstream society, but may have little respect for the interests of the community (American Indian Law Center, 1994, 1999: 4).

The focus of The Model Tribal Code is on the tribe as the legally mandated locus of community approval; however, the Code does not specifically deal with group consent among specific communities or collectivities. Initial model tribal frameworks did not engage the role of group consent of less geographically focused communities, such as urban inter-tribal communities, people without treaty status or genetically defined constituencies that may cross-cut the political boundaries of tribes.

A primary impact of the American Indian Law Center's initiative effected national and tribal levels by providing a model framework for ethics codes that could be used by tribes to develop laws, regulations, and ethical review systems. The model engages a number of issues central to the concept of community consultation and consent at tribal level. Issues include:

1. Definition of the community (the framework focuses only as the tribe as the legitimate locus of legal authority);

2. Community oversight and accountability (the model calls for specification of what specific agency of the tribal government or local IRB will administer and enforce the regulatory process);
3. Community review processes (the model suggests information of objectives, risks and benefits to the tribe and individual and models for control, access and just sharing of research products).

Finally, *The Model Tribal Code* concludes with a checklist intended for use by Indian Health Boards to document the extent to which researchers and participating communities meet the criteria for ethical and participatory research.

Regional Ethics Review Frameworks

The regional level of Indigenous research ethics review in the United States involves regionally organized Institutional Review Boards with oversight over multiple tribal governance structures. A more recent initiative at the regional or inter-tribal level combining research initiation and ethical oversight has been the establishment of Native American Research Centers for Health [NARCH]. These federal grants were established in order to support tribes, or regional consortia of tribes, in developing and conducting research with academic partners. Through the initiative, the receiving tribe or tribal consortium must directly use at least 30% of all funds while the tribe or tribal consortium may subcontract no more than 70% of the funds to research institutions. Additionally, the review and funding process combines scientific review along with an assessment of community and regional relationships between the tribe and the researcher.

Freeman stresses the centrality of community relationships in process of application and funding a regional centre involving documentation of community consultation and consent.

> In science review, each grant proposal is judged on both the scientific merits of the research projects and also the quality of the relationship of the tribe and the researcher. For instance, the Request for Application for NARCH gave the following criteria for judgment: ‘ the quality of the partnership of the institutional and community partners, and the quality of the involvement of the Community and Scientific Advisory Council, as demonstrated by documentation of, for instance: the intellectual and tangible contributions and activities of the partners, and of the Council, in developing the application and the proposed NARCH; the interactions of the partners, and the members of the Council, in meetings such as those to develop the application and proposed NARCH; the past activities and future plans to increase the capacity of the partners and of the Council; the plans for future contributions and activities by the partners; and by the Council, in development of the partnership itself (Freeman, 2003b: 42).

Examples of research ethics oversight involving community participatory review as mechanism for community consent were described by Dr Francine Romero, who worked in the areas of genetics and research ethics at the Northwest Tribal Epidemiology Centre, affiliated with a regional board, the Northwest Portland Area Indian Health Board (Romero, 2001). The planned community consultation process initiated within ACADRE Centers to review and redraft guidelines for a revised version of Section 6 of the TPCS in Canada may hold some parallels with NARCH Centers in the U.S.A.

Community or Tribal Level Frameworks

A significant initiative in the development of Indigenous ethics impacting the concept of community consent in the United States (paralleling developments in Canada) has been the development of Tribal Institutional Review Boards and community or even project-specific codes or frameworks for research frameworks.

After 1970 the Indian Health Service embraced a more general policy of consultation with tribal governments and worked with these governments to establish tribal Health Boards at a local level. Ultimately, the mission of these tribal Health Boards was to advise individual tribal or community-based clinics and hospitals. They were community level boards within the wider system of regional Health Boards and a National Indian Health Board. Health Boards associated with individual facilities and reservations played broader roles in policy-making, representing the perspectives of individual consumers and stakeholder groups within the community. These Health Boards were not formally constituted as formal IRBs (REBS) but instead, represent tribal communities in a wide range of policy areas, engaging in issues related to ethical and cultural acceptability within a more generalized role. The members of each Health Board were chosen by the respective tribal governments.

Development of tribal IRBS were proposed as having the advantage of authority that was officially recognized by the Department of Health and Human Services. This authority has also been represented as a source of interpretation of the potential role of the Indian Health Service Institutional Review Boards. The Tribal Institutional Review Boards are described in the *Model Tribal Agreement*:

> The fundamental responsibility to govern Indian tribes and to protect their members lies in the tribes themselves. Tribal regulations should be seen by the tribes as establishing the fundamental tribal policies in this area. The tribal and IRB processes should be seen as complementary to each other: the IRB may be able to provide technical support to the tribal process, and a clear statement of tribal policy will guide the deliberations of the IRB. Indeed, it is difficult to imagine an IRB approving a project in defiance of clear tribal policies (American Indian Law Center, 1994, 1999: 4).

The writers of the introductory sections of the Model Tribal Code also recognized some of the potential disadvantages to the development of separate Institutional Review Boards at tribal level:

> But tribes should be aware that the IRB [Institutional Review Board] in the minds of the OPRR [Office for Protection from Research Risks] and DHHS [Department of Health and Human Services] is a specific body organized under federal regulations (CFR) and exercising delegated federal power in accordance with those regulations, as compared with a tribal regulatory process utilizing inherent tribal sovereignty in accordance with tribal law. An IRB, for example, is not empowered by the regulations to consider the long-term social impact of research in deciding whether to grant approval, while tribally sponsored regulation would likely take long-range impact on the tribe heavily into account. In approaching the question of the regulation of research, as in any governmental activity, tribes would be well advised to keep in mind the distinction between tribal and federal power and be sure that they are relying on the appropriate source of power to accomplish a certain purpose. In the final analysis, tribes with a strong interest in the regulation of research would probably decide in the end to establish a tribal IRB [Institutional Review Board] in conformance with the DHHS [Department of Health and Human Services] regulations and to enact tribal legislation and create a parallel tribal regulatory process… (American Indian Law Center, 1994, 1999: 4)

An example of a particularly successful and well documented research policy framework and system of ethical review at the tribal level is that developed by the Zuni Pueblo Tribal organization in New Mexico. It represents a homogenous population of 9,500 Zuni people living on reservations in New Mexico and Arizona. The organization in its scale and budget and administrative oversight, resembles a regional configuration representing multiple communities.

Malcolm Bowekaty former Governor of Zuni Pueblo describes the gate keeping role and ultimate locus of community consent assumed by the organization:

> In the Zuni Pueblo tribal organization, tribal leaders are the gatekeepers for researchers who want to come into our community. Their job is to see that any research is done in the best interests of the tribe, not just the researchers. The tribal organization first looks at proposals researchers bring in to see if they are ethical. Then we jump the researchers through our hoops, to make sure that their proposals deal with issues of trust and rapport that to us are fundamental (Bowekaty, 2001: 58).

In the Zuni system, the Tribal Council performs both a review of the ethical framework and analyzes local relevance and contributions to the tribal community. Access to the group as well as community level consent or approval is contingent on the Council's assessment of relevance and potential benefit. Governor Bowekaty's summary of recent research approval emphasized that the community had looked less favorably on descriptive and population studies and was currently (in 2000) most interested in clinical and genetic studies "…because our people have suffered too long, and these more powerful research designs are likely to give us useful answers more quickly" (Bowekaty, 2001: 58). He also emphasized that the tribe commissioned its own research and worked in partnership with academic institutions that were regarded as providing information relevant to improving quality of care and extending direct benefits to the community. In order to insure that Council decisions and approval reflect community awareness and informed understanding, the Zuni system requires investigators to make public presentations. Bowekaty described the role of Council approval as a second level of protecting individual consent and the role of contact persons as providing a locus of accountability:

> As the prime protectors of our people, we also look at informed consent, especially with regards to questions such as, 'Is the risk minimal? Will there be backlash? Will the researchers have to come back three and four times?" We need good answers to all of them. Researchers have to work with our people to make sure that our consent really is informed, that we understand the risks, and that someone from the community acts as the contact person when there are problems (Bowekaty, 2001: 59).

Additionally, it is apparent that the Tribal Council as the locus for review and group consent must deal with multiple, sometimes conflicting perspectives on the ethics and values influencing perception of risks and benefits to sub communities within a community. Further touching on issues of potential intra community conflicts Bowekaty states:

> I think that we have to look at going beyond that, but doing so brings up a hard ethical dilemma within our community. One group says we can't afford to do more. Another group

> sees the misery within some families, and needs to know that these families will get all the medical help that's possible, so it argues that we must take research projects to the next level (Bowekaty, 2001: 59).

Tribal Consent and Research Ethics Review in the United States: Implications for Canada

A key feature of the development of research ethics review processes as it has developed within the US Indian Health Service has been clear legal and administrative support for tribal government's role in reviewing and consenting to participate in research.

