



CIHR GUIDELINES FOR HEALTH RESEARCH INVOLVING ABORIGINAL PEOPLE



*The cover design is called "Hummingbirds" and depicts
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EXECUTIVE SUMMARY

Purpose and Application

These Guidelines have been prepared by the Ethics Office of the Canadian Institutes of Health Research (CIHR), in conjunction with its Institute of Aboriginal Peoples' Health, to assist researchers and institutions in carrying out ethical and culturally competent research involving Aboriginal people. The intent is to promote health through research that is in keeping with Aboriginal values and traditions. The Guidelines will assist in developing research partnerships that will facilitate and encourage mutually beneficial and culturally competent research. The Guidelines will also promote ethics review that enables and facilitates rather than suppresses or obstructs research.

These Guidelines are applicable to researchers carrying out research to which CIHR has made a financial contribution. The reader should note that these Guidelines are not regulations nor are they meant to be of general application. Rather, they are guidelines that should be followed by anyone who carries out research involving Aboriginal people in Canada if the research is funded by CIHR. The obligation on the researcher to abide by the Guidelines is contractual, i.e. it is voluntarily assumed by the researcher in return for the funding provided by CIHR.

As these guidelines primarily address the special considerations that arise when carrying out research involving Aboriginal people, researchers must also refer to, and comply with, other Tri-Council and CIHR policies, as well as any applicable legislation and, for those to whom it applies, the *Canadian Charter of Rights and Freedoms*. Other agencies of government may impose additional regulatory or other requirements.

Background

CIHR established the Aboriginal Ethics Working Group (AEWG) in March 2004 as part of a broader national endeavour to develop research ethics guidelines for Aboriginal people. The AEWG was representative of Aboriginal interests and academic disciplines in providing advice and support for the development of the Guidelines. 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 Developmental Research Environments (ACADRE) network informed the deliberations of the AEWG. It followed a hands-on, active approach to the development of the Guidelines and adopted ethical principles to guide its 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 Nation, Inuit and Métis communities. Proposals for research ethics collaboration were accepted from the ACADRE centres; 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 draft of the research ethics Guidelines was completed in May 2005. Initial vetting of the Guidelines took place through the ACADRE centres and their community partners to determine cultural appropriateness.



and acceptability. Then, feedback was sought from the wider academic community. Consultations and vetting throughout Aboriginal and research communities were initiated in the fall of 2005 and continued through March 2006; these sessions were conducted by the ACADRE network.

The Ethics Office along with the National Council on Ethics in Human Research conducted workshops and consultations with Aboriginal communities, researchers and members of research ethics boards to obtain feedback on the draft Guidelines. The document was electronically posted by CIHR and its partners to enable widespread access and awareness, and to solicit comments prior to 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 the development of the Guidelines helped achieve a workable balance on specific issues, given the multiple and diverse perspectives expressed. The Guidelines were then edited by CIHR's Ethics Office, in consultation with Health Canada and Justice Canada, to optimize internal consistency, and to ensure that the Guidelines reflected CIHR's mandate.

These Guidelines will contribute to the Tri-Council process established to revise Section 6 of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, which addresses research involving Aboriginal people.

Summary of Articles

Article 1 A researcher should understand and respect Aboriginal world views, including responsibilities to the people and culture that flow from being granted access to traditional or sacred knowledge. These should be incorporated into research agreements, to the extent possible.

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

Article 2 A community's jurisdiction over the conduct of research should be understood and respected. This article should be read in the context of the discussion in Section 1.5, which addresses the application of this document.

Some Aboriginal communities manage and control matters dealing with health. Where this is the case, a researcher should comply with any by-laws, policies, rules or procedures adopted by the community. For example, an Aboriginal community may have its own Research Ethics Board and/or community research protocols.

Article 3 Communities should be given the option of a participatory-research approach.

Genuine research collaboration is developed between researchers and Aboriginal communities when it promotes 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 research proceeds in a manner that is culturally sensitive, relevant, respectful, responsive, equitable and reciprocal, with regard to the understandings and benefits shared between the research partner(s) and Aboriginal community(ies).



Article 4 A researcher who proposes to carry out research that touches on traditional or sacred knowledge of an Aboriginal community, or on community members as Aboriginal people, should consult the community leaders to obtain their consent before approaching community members individually. Once community consent has been obtained, the researcher will still need the free, prior and informed consent of the individual participants.

A process to obtain the free, prior and informed consents from both the community affected and its individual participants should be undertaken sufficiently in advance of the proposed start of research activities and should take into account the community's own legitimate decision-making processes, regarding all the phases of planning, implementation, monitoring, assessment, evaluation and wind-up of a research project. The requirement for community consent is distinct from the obligation of researchers to obtain individual consent from research participants.

Article 5 Concerns of individual participants and their community regarding anonymity, privacy and confidentiality should be respected, and should be addressed in a research agreement.

The researcher, the individual participants and the community should have a clear prior understanding as to their expectations with regard to the anonymity of the community and of the individuals participating in the research project, and the extent to which research data and results will remain confidential to the researcher. If anonymity is not possible, or if there are necessary limitations to anonymity or confidentiality, these should be clearly communicated.

