

# CIHR Guidelines for Health Research Involving Aboriginal Peoples

Draft for consultation

Prepared by CIHR Ethics Office  
April 2006

## Executive Summary

This document is designed to facilitate the ethical conduct of research involving Aboriginal peoples. The intent is to promote health through research that is in keeping with Indigenous values and traditions. The guidelines assist in developing research partnerships that will facilitate and encourage mutually beneficial and culturally competent research. The guidelines also promote ethical reviews that enable and facilitate rather than suppress or obstruct partnership research. The guidelines have been prepared for the CIHR, an agency of government, and compliance with them as a criterion for the awarding of health research funding.

CIHR established the Aboriginal Ethics Working Group (AEWG), in March 2004, as part of a broader national endeavor to develop research ethics guidelines for Aboriginal people. The AEWG is representative of Aboriginal interests and academic disciplines to provide advice and support for the development of ethics guidelines for health research. The AEWG met to deliberate, discuss and draft the guidelines over the course of two years. A series of commissioned background papers and contributions from the Aboriginal Capacity and Development Research environment (ACADRE) Network informed the deliberations of the AEWG. The group adopted a hands-on, active approach to guidelines development and adopted ethical principles to guide its own work.

A comprehensive nation-wide strategy for consultation with aboriginal communities, researchers and institutions was built on the ACADRE Network. The ACADRE Network is a unique university-based resource with links to academic research communities and partnerships with regional First Nations, Inuit and Métis communities. Proposals for research ethics collaboration were accepted from the ACADRE centers; each proposal was unique to the centre. Early ACADRE activities focused on work with communities to translate traditional values and ethics into guidance for health researchers; this formed the foundation for the guidelines. The first complete draft of research ethics guidelines was completed in May 2005.

Initial vetting of the guidelines was through the ACADREs and their community partners to determine the cultural appropriateness and acceptability, then feedback was sought from the wider academic community. Consultations and vetting throughout Aboriginal and research communities were initiated in Fall 2005 and continued through March 2006; these sessions were conducted by the ACADRE Network as a part of their proposals for collaboration. Additionally, the Ethics Office along with the National Council on Ethics in Human Research conducted workshops and consultations with Aboriginal communities, researchers and REB members to obtain feedback on the draft guidelines. The guidelines were electronically posted by CIHR and its partners to enable widespread access and awareness and to solicit commentary prior to the final revision. Two timeline extensions for feedback were granted to accommodate the high level of interest by the Aboriginal and research communities and requests for additional workshops and consultations. This inclusive and adaptive approach to development of the guidelines contributed to achieving a workable balance on specific issues, given the multiple and diverse perspectives expressed. The productive dialogue stimulated through the guidelines development process is significant educative contribution to research ethics.

The resulting ethics guidelines for health research will contribute to the Tri-Council process that has been established to revise section 6 of the Tri-Council Policy Statement on Research involving Aboriginal People.

A summary of the articles follows:

**Article 1.0:** The researcher should understand the cultural responsibilities that accompany traditional knowledge or sacred knowledge and strictly comply with community expectations and protocols in possessing such knowledge.

The first principle of these Guidelines is premised on a need for researchers to understand and respect Indigenous world views, particularly when engaging the sphere of traditional knowledge and the corresponding responsibility that possession of such knowledge entails. Researchers must understand the broader senses of accountability in order to understand the responsibility that they have once they enter into the research relationship.

**Article 2.0:** Community jurisdiction over the conduct of research must be understood and respected.

Significant changes have occurred in the research environment involving Aboriginal peoples. Aboriginal peoples who maintain their authority as self-determining nations to exercise self-governance have a right to regulate research within their jurisdiction. As a result, academic researchers will need to meet certain community standards, and recognize the Aboriginal community's authority over the research process

**Article 3.0:** Communities should be given the option of a participatory research approach.

Genuine research collaboration is developed between researchers and Aboriginal communities when it promotes a partnership within a framework of mutual trust and cooperation. Participatory research enables a range of levels and types of community participation while ensuring shared power and decision-making. Such partnerships will help to ensure that a research process will proceed in a manner that is culturally sensitive, relevant, respectful, responsive, equitable and reciprocal in terms of the understandings and benefits shared between the research partner(s) and Aboriginal community/communities.

**Article 4.0:** Research conducted in an Aboriginal community shall obtain free, prior and informed consent from individual participants and the Aboriginal community as appropriate.

A process for free, prior and informed consent at individual and collective levels process should be sought sufficiently in advance of commencement or authorization of research activities. Consent processes must take into account Aboriginal community's own decision-making processes, in all phases of planning, implementation, monitoring, assessment, evaluation and closure of a research project. **This requirement of collective community consent is distinct from the obligation of researchers to obtain individual consent from each research participant.**

**Article 5.0:** Confidentiality concerns of the community and individual participants shall be respected and addressed.

Research partners shall provide information regarding the anonymity or confidentiality of communities participating in research projects. When anonymity is not possible, or when there are limitations to anonymity or confidentiality, these must be clearly communicated to participants.

**Article 6.0:** Inclusion of cultural knowledge in research should be under mutually agreed terms and with the guidance of the knowledge holders in the community.

**Article 7.0:** Aboriginal peoples and their respective communities retain inherent rights to their knowledge, cultural practices and traditions that are shared with the researcher(s). It is the responsibility of the researcher to support mechanisms for protection of cultural knowledge that is shared during the research.

Any research involving Aboriginal peoples will involve the sharing of some cultural knowledge, practices and/or traditions, even when these are not the subjects of the study, as they provide necessary context. The recording of knowledge, practices and traditions in any form (written notes, audio, video, or otherwise) must only be done with explicit permission and under mutually-agreed terms that are set out in advance of the research with the guidance of appropriate Elders and knowledge holders. All uses and wider dissemination of cultural knowledge, practices and traditions must also be by permission.

**Article 8.0:** Indigenous concerns over and claims to intellectual property must be explicitly acknowledged and addressed as part of the research process. Expectations regarding intellectual property rights of communities, researchers, and any other parties involved in research should be outlined in a research agreement.

Not all information and knowledge can be protected by existing intellectual property laws; strict eligibility criteria are used to define these legal rights. Understanding what does and does not qualify as intellectual property under current Canadian and international laws is the joint responsibility of the researchers and communities involved. Research with explicit commercial objectives and/or direct or indirect links to the commercial sector must be clearly communicated as such to all research partners.

**Article 9.0:** Research should be of mutual benefit to the community and researchers.

The research project should lead to outcomes that are deemed beneficial to the participating Aboriginal community/communities or individuals as well as the researcher. The benefits and the sharing of research benefits need to be defined from the local community perspective.

**Article 10.0:** Researchers should support the development of education, research, and training (including training in research ethics) for Aboriginal peoples and communities.

Researchers should work to foster capacity building of Indigenous peoples to enhance their participation in research projects and improve the overall interactions between Indigenous governance mechanisms and public educational institutions.

**Article 11.0:** Researchers have an obligation to learn about and apply Aboriginal cultural protocols relevant to the particular Aboriginal community.

**11.1** Researchers should ideally translate all related publications or reports into the language of the community.

**11.2** Researchers should ensure that there is effective on-going communication in a manner that is accessible and understandable to the community.

Aboriginal communities often have cultural protocols involving interactions within the community. It is important that researchers learn about these and comply with them appropriately. When providing a research project report to the community, at minimum, researchers should provide an executive summary in the language of the community unless the community has expressly waived such a requirement. These reports or communication of results with the Aboriginal group should be done using language and terminology that are readily understood by the community.

**Article 12.0** Aboriginal communities have inherent rights to control and determine their proprietary interests in the collection, use, storage and potential future use of data.

The collection, use, storage and potential future use of data needs to be negotiated as part of the research process and be specified in a research agreement. Co-ownership of data between researchers and communities is recommended because the Aboriginal community and the researcher are both integral to the production of data (pre and post-analysis), subject to the community's views on traditional or sacred knowledge. Secondary use of the data by either party requires a re-consent process.

**Article 13.0:** Biological research samples should be considered “on loan” to the researcher.

Newly collected samples from Aboriginal participants will be considered “on loan” to the research, analogous to a licensing arrangement and detailed in the research agreement. Only research that has been consented to can be carried out; no secondary research without the consent of the community where samples are anonymous or individual participant where samples are linkable to identity; the researcher is considered the steward rather than the owner of the samples; and no samples will be transferred to third parties without consent.

**Article 14.0:** All Aboriginal communities should have an opportunity to participate in the interpretation of data and/or review of conclusions drawn from the research to ensure accuracy and sensitivity of interpretation.

An opportunity for review of the research results by the Aboriginal community/communities should be provided before the submission for publication of research findings. Such a review is to ensure that sensitive information is not divulged to the public and that misrepresentations are corrected prior to wider dissemination.

**Article 15.0:** It is the discretion of the community partners as to how their contributions will be acknowledged. Community members have the right to due credit and participation in dissemination of results and publications must recognize the contribution of the community where appropriate and in keeping with confidentiality agreements.

Research involving Aboriginal groups is susceptible to manipulation or misrepresentation when information about the group is isolated and analyzed without consideration of a sufficient amount of other cultural characteristics which make the group distinct and add greater merit to the scholarship.

A sample research agreement and charts which describe the step-by step procedures of the research process have been developed and included as appendices.

# Contents

Acknowledgments .....	7
<b>Section I - Introduction.....</b>	<b>8</b>
1.1 Purpose.....	8
1.2 Guidelines, History and Background.....	8
1.3 The Aboriginal Ethics Working Group.....	9
1.4 Guidelines Application .....	10
1.5 Who is an Aboriginal Nation or Community?.....	11
1.5.1a What is Aboriginal about the research? .....	12
1.5.1b Complex authority structures.....	12
1.5.2 Individuals or sacred societies as decision-makers .....	13
1.5.3 Challenges to formal community authorities .....	13
1.6 Rationale .....	14
1.7 Summary .....	15
<b>Section II - Ethical Principles of Aboriginal Health Research .....</b>	<b>16</b>
2.1 Ethical space .....	16
2.2 Sacred Space and Traditional Knowledge .....	16
2.3 Community Jurisdiction and Approval Processes .....	17
2.4 Research as a Partnership.....	19
2.5 Collective and Individual Consent.....	20
2.6 Confidentiality/Privacy .....	22
2.7 Inclusion and Protection of Cultural Knowledge in Research.....	22
2.8 Intellectual Property Rights and Indigenous Knowledge .....	23
2.9 Benefit Sharing .....	24
2.10 Empowerment and Research Capacity Development.....	25
2.11 Cultural Protocol, Language and Communication.....	25
2.12 Data Collection, Storage, Use, Management and Ownership.....	26
2.13 The Collection, Storage, Management, of (Human) Biological Samples.....	27
2.14 Interpretation of Results and Dissemination.....	28
2.15 Research Agreements and Memoranda of Understanding.....	29
<b>Section III – Procedure, Protocol and the Research Process .....</b>	<b>31</b>
3.1 Step-by-step procedure .....	31
3.2 Protocol and Research Process .....	34
3.2.1 Protocol.....	34
3.2.2 Research Process.....	36
<b>Section IV – Articles .....</b>	<b>39</b>
<b>Appendix A: Sample agreement provided by the Centre for Indigenous Peoples' Nutrition and Environment (CINE) .....</b>	<b>39</b>
<b>References .....</b>	<b>43</b>

## Acronyms

<b>AEWG</b>	Aboriginal Ethics Working Group
<b>ACADRE</b>	Aboriginal Capacity and Developmental Research Environments
<b>CIHR</b>	Canadian Institutes of Health Research
<b>IAPH</b>	Institute of Aboriginal Peoples' Health
<b>IK</b>	Indigenous Knowledge
<b>IP</b>	Intellectual Property
<b>NCEHR</b>	National Council on Ethics and Human Research
<b>NSERC</b>	Natural Sciences and Engineering Research Council
<b>PRE</b>	Interagency Advisory Panel on Research Ethics
<b>SSHRC</b>	Social Sciences and Humanities Research Council
<b>REB</b>	Research Ethics Board
<b>TCPS</b>	Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans
<b>Tri-Council</b>	The three federal funding agencies (CIHR, NSERC, SSHRC)
<b>TK</b>	Traditional Knowledge
<b>UNESCO</b>	United Nations Educational, Scientific and Cultural Organization

## Acknowledgments

We, the members of the Aboriginal Ethics Working Group (AEWG), take the time to acknowledge the Creator and those who came before us without whom this document could not have been written. We also acknowledge the hard work of the many individuals, communities and organizations that generously provided input, and responded to the drafting of this document. We understand the English and French languages do not always allow Aboriginal concepts and worldviews to be effectively communicated across cultures and we do not wish to offend with words that have been written. We do encourage continuous input as Aboriginal ethics are articulated within an academic research context.

In particular, the AEWG thanks Joe Kaufert for his insightful guidance and assistance throughout our deliberations, Therese DeGroot and Daryl Pullman for their thoughtful comments and, Jewel Peters, Theresa Willoughby, and Yumna Kanda for their assistance in this project. The AEWG is deeply grateful for the leadership and commitment of Doris Cook throughout this endeavour.