The impact of the Indian Health Service requiring all research to receive tribal approval is discussed by Freeman on the basis of his experiences developing and heading a regional and national board.

> Did the policy of prior tribal approval achieve its goal of meaningful careful review by tribal governments of every research protocol, or did it achieve just a 'quasi-legal…compliance with rules to produce meaningless letters or resolutions of approval by tribal governments? Based on my experience , that goal was usually achieved, and increasingly so in the past few years. The major reason for the increase in meaningful review by tribal governments has been their increased interest, ability and desire to review all research and approve only that research that meets their concerns. Many tribal governments have established formal structures and procedures to review research in their tribal codes (Freeman, 2003b: 43).

Freeman's assessment of the extent to which Tribal governments fulfill the role as a gatekeeper and a legitimate locus for ethical review, representing the informed consent of communities, is summarized in his reactions to a proposal similar to Australian frameworks, suggesting greater Indigenous power and control. Freeman states:

> In summary, the tribal governments themselves ensured that tribal review and approval is truly meaningful, and not just an empty compliance with quasi-legal rules that a researcher can 'game', or simply go through the motions. Innovative request for grants have supported CBPR (Community Based Participatory Research) involving Indigenous communities and tribes themselves have insured that CBPR is real and not just a show (Freeman, 2003b: 42).

In the re-development of Canadian policy defining research ethics review processes as they relate to Aboriginal communities, clear definitions of the First Nations, Inuit or Métis community's role in review and consent should be considered.

New Zealand

Relationships in Indigenous research ethics and more specifically, approaches to community protection and consent may reflect broader structural factors and historical context of relationships between the state and Indigenous communities. The successful decolonization in relationships between Māori and the state in New Zealand is grounded in mutual adherence to a single treaty reinforced by contemporary structures that interpret, mediate and enforce these relationships. In New Zealand, unique treaty relationships defining the rights of Māori people have influenced both formal regulations and granted real power to Indigenous people in the areas of governance relationships and oversight of research ethics. The process of community consent is engaged through both formal ethics review and through the related, but independent process "Relevance To Māori" which involves an assessment of cultural appropriateness, contributions to Māori life and acceptability of the project.

Māori –State Relationships Impacting Community Consent

A significant factor contributing to the progress in New Zealand has been the proportion of the national and local populations who are Māori and who assert uninterrupted continuity and sovereignty of Māori peoples and authority of iwi (tribal communities). In 2001 14.1 % of New Zealand's population was Māori and an additional 6.2% were Pacific People (McPherson,

Harwood, et al., 2003: 443). In addition to the significant representation of Māori in the general population, strong representation from both health professionals as well as those in senior level positions in areas of policy making and decision, has been reflected in the rapid growth of an Indigenous health sector.

The Treaty of Waitangi

Relationships between Māori and the state are defined in the legal and historical context of a single agreement, The *Treaty of Waitangi* which was signed 1840 by about 500 Māori chiefs and involved the initial claim of sovereign authority by Britain. The treaty reflected an early recognition that cultural contact with settlers had a negative impact on the health of Indigenous peoples and their cultures. The treaty defined a policy of inclusion of Māori into the governmental structure and legislative system. It was translated into Māori language, without validation of interpretation of provisions guaranteeing sovereignty (Lavoie, 2004). Māori interpretation of the impact of the treaty in terms of the sovereignty of the iwi (or tribe) conflicted with those of contemporary and more recent interpretations by colonial administrators. The Crown interpreted *The Treaty of Waitangi* as an agreement involving surrender of the sovereignty of the tribe (iwi) or sub tribe (hapu) (Lavoie, 2004). From the perspective of the colonial government the measures were intended to extend central authority into Māori areas, thereby undermining the authority. Following the Treaty, the *Constitutional Act of 1852* established a representative parliament with representatives chosen by voters with land ownership. This officially enfranchised Māori's ownership of land and entitled them to vote, but representation was ultimately eroded through the exclusion of people with more than 50 percent Māori descent from the general voting lists. Māori initiatives reflected continuing resistance to racial amalgamation and proposals from Māori to develop a separate Māori parliament (Lavoie,

2004). Māori assertion of sovereignty continued during armed conflict that developed as a result of settler encroachment and confiscation of Māori land in the 1860s. Development of health systems for Māori continued after 1900 with the appointment of an Indigenous physician as the Māori Health Officer and formation of Māori community councils providing public health oversight. In contrast the development of a separate system of Native American tertiary care hospitals in the US and regional First Nations and Inuit Branch-supported hospitals in some areas of Canada, New Zealand built a system of hospitals accessible to both Māori and Europeans which was non-segregated and accessible (Lavoie, 2004).

Māori interpretation of the provisions of the treaty emphasized that the chiefs who signed the treaty were not empowered to relinquish sovereignty of either the tribe or sub-tribe. The implications of this concept of "inalienable sovereignty" at the level of the tribal community for systems of ethical review may be significant in terms of whether an alternative to community consent can be provided by external administrative authority.

In 1975 the passage of *The Treaty of Waitangi Act* limited the erosion of sovereignty by removing the implementation of *The Treaty* from the sphere of administrative control. *The Treaty of Waitangi Act* established an advisory body, The Waitangi Tribunal, to resolve disputes in interpretation and define spheres of authority. The tribunal developed an important interpretation that reinforced the legitimacy and sovereignty of both differentiated tribal communities (iwi) and urban Māori pan-tribal groups. The interpretation has important implications in providing a model for community consent in research involving urban Aboriginal bodies in Canadian cities. The interpretation by the Waitangi Tribunal grants legitimacy to pan

iwi (pan-tribal bodies) who are able to demonstrate their capacity as self-governing entities (Lavoie, 2004). In Canadian governance relationships the legitimacy of urban Aboriginal organization/government assertion of ethical oversight over research in cities continues to be ambiguous. The framework for assessing the legitimacy of pan- iwi (pan –tribal) bodies in urban centers of New Zealand, involved assessment of both the organizations representative of the Māori community and capacity for self-governance.

Several other dimensions of *The Treaty of Waitangi* have implications for community consent, participation and distributive justice in the sharing of resources. In 2004 The Health Research Council recognized that its role as an entity of government was to insure that Māori (tangata whenua) have access to and are able to utilize resources to improve the health status of the community. Article 2 of *The Treaty* articulates rights defining Māori control over Māori resources, including people. The gate-keeping role of the community is based on the recognition that Māori (tangata whenua) have an authority over their people's involvement in research (Health Research Council of New Zealand [HRCNZ], 2004). Interpretation of Article 3 of the Treaty commits the Crown to allocate an equitable share of the benefits to evidence based research leading to equalization of health status.

Current Community Research Ethics Review Processes and Relationships with Māori Communities

The Health Research Council and National Ethics Advisory Committee are mandated to insure that all research involving humans conforms to recognized ethical guidelines and complies with accepted science practice. The current national ethics review policy statement is the *HRC*

Guidelines on Ethics and Research and Operational Standards for Ethics Committees. The Council is currently developing a document for general discussion (National Ethics Advisory Committee [NEAC], 2003). A supplementary document, *Draft of Ethical Guidelines for Observational Studies*, has also been produced to engage the specific issues in qualitative research (NEAC, 2003).

Current document developments include some consultation with Māori communities. Community relationships are emphasized in the Health Research Council's commitment to building sustainable Māori health research capacity and fostering fair long-term relationships between Māori and non Māori as researchers, research participants or representatives of communities. Furthermore, the Council also emphasized a commitment to recruitment and training of Māori researchers in all disciplines (HRCNZ, 2004).

The NEAC is involved in ongoing work to develop a Māori framework for ethical review, but had not yet (in 2004) developed a parallel, values statement analogous to the Australian, *Draft Values and Ethics in Aboriginal and Torres Strait Islander Health Research* (NHMRC, 2003).

As the first stage in developing generalized and more specific Māori frameworks for ethical review, the New Zealand Ethics Advisory Committee completed a series of interviews with key stakeholders. Questionnaires were also sent to 85 Māori researchers and 17 individuals who asked to contribute to the review. The second stage of development involved a commissioning of background papers and international surveys of the relevant literature (paralleling the current initiatives in Canada by PRE and the CIHR institute). In workshops and feedback from

stakeholder communities, critical feedback raised issues of Māori responsiveness. One Māori researcher responded to the discussion documents commenting that:

> This whole review doesn't deal sufficiently with Māori research communities' needs and concerns, the Treaty of Waitangi and its appropriate application in research or ethical review (NEAC, 2003: 8).

Māori stakeholder reactions to the general discussion and consultation process may also reflect the problems of imbedding Indigenous review within a generic process of rewriting more generalized and universal guidelines. This process is described in a recent summary of the consultation process:

> In addition to the general consultation activities outlined above, there were a number of points in the review process where NEAC specifically sought Māori input(e.g. the additional sample of Māori researchers surveyed, invitations to participate in the cross-sectoral workshops). However , these opportunities were not taken up to the extent that the Committee feels confident as it would wish that it has obtained fully representative statements of Māori stakeholders views. For Example, of 85 Māori researchers who were sent the questionnaire survey in the additional sample, only 16 responses were received (NEAC, 2003: 8).