Article 6 The research agreement should, with the guidance of community knowledge holders, address the use of the community's cultural knowledge and sacred knowledge.

Article 7 Aboriginal people and their communities retain their inherent rights to any cultural knowledge, sacred knowledge, and cultural practices and traditions, which are shared with the researcher. The researcher should also support mechanisms for the protection of such knowledge, practices and traditions.

Any research involving Aboriginal people 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) should 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 should also be by permission.

Article 8 Community and individual concerns over, and claims to, intellectual property should be explicitly acknowledged and addressed in the negotiation with the community prior to starting the research project. Expectations regarding intellectual property rights of all parties involved in the research should be stated in the research agreement.

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



Article 9 Research should be of benefit to the community as well as to the researcher.

A research project should lead to outcomes that are beneficial to the participating Aboriginal community and/or individual community members. Benefit sharing vis-à-vis a community should be interpreted from the community's perspective. This may include tangible and intangible benefits, including those arising from altruism.

Article 10 A researcher should support education and training of Aboriginal people in the community, including training in research methods and ethics.

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

Article 11.1 A researcher has an obligation to learn about, and apply, Aboriginal cultural protocols relevant to the Aboriginal community involved in the research.

Article 11.2 A researcher should, to the extent reasonably possible, translate all publications, reports and other relevant documents into the language of the community.

Article 11.3 A researcher should ensure that there is ongoing, accessible and understandable communication with the community.

Aboriginal communities often have cultural protocols involving interactions within the community. It is important that researchers learn about these and respect them. When providing a research project report to the community, the researcher should, at a minimum, provide an executive summary in the language of the community unless the community has expressly waived this. The reports or other communications of results should use language and terminology that are readily understood by the community.

Article 12.1 A researcher should recognize and respect the rights and proprietary interests of individuals and the community in data and biological samples generated or taken in the course of the research.

Article 12.2 Transfer of data and biological samples from one of the original parties to a research agreement, to a third party, requires consent of the other original party(ies).

Article 12.3 Secondary use of data or biological samples requires specific consent from the individual donor and, where appropriate, the community. However, if the research data or biological samples cannot be traced back to the individual donor, then consent for secondary use need not be obtained from the individual. Similarly, if research data or biological samples cannot be traced back to the community, then its consent for secondary use is not required.

Article 12.4 Where the data or biological samples are known to have originated with Aboriginal people, the researcher should consult with the appropriate Aboriginal organizations before initiating secondary use.

Article 12.5 Secondary use requires REB review.

These guidelines set out basic principles for the collection, disclosure, use and transfer of data and biological samples. The details of safeguards protecting the privacy and confidentiality of data and biological samples



should be negotiated as part of the research process and specified in a research agreement. Subject to the community's views on traditional or sacred knowledge, 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.

If there is to be transfer of data or biological samples to a third party, this should be done only with the consent of the researcher, the individual participants and the community. If the third party is to engage in secondary use of the transferred data or biological samples, then a further consent to that use must be obtained. The consent should address how confidentiality and privacy will be respected.

In any case, secondary use of data or biological samples requires new consent unless such use is specifically agreed to in the research agreement. Notwithstanding the above, individuals retain the right to access data about themselves.

In cases where the research is a governmental activity, other standards for protecting privacy may apply, flowing, for example, from the *Canadian Charter of Rights and Freedoms* or privacy legislation.

Article 13 Biological samples should be considered “on loan” to the researcher unless otherwise specified in the research agreement.

Subject to the terms of the research agreement with their community, biological samples from Aboriginal participants should be considered “on loan” to the researcher, analogous to a licensing arrangement, and this should be detailed in the research agreement.

Article 14 An Aboriginal community should have an opportunity to participate in the interpretation of data and the review of conclusions drawn from the research to ensure accuracy and cultural sensitivity of interpretation.

Research involving Aboriginal people is susceptible to misinterpretation or misrepresentation when information about the group is analyzed without sufficient consideration of other cultural characteristics that make the group distinct.

The opportunity for review of research results by the Aboriginal community should be provided before the submission of research findings for publication, to ensure that sensitive information is not inappropriately divulged to the public and that errors are corrected prior to wider dissemination.

This should not be construed as the right to block the publication of legitimate findings; rather, it refers to the community's opportunity to contextualize the findings and correct any cultural inaccuracies.

Article 15 An Aboriginal community should, at its discretion, be able to decide how its contributions to the research project should be acknowledged. Community members are entitled to due credit and to participate in the dissemination of results. Publications should recognize the contribution of the community and its members as appropriate, and in conformity with confidentiality agreements.

A sample research agreement and charts describing the step-by-step procedures of the research process are included as preliminary guides in Section III and in the Appendix.