# Section I - Introduction

## 1.1 PURPOSE

This document is designed to facilitate the ethical conduct of research involving Aboriginal peoples.<sup>1</sup> The intent is to promote health through research that is in keeping with Indigenous values and traditions. Health is understood in a broader sense than the notion of bio-psycho-social well-being (Romanow, UNESCO). In keeping with Indigenous understandings of health, the concept as used in this document also includes spiritual, cultural, community and environmental well-being. Fostering health in this sense includes enabling growth, balance, self-determination, reciprocity, relationships and peace. This is a living document, as a part of an ongoing process it is intended to be reviewed and revised in four-year cycles.

The guidelines are intended to promote ethical reviews that enable and facilitate rather than suppress or obstruct research. The guidelines promote research partnerships that will facilitate and encourage mutually beneficial and culturally competent research.

There is an increasing recognition that improvements in the health status of Aboriginal people require changes both at the individual level as well as at the community level. Concurrently, there is a growing interest in working with communities to create healthful changes through academic/practice/community partnerships. There is also recognition that the knowledge, expertise and resources of the community are often key to successful research. While developing partnerships may initially require more time and effort, research partnerships based on mutual trust and respect leads to better research and a more positive relationship with communities and individuals affected by the research. Following the principles and articles embodied in these guidelines will over the long run be beneficial for both partners.

## 1.2 GUIDELINES, HISTORY AND BACKGROUND

Since the adoption of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) in 1998, there has been a general acknowledgement that Section 6, Research involving Aboriginal Peoples, required further development. In fact, a statement indicating that insufficient consultation had taken place and that it was premature to establish policy in this area is included in a preface to Section 6.

To redress the lack of policy in this area, in July 2003, the three funding agencies, CIHR, NSERC and SSHRC, committed to a collaboration intended to produce a revision of Section 6 of the TCPS. The scope and coverage of the project required a process that is broadly inclusive of the health, social and natural sciences as well as the engagement of Aboriginal peoples. It has been recognized that conducting an open participatory process that involves national Aboriginal organizations and the research communities requires an extended timeframe. The revision of Section 6 is anticipated to be complete by Spring 2007.

In an effort to meet the needs for corporate accountability and the calls for guidance in ethics from the ACADRE centers, researchers and Aboriginal communities, the CIHR-Ethics Office and IAPH decided to establish a parallel process that would lead to the timely production of health research

---

<sup>1</sup> Throughout this document, the terms Aboriginal and Indigenous are used interchangeably, with a tendency to use Aboriginal when referring to Indigenous peoples within Canada. See [http://www.unhchr.ch/Huridocda/Huridoca.nsf/TestFrame/42263fd3915c047ec1256929004f1ffc?](http://www.unhchr.ch/Huridocda/Huridoca.nsf/TestFrame/42263fd3915c047ec1256929004f1ffc?OpenDocument) Open document for discussion of Indigenous people in the context of protection of Indigenous heritage.

guidelines. Guidelines would be developed in partnership with ACADRE centres and other relevant stakeholders to ultimately feed into the larger Tri-Council process. The process would be harmonized to ensure collaboration and sharing of information and products, thereby ensuring coherence and consistency in ethical standards and protocols.

### **1.3 THE ABORIGINAL ETHICS WORKING GROUP**

To provide guidance and oversight to the development of Aboriginal specific research guidelines, an external advisory body – the Aboriginal Ethics Working Group (AEWG), has been created.

The following considerations were key in guiding the work of the AEWG: a recognition that health research is essential to improve the health and well-being of Aboriginal people; a belief that there are researchers who want to address some of the significant disparities in health that affect Aboriginal communities; the need to balance individual and collective interests; respect for Aboriginal values, knowledge, methodologies and decision-making processes; and a commitment to an inclusive, participatory process that engages the Aboriginal and research communities. In addition to the broad ethical principles that guided the development of Aboriginal ethics policies by the AEWG, additional values guided the management of the process, such as broad-based representation, efficiency, responsiveness and transparency in fulfilling its mandate and enhancing the confidence of its stakeholders (the Aboriginal, research and institutional communities) in the guideline development process. The AEWG recognized that ethics in research is not just a review moment but begins with the establishment of partnerships with communities and extends beyond the dissemination of research results.

The AEWG is composed of twelve appointed members who advised on the implementation of the project work plans and provided scientific and technical advice on the development of the research guidelines. The composition of the AEWG ensured diverse citizen engagement in this issue and reflected a broad range of relevant disciplines and interests, such as the Aboriginal community, Indigenous studies, anthropology, ethics, law, medicine, public health and the natural and social sciences. Majority of the members of the AEWG are Aboriginal people (Indians, Inuit and Métis) from First Nation, Northern, rural and urban communities. Members of the AEWG included:

- Laura Arbour, MD, Department of Medical Genetics, University of British Columbia
- Kelly Bannister, PhD, POLIS Project on Ecological Governance, Law and Environmental Studies University of Victoria
- Elder Ed Borchert, Alberta ACADRE Centre
- Fern Brunger, PhD, Health Care Ethics, Memorial University of Newfoundland
- Laurie Chan, PhD, BC Leadership Chair in Aboriginal Environmental Health and NSERC Northern Research Chair, University of Northern British Columbia
- Larry Chartrand, LLM, Aboriginal Governance Program, University of Winnipeg, AEWG Co-Chair
- Jeff Corntassel, PhD, Indigenous Governance Programs, University of Victoria
- Veronica Dewar, Past President, Pauktuuit Inuit Women's Association
- Elder Shaun Hains, PhD, Educational Psychology, University of Alberta
- Phyllis Kinoshameg, Wikwemikong Band Member
- Dawn Martin-Hill, PhD, Indigenous Studies Programme and ACADRE Centre, McMaster University
- Francine Romero, PhD, Jemez Pueblo Department of Health and Human Services, AEWG Co-Chair

The guidelines are a result of a process that engaged Aboriginal elders and communities from First Nation, Inuit and Métis communities across Canada in dialogue and consultation on traditional values and ethics related to health research. Traditional values and ethics provided the foundation

upon which the guidelines were developed. The guidelines have been vetted extensively within the Aboriginal, research and institutional REB communities across Canada.

## **1.4 GUIDELINES APPLICATION**

These guidelines are to be used in conjunction with the Tri-Council Policy Statement (TCPS) governing research involving human subjects. The TCPS defines individual level protections while these guidelines focus on research with an Aboriginal group or community(ies). This document identifies a number of specific areas in which the TCPS is to be modified by these guidelines. The guidelines are designed for use by researchers conducting health research involving Aboriginal peoples; by research ethics boards (REBs), including institutional and private REBs; and by locally established Aboriginal ethics review committees, where they exist. These guidelines may also inform individuals and communities who are the subjects of or participants in research to assist them in understanding what to expect from a research relationship.

This document provides general guidelines that should be seen as a minimal acceptable standard for research funded by CIHR. Researchers should also refer to the relevant Aboriginal communities' own research ethics guidelines and processes. When communities do not have such guidelines in place or do not have an identifiable political leadership, then these guidelines will be especially useful in providing a template to enable the development of a process for ethical research. In cases where differences exist between these guidelines, the TCPS, and local Aboriginal community guidelines for ethical research, then the guidelines that provide the most rigorous protection for Aboriginal research participants shall prevail. Parties would be expected to work toward achieving consensus on research protections that are appropriate to their specific context. Ensuring that all parties are aware of, understand existing institutional, professional and community standards will be important factors in achieving consensus.

Researchers may be concerned that not all research carried out with Aboriginal people seem relevant to these guidelines. For example if a 12 year old Aboriginal girl is diagnosed with leukemia, she may be eligible for a research protocol for treatment. In that case, and other similar cases, community consultation and consent would not seem relevant. In general, exemptions to the guidelines include: those research projects where: Aboriginal individuals are recruited along with non-Aboriginal participants and the research hypothesis does not relate specifically to the fact that the person is Aboriginal; the inclusion criteria for recruitment does not classify membership of Aboriginal status either for the entire study or as a sub-group; the analysis will not use Aboriginal community membership as a variable in the analysis; and, the interpretation will not refer to Aboriginal people, their language, history or culture. In general, research that is not Aboriginal community or population directed for clinical trials for development of new diagnostics, drugs or therapies for breast cancer, epidemiological or genetic studies where a disease is the subject of study. However, research that will explore aboriginal health on a population basis rather than a community basis must have been preceded by consultation of an appropriate governing body. In these cases, 'community consent' would not be possible, however, Aboriginal governing bodies overseeing health, such as the First Nations Chief's Health Committee in British Columbia, or the Nunavut Research Institute must have been consulted with prior to the onset of the research. For further discussion of these issues see articles entitled DNA on Loan: Issues to consider when carrying out genetic research with Aboriginal Populations (Arbour & Cook, 2006) and Section 1.5.1a.

This document is structured in two main parts. The first part provides an overview as to why it is appropriate to have ethical principles that are unique to Aboriginal peoples' context. Rationales are included that describe need for such principles and the importance of developing them from an Aboriginal worldview. The second part sets out several articles that collectively summarize key ethical principles. Following each article is a brief discussion, rationale for inclusion and application to research projects.

The definition of health within Aboriginal conceptions of the term is broad in scope; therefore these guidelines may also apply to research on issues not typically considered to be “health” research from a Western scientific perspective. For a discussion on the differences between Aboriginal and Western perspectives of health, see *Gathering Strength*, Vol. 3 of the Royal Commission on Aboriginal Peoples Final Report.

## **1.5 WHO IS AN ABORIGINAL NATION OR COMMUNITY?**

Community, in its most straightforward definition, refers simply to “a sense of belonging together.” It may refer to a group of people living together in one place; it may include reference to a particular place as well as to its inhabitants; or it can refer to a group of people having a religion, ethnicity, profession or other particular characteristics in common, even where these people do not live in the same geographical area. A group of individuals may have shared traits or geography without a sense of or shared solidarity or community. Alternatively, “community” may be based on a feeling of solidarity, and exist in the absence of shared geography, language, culture, or other clearly identifiable shared characteristic.

Community in the context of Aboriginal research constitutes a structure of support mechanisms that includes the personal responsibility for the collective and, reciprocally, the collective concern for individual existence. Importantly, Aboriginal conceptions of community often encompass relationships in a very broad sense, including relationships of human, ecological and spiritual origin.

Aboriginal peoples in Canada have distinct political, legal and cultural governance structures and have political legitimacy that supports their jurisdictional and decision-making authority on issues, including health research projects that directly affect the community. The right to make decisions on behalf of the community is grounded in constitutional law and is generally vested in Aboriginal communities as represented by their leadership. As defined by the *Constitution Act*, 1982, s.35 (2), Aboriginal peoples include people of First Nations, Inuit and Métis groups.

Researchers should consider that Indigenous communities have historically been voluntarily or involuntarily dislocated from their original homelands and may constitute diasporic communities in urban areas. Urban Aboriginal communities should be recognized as such. Urban Aboriginal communities may, but do not necessarily, maintain significant contacts with their families/communities within their original homelands.

It should be recognized that Indigenous peoples are not homogeneous. As with other cultural groups, Indigenous groups comprising “community” are diverse and varied according to gender, sexual orientation, religious affiliation, age, etc. Every effort should be made by researchers to respect cultural diversity and pluralism and to accommodate such groups within the research project where appropriate. The *Universal Declaration on Bioethics and Human Rights* (2005) provides broad support to the ethical standards contained herein as many of the articles reflect important standard-setting, human rights principles relevant to Indigenous populations within Nation States.

Researchers and research ethics boards (REBs) need to recognize the importance of identifying the appropriate authority(ies) representing the community in the development of the research project and the subsequent negotiation of the research agreement. There are a variety of factors that can make this task difficult. The identification of appropriate leadership in an urban Aboriginal environment can be challenging for health researchers unfamiliar with the urban Aboriginal community. The central and vital role played by Friendship Centres in urban Aboriginal life makes the Friendship Centres the place a logical place to initiate discussions. The 117 centres are located across Canada and are the main instrument for delivery of programs and services to urban Aboriginal people. The centres provide a range of programs and services in areas such as housing,

education, skills training and employment, youth and family services and health to off-reserve First Nations, Non-Status Indian, Métis and Inuit people. They serve as a cultural hub for Aboriginal people living in cities and for the newly relocated. Friendship Centres started as local grassroots organizations but since the 1970's have received core funding from government, Heritage Canada, and program and services funding from Health Canada, Human Resources Development Canada, Indian and Northern Affairs Canada, Department of Justice and provincial and municipal agencies in each province and territory. Additionally, Aboriginal regional and provincial organizations exist in every province that can offer assistance in determining appropriate community authorities.