Comments about the consultation with Māori on a separate policy framework by the Minister of Health in November 2002, conveys the recognition of issues pertaining to legitimacy and perception of community consultation as a "top down process" similar to disclaimers included in Section 6 of the 1998 draft of the Tri-Council Policy guidelines.

The New Zealand Minister of Health stated:

> I would appreciate being informed of how you plan to progress work to develop a framework for Māori ethical review. NEAC [National Ethics Advisory Committee] anticipates that the information gathered from stakeholders in this review that relates to Māori responsiveness will inform both its work on the Māori framework and its review of the Operational Standard (Hon Annette King, 2002: 9).

National and Regional Ethics Review Systems

At present (2004), the system of ethical review of national and multi-centre research is based on a system of 15 regional health and disability ethics committees, linked with the original 15 Area Health Boards. Most recently the number of Health Boards has been extended to 21 Boards (NEAC, 2003). These committees provide independent ethical review of innovative practice and health or disability research conducted in the health region. Regional committees also participate in multi-centre research, reviewing proposals of investigators within their jurisdiction and coordinating the review with other ethics committees assessing the same research. The 2003 National Ethics Advisory Committee Review of Current Processes for Ethical Review recommends that a new national ethics committee be established as the primary review body for multi-centre and national research studies (NEAC, 2003).

To assure local review and consent from communities impacted by research, the committee recommended:

> …part of the review of national and multi-centre studies, there should be a 'locality assessment' for each region in which the research is to be conducted, assessing 'locality issues' only (suitability of any local researcher and of any local research environment and facilities; any specific issues relating to the local community). The key locality assessment question is, 'Given that this research would meet established ethical standards is this particular locality and local researcher satisfactory? (NEAC, 2003:1)

Separation of Research Ethics and Responsiveness in Research Review Process

Development of research review in health in New Zealand involved an assertion of the connection between cultural acceptability (i.e. compatibility with Māori values) and research ethics review. New Zealand has developed discrete processes to assess the "Responsiveness to Māori" (i.e. responsiveness of proposed research to the culture, needs and expectations of

Māori). It has differentiated this process of review of responsiveness as separate from, but interrelated to, processes assessing ethical acceptability (Cunningham, 2003). The concept of "Responsiveness to Māori" was initially adopted in the 1980s and was based on a Canadian policy emphasizing the mandatory compliance with cultural acceptability in contracts between the federal government and First Nations (Cunningham, 2003). Assessment of responsiveness presumes initial co-participation and consent by the Māori community. However the discrete process of evaluating proposed research for responsiveness is also implemented and enforced by government funding bodies in collaboration with Māori organizations and policy makers, at the national level. The review of responsiveness is implemented by the Health Research Council of New Zealand as a part of the application review for research funding. Funding proposals must contain clear description of responsiveness to Māori including:

1. Its contributions to the needs of Māori;
2. The "health significance and context of the research;
3. Description of where and who identified the research problem as a priority, and;
4. The potential of the proposed research "…to advance knowledge on health issues for Māori" (Cunningham, 2003: 28).

These requirements imply broad community participation and consent because they require actual interaction with tribal or urban communities to mutually define a problem with local relevance, specifying the community and who speaks for it, and validate the contribution in terms of local knowledge for Māori. The formal review of responsiveness provides criteria for Māori participation in that it requires researchers to identify the Māori groups that were consulted, the selection process used to define the group and its leaders and the continuing role

of the group and its leaders in the project. Cunningham (2003) makes the important distinction between requirements equating community consent with community consultation. The "Responsiveness to Māori" framework requires that information received through community consultation should be acted upon, as well as documented by researchers. The requirement for researchers to meet the responsiveness criteria in order to demonstrate relationships involving mutual understanding, agreement on research goals and relevance to Māori, provides a much broader model for community consent. Within the concept of responsiveness, community relationships are not negotiated merely at a single point in time, but evolve as part of a process through which the investigator demonstrates experience with a community and/or willingness to incorporate Māori co-investigators or advisors to represent both the interests of the community and Māori. Cunningham observes:

> The philosophy in a health research setting is clear. Either applicant must demonstrate their experience in undertaking research with and for Māori, or they must demonstrate that they have access to the required expertise and advice from Māori on meeting Māori expectations. Such advice might be offered through advisors, advisory committees, research collaborators, or Māori community groups such as iwi, Hapu and whanau (tribes, sub-tribes and extended families) (Cunningham, 2003: 28).

Māori Community Participation in Research Ethics Committees

New Zealand's primary experience contributing to progress in both interpreting community consent and protecting Indigenous Communities in research ethics review processes, has been the requirement of Māori representation on committees. The centrality of the national level relationship between Māori and the Crown is reflected in policy defining a partnership model that assures representation of Māori on the primary system of ethics committees. Rather than opting for separate or parallel regional or community-based Indigenous ethics committees, the current policy *Operational Standards for New Zealand's Ethics Committees* defined partnership

in terms of mandatory representation of at least two Māori members on all research ethics committees (Cunningham, 2003). These members must have knowledge of Māori culture, community values and the treaty mandated relationships by the state. The standards also include requirements that all members of ethics committees receive training in Māori culture and have awareness of *The Treaty of Waitangi* and its implications for research ethics review. The role of Māori members in representing community interests and providing an alternative value perspective to those emphasized in western research ethics. Chris Cunningham, Director of the Health Research School of Māori Studies describes the role of Māori members on research ethics committees:

> It has been important for Māori committee members to clearly negotiate their role in the review processes. Are they there to provide a Māori perspective on essentially western standards of ethical review, or is their role to provide for a Māori ethical review against Māori standards? Is there a middle ground, perhaps, or a transition from the former to the latter situation? By-and-large the process of current review is the former case, whereby Māori members provide a Māori perspective. Yet there is some pressure from Māori researchers and respondents to see 'by Māori for Māori' research reviewed against Māori standards only. Some authors have furthered the debate by suggesting appropriate standards for review (Cunningham, 2003: 27).

Strengthening Indigenous involvement in review of responsiveness and ethics through, mandated numbers of members on research ethics committees, developing community advisory boards and Indigenous ethics advisors have been proposed as mechanisms of respecting communities in both Australia and New Zealand (Gillam & Pyett, 2003; Cunningham, 2003). Despite the advantages of having legally mandated representation of Indigenous peoples and even a commitment to represent geographically and politically identifiable communities, Freeman's reservations about the risks of inclusion of a small number of committee members requires discussion. Specifically, the membership of the US Indian Health Service Institutional Review Board [IHS IRB] was more than 70% Aboriginal – Native medical and PhD doctors,

other health and research professionals, and community members whose background and interest was 'non-scientific'. During the last years that William Freeman chaired the IRB, 1999-2001, that IRB missed significant harms to the tribal community that only review by the tribal government involved picked up. He asked, "If the IHS IRB, with 70% Indigenous membership, occasionally misses such potential harms, how good can IRBs/HRECs be with 5-10% Indigenous membership?" (Freeman, 2003b). If that experience is a guide, including Aboriginal people as members on REBs is therefore, no doubt a good idea, and indeed may be necessary for the ethical review to be adequate; however, it is likely not sufficient for good ethical review. Moreover, such individual IRB members may also be asked to represent the interests of communities, tribes or First Nations Indigenous members but may have minimal knowledge of community research sites and lack any community mandate to officially represent community perspectives.

The Relevance of New Zealand Policy Framework for Aboriginal Ethics Policy Development in Canada

Māori researchers and policy makers have identified similar legacies of colonization in terms of the impact on health status, service access and research practice to those identified by Aboriginal researchers and ethicists in Canada (Cunningham, 2003; Brant-Castellano, 2004). International Indigenous discourse on research ethics and decolonization has profoundly impacted the work by Māori researchers including Chris Cunningham and Linda Tuhiwai-Smith who emphasize the need for decolonization in both ethical review, evaluation of responsiveness and research methodology. Tuhiwai-Smith writes:

> [Indigenous peoples] share experiences as peoples who have been subjected to the colonization of their lands and cultures, and the denial of their sovereignty by a colonizing

> society that has come to dominate and determine the shape and quality of their lives, even after it has formally pulled out (Tuhiwai-Smith, 1999: 7).

As this preliminary review suggests evolution of the relationship between Māori and the state, centers on a primary treaty relationship. Evolving relationships in New Zealand emphasize the need to re-examine initial treaty relationships. In Canada the impact of Treaty relationships and evolving claims by Inuit and Métis communities to be locally sovereign need to be re-examined. The ambiguity of the last draft of the Tri-Council Policy Statement concerning definition of rights and relationships with First Nations, Inuit and Métis communities contrasts with the centrality of the references found in *The Treaty of Waitangi* defining frameworks for governance, ethical and cultural responsiveness, and equity in Māori–State relationships.