TABLE OF CONTENTS

Acronyms	8
Acknowledgments	9
Section I – Introduction	10
1.1 BACKGROUND	10
1.2 RATIONALE	10
1.3 SCOPE, PURPOSE AND LIMITATIONS	12
1.4 THE ABORIGINAL ETHICS WORKING GROUP	12
1.5 APPLICATION OF THE GUIDELINES	13
1.6 KEY CONCEPTS AND DEFINITIONS	14
1.6.1 Complex authority structures	15
1.6.2 Challenges to formal community authorities	16
1.6.3 Individuals or sacred societies as decision-makers	16
Section II – Ethical Principles of Aboriginal Health Research	17
2.1 RECONCILIATION OF ETHICAL SPACES	17
2.2 SACRED SPACE AND TRADITIONAL KNOWLEDGE	17
2.3 COMMUNITY CONTROL AND APPROVAL PROCESSES	18
2.4 PARTICIPATORY RESEARCH	19
2.5 COMMUNITY AND INDIVIDUAL CONSENT	20
2.6 CONFIDENTIALITY / PRIVACY	21
2.7 INCLUSION AND PROTECTION OF CULTURAL KNOWLEDGE IN RESEARCH	22
2.8 INTELLECTUAL PROPERTY RIGHTS AND INDIGENOUS KNOWLEDGE	22
2.9 BENEFIT SHARING	23
2.10 EMPOWERMENT AND RESEARCH CAPACITY DEVELOPMENT	23
2.11 CULTURAL PROTOCOL, LANGUAGE AND COMMUNICATION	24
2.12 INITIAL AND SECONDARY USE, PROPRIETARY INTEREST, AND STORAGE AND TRANSFER OF DATA AND BIOLOGICAL SAMPLES	24
2.13 BIOLOGICAL SAMPLES ON LOAN	25
2.14 INTERPRETATION AND DISSEMINATION OF RESULTS	26
2.15 MEMORANDA OF UNDERSTANDING AND RESEARCH AGREEMENTS	26
Section III – Procedure, Protocol and the Research Process	28
3.1 STEP-BY-STEP PROCEDURE	28
3.2 PROTOCOL AND RESEARCH PROCESS	31
3.2.1 Protocol	31
3.2.2 Research process	33
Section IV – Articles	36
Appendix: Sample agreement provided by the Centre for Indigenous Peoples' Nutrition and Environment (CINE)	38
Bibliography	41



Acronyms

AEWG	Aboriginal Ethics Working Group
ACADRE	Aboriginal Capacity and Developmental Research Environments
CIHR	Canadian Institutes of Health Research
IAPH	Institute of Aboriginal Peoples' Health
NCEHR	National Council on Ethics and Human Research
NSERC	Natural Sciences and Engineering Research Council of Canada
PRE	Interagency Advisory Panel on Research Ethics
SSHRC	Social Sciences and Humanities Research Council of Canada
REB	Research Ethics Board
TCPS	<i>Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans</i> , 1998 (with the 2000, 2002 and 2005 amendments)
Tri-Council	The three federal funding agencies: CIHR, NSERC, SSHRC



Acknowledgments

The members of the Aboriginal Ethics Working Group (AEWG) would like 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 to this document. In particular we would like to acknowledge the contribution made by the Kahnawake Schools Diabetes Prevention Project with their *Code of Research Ethics*. We understand that the English and French languages do not always allow Aboriginal concepts and world views to be effectively communicated across cultures and we do not wish to offend with words that have been written. We do encourage continuous dialogue as Aboriginal ethics are articulated within an academic research context.

The AEWG thanks Joe Kaufert for his insightful guidance and assistance throughout its deliberations, Thérèse DeGroote 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.

CIHR's Ethics Office would like to thank Health Canada and Justice Canada for their valuable contributions to these Guidelines.



Section I – Introduction

1.1 BACKGROUND

Section 6 of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS)¹ states that “there is growing recognition that some research involving Aboriginal individuals may also involve the communities or groups to which they belong. The Councils [Agencies] affirm that in developing ethical standards and practices, Aboriginal peoples have rights and interests which deserve recognition and respect by the research community.”

However, Section 6 was left incomplete because the Agencies ... “had not held sufficient discussions with representatives of the affected people or groups, or with the various organizations or researchers involved.” To redress this, in July 2003, CIHR, NSERC and SSHRC committed to a collaborative effort intended to produce a revision of Section 6 of the TCPS. The scope and coverage of the project required a process that was broadly inclusive of the health, social and natural sciences as well as the engagement of Aboriginal people. Such an open participatory process required an extended timeframe.

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

1.2 RATIONALE

This document is designed to facilitate the ethical conduct of research involving Aboriginal people. The intent is to promote health through research that is in keeping with Aboriginal values and traditions. Health is understood in a broader sense than the notion of bio-psycho-social well-being. In keeping with Aboriginal understandings of health, it also includes spiritual, cultural, community and environmental well-being. Fostering health in this sense includes enabling growth, balance, self-determination, reciprocity, relationships and peace.

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 systematic gathering of information through observation of the natural world and empirical testing in real life situations, has always had an important role in the lives of Aboriginal people of Canada when 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 guided this learning are woven through all aspects of Aboriginal culture.

The evolution of western scientific thought since the Enlightenment has largely diverged from other ways of “knowing”. During the European colonization of Canada, Aboriginal people were largely prevented from using Aboriginal languages, practices and ways of gaining knowledge. The western scientific paradigm predominated and, through the research process, Aboriginal people and their cultures became largely the subjects and objects of study.