### 1.5.1a What is Aboriginal about the research?

For the purpose of these guidelines, research involving Aboriginal peoples is defined on a continuum as follows:

1. Research involving exclusively Aboriginal communities directly.  
e.g., a research project that examines the status of diabetes in Pond Inlet
2. Research involving Aboriginal peoples where they comprise a sizable proportion of the study or community and Aboriginal specific conclusions are intended. The researcher is not absolved of obtaining appropriate collective consent if the research is physically conducted outside the community but nonetheless implicates the community.  
e.g., a research project that involves a study of Yukon resident dietary preference
3. Research involving Aboriginal peoples where the Aboriginal peoples (regardless of their proportion within the larger community) are part of a larger community that is the subject of research and Aboriginal-specific conclusions are intended or it is foreseen that Aboriginal-specific conclusions may come about after the research is complete  
e.g., a finding that the Aboriginal residents of the Spence neighborhood are disproportionately poor and experience high levels of illness, as opposed to a general finding about the neighborhood
4. Research involving Aboriginal peoples where the Aboriginal peoples are a sizeable proportion within the larger community that is the subject of research even if no Aboriginal-specific conclusions will be made.  
e.g., research on the extent of poverty in the Spence neighborhood of the Winnipeg inner city
5. Research not intended to single out or describe characteristics of Aboriginal people in the study, where Aboriginal people live in the community but not in significant numbers and are only indirectly affected, and are not specifically targeted in the research. In such cases it would be good practice to consult with Aboriginal representative groups since the outcome of the research is likely to affect the environment or have an impact on the environment where they live.

Depending on the extent to which the research involves Aboriginal people, the researcher will be obliged to obtain community consent and/or consult with community representatives. In the above scenarios, consent would be required in the first and second instances. Consultation is required in the third example, provided there is an accessible political body to consult. In the fourth and fifth example, consultation would be good practice, but is not required.

### 1.5.1b Complex authority structures

The legal authorities of a community may be band Elders, traditional leaders, municipal leaders, tribal leaders, confederate leaders, regional Aboriginal leaders, and so on.

The recognized authorities of a community may be traditional leaders, Elders, municipal leaders, tribal leaders, confederate leaders, regional Aboriginal leaders, Inuit land claim organizations, research institutes and so on. For example, a First Nations community may have both a band chief and a mayor, who may or may not be different individuals, as recognized political authorities. A community's best interests in terms of knowledge may be the responsibility of the family, the band (several families combined), the tribe (several bands combined) or the confederacy (several tribes combined). An Inuit community may have a mayor, health committee and regional Inuit organization president, as well as a Territorial Research Institute which licenses research in the region.

Responsibility and accountability operate in different ways depending on the specific context of a particular research project and the specific context of a particular community and its authority structure. Individuals may be merely members of a community or they may be the holders of sacred or traditional knowledge on behalf of a community (in a sense that may include the recognized spiritual deity, the Land and past and future generations). Kinship groups may be kin in the sense of extended family or they may be clans in which both biology and sacred knowledge are hereditary. Because Aboriginal communities generally have multiple structures of political authority, the final decision on research projects will often originate with the individual band authority. However, in the case of sacred or traditional knowledge, individuals (Elders or Knowledge Keepers) or community groups (Clans, Sacred Bundle societies) may have the final political authority over certain types of knowledge. Researchers and participants, therefore, cannot assume that one political body has complete authority; one must determine on a case-by-case basis the extent to which each type or level of authority has a role to play in the research and ethics review process.

Aboriginal communities have a ground-up structure of political authority, researchers and participants cannot assume that one political body has the authority over research.

### 1.5.2 Individuals or sacred societies as decision-makers

Although sacred knowledge is often held collectively by an Aboriginal community, sacred knowledge may, in some cases, be considered to be held by certain designated individuals and not necessarily the community. For example, some Elders may be keepers of sacred knowledge. Another example of specialized authority occurs when a sacred society (rather than an individual Elder) or a clan is given the responsibility of keeping traditional knowledge. For example, the Blackfoot rely on the "sacred bundles" as the source of authority on important spiritual and cultural matters and the band councils would never presume to interfere with the decisions of a society that is responsible for a sacred bundle and its knowledge. In such cases, a thorough review of values and beliefs will help to clarify for the researcher, the community, and the individual Elder the best way to proceed.

### 1.5.3 Challenges to formal community authorities

There may be rare cases where the researcher does not believe the formal community leadership is acting in the best interests of the community. For example, a community mayor or representative of a regional Inuit organization may be blocking research deemed beneficial by other members of the community (e.g., male leaders preventing research on violence against women). Researchers and research participants must

Confrontation can be avoided by having an ethics review process that is separate from the political authority consent process in cases of conflict of interest.

take responsibility for working together to determine whether the leadership is in a conflict of interest and not able to make a decision in good faith. If such a dynamic exists, a community system or structure e.g., elders council, may be in place to resolve the issue and should be employed. The parties within this process should respect the decision making processes of the Aboriginal community (ies) involved. (UN, 1994 Article 19).

## 1.6 RATIONALE

It is necessary to view contemporary ethical standards for Aboriginal health research within a broader historical context and through both Aboriginal and western scientific perspectives. Research in the broad sense of systematically gathering information through observation of the natural world and empirical testing in real life situations has always had an important role in the lives the Indigenous peoples of Canada in learning to live with the land. Communities have developed many ways of learning and sharing that are important to health and survival, and the principles that have guide this learning are woven through all aspects of Aboriginal culture.

By comparison, the evolution of western scientific thought since the time of Enlightenment has largely diverged from other ways of knowing, with the “standard view” of quantitative and experimental science prevailing in contemporary scientific research theory and practice.

During European colonization of Canada, Aboriginal peoples were largely prevented from using Indigenous languages, practices, and Indigenous ways of gaining knowledge. The western scientific paradigm predominated and through the research process Indigenous peoples and their cultures largely became the subjects and objects of study.

Since the time of colonization, the standard view of western science has shifted. Qualitative research has begun to look in more depth at the complex nature of problems, and new philosophies and methods have emerged that require consideration of non-western value systems and ways of knowing. For example, in “participatory research” and “action research” people from the community of study are included to share in exploring a problem with the researcher.

In recent decades, awareness has grown within the academic research community and within Aboriginal communities about incompatibilities and historical injustices due to Euro-colonial influences on research. Support and respect for Indigenous ways of knowing and conducting research have steadily increased. The scientific community has come to realize that Indigenous peoples often hold unique cultural knowledge within complex knowledge systems and that this knowledge requires specific consideration in research. Certain areas in science such as ethnobotany have come to appreciate Aboriginal contributions to science.

On many occasions, Indigenous peoples and cultures have been harmed through research, and numerous examples are documented in the literature. For example, in a report prepared by the National Aboriginal Health Organization, thirty examples are identified; listing various complaints that have been made against researchers over the years by Aboriginal communities.<sup>2</sup>

It is now widely agreed that mechanisms to prevent further harm are needed. Outlining ethical protocols for research conducted with and within Aboriginal communities is an important step in this regard. Many Aboriginal communities and organizations within Canada are in various stages of

---

<sup>2</sup> First Nations Centre, NAHO, *Ownership, Control, Access and Possession or Self-Determination Applied to Research; A Critical Analysis of Contemporary First Nations Research and Some Options for First Nations Communities* (NAHO, 2002) at 3-4. See also the report by the Indigenous Peoples’ Health Research Center, *The Ethics of Research Involving Indigenous Peoples* (Saskatoon: IPHRC, 2004) at pages 12-34 where the authors provide an overview of the historical problems associated with research in Aboriginal communities from a theoretical perspective. See <http://www.iphrc.ca>

creating independent ethical research guidelines and protocols. In some cases, legislatures have enacted research requirements such as the Northwest Territories *Scientists Act*, which sets out the requirements for obtaining a license to conduct research for the purpose of gathering western scientific knowledge and/or Indigenous knowledge.<sup>3</sup> The drafting of these *Guidelines for Health Research Involving Aboriginal Peoples* has been influenced by this trend and has drawn upon the significant local and international efforts to respect Aboriginal knowledge and worldviews on ethics and protection of cultural heritage. In addition, the development of the guidelines was influenced by the desire to provide assistance and direction to researchers who want to do no harm but also to conduct health research that benefits Aboriginal people.

## 1.7 SUMMARY

Jurisdiction to control or consent to research is not the same as ethics review. Aboriginal communities have jurisdiction to control the conduct of research in their communities. Aboriginal communities also have a right to collectively consent to research. Research agreements should be negotiated and formalized with the relevant authorities of various Indigenous jurisdictions before any research is conducted. Aboriginal communities may (and ideally do) have their own research ethics guidelines and processes, including a research ethics board. However, the research ethics board is not necessarily the same entity as the authoritative structure that controls the conduct of research in the community. For example, the formal authority that governs how research is conducted in the community is typically the band council in First Nations communities, and varies in Inuit communities among the Community Council, Research Institute and Regional Inuit Land Claim Organization. However, there may be a separate (politically independent) board that represents the interests of the community to negotiate (within the ethical space) the research and/or to conduct an ethics review of the research.

Some Aboriginal land and/or self-government agreements contain provisions regarding the conduct of research within the jurisdiction of the Aboriginal government. See for example section 17.13.1(f) and (k) of the *Land Claims Agreement Between the Inuit of Labrador and Her Majesty the Queen in Right of Newfoundland and Labrador and Her Majesty the Queen in Right of Canada (2005)* which states:

“The Nunatsiavut Government may make laws in Labrador Inuit lands and the Inuit communities in relation to ... health related research involving Inuit, including establishment of ethical standards for and the ethical review of medical research involving Inuit ... and the creation of boards, authorities and other entities to establish, manage and operate health care and research programs, services and related facilities.”

Indigenous social norms and values tend to be organized around an operative principle of collective Indigenous knowledge and ownership. This is one of the reasons why the notion of community consent is so important in the context of research involving Indigenous peoples. However, there may be exceptions to this principle, depending on whom or what entity has authority over its dissemination and communication. Therefore, it is important to clarify the value and appropriateness of a community's or nation's authority regarding consent to research, compared to community negotiation of research, compared to individual consent, for each project and context.

The following section outlines a number of ethical principles, often followed by a description of the principle's rationale and/or advice on its implementation.

---

<sup>3</sup> See *Scientists Act*, R.S.N.W.T. 1988, c. S-4

## Section II - Ethical Principles of Aboriginal Health Research

Substantive principles must be understood in the context of sacred space, described below. This includes an understanding of sacred knowledge as engaging the relationship between the recognized spiritual entity, Land, and the Ancestors. This means that principles familiar to researchers, such as autonomy, beneficence and justice, may need to be reinterpreted by researchers in the context of the values and beliefs of the local community.

### 2.1 ETHICAL SPACE

Ethical space (Ermine, Sinclair and Browne, 2005) refers to the meeting of two entities with different intentions. This could be two cultures coming together in a research endeavor; it could also apply within one community of Indigenous peoples (for example, the ethical space in which Elders and band members negotiate an understanding of a research project). In this document ethical space means the process by which specific values and beliefs related to a specific research project are articulated, discussed and negotiated.

Ethical space includes a series of stages of dialogue beginning from the conversations prior to the design of the research, through to the dissemination of results and perhaps even afterward. The fundamental requirement of the establishment of an ethical space is the ongoing affirmation of this space, a continual questioning of "is this ethical?" The affirmation of ethical space requires dialogue about intentions, values and assumptions throughout the research process. It offers a valuable means of negotiating norms and understandings and bridging gaps between Aboriginal and non-Aboriginal societies.

### 2.2 SACRED SPACE AND TRADITIONAL KNOWLEDGE

**Article 1.0:** The researcher should understand the cultural responsibilities that accompany traditional knowledge or sacred knowledge and strictly comply with community expectations and protocols in possessing such knowledge.

Sacred space is used in this document to refer to the relationships between the individual and a recognized spiritual entity, the Land, Kinship networks (including all plant and animal life) and Ancestors. This relationship is both spatial (where the individual is inclusive of the family and the community) and temporal (where the present generation is inclusive of past and future generations). In this sacred space, there is an interconnectedness founded in purity, clarity, peace, generosity and responsibility between the recognized spiritual entity, the Land and the Ancestors.

The notion of sacred space is key to understanding accountability in the production and transmission of traditional knowledge. Traditional knowledge is a term that has been widely discussed and debated by Indigenous people, scholars, policy makers and others throughout the world for decades and there is no single agreed definition. Two examples are:

- knowledge, innovations and practices derived from customary uses and associated cultural practices and traditions (<sup>iii</sup>CBD, 1992, Art 8j);
- a body of knowledge, spirituality and art forms that reflect history, culture, ethics, creativity, are based on customary laws and protocols and have been handed down from generation to generation (<sup>iv</sup>Cassidy & Langford, 1999).

However, in the context of research ethics, Aboriginal groups, local communities and other traditional knowledge holders have the right to decide what constitutes their own knowledge, innovation, cultures and practices and the ways in which they should be defined. Values such as respect, wisdom, love, honesty, humility, trust and bravery are common among Aboriginal communities but they do not have the same meaning or relevance within all Indigenous communities, or even within one given Indigenous community.<sup>4</sup> The Inuit, for example, use the term “Inuit Qaujimagatugangit” to describe their holistic approach to environmental and traditional knowledge.