A second contribution helping to guide understanding of community consent is emphasized through New Zealand's experience with defining rights of protection of "Indigenous peoples", as the reference framework recognizes multiple and different Indigenous peoples. In engaging how to define and legitimize representation of communities, frameworks for community consent must engage the reality of pluralism within communities and develop methods of representing and reconciling alternative perspectives between sub-communities and between stakeholder groups within communities (McKendrick &Bennett, 2000). Smith describes the need to recognize pluralism within and between communities:

> The final 's' in 'Indigenous peoples' has been argued for quite vigorously…because the rights of peoples to self determination. It is also used as a way of recognizing that there are real differences between different Indigenous peoples (Smith quoted in McKendrick & Bennett, 2003: 20).

A third feature of development of research ethics frameworks in New Zealand relevant to development of Canadian frameworks for community consent and research participation, relates to the involvement of Indigenous peoples living in cities and issue of representation. The framework for assessing the legitimacy of pan- iwi (pan –tribal) bodies in urban centers of New Zealand emphasizes assessment of both the extent to which organizations represent the Māori community and their capacity for self-governance. This approach offers a potential model for assessing the legitimacy of urban Aboriginal bodies in Canada who may seek to represent urban communities.

Finally, the New Zealand experience in developing separate, but interconnected processes of reviewing "Responsiveness to Māori" to deal with issues of relevance and responsiveness of research to Māori expectations, and research ethics evaluation may have applications in the re-development of Canadian research policy frameworks. Community acceptance of research and the evaluation of cultural appropriateness, and the extent of balanced mutual participation and resource sharing in the research process could be evaluated as an initial stage of research relationships before formal research ethics review is initiated by either academic or community-based research ethics committees.

Summary of Review of International, Pan- Indigenous Policy on Issues of Group or Community Consent

This review of the policy documents, reports, and academic publications summarizes the comparative, international, and pan-Indigenous context for interpreting the utility of group consent as a way of protecting the rights of communities, Tribes or First Nations. The historical,

policy and international policy context is characterized by converging values and the emergence of diverse models of community ethics review. Areas of convergence may reflect the continuing exchange between pan-Indigenous leaders and science policy communities in Australia, the United States, New Zealand and Canada.

Figure 1 proposes a matrix for comparing developments at four levels (the national government, national Indigenous organizations, regional and community level research ethics codes). However, the analysis of developments in each country shows both the development at ethics policy and implementation structures at different levels and international and regional variation in the cultural and philosophical value frameworks adopted, and models of review and enforcement applied.

Cross-national comparisons suggest an even more critical difference was in the degree to which the rights of Indigenous communities to review and control research was legitimated by Tribes, First Nations or communities recognized as legitimate and sovereign bodies in the governance of health services and research. The presence of treaty agreements and the recognition of legal sovereignty at tribal level appear to have influenced both Māori treaty-based frameworks in New Zealand and Tribal research ethics review in the U.S.

Another area of cross-national variation was the extent to which national governmental policy engaged Indigenous perspectives on research ethics within the context of a unified multidisciplinary framework or developed separate value statements and agreements designated as applying the research within Indigenous communities. Important parallels were observed in

the experience of Canada and Australia in the development of initial general frameworks and ongoing consultation with Indigenous and science communities to revise original policy frameworks. Both systems demonstrate the complexity of this process of developing and obtaining stakeholder feedback and approval of research ethics review frameworks accommodating Indigenous and bioethical values. This emerging process may mean that like participatory research ethics relationships at a community level, national level policy frameworks will never be static codes, but growing and changing documents reflecting changing processes required to respect and protect communities.

Figure 1

	CANADA	UNITED STATES	AUSTRALIA	NEW ZEALAND
1] National Level Research Ethics Guidelines and definitions of individual and community consent in[1] Government Science Policy	Tri Council Draft (1996-1997) - - - - - - - - - - - - - - - - Tri Council Policy statement: (1998); Section 6	IHS Policy Tribal Approval (1970) - - - - - - - - - - - - - - - - Belmont Report (1979) - - - - - - - - - - - - - - - - National Institutional Review Boards, Indian Health Service (1991) - - - - - - - - - - - - - - - - National Bioethics Advisory Committee (1995-2001)	WHMRC – Interim (1991): Guidelines of Ethical Matters in Aboriginal and Torres Strait Islanders Research - - - - - - - - - - - - - - - - National Statement on Ethical Conduct of Research Involving Human Subjects (1999) - - - - - - - - - - - - - - - - Draft of Values and Ethics in Aboriginal and Torres Strait Islanders (2002/03)	Treaty Defined Māori – Crown Relationships (1975) - - - - - - - - - - - - - - - - Policy Separation and Ethical Review and Review of Responsiveness to Culture, Capabilities and Needs of Māori (1998) - - - - - - - - - - - - - - - - Operational Standards for Ethics Committees - MOH; (2002)
2] Nongovernmental Organizations; National Level Research Ethics Policy and Value Statements	NAHO – Toolkit (2003) - - - - - - - - - - - - - - - - National Regional Health Survey – OCAP Principles (1994)	Model Tribal Research Code: (1994), (1999)		

Figure 1 continues on next page

Figure 1 – International, National and Local Frameworks for Determining Community Consent

3] Regional Ethics Review Frameworks and Processes (Involving Multiple Communities)	Inuit Tapirsat Negotiating Research Relationships (1994) - - - - - - - - - - - - - - - - Dene – Métis Tracking Model Agreement (1993)	Regional Indian Health Service Institutional Review Board	Regional, State, Territorial Level Boards for Indigenous Ethics Review (1989)	Regional Health and Disability Ethics Committees (2004)
4] Community/ Tribe/ First Nation-Based Frameworks and Review Boards	Local Advisory Committees and Kahnawake Schools Diabetes Research Code	Tribal Health Boards and Institutional Review Boards constituted by specific Tribal Communities (e.g. Zuni, Mowhawk, Navajo, Cherokee of Oklahoma, and others) - - - - - - - - - - - - - - - - Tribal and Community Colleges and Universities	Community Boards (e.g. Koorie Health Partnership Committee)	Requirements for Māori representation on local research ethics Committees

Section III:

ISSUES FOR RESEARCH ETHICS BOARDS IN EVALUATION OF COMMUNITY CONSENT

This section looks at the roles played by Research Ethics Boards (REBs), and Institutional Review Boards (IRBs) in relation to research in Aboriginal communities. We will briefly discuss the history of the research ethics review process, the purposes for which these boards were established, the structure of REBS and their place within the process and procedures of medical research. REBs and IRBs have had a number of problems in dealing with issues of concern to Aboriginal communities. Some of these are the result of REBs having been set up for the protection of the individual research subject. Their members are alert to assessing the potential risks and benefits of research to the individual, but are not accustomed to thinking about the implications of a research project for a community.

Other problems can be traced back to the composition of REBs and IRBs and the characteristics of their membership. The majority of those serving on REBs, particularly those operating within a medical research environment, have been trained either in science or bioethics, or sometimes in both. Their familiarity with scientific ways of thinking and their commitment to traditional ethical principles, such as individual autonomy, have been a strong influence on the development and working of the REB system. Moreover, the life experiences and community heritage of most REB members often do not include the unique experiences and heritages of many Indigenous people. These principles, commitments, and life experiences do not necessarily clash with those of the Aboriginal community, but we will suggest that they make it difficult for REB

committee members to understand Aboriginal values or to appreciate their implications for research.

Some problems are the result of changes within Aboriginal communities. Aboriginal leaders have become more critical of both past and ongoing research and more interested in playing a more active role in projects set in their own community. They also set a high priority on whether a research project was culturally appropriate, respectful of local knowledge, and potentially able to solve some community health problem. REBs were accustomed to being the sole arbiters of the ethical acceptability of a project. They must now sometimes accept a system of independent and parallel Aboriginal research ethics review boards at the national, regional and local levels. REBs also developed at a time when research subjects were expected to remain relatively passive and were not well prepared to meet the demand of communities for a more interactive research partnership. Yet despite an initial reluctance, this section will show that REBs have accepted that the rules for researchers working in Aboriginal communities must not only be different, but must include some form of community participation and consent.

We will discuss the difficult challenges faced by REBs in trying to reconcile the new innovation of the participatory research model with the scientific model with which they are most familiar and on which their ethical principles and regulations have been based. For example, the participatory research model assumes a continuing dialogue between the community and the researcher and also recognizes the rights of the community to ask for changes at any point throughout the life of the project. The problems is REB regulations have made it increasingly difficult for researchers to make more than minor changes to a project once it has been given

ethical approval by an REB. The idea of a research design which is constantly evolving and potentially changing is difficult for REBs to accommodate within its own frame of reference.

A fundamental problem is the more general lack of information on Aboriginal issues among members of REBs. For example, there is extensive debate over what criteria should be used in defining a community (geographical, cultural, genetic or political). REBs have also had problems in knowing how to determine the adequacy of community consultation, or whether claims of community consensus are valid, or whether the consent given by the community leadership is truly based on the community's best interest.