¹ The TCPS is the foundational ethics policy governing research on humans funded by CIHR. It is available at www.pre.ethics.gc.ca.



Research paradigms have evolved over the past fifty years. 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 Aboriginal communities about incompatibilities and historical injustices associated with research involving Aboriginal people. Support and respect for Aboriginal ways of knowing and of conducting research have steadily increased. The scientific community has come to realize that Aboriginal people often hold unique cultural knowledge within complex knowledge systems and that this knowledge requires specific consideration in research. Certain areas of science such as ethnobotany have come to appreciate the potential for Aboriginal contributions to science.

In the past, Aboriginal people and cultures have sometimes been harmed through research, and numerous examples are documented in the literature. It is now widely agreed that mechanisms to prevent further harm are needed. Local ethics protocols for research conducted with and within Aboriginal communities are an important step in this regard. Many Aboriginal communities and organizations in Canada are at various stages of creating independent ethics research guidelines and protocols. In some cases, legislatures have enacted research requirements; for example: 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 Aboriginal knowledge. Drafting of these Guidelines has been determined by this trend and has drawn upon the significant local and international efforts to respect Aboriginal knowledge and world views on ethics and the protection of cultural heritage. In addition, the development of the Guidelines has been guided by a desire to provide assistance and direction to researchers who want to do no harm, but also to conduct health research that benefits Aboriginal people.

Some Aboriginal communities manage and control matters dealing with health. As part of this control, the community may choose to be a full participant in any

- Research conducted within or about it;
- Community consent process.

Consequently, researchers will need to meet those communities' standards and recognize their authority over such research.

Research agreements should be negotiated and formalized with the appropriate community authority before research is commenced. Aboriginal communities may have their own research ethics guidelines and processes, including research ethics boards.

Although individual consent is essential, Aboriginal social norms and values tend to be organized around an operative principle of collective Aboriginal knowledge, ownership and decision-making. This is one of the reasons why the notion of community consent is so important in research involving Aboriginal people. Thus, an Aboriginal community is entitled to decide whether a research project is in the best interest of the community (community consent) as a precondition to the researcher seeking individual consent from community members.



1.3 SCOPE, PURPOSE AND LIMITATIONS

These Guidelines are designed for use by researchers conducting health research involving Aboriginal people; by research ethics boards (REB), including institutional and private REBs; and by locally established Aboriginal ethics review committees where they exist. The Guidelines are also intended to 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. The Guidelines are to be used in conjunction with the TCPS and applicable CIHR policies.

This document sets threshold standards for research funded by CIHR. Community guidelines may be more stringent. When communities do not have such guidelines, this document will be especially useful in providing a template to enable the development of ethics processes. Parties are expected to work toward achieving consensus on research protections that are appropriate to their specific context. Ensuring that all parties are aware of and understand existing institutional, professional and community standards will be important to achieving consensus.

The Guidelines are intended to promote ethics review that enables and facilitates rather than suppresses or obstructs 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 community level and at the individual level. There is 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 require more time and effort initially, partnerships based on mutual trust and respect lead to better research and a more positive relationship with the communities and individuals affected by the research. Following the principles and articles embodied in these Guidelines will, over the long run, be beneficial for all parties involved.

The definition of health within Aboriginal conceptions of the term is broad in scope; therefore, these Guidelines may apply to research on issues not typically considered to be “health” research from a western scientific perspective. In case of doubt, the researcher should consult the community as to whether the proposed research falls within the community’s concept of health.²

These guidelines will be reviewed at least every four years.

1.4 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) – was 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 researchers 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

² For a discussion of differences between Aboriginal and western perspectives on health, see *Gathering Strength*, Volume 3 of the Final Report of the Royal Commission on Aboriginal Peoples available at: http://www.ainc-inac.gc.ca/ch/rcap/sg/si1_e.html.



research communities. Values that guided management of the process included broad-based representation, efficiency, responsiveness and transparency in fulfilling its mandate and enhancing the confidence of its stakeholders (Aboriginal, research and institutional communities) in the guidelines development process. The AEWG recognized that ethics in research is not just a “review-moment” but begins with the establishment of a partnership with a community regarding a proposed research project and extends beyond the dissemination of research results.

The AEWG was 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. A majority of the members 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 the result of a process that engaged Aboriginal elders and First Nation, Inuit and Métis communities across Canada in a 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 Aboriginal, research and institutional REB communities across Canada.

1.5 APPLICATION OF THE GUIDELINES

As a general rule, the principles in this document should be applied whenever a research project includes Aboriginal research participants unless:

- a) It includes both Aboriginal and non-Aboriginal participants; and
- b) the research hypothesis does not concern whether or not a participant is Aboriginal; and
- c) the project’s recruitment criteria do not include membership of an Aboriginal community either for the entire study or for a sub-group; and
- d) the analysis of the research results will not use Aboriginal community membership as a variable; and
- e) the interpretation of the research results will not refer to Aboriginal people, language, history or culture.