While a researcher is accountable to funding bodies, institutions, colleagues and students, once they share Indigenous knowledge they are also accountable to the recognized spiritual entity, the Land and past and future generations. In some cases, the notion of accountability may imply responsibility across a temporal dimension that is foreign to western notions of accountability (for example, accountability to past and future generations may take primacy over accountability to community authorities for certain types of knowledge). Accountability may also involve a sacred dimension such as a sense of relational accountability to a recognized spiritual entity or to the Land. Researchers must understand these broader practices of accountability in order to understand the responsibility that they have once they enter into the research relationship. Canadian society at large may benefit from a better understanding of this perspective and its implications for health. For a further discussion of this concept of sacred space see the report by the IPHRC, entitled *Kwayask itôtamowin: Indigenous Research Ethics* (Ermine, Sinclair and Browne, 2005).

Hence, the first principle of these Guidelines is premised on the researchers understanding and respecting Indigenous world views, particularly when engaging the sphere of traditional knowledge and the corresponding responsibility that possession of such knowledge entails.

## **2.3 COMMUNITY JURISDICTION AND APPROVAL PROCESSES**

**Article 2.0:** Community jurisdiction over the conduct of research must be understood and respected.

Aboriginal communities have the right to regulate research within their communities. This includes the following rights:

- to partner in research conducted within or about their communities if so desired;
- to provide informed collective consent; and
- to manage the research process, including the creation of ethics review principles and procedures.

Researchers must determine if the Aboriginal community has exercised authority in the area of research.<sup>5</sup> Scientists and academics need to comply with any such policies, rules or regulations

---

<sup>4</sup> See the Guidelines for Ethical Aboriginal Research in the Manitoulin Area (2003) for an example of an Aboriginal regional approach that relies on the articulation of these values as the guiding principles for ethical research.

<sup>5</sup> The source of this authority is based on the assumption that Aboriginal communities have an Aboriginal or treaty right to regulate research within the community. Research involves the activity of seeking knowledge, an activity that is culturally specific and fundamental to all societies. Hence, control over such an activity would by its very definition meet the current doctrinal requirements of the Supreme Court of Canada regarding proof of Aboriginal rights as activities, customs or traditions that are integral to the distinctive culture of the Aboriginal community. The right to control research would therefore have constitutional force under s.35 of the *Constitution Act*, 1982. However, the analysis regarding Aboriginal control and jurisdiction within this document does not necessarily reflect official federal government policy.

adopted by the community. Aboriginal communities may have their own Research Ethics Board and/or community research protocols established. In this case, the Aboriginal community has jurisdiction to require research conducted in their region or territory to comply with such procedures as are required by the local or regional Research Ethics Board. Every effort should be made by researchers to respect cultural diversity and pluralism within these communities.

In Inuit regions, land claims may also have significant impacts on the way research is to be conducted. For example, Article 32 of the *Nunavut Land Claims Agreement* sets significant consultation requirements, in that Inuit have the right to “participate in the development of social and cultural policies, and in the design of social and cultural programs and services, including their method of delivery”. Since much of the health research is carried out in conjunction with government programming or initiatives, researchers should also be aware of these potential land claim implications.

Researchers and participants cannot assume that a particular political body has sole authority over research. One must determine on a case-by-case basis the extent to which each type or level of authority has a role to play and be represented in the ethics review process.

It is important to recognize that, even if some Aboriginal communities are not homogeneous or closed entities and may not meet all the criteria on the cohesiveness and/or homogeneity continuum, such communities may still have distinct political, legal and cultural rights as nations and thus have political legitimacy to make decisions about issues, including health research projects, that directly affect the community (<sup>vi</sup>Kaufert, Glass and Freeman, 2004, p.18). This is particularly the case for urban Aboriginal communities.

Researchers must determine if the Aboriginal community has exercised authority in the area of research. Scientists and academics would need to comply with any such policies, rules or regulations adopted by the community.

The principle of respect for community jurisdiction includes ensuring the survival and protection of Indigenous peoples’ culture, heritage and knowledge. The four principles of ownership, control, access and possession (also interpreted as protection) are elements of Aboriginal jurisdiction and control as they relate to research. These elements, commonly known as “OCAP”, are widely entrenched in Aboriginal health research and are ideally addressed in a research agreement (<sup>vii</sup>Schnarch, 2004), as their specific implementation will vary in any given research project according to the priorities and capacities of those involved.

Significant changes have occurred in the research environment involving Aboriginal peoples. Aboriginal communities and peoples maintain the authority as self-determining nations to exercise self-governance. As a result of the governing authority of Aboriginal nations, scientific and academic researchers will need to meet certain community standards, including recognizing authority over the research process within their jurisdiction. No longer is it sufficient to simply pursue a project within an Aboriginal community without appreciating the community’s rights to regulate research. Such obligations ought not to be especially burdensome, since in most cases, they will likely mirror the development of specific ethical principles regarding research in Aboriginal communities by Canada’s granting agencies and universities.

Aboriginal communities may have their own “Ethics Review Board” established. In this case, the Aboriginal community has jurisdiction to require research conducted in their territory to comply with such procedures.

However, conflict may arise between the requirements of granting agencies like CIHR (or the TCPS guidelines), universities and institutes and Aboriginal communities. For example, an Aboriginal community’s ethical guidelines may require that researchers commit to certain undertakings that are

A researcher would not only have to submit their proposal to their own institution’s REB (likely a university) but also the Aboriginal communities REB.

not required by funding agencies or institutional REBs. Because the Aboriginal community possesses the inherent authority to regulate research as part of its self-governing powers, compliance by researchers will depend on whether the community has made compliance mandatory or voluntary. Many communities may not be comfortable in making compliance with their ethics guidelines mandatory. They may prefer to develop ethics requirements as “guidelines” which should be followed, but do not have legal force. Regardless, it is likely that there will be an ethics community review procedure that is mandatory. In this case, a researcher may need approval from his or her own institution and from the community authority/ies. In cases of conflict between requirements of the TCPS and local or regional Aboriginal REBs, the procedure that provides the most rigorous protection of Aboriginal research participants must be followed (see Section 1.4 for discussion).

This requirement of dual vetting is not unusual. For instance, researchers from Canada who would like to undertake research in another country must not only comply with Canadian procedures but also with the procedures of the country where the research will take place. In some jurisdictions within Canada, health research undertaken by university researchers requires dual review by the university and a community ethics review board, such as the joint process of the University of Victoria and the Vancouver Island Health Authority in British Columbia.

## 2.4 RESEARCH AS A PARTNERSHIP

**Article 3.0:** Communities should be given the option of a participatory research approach.

Historically, Aboriginal communities have been the subjects of much research by “outsiders”. This colonial approach to research in Aboriginal communities must give way to an understanding that Aboriginal people have an inherent right to be agents of research in contrast to mere passive subjects when the research topic involves their community or culture. One important means of respecting this right to participate is to actively enable community participation in the research project. Building research partnerships is not only a valuable method of facilitating participatory research with Aboriginal communities but must be viewed as an integral and ongoing component of the research project. Relevant communities and individuals should be involved at all stages of the research process, from formulating projects and methods to determining research outcomes to interpreting and disseminating results.

Aboriginal communities must be given the option of participatory research as equal partners in the research process.

Genuine research collaboration is developed between researchers and Aboriginal communities when it promotes a partnership within a framework of mutual trust and cooperation. This relationship building process will result in shared power, shared resources and mutual understandings. Such partnerships will help to ensure that a research process will proceed in a manner that is culturally sensitive, relevant, respectful, responsive, equitable and reciprocal in terms of the benefits shared between the research partner(s) and Aboriginal community/communities. At the same time, it must be recognized that a community may not wish to be actively involved in a research project nor wish to be an equal partner. The community may be satisfied with simply monitoring the research, but otherwise staying distant from it. Respecting the autonomy of Aboriginal communities is of primary importance, provided that the community is fully informed of its right to participate as equal and full partners if so desired.

Community consultation means discussing the research with individuals, in groups, and in other ways that will become apparent from these initial discussions (such as public meetings in the community).

Communication and meaningful consultation with the community is essential to establishing a partnership. If researchers already have an ongoing relationship with subgroups and leaders in a

community, community consultation means discussing the research with appropriate individuals, in groups and in other ways that will become apparent from these initial discussions (such as public meetings in the community). If researchers do not have an existing relationship, they can start the process by asking people from or knowledgeable about the community for names of individuals to discuss what an appropriate process of community consultation should involve. Researchers thus need not shy away from community consultation simply because it may be an unfamiliar process or because there is no standard way of obtaining this kind of input.

Meaningful consultation and participation are crucial components of a consent process (see below). Consultation should be undertaken in good faith and with relational accountability (see Section 2.2 paragraph 4). The parties should establish a dialogue allowing them to find appropriate solutions in an atmosphere of mutual respect in good faith, with full and equitable participation. Consultation requires time and an effective system for communicating among those who hold an interest in the research. Indigenous peoples should be able to participate through their own freely chosen representatives and customary or other institutions. The inclusion of a gender perspective and the participation of Indigenous women are viewed as essential, as are participation of children and youth when deemed appropriate by the recognized community authorities. This process may include the option of withholding consent (<sup>viii</sup>UNESCO, 2005).

The exchange of ideas and understanding during the partnership-building process also includes obligations on behalf of the community to be available for meetings and discussions to inform researchers about its values and beliefs in relation to the research and the appropriate protocols for accessing the information or data sought. This process of developing a research relationship can be the subject of a written agreement in the form of a “Memorandum of Understanding”.

Development of a true partnership will be instrumental in satisfying the required obligation of obtaining collective consent. A community that is truly an active partner in the research enterprise will by definition be consenting to the research. However, formal consent should nonetheless be obtained from the community to ensure certainty of expectations between research partners (see below). This consent process and, indeed, the principles upon which the research partnership is based may (but not necessarily) be an integral part of a research agreement. However, the research agreement will likely address many other issues and is discussed more fully in the section on Research Agreements, below.

## **2.5 COLLECTIVE AND INDIVIDUAL CONSENT**

**Article 4.0:** Researchers conducted in an Aboriginal community shall obtain free, prior and informed consent from individual participants and the Aboriginal community as appropriate.

### ***Collective Consent***

A free, prior and informed consent process should be sought sufficiently in advance of commencement or authorization of activities, taking into account Indigenous peoples’ own decision-making processes, in all phases of assessment, planning, implementation, monitoring, evaluation and closure of a research project. **This requirement of collective community consent is distinct from the obligation of researchers to obtain individual consent from each research participant (UNESCO, 2005).**

Elements of free, prior and informed consent relevant to communities are summarized below:

- Free implies consent is voluntary, without no coercion, intimidation or manipulation;

- Prior implies consent has been sought sufficiently in advance of any authorization or commencement of activities and respects time requirements of Indigenous consultation/consensus processes;
- Informed requires that information is provided that covers (at minimum) the following aspects:
  - The nature, size, pace, reversibility and scope of any proposed project or activity;
  - The reason(s) or purpose of the project and/or activity;
  - The duration of the above;
  - The locality of areas that will be affected;
  - A preliminary assessment of the likely economic, social, cultural and environmental impact, including potential risks and fair and equitable benefit sharing in a context that respects the precautionary principle<sup>6, ix</sup>;
  - Personnel likely to be involved in the execution of the proposed project (including Indigenous peoples, private sector staff, research institutions, government employees and others); and
  - Procedures that the project may entail;
  - Sources of project funding and support, as well as obligations to these sources.

The above criteria apply to the process of obtaining consent from the community or other appropriate authorities. The criteria for ensuring that informed collective consent is obtained do not replace the obligations of researchers to obtain informed consent from individual research participants. Moreover, some of the above items of information may also be relevant to ensuring informed individual consent. There will not be circumstances in which an individual within an Aboriginal community would be required to participate in a research project without their individual consent<sup>7</sup>. This right belongs to the individual and whether the leadership of a community has approved the project does not affect the right of the individual to decide not to participate or to withdraw at any time after originally agreeing to participate. An Aboriginal community authority may, however, decide that a research project would be harmful to the community and elect not to participate. A researcher must comply with such assessment and not conduct research in the community (unless as described in Section I Challenges to Formal Community Authorities.).

### ***Individual Consent***

Individual community participants shall be fully informed of possible consequences of their choice to be involved in the research and their rights to withdraw consent or participation in the research at any time. The requirements of obtaining informed consent from individuals in research that are addressed in the Tri-Council statement apply equally to the Aboriginal research context. However, there are some unique cultural considerations that may arise. For example, Aboriginal societies are traditionally oral societies and written consent may be seen as contrary to respecting Aboriginal approaches to research initiatives. Oral consent is an appropriate alternative to obtaining written consent. A researcher, however, should document the date, time and place in which the oral consent of the participant was received. Language may be an important consideration as well and it may be appropriate to have a written consent form translated into the community's language.