The Process and Context of Research Ethics Board Review

The current system of ethics review processes was initiated by government agencies and implemented by academic and health care institutions. The origins of the ethical review process may be traced back to the response of the general public and of the scientific community to the revelation of the abuse of human rights in the name of research in Nazi Germany, and to the revelation of a number of unethical research projects in the United States and elsewhere in the 1960s and 1970s. The primary purpose in setting up REBs and IRBs was to ensure the protection of those taking part in research through the regulation of the researcher and the research process. The current system of REBs and IRBs has evolved gradually over time responding partly to criticism and partly to the need for ensuring consistency of standards from one REB to another.

The current Canadian model involves a process in which the investigator presents a completed protocol describing the purpose of the research, previous work surrounding the research question or subject (systematic review of the literature), information on sponsorship and financing. Proposals must also describe in detail the proposed procedures or interventions, if any, the participants to be recruited, recruitment methods, risk/benefit profile and consent process. The REB will also expect to see completed research tools, where appropriate, such as questionnaires and other research instruments, as well as the written consent documents. REB approval must be received before an investigator can recruit participants. The notion of co-partnership between researchers and communities or their representatives is foreign to many, if not most REBs, who as a general rule, see the researchers as those holding the expertise and participants as the subject/object of research. An REB will review an investigator's credentials to determine if he or she has the requisite expertise to accomplish the research, but not those of the participant.

Canadian REB members tend to have a relatively beneficent view of the contributions of medical science and are generally unfamiliar with the history of research as seen by Aboriginal communities. The views of Aboriginal people on the history of scientific research in their communities associate it with other aspects of their economic, political and physical marginalization dating back to earliest contacts with non-natives (Fletcher, 2003). For example, Maddocks claims that many Indigenous communities saw research as "…insensitive, intrusive and exploitative, and conferring no benefit on the communities involved" (Maddocks, 1992: 553). Seen from this perspective, research relationships were characterized by a lack of respect for Indigenous peoples, a lack of consultation and a lack of protection. Aboriginal leaders now

demand a more consultative, participatory process in which they have rights to control what research is done in their communities based on its value to the community.

Given the gap between REB members and community perceptions of the research process, it is perhaps not surprising that significant areas of misunderstanding and disagreement should have developed. We see the problems in the relationship between REBs and Aboriginal communities as falling into two main categories, which we will discuss one by one:

1. Issues arising out of the adherence of Canadian REBs to established scientific values relative to the value that Aboriginal communities attach local to Indigenous knowledge;
2. Issues related to the relative lack of training and experience of Canadian REBs in how to evaluate non-traditional research designs better suited to research in Aboriginal communities and congruent with Aboriginal values

Local Knowledge and Scientific Values

A critical issue in REB review of community consent is the impact of differences in values and emphasis on objective, scientific or local knowledge in REB culture and Aboriginal communities involved in the research. The majority of clinical and research scientists regard science as a "…highly authoritative form…" of discourse that 1) demands "…an uncritical acceptance of the knowledge it produces…" and 2) promotes the value of that knowledge as "…superior to other ways of understanding" (Fletcher, 2003: 34). They see themselves as "liberal and objective, upholding a view of science that is value-free, fearlessly adding to the sum of human knowledge." (Maddocks, 1992: 553). They claim status as "…unbiased experts, endorsed by others with power, and able to speak with authority," thus locating control of the research – "…what gets done and how it is done – and who knows about it…" with the researchers and not

the community (Schnarch, 2004: 83). They also mistrust any claims to intuitive insight or visions in scientific breakthroughs, even when made from within western disciplines and institutions.

Aboriginal communities and Indigenous researchers may in contrast, assert the place and relevance of local knowledge as being as significant as scientific and scholarly. In their view "objective" or "value free" information may be less important to a community than knowledge created for social benefit, in particular, for the benefit of the community. According to Brant-Castellano, "[a]boriginal world views assume human action, to achieve social good, must be located in an ethical, spiritual context as well as in its physical and social situation." She contrasts this perspective with scientific research which is dominated by "…positivist thinking that assumes only observable phenomena matter" (Brant- Castellano, 2004: 103).

The issue of local knowledge is crucial to Aboriginal communities. As Masuzumi put it:

> …even before a researcher comes into a community, we hope he or she addresses the "what, why, who, when" questions, collaboratively, so that in the end we address the how dimension. Otherwise researchers run the risk of communities rejecting their interpretations of the data (Masuzumi, 2001: 70).

Yet finding answers for many of the research questions relevant to the health of Aboriginal communities may depend on reconciling scientific knowledge with the local knowledge of the Indigenous community. This will depend partly on the development of new types of research design and training REBs in how to evaluate their ethical implications.

Participatory Research and the REB

REBs are caught up by their reliance on the traditional scientific model and their adherence to conventional ethics guidelines (Kaufert et al., 1999). REBs need direction in order to appropriately assess research protocols dealing with Aboriginal communities without sacrificing the scholarly integrity of the research. For REBs that rarely view protocols for community based participatory research, the assistance of not only community representatives and Aboriginal researchers, but also outside experts familiar with research ethics issues relevant to the proposed research may be required.

Research Design

The terms of reference for many contemporary research grant applications require researchers to provide evidence of community consultation and approval by community research advisory boards or First Nations governments. This evidence must also be sent to the institutional REB which must assure itself that the final approval described in supporting documentation is valid. Unfortunately many REBs have lacked the cultural expertise and local knowledge to evaluate research sited in remote Aboriginal communities. This may be a particular problem for external REBs appointed in research-intensive, scientifically oriented research institutions. Members may not recognize these gaps in their knowledge, but they may also be reluctant to make any explicit commitment to including Aboriginal members within their own membership, or consulting with Aboriginal research ethics boards or community advisory committees.

Such thinking, along with the requirements involving participation of non-scientists in the research endeavor may create problems for REBs lacking local knowledge and experience with a

participatory model of research. An REB unfamiliar with a cultural body of knowledge may not only lack understanding of issues of importance to a community, it will be ill-prepared to "maintain the privileged nature of the knowledge where appropriate" (Fletcher, 2003: 54).

Local Knowledge: Challenges of Participatory Research Models for REBs

Many Aboriginal communities and Aboriginal Research bodies emphasize an alternative, participatory framework through which their communities can be involved in all stages of research and can own and benefit from the research product (Kaufert & Glass, 2002). According to this model, a researcher presents an idea for research to be developed into a protocol with community partners. The community and the research team work cooperatively to set the research agenda, including agreement on the topics to be studied and the process for studying them (Zolner, 2003), thus assuring that the projects would be sensitive and responsive to community needs. Developing Aboriginal capacity in research methodology, including data collection, analysis, policy development and writing for dissemination are also a part of participatory agreements.

Participatory research attempts to negotiate a balance between developing valid generalizable knowledge and benefiting the community that is being researched and to improve research protocols by incorporating the knowledge and expertise of community members (Macaulay et al., 1999). The research process becomes a dual cycle of data collection and community learning, forming an integral part of community development and providing a more accurate and authentic reflection of the reality of community life (Natpracha & Stevens, 1990). Resource sharing and capacity building within the community can be key features of this kind of research.

The participatory research project develops through stages, and does not fit neatly into the standard model emphasized in REB review of defined elements of a research design at a single point in time. Codes of research ethics designed by centralized science councils emphasizing review processes exclusively controlled by university-based research ethics boards may not be able to accommodate the alternative models and power relationships inherent in participatory frameworks favored by Indigenous communities. For example, external research ethics boards emphasizing the need for review of a detailed research plan, (with detailed consent documents) may have difficulty approving a proposal for an evolving paradigm in participatory research. Participatory research may involve an initial stage where the research problem and methodology cannot finally be defined until the investigator has undertaken full consultation with the community, or where the research objectives may change during the course of research. Most conventional human subjects committees would have difficulty assessing and approving this evolving process, which may not be fully defined in the initial research proposal (Kaufert, 2002). Not only would it not fit in with their conception of an appropriate REB review, most committees lack a local community knowledge base and must rely exclusively on ethics or science review that is external to the community.

Analysis of Risks and Potential Benefits

Risks and potential benefits of research will depend on both the nature of the research and the community in question. Risks and benefits can be physical, psychological, social, economic or even spiritual. They may be a result from clinical or social interventions, from knowledge gained either by the participants or others, or from the dissemination of the research results.

Two veteran members of the Indian Health Service Institutional Review Board, that reviews research involving Indigenous communities in the US, noted several harms that have actually occurred in one or more research protocols: external stigmatization of the community by others; internal stigmatization by members of the community (or "self-stigmatization"), genetic determinism to define membership of an Indigenous community by the presence or absence of certain genetic markers; disruption within the community; loss of status vis-à-vis the dominant society; "dignitary harms"; and increased distrust of research, researchers and even health care (Freeman et al., 2002). They estimate that the most frequent and greatest harm has been self-stigmatization, in which people internalize negative research results about their community, and feel badly about themselves and their community. Dignitary harms, however, are the most public harm. Dignitary harms are the researcher doing procedures without the permission of the community or of individual participants, such as using specimens originally collected for one research purpose and using them for an entirely different purpose, or doing research surreptiously. Recent publicity about dignitary harms in research involved in the Nuu-chah-nulth in Canada (Tymchuk, 2000), and the Havasupai in the US (Rubin, 2004).