There are many different situations in which a proposed research study may involve Aboriginal people. Here are some of the more common examples:

1. Research directly and exclusively involving Aboriginal communities.
e.g., a research project that examines the incidence of diabetes in Pond Inlet.
2. Research involving Aboriginal people where they comprise a sizable proportion of the study or community and Aboriginal-specific conclusions are intended.
e.g., a study of Yukon residents' dietary preferences.
3. Research involving Aboriginal people where the Aboriginal people are part of a larger community (regardless of their proportion) that is the subject of research, and Aboriginal-specific conclusions are intended, or it is foreseen that Aboriginal-specific conclusions may emerge after the research is completed.
e.g., a finding that Aboriginal residents of the Spence neighbourhood are disproportionately poor and /experience high levels of illness, as compared with the neighbourhood as a whole.
4. Research involving Aboriginal people where the Aboriginal people are a sizeable proportion of 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 neighbourhood of Winnipeg's inner city.
5. Research which is not intended to single out or describe characteristics of Aboriginal people in the study, if Aboriginal people live in the community but not in significant numbers and are only indirectly affected, and are not specifically targeted in the research.

Where the research project falls within the above continuum will of course influence how the Guidelines will be applied. For example, in situations (1) and (2) above, community consent and/or consultation with community representatives should be obtained. Consultation should occur in the third example, provided there is an accessible political body with which to consult. In the fourth and fifth examples, consultation would constitute good practice, where possible, but would not be required.

1.6 KEY CONCEPTS AND DEFINITIONS

Some of the terms used in these Guidelines, including "Aboriginal", "community" and "sacred knowledge", do not lend themselves to precise and all-encompassing definitions and, in some cases, there is no consensus as to what they may mean in all situations. Every effort has been made to use the terms consistently throughout this document. The reader is invited to contact CIHR to seek clarification if necessary.

WHO ARE ABORIGINAL PEOPLE? WHAT IS AN ABORIGINAL COMMUNITY?

For the purposes of this document, Aboriginal people include Inuit, Métis and members of First Nations. Most Aboriginal individuals consider themselves to be members of an Aboriginal community.

In the simplest sense, "community" refers 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 an individual's personal responsibility for the collective and, reciprocally, the collective's concern for individual existence. Importantly, Aboriginal conceptions of community often encompass relationships in a very broad sense, including relationships of human, ecological and spiritual origins.

Many Aboriginal communities in Canada have distinct political, legal and cultural governance structures that have political legitimacy and that support their jurisdictional and decision-making authority on a broad spectrum of issues, including health.

Researchers should consider that Aboriginal communities often 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. Such communities may, but do not necessarily, maintain significant contacts with their families/communities in their original homelands.

Many Aboriginal communities are not homogeneous. As with other cultural groups, individuals making up a community will vary as to religious affiliation, age, etc. Researchers should respect cultural diversity among communities and pluralism within communities.

1.6.1 Complex authority structures

Researchers and REBs should recognize the importance of identifying the appropriate authority(ies) representing the community in the development of the research project and the negotiation of a research agreement. A variety of factors can make this task difficult. Identification of the 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 these Centres a logical place to initiate discussions. One hundred and seventeen such centres exist across Canada. They are the main instrument for delivering programs and services to urban Aboriginal people in areas such as housing, education, skills training and employment, youth and family services and health to off-reserve First Nation, Non-Status Indian, Métis and Inuit people. They serve as a cultural hub for Aboriginal people living in cities and for newly relocated individuals. In addition, other Aboriginal regional and provincial organizations exist in every province and can offer assistance in determining appropriate community authorities.

The recognized authorities of a community may be traditional leaders, Elders, municipal officials, tribal leaders, confederate leaders, regional Aboriginal leaders, Inuit land claim organizations, research institutes and so on. For example, a First Nation community may have both a band chief and a mayor, who may or may not be different individuals. The determination of a community's best interests regarding 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, a health committee and a 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, the community and its authority structure. Responsibility and accountability may include that owed to the recognized spiritual deity, the Land and past and future generations. Individuals may merely be members of a community or may be the holders of sacred or traditional knowledge on behalf of the community. 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 reside with the individual band authority. However, in the case of sacred or traditional knowledge, individuals (Elders or knowledge



keepers) or communities (clans, sacred bundle societies) may have the final political authority over certain types of knowledge.

Therefore, researchers should not assume that one political body has complete authority. The extent to which each type or level of authority has a role to play in the research and ethics review process should be determined on a case-by-case basis. This determination should be a joint responsibility of the researcher and the community.

1.6.2 Challenges to formal community authorities

There may be cases where the researcher does not believe that the formal community leadership is acting in the best interests of the community. For example, a community mayor or representative of a regional Aboriginal 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 community members should take responsibility for working together to determine whether the leadership is in a conflict of interests or unable to make a decision in good faith. In such situations, a community system or structure (e.g., Elders council), may be in place to resolve the issue and should be employed. The parties involved should respect the decision-making processes of the Aboriginal community.