---

<sup>6</sup> The precautionary principle is the idea that if the consequences of an action are unknown, but are judged to have some potential for major or irreversible negative consequences, then it is better to avoid that action. The concept includes risk prevention, cost effectiveness, ethical responsibilities towards maintaining the integrity of natural and social systems, and the fallibility of human understanding. The precautionary principle suggests an inherent responsibility of researchers to acknowledge potential harms resulting from their work before, during, and at the completion of the research process (Bannister and Barrett 2006).

<sup>7</sup> Except for the usual circumstances of public health and health surveillance.

## 2.6 CONFIDENTIALITY/PRIVACY

**Article 5.0:** Confidentiality concerns of the community shall be respected and addressed<sup>8</sup>.

Research partners shall provide information regarding the anonymity or confidentiality of communities participating in research projects. When anonymity is not possible, or when there are limitations to anonymity or confidentiality, these must be clearly communicated to participants. The idea that a collectivity such as an Aboriginal community has a right to confidentiality has not been a prominent issue in research ethics. However, given the historically negative impact that research has had on some Aboriginal communities, including the communication of unsubstantiated stereotypes, Aboriginal communities may wish to minimize their exposure to potential harm by having their community's identity remain anonymous in relation to certain conclusions reached by the research project. At the same time, Aboriginal communities who actively participate as partners in the research may wish to be identified and acknowledged in the research. The level of participation in the planning and implementation of the research project and interpretation of the data by a community should be acknowledged appropriately if that is the desire of the community. Elders, for example may want to be acknowledged as contributors to the research outcomes, including recognition as an author. Elders are experts in their own right and their expertise ought to be equally recognized alongside researchers from Western academia. For further related guidelines dealing with interpretation of data and dissemination of the results see Articles 14 and 15 below.

## 2.7 INCLUSION AND PROTECTION OF CULTURAL KNOWLEDGE IN RESEARCH

**Article 6.0:** Inclusion of cultural knowledge in research should be under mutually agreed terms and with the guidance of the knowledge holders in the community.

**Article 7.0:** Aboriginal peoples and their respective communities inherent retain rights to their knowledge, cultural practices and traditions that are shared with the researcher(s). It is the responsibility of the researcher to support mechanisms for protection of cultural knowledge that is shared during the research.

Any research involving Aboriginal peoples will involve the sharing of some cultural knowledge, practices and/or traditions, even when these are not the subjects of the study, as they provide necessary context. Whenever knowledge is shared outside of the cultural context where it originates, however, there is potential for misunderstanding and misuse. Protection of Indigenous knowledge refers to appropriate sharing of knowledge in a way that acknowledges that some knowledge is sacred, that is, involving the recognized spiritual entity, Land, and the Ancestors. This must be interpreted in a manner appropriate to the particular context and community. For example, one community or region may prohibit the sharing of knowledge related to plants; it should not be assumed that the same prohibition will apply to all regions or research contexts. Because of the

It is the responsibility of the researcher to discuss the protection and sharing of Indigenous knowledge with each community and with appropriate Elders.

---

<sup>8</sup> For information on individual privacy and confidentiality refer to CIHR's Best Practice Guidelines for addressing privacy, confidentiality and security concerns in design, conduct and evaluation of health research.

importance of Aboriginal cultures and protection of Aboriginal sacred knowledge, access and protection issues should be the subjects of a research agreement.

The recording of knowledge, practices and traditions in any form (written notes, audio, video, or otherwise) must only be done with explicit permission and under mutually-agreed terms that are set out in advance of the research with the guidance of appropriate Elders and knowledge holders. All uses and wider dissemination of cultural knowledge, practices and traditions must also be by permission and explicitly acknowledge that the Aboriginal peoples and their respective communities who shared these retain their inherent rights and ownership over them.

Where cultural knowledge, practices and/or traditions are the subjects of study, in many cases research will result in “hybrid” products or outcomes that are based on a combination of these plus the academic knowledge, tools, or techniques contributed by the researcher. When hybrid products are the result of a “co-production” process of research, they should reflect an appropriate sharing of ownership in the new product that is mutually agreed to by all parties.

## **2.8 INTELLECTUAL PROPERTY RIGHTS AND INDIGENOUS KNOWLEDGE**

**Article 8.0:** Indigenous concerns over and claims to intellectual property must be explicitly acknowledged and addressed as part of the research process. Expectations regarding intellectual property rights of communities, researchers, and any other parties involved in research should be outlined in a research agreement.

The term “intellectual property” refers to certain kinds of knowledge that can be protected by the Western legal system. In general, intellectual property laws (e.g., copyright, patent, trademark, trade secret, industrial design) protect the tangible expression of a creator’s artistic or literary works, the proprietary technology in inventions, the words and symbols used to identify products and services in the marketplace and the aesthetic aspects of product designs (Cassidy and Langford, 1999). Intellectual property rights are largely commercial in nature, establishing exclusive legal rights for a creator or inventor to benefit commercially from their intellectual know-how for a period of time, in exchange for sharing their knowledge with wider society.

It is important to note that not all information and knowledge can be protected by existing intellectual property laws; strict eligibility criteria are used to define these legal rights. Understanding what does and does not qualify as intellectual property under current Canadian and international laws is the joint responsibility of the researchers and communities involved (for information on Canadian criteria, see <http://cipo.gc.ca/>).

It is widely recognized that some Indigenous knowledge may have commercial applications and lead to the development of marketable products (e.g., traditional plant medicines). Intense international debate has occurred on issues related to misappropriation, commodification and unfair or harmful commercial exploitation of Indigenous knowledge. Research with explicit commercial objectives and/or direct or indirect links to the commercial sector must be clearly communicated as such to all research partners as a requirement of the free and prior informed consent process. Additionally, research partners must realize that all research involving Indigenous knowledge, even when not commercially motivated, has the potential to contribute to this kind of misappropriation and

There must be clear guidelines stating that Indigenous peoples and their respective communities retain ownership of any traditional knowledge, cultural practices and traditions that are shared with the researcher(s). (From Alberta ACADRE Network, p. 49).

commercialization by making the results of research publicly available and thus accessible to third parties who may have commercial interests.

Existing intellectual property laws have been deemed inadequate in most cases for protecting the intellectual expertise embodied in Indigenous knowledge and the rights of Aboriginal peoples, either to limit use of such knowledge by others or to use it for their own commercial benefit (Cassidy & Langford, 1999). A number of initiatives are in progress internationally and within Canada to better understand and address Indigenous intellectual property and cultural heritage rights issues that are raised by research involving Indigenous knowledge (e.g., see initiatives of the World Intellectual Property Organization at <http://www.wipo.int/tk/en/>, and UNESCO at [http://portal.unesco.org/culture/en/ev.php-URL\\_ID=15782&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/culture/en/ev.php-URL_ID=15782&URL_DO=DO_TOPIC&URL_SECTION=201.html)).

In the meantime, the onus rests on the researcher to be informed about these issues and communicate them to community partners so decisions about access to and use of Indigenous knowledge in research proceed under mutually-agreed terms. Researchers also have a responsibility to know their university's specific institutional policies regarding ownership of intellectual property derived from research, and to communicate this accurately to community and other research partners.

## 2.9 BENEFIT SHARING

**Article 9.0:** Research should be of mutual benefit to the community and researchers.

The research project should lead to outcomes that are deemed beneficial to the participating Aboriginal community/communities or individuals<sup>xi</sup>. Benefit sharing is to be interpreted from local community perspectives. It may be that, from the local perspective, there is no direct benefit to the community itself but knowledge gained may be of scientific or social benefit to Indigenous peoples in general or to humankind and therefore, may be deemed worthwhile by participating communities. The issue of benefit sharing is a predominant feature of Aboriginal research norms and thus the importance of research benefiting the community cannot be overstated.<sup>xii</sup>

On a community level, there is the basic expectation of the relevancy of the research to the Community involved. In this context, the community not only expects the research to address needs within the community, but to also be a derivative of their cultural distinctiveness (Martin, 2005).

The concept of benefit sharing involves fair reward for investments in research. Benefit sharing can take a number of forms depending on the type of research being conducted. Benefits may be immediate or longer term, tangible or intangible, and monetary or non-monetary, including but not limited to widespread community accessibility to the final results of the study.<sup>9</sup> For instance, a diabetes study could provide the scientific community with a more in-depth understanding of the causes and effects of the disease, but in terms of benefit sharing it could also help the Aboriginal community identify foods or dietary habits which are contributing to the high incidence of diabetes in their group. While this does not have a direct economic benefit, it does have great social and health benefits for the community.

<sup>9</sup> A wide range of different forms for benefit sharing related to scientific research and individuals and groups is articulated in the UNESCO *Declaration on Bioethics and Human Rights*, 2005. See [http://portal.unesco.org/shs/en/ev.php-URL\\_ID=1372&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/shs/en/ev.php-URL_ID=1372&URL_DO=DO_TOPIC&URL_SECTION=201.html)

## 2.10 EMPOWERMENT AND RESEARCH CAPACITY DEVELOPMENT

**Article 10.0:** Researchers should support the development of education, research and training (including training in research ethics) for Aboriginal peoples and communities.

Whether in the context of a research partnership or not, academic researchers should work to foster financial and policy support for capacity building and governance mechanisms of Indigenous peoples to enhance their participation in research projects and improve the overall interactions between Indigenous governance mechanisms and public educational institutions at the local and national levels (<sup>xiii</sup>United Nations, 2005). Practical methods that researchers can undertake to assist in community capacity development in research skills include hiring local people and providing training as part of the research plan.

In addition, governments, international agencies, academic researchers/institutions, the private sector and Indigenous communities should develop the capacity of Indigenous women, youth and children so that they may meaningfully participate in the processes of free, prior and informed consent within their communities.

## 2.11 CULTURAL PROTOCOL, LANGUAGE AND COMMUNICATION

**Article 11.0:** Researchers have an obligation to learn about and apply Aboriginal cultural protocols relevant to the particular Aboriginal community.

Aboriginal communities often have cultural protocols involving interactions within the community. It is important that researchers learn about these and apply them appropriately. For example, it is customary among many Aboriginal communities for someone seeking knowledge or advice from an Elder to offer tobacco prior to asking any questions. This is not the custom in all Aboriginal communities; however, the researcher has an obligation to learn about the local customs of the Aboriginal community.

**Article 11.1:** Researchers should ideally translate all related publications or reports into the language of the community.

Ideally, researchers should translate all related publications or reports into the language of the community. However, for many researchers such an endeavor may be too costly to justify. At minimum, researchers should provide an executive summary in the language of the community unless the community has expressly waived such a requirement. Translation may require the paid assistance of a community language expert, thus the costs of translation should be factored into research budgets. The issue of language translation should be addressed in negotiation of a research agreement (see Appendix A).

**Article 11.2:** Researchers should ensure that there is effective on-going communication in a manner that is accessible and understandable to the community.

The task of gathering information about cultural protocol does not have to be onerous; it will usually suffice to simply ask the first contact person, when setting up an initial meeting, basic questions such as 'what is the appropriate thing to do when I meet with the Elders, does one bring tobacco or any other gift?'

It is important to point out that any report or communication of results with the Aboriginal group should be done in such a manner that enables the community to understand and broadens the avenues of knowledge-transfer of the research findings (<sup>xiv</sup>Martin-Hill and Soucy, 2005). Technical language should be minimized as much as possible, and defined or explained when used.

## 2.12 DATA COLLECTION, STORAGE, USE, MANAGEMENT AND OWNERSHIP

**Article 12.0:** Aboriginal communities have inherent rights to control and determine their proprietary interests in the collection, use, storage and potential future use of data.

Much of the criticism directed towards research in Aboriginal populations stems from the loss of control of data collected on and with the help of Aboriginal peoples. As well, serious concern has been raised over the inappropriate use of stored biological samples, including DNA and cell lines of Aboriginal groups, for unauthorized research. For example, it was recently brought to international attention that blood drawn for arthritis research in the Nuu-chah-nulth of British Columbia was used to establish ancestry in addition to the health-related research consented to. This constitutes an unacceptable violation of the consenting community's rights. Internationally, similar cases have exemplified the need to understand the issues that are important to Aboriginal people when biomedical research is carried out with them and in their communities [<sup>xv</sup>Dalton, 2004; <sup>xvi</sup>Anonymous, 2004]. The collection, use, storage and potential future use of data needs to be negotiated as part of the research process and be specified in a research agreement.

In 1985, Dr. Richard Ward took Blood samples of 833 Nuu-chah-nulth people (about 45% of the targeted population) under the auspices of carrying out research to explore the high rate of arthritis in that nation[1]. After the study was conducted, Dr. Ward kept the blood samples of the Nuu-chah-nulth people and, without their consent, used the blood isolate I DNA to carry out his own research relating to genetic anthropology.

For the purpose of this document, data is considered the information derived from the collection of research samples (biological and non-biological). Data may be derived from various qualitative and quantitative data collection methods such as documents review, interviews, observations, questionnaires and surveys. We deal with biological samples in more detail below.

Researchers need to be familiar with their existing university research policies regarding data collection, storage, use, management and ownership as well as the policies of any other collaborating institutions (e.g., other universities, companies, non-profit organizations, government bodies). Researchers are expected to uphold the best interests of the community partners and the standards of these guidelines in cases where there is inconsistency between the policies of the institutional partners and these guidelines. Terms of collection, management, storage, co-ownership and use of data must be agreed upon by communities and researchers in a research agreement.