Defining Communities and Identifying Legitimate Decision-Makers

In the current system, Research Ethics Boards based in academic institutions are the body most frequently asked to evaluate the validity of a community's or First Nation's consent to participate and commitment to research partnership described in the application. In the present system, the REB may be faced with answering questions of what or who defines the community in terms of membership criteria, spatial boundaries. Communities may also vary in terms of their claims to ownership and control of collective cultural property and genetic or cultural property. REBs

may also be asked to assess 'who speaks for the community and its constituent parts'. They may have to evaluate the validity of consent agreements or, memos of understanding, from both groups without formal elected leadership or self-governing status and decide whether letters of support from community members with varying relationships with researchers and service providers should legitimately speak for the community. Research Ethics Boards in academic institutions may also have to define their roles in relationship to the political authority of First Nations or Inuit governments as they develop and enforce their own internal research ethics review system and evaluate proposed research in terms of alternative criteria for research participation. The prospect of the development of parallel and either alternative or complementary Aboriginal research access reviews may combine ethical review with negotiation of frameworks for co-participation and agreements on allocation of risks and benefits. Systems following the New Zealand model of initial assessment in terms of appropriateness for Indigenous communities could present challenges for both individual REBs and for the national system of research ethics review that does not acknowledge a dimension of cultural appropriateness and value to the community (Cunningham, 2003).

Problems of interpreting group or community consent are particularly visible in REB reviews of research focusing on culture, genetics and/or population health research. These research initiatives confront external REBs with the problem of protecting and differentiating individual and collective interests of families and First Nations. REBs must also increasingly consider the issues of group consent in research involving secondary analysis of data including genetic materials and data on kinship groups where individuals are imbedded in or linked by data describing their group or subpopulation.

Problems in Risk Assessment of Community Based Genetic Research

Much has been written about the risks inherent in genetic research, both for individuals and for communities. This risk revolves around knowledge that could have a negative impact on sense of self-worth, social status, marriage prospects or solidarity. Stigmatization of individuals and communities is a risk in genetic and epidemiological research on risk factors within defined communities. Genetic information might raise the potential for actions running contrary to traditional values, such as pregnancy termination for genetic reasons. Genetic knowledge might conflict with traditional explanations of origin, or of suffering from disease and thus interfere with existing coping mechanisms (Kaufert, 2002). It has been suggested that results of some population genomic research might "deny social goods and opportunities" to individuals at risk – or even to justify coercive treatments (Juengst, 1998a).

Research ethics boards must therefore engage the problems of differentiating between individual and group consent in terms of the rights of individuals, families or groups within community or First Nation to be included in research. This may be problematic in research involving specific genetic or chronic illnesses where the individual, living within a community or First Nation that refuses research access, may claim their right to participate as an individual. Examples from genetic research highlight the problems of balancing risks and benefits for individuals, families, communities and First nations. Academic REBs and Community-based Advisory Committees within a community must both consider the rights of individuals and families who share genetic or environmental risk factors to participate in research that may have immediate individual or longer-term benefits. Ethics boards must also engage the limits of community consent in terms of the rights of individuals who do not consent to share individual or family-specific information

with community focused researchers or the rights of other family members impacted by data defining shared genetic or environmental risks.

Time Frame in Consent and Community Risk Assessment: Issues for REBs

A key issue for academic Research Ethics Boards in evaluating community based research may be time frame of relationships. Participatory action research may involve long term and continuous re-negotiation of the terms of consent, ownership and dissemination and ownership of data. In participatory research, there may be the risk of unrealistic expectations among community partners about the time frame required to produce results and benefits for improved health status. A one-year project may not produce measurable changes in markers of conditions that developed over generations. As Macaulay et al. put it, "…[p]articipatory research, like all research, is not guaranteed to succeed" (Macaulay, et al., 1999).

In contrast to emerging community expectations of long term and co-participatory relationships, most research ethics boards operate within a short term time frame in terms of both assessing the immediate consent framework presented for review and reviewing the research on a one time basis with yearly updates. Most REBs focus on harms to individuals, not group harms. "Group harms" can be defined as harms that accrue to individual members of a group via harms imposed on the entire group, even though those members were not subjects or participants in the originals research.

In the United States, the Common Rule directs IRBs to consider risks only to subjects and are specifically forbidden to consider the "…long range effects of applying knowledge gained in the

research (for example, the possible effects of the research on public policy)" (Code of Federal Regulations [CFR], 2001). Some observers interpret that restriction broadly, as essentially precluding consideration of group harms in assessing the risks and benefits of protocols in certain contexts (Clayton, 2002; Greely, 2001a).

Other observers, however, consider that restriction narrowly, to *long-range effects* when *applying* the knowledge in *public policy* (Freeman et al., 2002). For instance, the list of potential harms in research observed by William Freeman and Francine Romero were immediate (not long-range), and occurred to the members of the tribal or Indigenous community directly in the same way that disclosure of confidential research information about an individual is recognized by REBs as a risk to be minimized. Moreover, family harms, especially in genetic research, are well recognized by bioethicists. Family harms in genetic research are when the research adversely affects other members of the family not directly physically involved in the research. Family harms are a subtype of the category of group harms. Most REBs/IRBs do recognize and try to minimize family harms. Finally, the Office for human Research Protection [OHRP] (the organization in the United States Government that oversees the implementation of the IRB/REB regulations) does state in its public presentations that IRBs should try to minimize risks to groups. Many REBs/ IRBs insist that group harms at least be disclosed in the consent form (even if those REBs/IRBs do not consider group harms to be part of the risk/benefit analysis.

Minimizing Harms

Investigators and external REBs may not be in a position to recognize how to minimize all potential harms resulting from the research. Developing the protocol in a participatory fashion

and interpreting the data jointly can minimize potential harms, for example, external stigmatization of individuals and the community, self stigmatization, and community disruption, (Macaulay et al., 1999) which the community would be more sensitive to and more likely to recognize.

Process in Consent Negotiation

As noted earlier, the dominant North American framework for the review and approval of human subjects research is founded on a principle of respect for the person and personal autonomy. REBs are familiar with the language of individual rights and are required by policies and regulations to promote the informed, competent and voluntary consent of individual subjects or their legal representatives. It is not surprising, then, that REBs are concerned if they believe that individual consent is to be by-passed in research in communities where leaders perform the role of collective gate keeping. Add to this the numerous characterizations of the process of dealing with communities - “Group Consent”, “Community Consent”, “Community Filter”, “Collective Consent”, "Group Engagement", “Group Consultation”, “Group Mind”, “Collective Acceptability” - and it will not be surprising if problems emerge in the process of ethics review.

Rationales for Community or Group Consent

There are a number of different rationales for the notion of community or group consent some of which have been touched on above:

1. Research may have risks and benefits that impact on the entire community in ways that interact with, but are not identical to, the impact on individuals who identify with that group (Greely, 1997);

2. Individual informed consent is inadequate to justify research effects on groups because a participant's agreement to participate cannot authorize the acceptability of the effects of research on other persons (Burgess & Brunger, 2000: 120). Genetic research is a good example of this limitation. Greely (1997) argues that the Human Genome Diversity Group research studied populations, not individuals, and therefore both the individual and the population must give free consent to participate. Juengst also observes: "To the extent that research on human genetic variation can impose risks on all the members of a socially definable group, they have a collective interest in how the research proceeds" (Juengst, 1998b: 52);
3. Group leadership is more likely to know risks/benefits for members of the group as individuals and as a community, than are people from outside the community;
4. It has been argued that without some measure of respect for the "group", the interests of individuals themselves will not be met. According to this rationale, individuals have interests that they can protect only through group action, and individuals have interests in the well being of groups with which they identify (Davis, 2000: 40).

As noted earlier, Burgess and Brunger characterize disclosure and individual informed consent as giving that individual "…full control over exposure to risks and benefits" (Burgess & Brunger, 2000: 135). Yet the notion that individual informed consent can provide "full control over exposure to risks and benefits" may be a misreading of current guidelines which all require a thorough analysis of the potential for risk and the possibility of benefit before any research protocol may even be offered to potential participants. The idea that individual participants must knowingly accept the risks to them of participation in specific research projects assumes that

there has been a prior analysis of those risks as well as the potential for benefits. Risks must be considered reasonable by the scientific and ethics reviewers before a protocol is ever discussed with a potential participant.