1.6.3 Individuals or sacred societies as decision-makers

Although sacred knowledge is often held collectively by the members of an Aboriginal community, in some cases such knowledge may be considered to be held by certain designated individuals and not necessarily by the community. For example, some Elders may be keepers of sacred knowledge. Alternatively, a sacred society or a clan may be 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.



Section II – Ethical Principles of Aboriginal Health Research

These Guidelines need to be understood in the context of Aboriginal concepts such as sacred space, sacred knowledge and traditional knowledge, as described below. This may mean that ethical principles familiar to a researcher, such as autonomy, beneficence and justice, would need to be adjusted to harmonize with the values and beliefs of the Aboriginal community involved.

2.1 RECONCILIATION OF ETHICAL SPACES

Ethical space refers to the totality of a community's principles, values and beliefs. Where the ethical spaces of two or more communities meet, there may be a need to reconcile differences among those ethical spaces in ways that respect and protect the validity of each. In the context of health research, there are significant divergences between the ethical spaces of Aboriginal and western cultures. It is important that western-trained researchers understand and acknowledge the validity of Aboriginal ethical space, to ensure that it is respected and applied to research involving Aboriginal people. These Guidelines seek to provide a blueprint for the protection of Aboriginal ethical space in carrying out health research funded by CIHR.

Protecting Aboriginal ethical space involves a series of stages of dialogue beginning with the conversations prior to the design of the research, through to the dissemination of results and perhaps even afterward. Fundamental to this process is an ongoing respect for both parties' ethical spaces and a continual questioning of "is this ethical?" This requires a dialogue about intentions, values and assumptions throughout the research process.

2.2 SACRED SPACE AND TRADITIONAL KNOWLEDGE

Article 1 A researcher should understand and respect Aboriginal world views, including responsibilities to the people and culture that flow from being granted access to traditional or sacred knowledge. These should be incorporated into research agreements, to the extent possible.

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

The concept of sacred space is important to an understanding of Aboriginal world views. It 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 on purity, clarity, peace, generosity and responsibility between the recognized spiritual entity, the Land and the Ancestors.



The notion of sacred space is also key to understanding accountability in the production and transmission of traditional knowledge. This is a term that has been widely discussed and debated by Aboriginal 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;
- a body of knowledge, spirituality and art forms that reflect history, culture, ethics and creativity, that are based on customary laws and protocols and that have been handed down from generation to generation.

Within Aboriginal cultures, 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 should 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.

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

2.3 COMMUNITY CONTROL AND APPROVAL PROCESSES

Article 2 A community's jurisdiction over the conduct of research should be understood and respected. This article should be read in the context of the discussion in Section 1.5 which addresses the application of this document.

Some Aboriginal communities manage and control matters dealing with health.³ As part of this control, the community may choose to be a full participant in any:

- research conducted within or about the community;
- community consent process; or
- management of the research process, including the development of ethics review principles and procedures.

A researcher should comply with any by-laws, policies, rules and procedures adopted by the community. For example, an Aboriginal community may have its own Research Ethics Board and/or community research protocols. In such a case, the Aboriginal community may require that research conducted in its region or territory comply with these procedures, as 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.

³ 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.



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 legal implications.

Respect for community control includes ensuring the survival and protection of Aboriginal culture, heritage and knowledge. The four ethical principles of OCAP apply here, namely: ownership, control, access and possession (also interpreted as protection). These principles are widely used in Aboriginal health research. They should be addressed in a research agreement, to the degree that their guidance coincides with the priorities and capacities of the parties involved.

There may be differences between the Guidelines and the requirements of the Aboriginal community involved in a research project. In these situations, the more stringent requirements should prevail.

2.4 PARTICIPATORY RESEARCH

Article 3 Communities should be given the option of a participatory-research approach.

Historically, Aboriginal communities have been the subject of much research by “outsiders”. This colonial approach to research in Aboriginal communities should 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 involvement in the research project. ‘Participatory research’ is a valuable methodology and should be viewed as an integral and ongoing component of the research project. The affected community and its members should be involved at all stages of the research process, from formulating projects and methods, through determining research outcomes and to interpreting and disseminating results.

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, equitable resourcing and mutual understanding, and will help the research proceed in a manner that is culturally sensitive, relevant, respectful, responsive, equitable and reciprocal with regard to the benefits shared between the research parties and the Aboriginal community. At the same time, it should be recognized that a community may not wish to be actively involved in a research project nor wish to be an equal participant. The community may be satisfied with simply monitoring the research, but otherwise staying distant from it.

Communication and meaningful consultation with the community is essential to establishing a partnership. If a researcher already has an ongoing relationship with members or leaders of the community, community consultation will mean 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 a researcher does not have an existing relationship, he or she 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. The researcher 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, 4th



paragraph). The parties should establish a dialogue allowing them to find 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. Aboriginal people should be able to participate through their own freely chosen representatives and institutions. The inclusion of a gender perspective and the participation of Aboriginal women are viewed as essential, as is the participation of children and youth when deemed appropriate by the recognized community authorities.

The exchange of ideas and understanding during the partnership-building process also implies 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”.