Co-ownership of data between researchers and communities is recommended because the Aboriginal community and the researcher are both integral to the production of data (pre and post-analysis), subject to the community's views on traditional or sacred knowledge. The expectations for co-authorship of subsequent publications should be agreed upon in a research agreement.

Copyright of the publications and other materials (e.g. CD-ROM, videos, etc.) should be agreed in advance and shared when appropriate.

Secondary use of the data by either party requires the consent of the other party. Both parties have the right to transfer the data to a third party for further research only under the following conditions, namely if: i) the interpretations of the data of both parties are respected; and ii) any subsequent publications based on the data recognize the contributions of the original researchers in terms of authorship.

Communities should be kept apprised of continued use of the data. Secondary use of data unrelated to the original intention of the study (for example, public health or longitudinal studies) requires consultation and approval from community partners where data has been anonymized. Secondary use of data unrelated to the original intention of the study also requires re-consent from the original participants where data is linked to identity. When this is not possible, a representative body (e.g. community governing bodies or health units of friendship centres) may be able to provide guidance for the appropriate process for consent. The condition in which an authority other than the participant gives permission for secondary use of data should be highly exceptional and stringent conditions should apply in order to prevent authorities from making decisions on behalf of individuals under their power or within their sphere of influence.

## **2.13 THE COLLECTION, STORAGE, MANAGEMENT, OF (HUMAN) BIOLOGICAL SAMPLES**

**Article 13.0:** Biological research samples should be considered “on loan” to the researcher.

In keeping with the accepted standard of research practice in Canadian Aboriginal communities, which advocates a participatory approach, the collection, use, storage and potential future use of biological samples needs to be negotiated as part of the research process. In keeping with this model the researcher needs to understand that his or her beliefs may not be reflective of the community's and must be respectful of how differences may pertain to interpretations of data and the significance of biological samples.

Researchers need to be familiar with their existing university research policies as applied to the collection, storage and management of (human) biological samples, as well as the policies of any other collaborating institutions (e.g., other universities, companies, non-profit organizations, government bodies). However, researchers are expected to uphold the best interests of the community partners and the standards of these research Guidelines in cases where there is inconsistency between the policies of the institutional partners and these Guidelines. Alternatively, some Aboriginal communities may have exercised jurisdiction in this area and have legislation (by-laws) or policies dealing with these issues. It is incumbent on the researcher to comply with such authority.

For example, in the words of Dr. Frank Dukupoo, a Native American geneticist  
*“To us, any part of ourselves is sacred. Scientists say it’s just DNA. For an Indian, it’s not just DNA, it’s part of a person, it is sacred, with deep religious significance. It is part of the essence of a person.”*  
Interview, San Francisco Chronicle, 1998[1].

Unless otherwise agreed, newly collected samples from Aboriginal participants will be considered “on loan” to the researcher, analogous to a licensing arrangement.

Therefore:

- only research that has been consented to can be carried out;
- no secondary research will be carried out without the consent of the community where samples are anonymous, individual participant where samples are linkable to identity or pre-designated research review committee;

- the researcher will be considered the steward rather than the owner of the samples; and
- no samples will be transferred to third parties (including private companies) without the consent of the community where samples are anonymous or individual where samples are linkable to identity.

The research agreement and consent process needs to include conditions of the collection, place of storage, research lab/researcher involvement, industry roles, plans for governance and potential future use, to ensure that all parties are aware of mutual understandings. All samples should be collected, and stored in keeping with “best practice guidelines” to assure the safety of the donors, the optimum quality of the sample and the validity of the data derived from the samples.

Requests to withdraw, return or dispose of samples must be accommodated. Special decoding and recoding procedures must be put into place to facilitate the identification of the individual donor when needed.

For existing tissue banks, a series of consultations with Aboriginal stakeholders should be held to determine under what circumstances the samples can be used for future research.

## **2.14 INTERPRETATION OF RESULTS AND DISSEMINATION**

**Article 14.0:** All Aboriginal communities should have an opportunity to participate in the interpretation of data and/or review of conclusions drawn from the research to ensure accuracy and sensitivity of interpretation.

An opportunity for review of the research results by the Aboriginal community/communities should be provided before the submission for publication of research findings. Such a review is to ensure that sensitive information is not divulged to the public and that misrepresentations are corrected prior to wider dissemination. In so doing, research partners may need to provide expertise to scientifically answer questions about the research results that emerge from the community.

Research partners should promote a culturally relevant diffusion of knowledge through written publications and oral presentations to impacted Aboriginal communities. This includes documentation of the undertaking of the project and of the results. Furthermore, research partners should help address any health or social issues that are raised as a direct result of research.

Research partners should be guardians of the data until the end of the project (or in certain cases, much longer) with data disposition in accordance with the research agreement.

**Article 15.0:** It is the discretion of the community partners as to how their contributions will be acknowledged. Community members have the right to due credit and participation in dissemination of results, and publications must recognize the contribution of the community where appropriate and in keeping with confidentiality agreements. (also see article 5)

The right to control publication or dissemination of results or theories associated with research is another specific element or feature of the discourse for Aboriginal norms in research. While researchers and institutions may see this as a form of censorship, most researchers submit their research proposals to review for funding purposes and later submit to institutional review boards for oversight of their research and ethical conduct. As discussed earlier, the stigmatization experienced by Aboriginal peoples in the past by misused, misappropriated or misrepresented aspects of their society, culture, knowledge or other issues has led to an unfortunate situation where groups have closed themselves off from researchers and institutions to prevent further harm to their collective

and individual identity. The concept of having a right to the integrity and respect of one's work or identity is well recognized and protected in the legal realm (e.g., within copyright laws).

Research involving Aboriginal groups is susceptible to manipulation or misrepresentation when information about the group is isolated and analyzed without consideration of a sufficient amount of other cultural characteristics which make the group distinct and add greater merit to the scholarship. Unfortunately, academics are largely rewarded for publications and not necessarily thoroughness or cultural sensitivity. It would be difficult to imagine an outside researcher going to an Aboriginal community and writing on research derived from sacred or traditional knowledge without having the Aboriginal peoples of that community reviewing the process and product to better explain the culture and linkages to their traditions, values systems, spirituality, philosophies of life, their relationship to the land, animals, water, flora, fauna, and identity.

## **2.15 RESEARCH AGREEMENTS AND MEMORANDA OF UNDERSTANDING**

Where a researcher does not have a prior relationship with an Aboriginal community and wishes to develop a research relationship with the community, there may be a number of expectations on the part of the community as to what a researcher must do in order to be prepared and to be accepted by the community as a pre-requisite to the negotiation of a formal research agreement. The steps and expectations of the community and researcher may be appropriately addressed in a non-binding Memorandum of Understanding (MOU) with the community representatives. An MOU can usefully outline in broad terms the understandings of the parties in the relationship-building process. However, the relationship-building process is very contextual and community specific and there is no set formula for building such a relationship.

Once an effective and respectful research relationship has been established, it is appropriate to negotiate and set out the terms of the research project addressing any of the issues and points raised. A formal binding research agreement between the community authority/ies and the researchers should then be established.

In recognition of Indigenous jurisdiction, research agreements need to be negotiated and formalized with authorities of various Indigenous jurisdictions before any research is conducted with their people. The principles of OCAP, i.e., ownership, control, access, and possession/protection of data and information obtained from research involving Indigenous peoples, must become the normative standard (Ermine et al, 2005).

The agreement should detail issues of data ownership, data use, data interpretation/analysis, rights to intellectual property (if appropriate), and expectations regarding process, content and authorship of publications, with identified mechanisms for dealing with conflicting interpretations or inappropriate use of data. There should be prior agreement on respective roles for the parties, desired outcomes, measures of validity, control of the use of data, funding and dissemination of research findings.

All research partners shall inform participants in their own language about the use of data-gathering devices – i.e. tape, video recordings, photos, and physiological measurements – and how data will be used. For example, abstracts of publications should be translated into local languages and made available to local communities when possible and appropriate. The services of an interpreter should be used for the above purposes when the researcher is not fluent in the local language.

It is important to note that the strength and utility of a research agreement is directly related to the relationship of the research partners that it governs. An effective research agreement will be developed based on the same elements as respectful research relationship, such as good

communication, honesty, transparency, respect and trust. A sample Research Agreement is included in Appendix A.

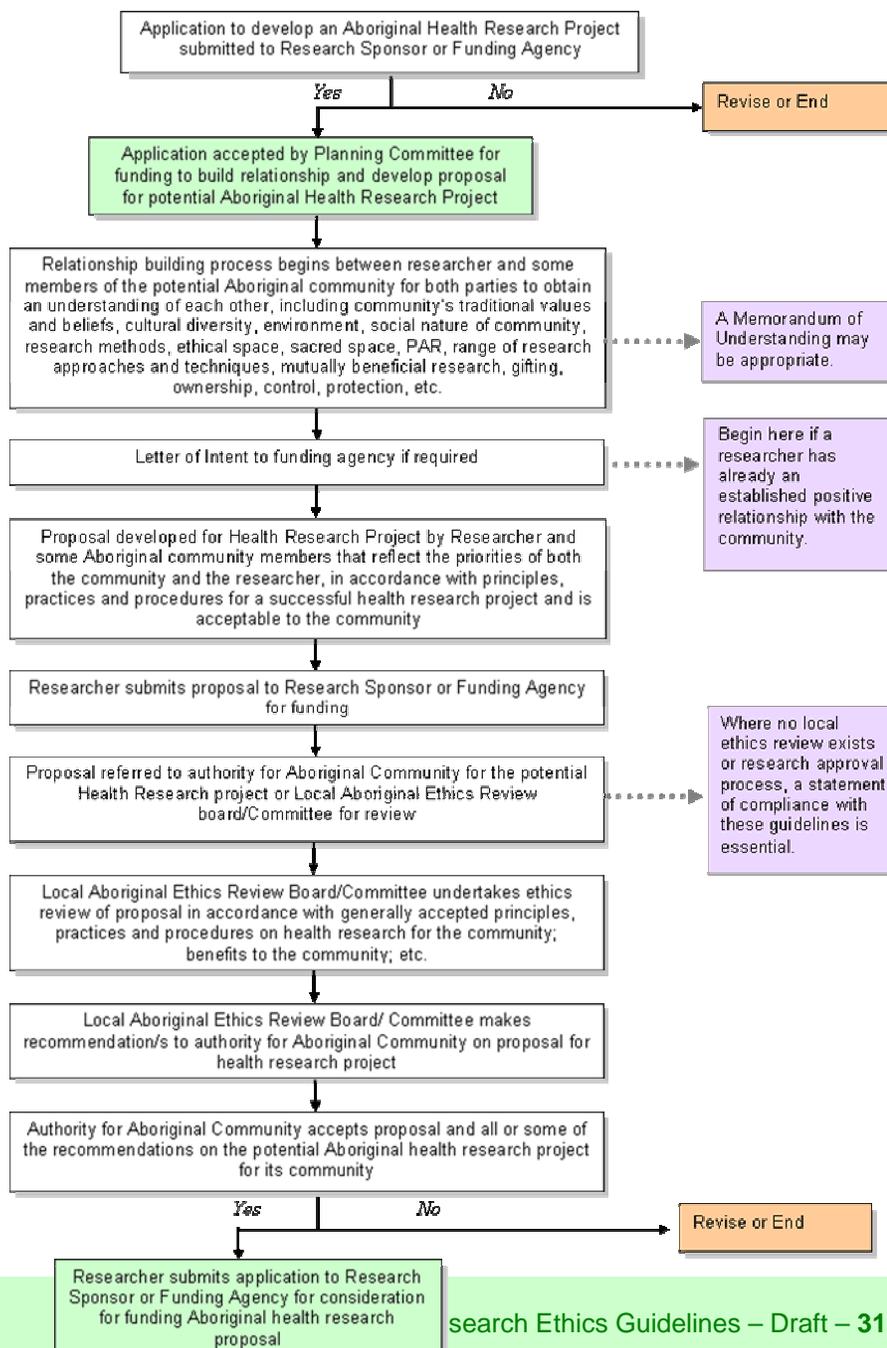
# Section III – Procedure, Protocol and the Research Process

The following charts are provided by the Noogmowin Teg Health Centre and modified with permission.