While community or group consent is discussed in other parts of this report, it may be important here to focus on an issue that will likely be most difficult for REBs. An REB may be prepared to support participatory research or engage with communities in review of a protocol. But some find it difficult to agree that an individual be bound by a community decision. No one has suggested that a group's acceptance of a project be allowed to override an individual's refusal, but some do call for allowing community refusal to act as a veto on the individual (Davis, 2000).

Some of the difficulties that have been suggested include the following:

1. Misuse of leadership's position of power or gatekeeper: A worst case scenario might be a band council most of whose members have sexually abused children and a researcher proposes community research on sexual abuse of children; the majority of the band council reject the research because they do not want this topic to be made public fearing disclosure of their own activity (Freeman, et al., 2002). Freeman also noted that, however, while this restriction would be quite regrettable, it is similar to restriction that politicians in the national governments of Canada and the United Sates have placed on research, and that the role of researchers in the scenario, and in the real instances on Canada and the US, is to try to persuade the band of tribe (or Canadian or US society) to lift the restriction;

2. Interpretation of voluntary and informed collective consent: What does it mean for a group's "collective permission" to be "informed and voluntary"? If group consent is required, are other protections, such as the right to withdraw from research, or confidentiality, also important for groups? How will "researcher-group" relations be managed administratively? (Juengst, 1998a: 673); and
3. Potential for duress: Prior acceptance of a project by recognized community leaders may well have a coercive effect that can "taint" the voluntariness of individual consent (Greely, 1999; Davis, 2000). It has been reported that "Individuals have felt pressured to participate in a study or other data gathering process because community authorities have consented or are involved" (Schnarch, 2004: 82).

Henry Greely (2000) reminds us that there is no legal right to be a research subject. However, this does not displace any moral concerns REBs might have. The ability to veto individual participation may be legal, Ellen Wright Clayton states, but is it ethical? (Clayton, 2002: 295) This may be an issue on which some REBs may be unwilling to compromise if they believe the research is otherwise sound and does not impose risks. However, as noted below in the discussion about "OCAP in other Research Settings," REBs and researchers seem wiling to accept vetoes by leadership of a group or family in certain other, Non-Aboriginal, research settings.

Protecting Confidentiality

The historical record of researcher and REB experience on the issue of identifying Aboriginal communities in research publications has left many communities sensitive to the issue of

confidentiality and the risk of breach. Both the communities and individuals within communities may be recognized, particularly when small, easily identified communities are the locus of research. Risks from breach of confidentiality may also affect different communities differently, an issue requiring sensitivity from researchers and REBs. Questions of privacy, storage and management of data collected, as well as access to the information by outside agencies are not dealt with in conventional codes of research ethics (Brant-Castellano, 2004).

Ownership and Use of Data

Control over data and publication, as described below, may be the best means of protecting confidentiality, although this in itself may create difficulties for REBs. However, some Aboriginal communities participate in research in which ownership and control are not in their hands, as with some pharmaceutical company research. In such cases, both they and the REB need to carefully consider the protections offered in the protocol.

Ownership refers to the relationship of a First Nations community to its cultural knowledge/data/information. The principle states that a community or group owns information collectively in the same way that an individual owns their personal information (Schnarch, 2004).

There is increasing discussion in Aboriginal communities of the OCAP principles: self-determination applied to research. Schnarch calls it "…a political response to tenacious colonial approaches to research and information management" (Schnarch, 2004: 80). OCAP principles include: collective ownership by first Nations communities of information about themselves and their members; authority to designate who controls or makes decisions about research affecting

them; criteria for access to information about themselves held outside the community and management of access to information held by communities or their agents; and possession of actual records by themselves or their designated agents (Brant-Castellano, 2004).

Anne Macaulay characterizes the problem:

> The trickiest questions in full partnership surround ownership of the data and publication of results. To date, the researcher has had complete control over data and results, but in a partnership, the community expects control over the data, too. Theory becomes reality when results have negative implications and are seen by the community as potentially damaging (Macaulay, 1994: 1889/1890).

Researchers see this as limiting intellectual freedom. Communities see it as protection from harm (Macaulay, 1994).

In an ideal situation, issues of data ownership and publication are worked out at the beginning, with specific mechanisms for dealing with conflicting interpretations or inappropriate use of data established at an early phase of the relationship between the community and the investigators and included in the written agreement between them (Fletcher, 2003).

OCAP in Other Research Settings

As noted previously, harms to families are a subset of group harms. One type of genetic family research is pedigree studies with genetic analysis of blood taken from a large percentage of family members. Often the researcher doing such studies relies on one member of a large extended family arranging a large family get-together or reunion, to allow the researcher to recruit other family members into the study. It is widely recognized that if the "leaders" of the

family oppose the research, the research will not happen. In effect, pedigree studies with DNA analysis of large families rely on approval of family leaders -- a parallel to OCAP in that setting

A more obvious parallel is the work of some advocacy organizations to influence and control research. PXE, Inc. is an organization to combat the rare genetic disorder Pseudoxanthoma Elasticum (PXE, 2001), and is made up of individuals or families with PXE. The leaders formed PXE, Inc, because there was little research on the condition, and what research being done was disjointed, duplicative, and in isolation. The leaders of the organization collect blood and medical histories from its members, as well as help set the research agenda with researchers, and approve or reject research proposals.

The Mormons in Utah are an extraordinary resource for genetic studies. The Mormon Church leaders encourage Church members to participate in the research, and in effect refuse to allow certain kinds of research that goes against their beliefs, such as research related to birth defects that might lead to more abortions (Johnson, 2004). Similarly, research in some institutions, both religious and non-religious, is constrained by institutional policy to refuse approval of certain types of research.

Funders of research are increasingly including "the community" in decisions to approve or to reject funding for specific projects, and promoting participatory research. In the US, the Department of Defense oversees special Congressional funds for breast cancer research, and has civilian, non-scientist, breast cancer advocates on all review panels; the purpose of their participation is to make sure that the research projects funded are likely to benefit people with

breast cancer or people at risk to get breast cancer, Similarly, the National Institute on Disability and Rehabilitation Research [NIDRR] has lay disability advocates at all levels of review and approval of funding, and require research projects to have research advisory boards that include disability advocates (NIDRR, 2004). Finally, the largest funder of biomedical research in the world, the National Institutes of Health, has for decades had lay members on its external Advisory Councils that make the final decisions to fund or not fund research, with the purpose of applying the concerns, needs and interests of the whole society to the research agenda, instead of letting the (self-interests of) researchers control funding decisions.

These examples suggest that in several contexts of non-Aboriginal research, participatory research and/or lay "community" OCAP (ownership, control, access, and possession -- such as approval and disapproval of research) are accepted by funders and REBs/IRBs.

Publication Rights

Notions of academic freedom are also based on the principle of autonomy and self-determination. Freedom to pursue knowledge unfettered by the institution and funders such as governments, foundations and private or commercial donors, is central to the notion of academic freedom, and is an important part of the researcher's agenda.

Mechanisms for publication of alternative interpretations of the data resulting from a study and dissenting opinions should be established early in the discussions. Fletcher asserts two levels of communication are needed: "1) communication regarding the findings within the community and 2) disseminating the findings externally" (Fletcher, 2003: 44).

Macaulay emphasizes:

> The partners should agree on their roles and responsibilities, desired outcomes of research, measures of validity, control of the use of data and funding and channels to disseminate findings. Some communities have requested - and researchers have agreed - that publication will include dissenting views of both researchers and community, if the partners cannot agree on the interpretation" (Macaulay et al., 1999: 776).

A community may require that it review and approve a paper before publication. Yet pre-publication approval could prevent the pursuit of important scientific questions changing the course of research, stopping publication of scientific findings and/or, cutting across the free exchange of information which is the very life-blood of science (Maddocks, 1992). While there should be an interpretive process between a researcher and a community as the research is accomplished, who should have the last word regarding publishing?

Conventional scientific and academic morality requires the free public dissemination of results. This model of dissemination of research results serves several purposes. It allows the researcher to contribute to knowledge in the public domain, and in the context of health research, to contribute to progress in this regard. It also prevents governments or commercial interests from suppressing knowledge to which the public has a right. But it also has another purpose, one that Canadian REBs will know well: it may offer protection to participants, or others to whom the knowledge is generalizable, when an investigator learns of the potential for harm during the course of research. This was the situation with the recent dispute involving Nancy Oliveri, her university and the commercial sponsor of her research. She signed a "gag" clause with the pharmaceutical company sponsoring her research. She later wanted to publish early trial results and warn participants of what she believed were the harmful effects of the treatment under study. The Canadian Association of University Teachers' [CAUT] Report on the incident recommends

that industrial sponsors of clinical trials not be allowed to prevent publication of risks to participants that investigators discover during the research (Thompson et al., 2001).