2.5 COMMUNITY AND INDIVIDUAL CONSENT

Article 4 A researcher who proposes to carry out research that touches on traditional or sacred knowledge of an Aboriginal community, or on community members as Aboriginal people, should consult the community leaders to obtain their consent before approaching community members individually. Once community consent has been obtained, the researcher will still need the free, prior and informed consent of the individual participants.

Community consent is distinct from, and additional to, individual consent from each research participant.

“Free” implies that consent is voluntary, without coercion, intimidation or manipulation. “Prior” implies that consent has been sought sufficiently in advance of any authorization or commencement of activities and respects time requirements of Aboriginal consultation/consensus processes. “Informed” suggests that the information provided includes:⁴

- complete disclosure of the risks and benefits to individuals and to the community of participation in the research;
- the nature, size, pace, reversibility and scope of any proposed project or activity;
- the reason(s) or purpose of the project 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 impacts, including potential risks, and fair and equitable benefit sharing in a context that respects the precautionary principle⁵;
- the conditions for collection, use, retention and disclosure of personal data in accordance with Article 5;
- personnel likely to be involved in the execution of the proposed project (including Aboriginal people, private sector staff, research institutions, government employees and others);
- procedures that the project may entail; and
- sources of project funding and support, as well as obligations to these sources.

⁴ For other necessary elements of consent, see *Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects*, Section 2.

⁵ The precautionary principle stands for the proposition 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.



A process to obtain the free, prior and informed consent from both the community affected and its individual participants should be undertaken sufficiently in advance of commencement or authorization of research activities and should take into account the community's own legitimate decision-making processes regarding all phases of planning, implementation, monitoring, assessment, evaluation and wind-up of a research project. It is now recognized that consent is an ongoing process and should be reaffirmed periodically, as appropriate to the research project.

The requirements for obtaining informed consent from individuals that are set out in the TCPS 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 a 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.

2.6 CONFIDENTIALITY / PRIVACY

Article 5 Concerns of individual participants and their community regarding anonymity, privacy and confidentiality should be respected and should be addressed in a research agreement.

The researcher and the community should discuss their respective expectations regarding the anonymity and confidentiality of information obtained and data produced. When anonymity is not possible, or when there are limitations to anonymity or confidentiality, these limitations should be clearly communicated to participants. A community may wish to remain anonymous in relation to certain conclusions reached in the research project. Conversely, as discussed in Article 15, a community that actively participates in the research may wish to be identified and acknowledged in the research. The level of participation by a community in the planning and implementation of the research project and in the interpretation of the data should be acknowledged appropriately, if that is the desire of the community. An Elder, for example, may want to be acknowledged as a contributor to the research outcomes, including recognition as author, where possible. Elders are experts in their own right and their expertise ought to be appropriately recognized alongside that of researchers.

The researcher, the individual participants and the community should have a clear, prior understanding as to their expectations with regard to the anonymity of the community and of the individuals participating in the research project, and the extent to which research data and results will remain confidential to the researcher. In other words, the researcher should, as early in the process as possible, discuss with the community and the proposed participants, the measures that will be taken to protect the privacy of individuals and the confidentiality of their medical records, and to ensure compliance with applicable laws. Although community consent is to be sought for the research project, this does not mean that the community is to have access to personal information of the participants without their express consent.

For related guidelines dealing with secondary use, proprietary interest, transfer and storage of data and samples, interpretation of data and dissemination of results see Articles 12.1 to 15 below. For information on individual privacy and confidentiality, refer to CIHR's document entitled *Best Practices for Protecting Privacy in Health Research* (September 2005). Where the research is considered to be a governmental activity, other standards for protecting privacy may apply, flowing, for example, from the *Canadian Charter of Rights and Freedoms* or privacy legislation.



2.7 INCLUSION AND PROTECTION OF CULTURAL KNOWLEDGE IN RESEARCH

Article 6 The research agreement should, with the guidance of community knowledge holders, address the use of the community's cultural knowledge and sacred knowledge.

Article 7 Aboriginal people and their communities retain their inherent rights to any cultural knowledge, sacred knowledge, and cultural practices and traditions, which are shared with the researcher. The researcher should also support mechanisms for the protection of such knowledge, practices and traditions.

In the context of research ethics, Aboriginal people, local communities and other traditional knowledge holders have the right to decide what constitutes their own cultural knowledge, innovation 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 in all Aboriginal communities, or even within one Aboriginal community. The Inuit, for example, use the term “Inuit Qaujimajatuqangit” to describe their holistic approach to environmental and traditional knowledge.

Any research involving Aboriginal people will involve the sharing of some cultural knowledge, practices and/or traditions, even when these are not the subject 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 the appropriate sharing of knowledge in ways that acknowledge that some knowledge is sacred – that is, involving the recognized spiritual entity, the Land and the Ancestors. This should be interpreted in a manner appropriate to the particular context and community. Thus, the researcher should ensure that cultural information considered by the community to be confidential will be obtained from a person recognized by the community as a knowledge holder, and authorized to disclose that knowledge. Because of the importance of traditional and sacred knowledge in Aboriginal cultures, access to and protection of such knowledge should be detailed in the research agreement.