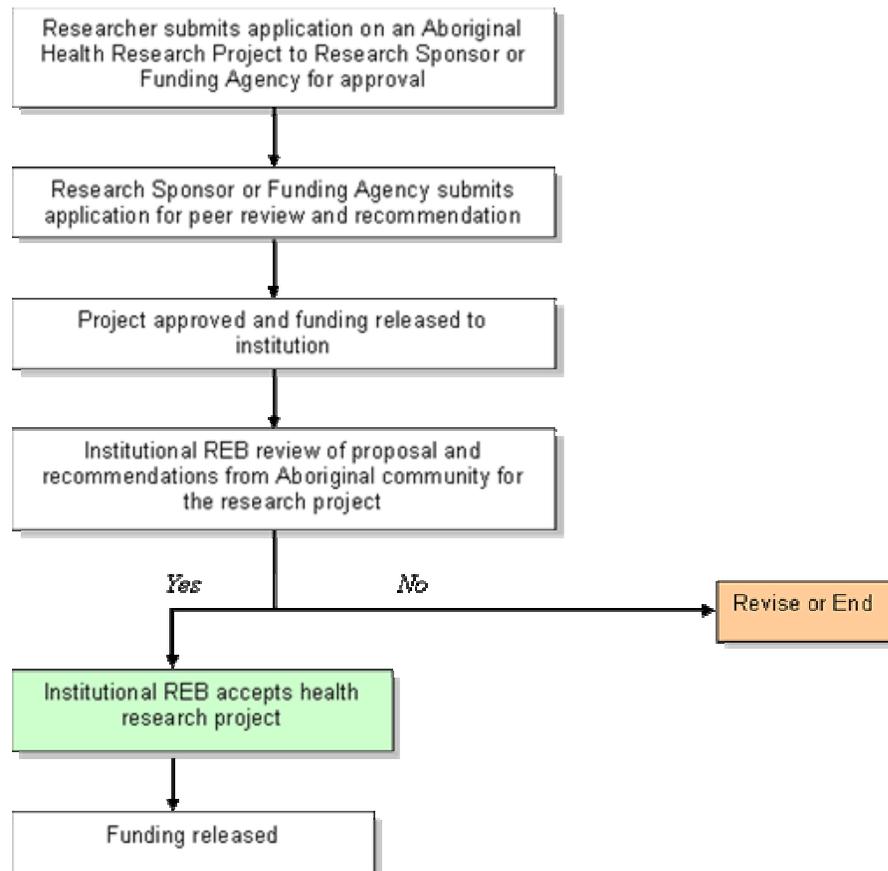
## 3.1 STEP-BY-STEP PROCEDURE

This section of the guidelines offers an idealized step-by-step process for engaging in a research project with an Aboriginal community. Specific steps and their order may vary depending on the capacity and priorities of the Aboriginal community or communities involved.

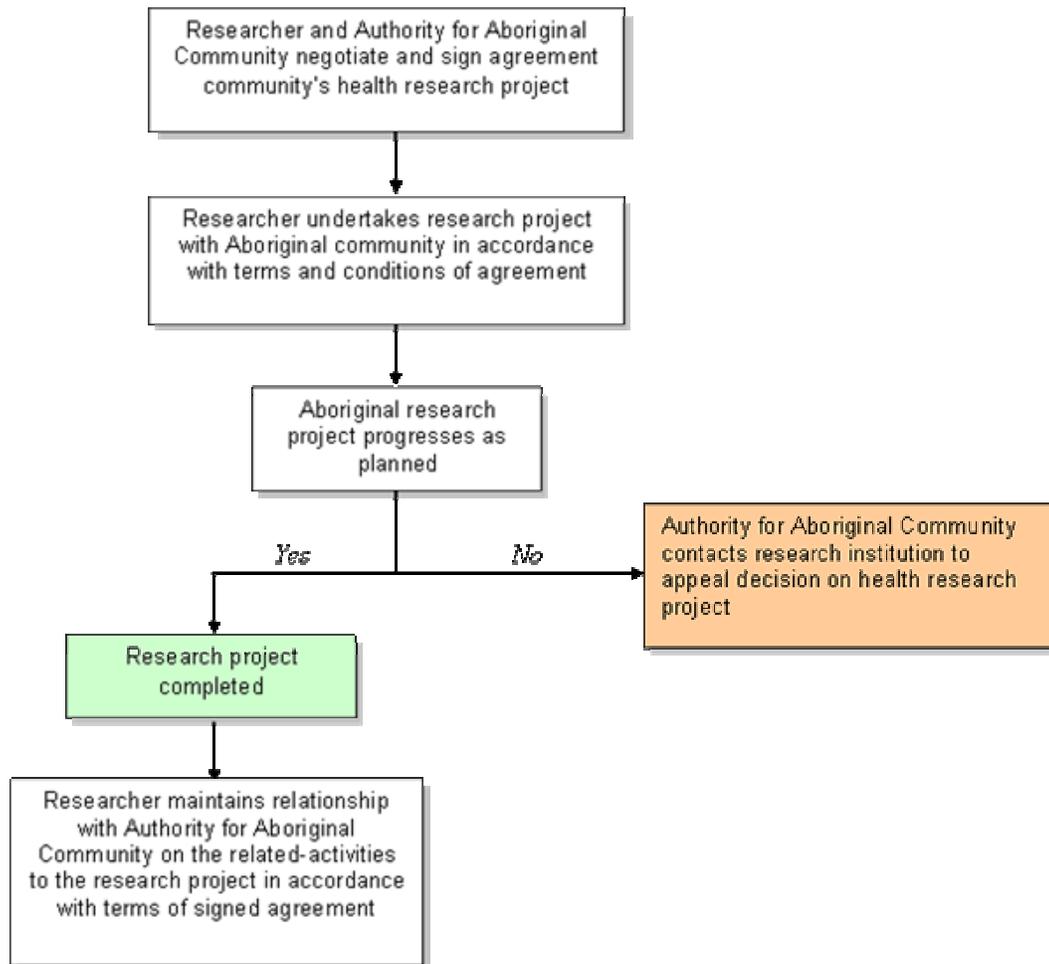
### STEP 1: Partnership Development for Aboriginal Health Research – A Representative Model



STEP 2: Submitting a Proposal for Aboriginal Health Research to Funder/Sponsor for Approval – A Representative Model



STEP 3: Maintaining the relationship with the Aboriginal community on the Aboriginal health research project – A representative model



## 3.2 PROTOCOL AND RESEARCH PROCESS

### Elements for Researcher Consideration for Research Involving Aboriginal Communities

#### 3.2.1 Protocol

##### Background

- Provides the context of the project
  - Underlines the burden of disease, need, priority, interest, especially in reference to the Aboriginal population to be included
  - Should provide as much information specific to Aboriginals as available
  - Should explain any relevant work that has been completed, including findings or initiatives

##### Significance

- Explains the importance of the proposed work for Aboriginal populations
- Explains how this approach may be new or different
- Explains any potential benefits, risks, harms for Aboriginal populations

##### Methods

###### Approval

- Should explain...
  - How Aboriginal group approval will be obtained
    - Band/Tribal/Community Council health director, health board, band/tribal/community council
    - Resolution
  - How funding agency approval will be obtained
    - Letter of support
  - How Research Ethics Board (REB) approval will be obtained

##### Sampling

###### Should explain....

- Who will be included (should include Power calculations), for example,
  - Males and/or females, and why
  - Adults and/or children, and why
  - Random or pre-selected, and why
- How long the involvement will last
  - Project will last for 6 months
  - Individual surveys will take 30 minutes
- Technical assistance should be provided to Aboriginal groups so they understand the calculations proposed for sampling

##### Recruitment

###### Should explain how participants will be recruited to the study

- Advertisement in local health newsletter, Aboriginal organization newsletter, etc.
- Clinic based, participants will be recruited by diagnostic status
- Convenience sample, people convening at a certain location
- Personalized letters, e.g., Chief writing a letter encouraging participation
- Inclusion of Aboriginal group members for assisting with recruitment should be clearly explained
- Inclusion of Aboriginal group members for recruitment is encouraged

### **Consent Process**

- In understandable terms, describes the project so that people know what they are being asked to participate in.
- The who, what, where, when, why, how of the project needs to be explained at 8th grade level (normal for consent forms for all studies); translators should be made available as necessary for understanding of informed consent and protocol
- There are required components of consent (based on TCPS)
- A clear statement that the study is "research"
- All the research purposes [i.e., research objectives] clearly stated
- How and why prospective volunteers are selected
- Expected duration of the volunteer's involvement
- Procedure(s) or treatment(s) to be done
- Reasonably expected benefits to volunteer and others
- Reasonably foreseeable discomfort & risks--including all in protocol
- Especially for experiments, a statement that the treatment(s) or procedure(s) "may involve risks that are currently unforeseeable" [Applicable most often in clinical trials of drugs or procedures]
- Which procedures-treatments are experimental--say "experimental" [Applicable only to experimental research, not observational]
- The alternatives to the research's diagnostic method or treatment [Applicable primarily to research of diagnosis or treatment]
- Procedure for the orderly termination of a volunteer's participation [Applicable primarily to clinical trials, sometimes to compensation--if early termination will decrease compensation]
  - Consequences of a volunteer's withdrawal from the research
  - When may the researcher terminate a volunteer's participation without the volunteer's consent
- Plans to inform volunteers of significant research findings during or after the study relevant to their continued participation or treatment [Applicable primarily either to clinical trials, or to "deception" research in which debriefing at the end is a standard procedure]
- If more than minimal risk: "In case of injury or severe adverse affect..."
  - Will medical care for adverse affects be given? By whom? Where?
  - Is compensation for adverse affects available? How?
  - Who should a volunteer contact with injury or adverse affect?
- Who will answer questions about the research itself? [Usually the PI, with telephone number--collect call or toll-free number if long distance]
- How confidentiality or anonymity is maintained?
- Who will answer other concerns, complaints, or grievances? [Regulations call this "subject rights"; usually the REB, with telephone number--collect call or toll-free number if long distance]
- Financial factors (extra costs of participation, details of sponsorship or funding)
- Extent of participation of the community research partners
- Other elements a reasonable person would want to know
- Non-coercion disclaimer.

### **Data Collection**

- Explains what information is going to be collected, e.g., Aboriginal group name, participant name, age, height, tobacco use
- Explains the way the information is going to be...
  - Identified, e.g., numbered, coded
  - Stored, e.g., software, locked, password protected

- Accessed, e.g., staff members only
- Linked to any other data (e.g., medical records)
- Explains how long the information is going to be kept, where, by whom
- Explains data ownership; to whom does the data belong?
- Inclusion of Aboriginal group members for data collection should be clearly stated
- Inclusion of Aboriginal group members encouraged

### **Data Analysis**

Explains...

- How the data will be computed
- What tests will be done
- What software program will be used
- How small numbers will be handled
- What other information the results will be or might be compared to
- Technical assistance should be provided to Aboriginal groups so that data analysis steps are clearly understood

### **Interpretation**

- Explains what steps will be taken in relaying results, for example, tables with labels will be included in some proposals
- Aboriginal leadership should be included in the interpretation steps

### **Reporting and Dissemination**

- Explains how the reporting of results will unfold, for example, results will be shared with the health committee, band/tribal/community council, regional Aboriginal organization, participants in a community open forum, in an article in the Aboriginal newsletter, etc.
- Reports can be either oral or written or both
- Availability of translators, as necessary

### **Follow-up or Next Steps**

- Based on results, the project should specify additional follow-up or next steps that will be pursued.

### **References**

- A list of other studies that have been completed
- Provides additional information on other related work pertinent to the current study
- Aboriginal leadership should feel free to request copies of cited materials

### **Supporting Documentation**

- Information Sheets – a one-page explanation of the study specifics
- Informed Consent Form
- Data Collection Forms
- Band/Tribal/Community Council or Aboriginal organization Resolutions
- REB Approval Letter
- Resource List – a list of resources specific to the topic under study

## **3.2.2 Research Process**

### **Funding**

All elements of the funding should be explained to Aboriginal leadership so that clear understanding exists between community and researchers on limitations, timeframes, requirements, and scope, i.e.,

- Requirements or eligibility

- Timeframe from announcement to submission
- Pre-determined focus of announcement
- Involvement of experienced grant writer
- Lead project person or project personnel
- Duration of the announcement
- Amount of money available
- Number of projects to be funded

### **Approvals**

All necessary levels of approval should be sought and adequate time should be allocated for these processes. The levels of approval will range from local and university approval for single community projects to regional or national approvals and university approvals for multi-site projects. If the project will target a specific community, approval should be sought as the project develops. If the project will recruit communities, approval should be sought once the project receives funding. REB approval is required once a project receives funding. The levels of approval include:

- Regional Approval
- Aboriginal Approval
  - Program Director
  - Band/Tribal/Community Council Health Director
  - Health Board or Committee
  - Band/Tribal/Community Council
- Health Service Approval
  - Service Unit Director
  - Clinical Director
- Research Ethics Board (REB) Approval
  - Aboriginal REBs, as applicable
    - Area level
    - National level
  - University, if affiliated

### **Approval from each individual participating Aboriginal community is necessary and includes the following components:**

- Schedule of meetings held by local health, health boards, and band/tribal/community councils should be obtained
- Getting on the agenda; requests should be made to request an audience with local health program, the health board, and band/tribal/community council
- Travel to the meetings; as much as possible an in-person presentation should be made to local health program, the health board, and the band/tribal/community council or Aboriginal group
- Prepare materials for the presentation and be prepared to provide technical assistance as necessary
- Project presentation
- Status updates to Aboriginal leadership, regular updates should be made throughout the duration of the project – at least once a year at minimum