Ideally, agreements defining data ownership and publication policy are entered into at the beginning of an investigator's relationship with a community, with specific mechanisms for dealing with conflicting interpretations or inappropriate use of data established at an early phase of the relationship between the community and the investigators included in the written agreement between them. An alternative to restricting publication could be allowing for publication of dissenting or conflicting interpretations of data.genous

INDIGENOUS RESEARCH ETHICS POLICY STATEMENTS AND PARALLEL SYSTEMS OF RESEARCH ETHICS REVIEW: IMPLICATIONS FOR RESEARCH ETHICS BOARDS

Some have called for "Aboriginal specific" REBs with a majority of Aboriginal members as a solution to this and other issues arising in research involving Aboriginal individuals and communities (Brant-Castellano, 2004; Maddocks, 1992). Another alternative is the development of codes of research ethics developed by the local community. For example, the Kahnawake research code emphasizes communities' reciprocal obligations: advising and promoting the research, control of the data and writing dissenting interpretation when needed (Macaulay, et al., 1998). While a number of communities have taken up these approaches, they do not entirely resolve all problems if academic or hospital researchers are still required to receive approval from their local REBs before proceeding, unless the local REB has developed expertise in this area. Most Aboriginal, First Nations and Regional Federations have not yet developed their own REB structure, or begun development of local policy guidelines.

Prospects for Co-participation Between Research Ethics Boards and Aboriginal Research Ethics Review Boards

Despite these issues, there may be solutions to the issues impacting advance planning for REB review. There is nothing in the Tri-Council Policy Statement (1998) that would preclude a staged or layered review of a project, one that could be sensitive to a process that would not begin with a fully formed research proposal. With three-way cooperation between the community, the researcher and the REB, the issues of process for REB review could be accommodated within a Tri-Council Framework, but should also be addressed specifically in redevelopment of Section 6. The development of complementary policy has the additional advantage of promoting the sharing of knowledge and capacity amongst researchers, ethicists and other REBs members, and community members in the areas of research methodologies and research ethics (Kaufert et al., 2001).

SUMMARY AND CONCLUSIONS

Group or community consent means more than applying an approval process culminating in a "yes" or "no" vote by community members or leaders to determine whether a specific research project will take place within community boundaries. Rather, it connotes an alternative approach to ethics review in research involving Aboriginal communities. This report is intended to provide background information from the perspectives of academic researchers and external Research Ethics Boards on the conceptual basis and pragmatic approaches to implementing group or community consent to participate in research in Aboriginal communities and First

Nations. We have summarized Canadian and international Indigenous literature describing a variety of historical contexts, policy frameworks and models of implementation. We have also evaluated a number of areas we view as problematic when traditional REB review is undertaken for community-based projects. In doing our work we have drawn on policy documents, including codes of research ethics and reports prepared by governments and Aboriginal communities, academic publications and personal encounters. We have attempted to draw lessons from those experiences that are relevant to current policy development and ongoing consultation with stakeholder communities in Canada in the process of revising the Tri -Council Policy Statement.

Our research demonstrates that there are workable models of community consent that do not necessarily conflict with the current Tri-Council Policy Statement (TCPS, 1998) requirement for free, autonomous and informed consent in order to participate in research. On the contrary, given a transparent and democratic process within the community, a community commitment to allow for each individual to decide whether to participate in community approved research, and a good working relationship between an Aboriginal community and community-based or outside researchers ,the potential exists for a better informed, more positive process of research ethics review.

We have evaluated existing models which allow for an integration of community and ethics perspectives in the research ethics review process. For example, in Canada, a number of First Nation communities have developed their own codes of research ethics as well as good working

partnerships with researchers based on mutual cooperation within the context of existing Canadian research governance structures.

The US offers an alternative regulatory approach, as Indian Health Service Institutional Review Boards and Tribal governments are responsible for both ethics review and the protection of communities in research initiatives. The national Institutional Review Board [IRB] is composed of at least 70% Aboriginal members, including Native American health professionals with both clinical and research experience (Freeman, 2003). This approach to mandate representation of Aboriginal communities and researchers provides a model for REB structure, as well as for boards and committees reviewing research programs involving Aboriginal communities. Indigenous organizations operating at the national level (such as the American Indian Law Center in the United States, and the National Aboriginal Health Organization in Canada) have developed model guidelines and summary "toolkits" proposing models for research ethics review based on Indigenous values. These models emphasize the moral significance of the community as distinct from the individual, and their frameworks recognize the importance of having the community consent to research participation, as well as individual consent.

Another approach has been taken by science governance bodies in Australia and New Zealand and involves development of both generalized policy statements and specific statements defining ethical values that should govern research within Indigenous communities. In New Zealand, the development of separate systems of research review in terms of responsiveness to Māori values and compliance with research ethics standards incorporates two significant dimensions of community oversight.

Despite the development and diffusion of these successful models, we have identified a number of issues that either requires further elaboration, or raises potential difficulties for the development of a workable model of community consent for Canada. We have listed some limitations of the current system below and conclude this working paper with recommendations for consideration.

1. There is currently no accepted, workable definition of "community" to provide guidance to REBs in recognizing First Nation, Métis or Inuit authority in the research review process.
2. REBs have received little or no guidance on the concept or implementation of community consent frameworks emphasized in Aboriginal health research models.
3. At present, there are no accepted alternative policy guidelines and monitoring processes in Canada to enable REBs or community advisory boards to appropriately review participatory action research protocols. Models of a "layered" review approach (through which community consultation and agreement on mutual obligations are negotiated) before REB review should be considered.
4. REBs reviewing protocols from Aboriginal communities may not have the capacity to assess the risk to individual research participants, nor risk of harm to communities. Evaluation of potential risks of harm often require intimate knowledge of a community in question that an external REB may not possess. Risk assessment may therefore require local participation and broad community consensus.
5. Issues of data ownership and control have the potential to create significant problems in community research. While we do not question the authority of an individual

community to determine whether research should be undertaken within their community, we recognize the impact of perceived barriers amongst the research community in implementing proposed guidelines for community ownership, data control and publication policies. The requirement for open access to research results serves a number of purposes which go beyond issues of community authority; these include obligations to protect and inform individual research participants, as well as communications and groups impacted by generalized research findings. The balance between legitimate community control and issues of protection need to be weighed carefully. Emerging models of participatory work in analysis and publication, combined with agreements committing researchers and communities to publish alternative interpretations of contested research findings, may maintain both freedom of scientific inquiry and demonstrate respect for communities and First Nations.

Recommendations

The challenge of closing the gap between the expectations of Aboriginal communities and the knowledge and capacity of external REBs to provide fair, culturally appropriate ethical review, should be met with the following points of consideration:

1. REBs need a definition of what constitutes a community and processes for determining who legitimately speaks for that community.
2. The REBs role in review of community-based research and development of new guidelines for community consultation should be re-examined and re-articulated.

3. Consideration of any new policy development should include Aboriginal community representation and membership on external REBs as well as development of Aboriginal community advisory committees or regional Research Ethics Board reviews.
4. REB members who review protocols to be implemented in Aboriginal communities should demonstrate relevant knowledge and practice reflecting:
    a. local knowledge;
    b. participatory and consensus-oriented decision-making processes;
    c. history of research relationships with Aboriginal communities;

5. Guidelines should be developed for systematic use by relevant REBs of Aboriginal consultants with both generalized and local expertise in ethical and cultural contexts.
6. A parallel consultation and educational process should also be developed to inform Aboriginal communities and policy makers of the history, science culture and ethical framework of external research ethics boards (IRBs or REBs).
7. Areas, such as the evaluation of potential risks of harm, often require intimate knowledge of the community in question that an external REB may not possess. This lack of relevant expertise can be accommodated by having the REB and community representatives conduct the evaluation jointly, or by seeking the services of an Aboriginal consultant on cultural and ethical issues. In order for such processes to be undertaken, the reviewing body must be sensitive to the issues at stake, or must be required by policy to undertake such a review. This process should be addressed in the development of guidelines or policy.

8. Guidelines or policy frameworks should be established requiring a formal agreement at an early phase of the relationship between the community authority and the investigators, detailing issues of data ownership, interpretation/analysis and publication, with specific mechanisms for dealing with conflicting interpretations or inappropriate use of data. Parties should agree in advance on their roles and responsibilities, desired outcomes, measures of validity, control of the use of data, funding and channels to disseminate findings. The guidelines or policy statement should protect both researchers and participating communities from unreasonable restrictions on access to data or the right to publish findings. One possible mechanism for resolving disputes over dissemination is advance agreement that publication will include dissenting views of both researchers and community, if the partners cannot agree on the interpretation.

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ACKNOWLEDGEMENTS

We acknowledge the support of the Canadian Institutes for Health Research. We acknowledge the significant contributions of Ms. Lisa LaBine to both the development of the literature review and editorial process, and we acknowledge the conceptual and editorial contributions of Dr. Patricia A. Kaufert. We also appreciate the informal advice and support from colleagues in the Centre for Aboriginal Health Research, Department of Community Health Sciences and Health Information and Research Committee. We also acknowledge the wisdom and guidance which Ms. Doris Cook, Project Manager for the Aboriginal Ethics Policy and Development Initiative have extended to us throughout the development of the project.

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