### **Research Timeline and Budget**

- A clear project timeline should be established for how and when project activities need to occur; sufficient time for necessary for Aboriginal consultation should be inherent
- Establishing a budget to pay for personnel and project activities, i.e., personnel time, travel, consultants, supplies, indirect
- The timeline and budget should be reviewed by the Aboriginal group/band/tribal/community council to determine if they are realistic and practical
- Outline of how Aboriginal personnel and/or programs are to be involved
- Clear understanding of what the project proposes to accomplish

### **Conducting Project Activities**

- Once approval and/or funding are received, the project is ready to begin; reassess the timeline for how and when project activities need to occur and reassess the budget to pay for personnel and project activities
- Regular status updates with Aboriginal leadership
- Regular and final reports should be made available to Aboriginal group, Band, Tribal or Community Council
- As the project progresses, the information accumulated will be analyzed and should be shared with the tribe
- Data bases will be established and statistical software programs used to analyze the information, capacity building including the training of Aboriginal personnel on data entry, data analyses, and interpretation should be considered and incorporated
- As part of capacity building, inclusion of Aboriginal group members in the project is advocated

### **Interpreting Results**

- The information gathered in the study should be relayed to the Aboriginal group, band, tribal, or community council, research community, and the general public
- The numbers should be explained in understandable terms to the program director, band/tribal/community health director, health board, band/tribal/community council and
- Rates, numerator and denominator, should be explained in understandable terms to program directors, health directors, health board members, band, tribal and community council members and Aboriginal groups
- The information will usually be...
  - Stratified by age and sex
  - Compared with other data sources, these elements should be explained to the Aboriginal group
- As the results are being written, the Aboriginal group should be consulted on findings and narration of Aboriginal identity
- Consider the Aboriginal group as a co-author

### **Publishing Results**

- The information gathered in the study will be relayed to the Aboriginal, research community (and the general public if appropriate and depending on the understanding between the researcher and the community). Researchers need to take into account community comments and allow a place for dissenting views to be expressed in publications if not resolved earlier.
- The Aboriginal group needs to approve the final report, manuscript, and dissemination
- The REB needs to approve the final report and manuscript
- Share the results with participants in Aboriginal newsletters, mailing, public open forums

### **Intellectual Property and Commercialization**

- Researchers must be explicit about any commercial applications of their research products and any intent to commercialize (if any).
- Researchers must work with their sponsoring institutions and community partners to fully understand and communicate the commercial potential of their research products (if any) and agree on intellectual property ownership, any limitations on commercialization, distribution of benefits that may arise from commercialization, and any reasonably foreseeable negative consequences that may result.

## Section IV – Articles

- Article 1.0:** The researcher should understand the cultural responsibilities that accompany traditional knowledge or sacred knowledge and strictly comply with community expectations and protocols in possessing such knowledge.
- Article 2.0:** Community jurisdiction over the conduct of research must be understood and respected.
- Article 3.0:** Communities should be given the option of a participatory research approach.
- Article 4.0:** Research conducted in an Aboriginal community shall obtain free, prior and informed consent from individual participants and the Aboriginal community as appropriate.
- Article 5.0:** Confidentiality concerns of the community and individual participants shall be respected and addressed.
- Article 6.0:** Inclusion of cultural knowledge in research should be under mutually agreed terms and with the guidance of the knowledge holders in the community.
- Article 7.0:** Aboriginal peoples and their respective communities retain inherent rights to their knowledge, cultural practices and traditions that are shared with the researcher(s). It is the responsibility of the researcher to support mechanisms for protection of cultural knowledge that is shared during the research.
- Article 8.0:** Indigenous concerns over and claims to intellectual property must be explicitly acknowledged and addressed as part of the research process. Expectations regarding intellectual property rights of communities, researchers, and any other parties involved in research should be outlined in a research agreement.
- Article 9.0:** Research should be of mutual benefit to the community and researchers.
- Article 10.0:** Researchers should support the development of education, research, and training (including training in research ethics) for Aboriginal peoples and communities.
- Article 11.0:** Researchers have an obligation to learn about and apply Aboriginal cultural protocols relevant to the particular Aboriginal community.
- 11.1** Researchers should ideally translate all related publications or reports into the language of the community.
- 11.2** Researchers should ensure that there is effective on-going communication in a manner that is accessible and understandable to the community.
- Article 12.0:** Aboriginal communities have inherent rights to control and determine their proprietary interests in the collection, use, storage and potential future use of data.
- Article 13.0:** Biological research samples should be considered “on loan” to the researcher.
- Article 14.0:** All Aboriginal communities should have an opportunity to participate in the interpretation of data and/or review of conclusions drawn from the research to ensure accuracy and sensitivity of interpretation.
- Article 15.0:** It is the discretion of the community partners as to how their contributions will be acknowledged. Community members have the right to due credit and participation in dissemination of results and publications must recognize the contribution of the community where appropriate and in keeping with confidentiality agreements.

# Appendix A: Sample agreement provided by the Centre for Indigenous Peoples' Nutrition and Environment (CINE)

**Project Title**  
**RESEARCH AGREEMENT**  
**[date]**

(Name of organization)\_\_\_\_\_ agree to conduct the named research project with the following understandings:

1. The purpose of this research project, as discussed with and understood in the community of \_\_\_\_\_, is:
2. The scope of this research project (that is, what issue, events, or activities are to be involved, and the degree of participation by community residents), as discussed with and understood in this community, is:
3. Methods to be used, as agreed by the researchers and the community, are:
4. Community training and participation, as agreed, is to include:

The development of this project is based on sincere communication between community members and researchers. All efforts will be made to incorporate and address local concerns and recommendations at each step of the project.

At the end of the project, the researchers will participate in community meetings to discuss the results of the analysis with community members.

5. Information collected is to be shared, distributed, and stored in these agreed ways:

The data collected is confidential and no name is attached to a record. Copies will be kept at CINE where the data will be converted to an electronic form. The data will be kept on diskettes in the community, at CINE. The researchers and CINE will be available to answer questions and assist community members should community members decide to use these data for different purposes, a final report will be distributed after approval from the community members.

6. Informed consent of individual participants is to be obtained in these agreed ways:

An individual consent form will be read by the interviewer to the respondent. A copy of the consent form will be left with the respondent where the addresses of each researcher can be used at any time, should the respondent wish to contact the researchers for additional information.

7. The names of participants and the community are to be protected in these agreed ways:

As mentioned on the consent form, the interviews are confidential. In no instance will the name of a respondent be attached to a record.

Before distribution of the final report, or any publication, or contact with the media, the community will be consulted once again as to whether the community agrees to share this data in that particular way.

8. Project progress will be communicated to the community in these agreed ways:
9. Communication with the media and other parties (including funding agencies) outside the named researchers and the community will be handled in these agreed ways:

## **FUNDING, BENEFITS, & COMMITMENTS**

### **Funding**

The main researchers have acquired funding and other forms of support for this research project from:

The funding agency has imposed the following criteria, disclosures, limitations, and reporting responsibilities on the main researchers.

### **Benefits**

The main researchers wish to use this research project for benefit in these ways (for instance, by publishing the report and articles about it):

The researchers will publish a final report to the funding agency in 2001. Scientific presentations in peer-reviewed conferences and publications will be made. The final report will be reviewed by community members prior to publication. Scientific presentations and articles will be published after discussion with the respective communities' leaders.

Benefits likely to be gained by the community through this research project are:

- Educational
- Informational
- Financial

### **Commitments**

The community's commitment to the researchers is to:

- Recommend capable and reliable community members to collaborate/be employed in this project.
- Keep informed on the project progress, and help in leading the project toward meaningful results.

The researcher's main commitment to the community is to:

- Inform the community as to the project progress in a clear, specific, and timely manner.
- Act as resource to the community for nutrition-related questions.

**DRAFT Version 2.0 April, 2006**

The researchers agree to stop the research project under the following conditions:

- If community leaders decide to withdraw participation.
- If the researchers believe that the project will no-longer benefit the community

**Signed by:**

Date:

Date:

Community:

---

(Signature of Main Research)

Name:

Position:

---

(Signature of Community Contact Person)

Name:

Position:

## References

---

- <sup>i</sup> Arbour L, Cook D. DNA on Loan: Issues to consider when carrying out genetic research with Aboriginal Populations; *Community Genetics* 2006 (In press).
- <sup>ii</sup> United Nations High Commissioner for Human Rights, 1994. Draft UN Declaration on the Rights of Indigenous Peoples. Available at: [http://www.unhcr.ch/huridocda/huridoca.nsf/\(Symbol\)/E.CN.4.SUB.2.RES.1994.45.En?OpenDocument](http://www.unhcr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.SUB.2.RES.1994.45.En?OpenDocument)
- <sup>iii</sup> Convention on Biological Diversity, 1992. Article 8(j): Traditional knowledge, innovations and practices. United Nations Conference on Environment and Development, Rio de Janeiro, Brazil. Available at: <http://www.biodiv.org/programmes/socio-eco/traditional/>
- <sup>iv</sup> Cassidy, M. and J. Langford (eds.) 1999. Intellectual property and aboriginal people: A working paper. Contractors: S. Brascoupé and K. Endemann. Indian and Northern Affairs, Research and Analysis Directorate. Available at: [http://www.ainc-inac.gc.ca/pr/ra/intpro/intpro\\_e.html](http://www.ainc-inac.gc.ca/pr/ra/intpro/intpro_e.html)
- <sup>v</sup> Ermine, W., Sinclair, R., and M. Browne, 2005. Kwayask itotamowin: Indigenous Research Ethics. Report of the IPHRC. Commissioned by the Aboriginal Ethics Policy Development Project and supported as a joint undertaking of the Canadian Institutes of Health Research – Ethics Office & the Institute for Aboriginal Peoples Health.
- <sup>vi</sup> Kaufert, J., Glass, K., and W. Freeman., 2004. Background paper on issues of group, community or first nation consent in health research. Commissioned by the Aboriginal Ethics Policy Development Project and supported as a joint undertaking of the Canadian Institutes of Health Research – Ethics Office & the Institute for Aboriginal Peoples Health.
- <sup>vii</sup> Schnarch, B., 2004. Ownership, Control, Access and Possession (OCAP) or self-determination applied to research: A critical analysis of contemporary first nations research and some options for first nations communities, *J. Aboriginal Health*, 80.
- <sup>viii</sup> UNESCO, 2005. Universal Declaration on Bioethics and Human Rights. Available at: [http://portal.unesco.org/shs/en/file\\_download.php/46133e1f4691e4c6e57566763d474a4dBioethicsDeclaration\\_EN.pdf](http://portal.unesco.org/shs/en/file_download.php/46133e1f4691e4c6e57566763d474a4dBioethicsDeclaration_EN.pdf)
- <sup>ix</sup> Bannister, K and K. Barrett., 2006. Harm and Alternatives: Cultures under Siege. In Nancy Myers and Carolyn Raffensperger (eds), *Precautionary Tools for Reshaping Environmental Policy* (Cambridge: MIT Press), 215-239.
- <sup>x</sup> Cassidy, M. and J. Langford (eds.) Intellectual Property and Aboriginal People: A Working Paper (1999). Contractors: S. Brascoupé and K. Endemann. Indian and Northern Affairs, Research and Analysis Directorate. Available at: [http://www.ainc-inac.gc.ca/pr/ra/intpro/intpro\\_e.html](http://www.ainc-inac.gc.ca/pr/ra/intpro/intpro_e.html)
- <sup>xi</sup> Martin, M., 2005. Health Research with Urban Aboriginal Populations: A Case Study of Montreal, Quebec. Commissioned by the Aboriginal Ethics Policy Development Project and supported by the Canadian Institutes of Health Research – Ethics Office.
- <sup>xii</sup> Martin-Hill, D. and D. Soucy, 2005. Ganono'se'n e yo'gwilode' - Ethical Guidelines for Aboriginal Research Elders and Healers Roundtable. Commissioned by the Aboriginal Ethics Policy Development Project and supported as a joint undertaking of the Canadian Institutes of Health Research – Ethics Office & the Institute for Aboriginal Peoples Health.

- <sup>xiii</sup> United Nations. 2005. Advanced unedited version - UN report of the International Workshop on Methodologies regarding Free Prior and Informed Consent and Indigenous Peoples. Available at: [www.un.org/esa/socdev/unpfii/documents/FPIC\\_%202005\\_CBD.doc](http://www.un.org/esa/socdev/unpfii/documents/FPIC_%202005_CBD.doc)
- <sup>xiv</sup> Martin-Hill, D. and D. Soucy, 2005. Ganono'se'n e yo'gwilode' - Ethical Guidelines for Aboriginal Research Elders and Healers Roundtable. Commissioned by the Aboriginal Ethics Policy Development Project and supported by the Canadian Institutes of Health Research – Ethics Office.
- <sup>xv</sup> Dalton, R. 2004. When two tribes go to war. *Nature*, 6999 (430) 500-502.
- <sup>xvi</sup> Anonymous, 2004. Tribal Culture versus Genetics. *Nature*, 6999 (430) 489