The recording of knowledge, practices and traditions in any form (written notes, audio, video or otherwise) should 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 should also be by permission and explicitly acknowledge that the Aboriginal people and their respective communities who shared such knowledge, practices and traditions retain their inherent rights and ownership over them.

Where cultural knowledge, practices and traditions are the subject of study, in many cases research will result in “hybrid” products or outcomes, based on Aboriginal input plus the academic knowledge, tools or techniques contributed by the researcher. When hybrid products or outcomes are the result of a “co-production” research process, there should be an appropriate sharing of ownership agreed to by all parties.

2.8 INTELLECTUAL PROPERTY RIGHTS AND INDIGENOUS KNOWLEDGE

Article 8 Community and individual concerns over, and claims to, intellectual property should be explicitly acknowledged and addressed in the negotiation with the community prior to



starting the research project. Expectations regarding intellectual property rights of all parties involved in the research should be stated in the 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 and communicating what does and does not qualify as intellectual property under current Canadian and international laws is the joint responsibility of the researcher and communities involved.

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). There is an ongoing international debate regarding issues related to misappropriation, commodification, and unfair or harmful commercial exploitation of Indigenous knowledge. If the proposed research has explicit commercial objectives or direct or indirect links to the commercial sector, these should be clearly communicated to all parties as a requirement of the free, prior and informed consent process. All parties should understand that all research involving Indigenous knowledge, even when not commercially motivated, has the potential to be commercialized and, possibly, misappropriated when publication occurs. Thus, the researcher and the community should fully and openly discuss questions of potential secondary use of traditional and sacred knowledge, and the research agreement should address how best to protect this knowledge – including by way of intellectual property rights.

2.9 BENEFIT SHARING

Article 9 Research should be of benefit to the community as well as to the researcher.

Benefit sharing in research is an essential concern of Aboriginal communities. A research project should lead to outcomes that are beneficial to the participating Aboriginal community and/or individual community members. Benefit sharing vis-à-vis a community should be interpreted from the community's perspective. This may include tangible and intangible benefits, including those arising from altruism.

Benefit sharing involves fair reward for investments in research. Benefits can take a number of forms depending on the type of research being conducted. They 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. 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 that are contributing to the high incidence of diabetes in the group. While this does not have a direct economic benefit, it does have great social and health benefits for the community.

2.10 EMPOWERMENT AND RESEARCH CAPACITY DEVELOPMENT

Article 10 A researcher should support education and training of Aboriginal people in the community, including training in research methods and ethics.

To the degree reasonably possible, a researcher should work to foster education and training of community members to enhance their participation in the research project. Researchers should, where possible, employ community members.



2.11 CULTURAL PROTOCOL, LANGUAGE AND COMMUNICATION

Article 11.1 A researcher has an obligation to learn about, and apply, Aboriginal cultural protocols relevant to the Aboriginal community involved in the research.

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

Article 11.2 A researcher should, to the extent reasonably possible, translate all publications, reports and other relevant documents into the language of the community.

However, for many researchers such an endeavour may be too costly to justify. At a 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 the research budget. The issue of language translation should be addressed in the negotiation of a research agreement (see Appendix).

Article 11.3 A researcher should ensure that there is ongoing, accessible and understandable communication with the community.

The researcher should communicate in ways that will promote clear understanding by the community and broaden the avenues of knowledge transfer of the research findings (Martin-Hill and Soucy, 2005). Technical language should be minimized as much as possible and defined or explained when used.

2.12 INITIAL AND SECONDARY USE, PROPRIETARY INTEREST, AND STORAGE AND TRANSFER OF DATA AND BIOLOGICAL SAMPLES

Article 12.1 A researcher should recognize and respect the rights and proprietary interests of individuals and the community in data and biological samples generated or taken in the course of the research.

Article 12.2 Transfer of data and biological samples from one of the original parties to a research agreement, to a third party, requires consent of the other original party(ies).

Article 12.3 Secondary use of data or biological samples requires specific consent from the individual donor and, where appropriate, the community. However, if the research data or biological samples cannot be traced back to the individual donor, then consent for secondary use need not be obtained from the individual. Similarly, if research data or biological samples cannot be traced back to the community, then its consent for secondary use is not required.



Article 12.4 Where the data or biological samples are known to have originated with Aboriginal people, the researcher should consult with the appropriate Aboriginal organizations before initiating secondary use.

Article 12.5 Secondary use requires REB review.

Much of the criticism directed towards research involving Aboriginal populations stems from the loss of control of data or of biological samples collected from Aboriginal people. As well, serious concern has been raised over the inappropriate use of stored biological samples, including DNA and cell lines, for unauthorized research. Ownership of traditional and sacred knowledge should always remain with the community.

These guidelines set out basic principles for the collection, disclosure, use and transfer of data and biological samples. The details of safeguards protecting the privacy and confidentiality of data and biological samples should be negotiated as part of the research process and specified in a research agreement. Subject to the community's views on traditional or sacred knowledge, co-ownership of data and samples between researchers and communities is recommended.

If there is to be transfer of the data or biological samples to a third party, this should be done only with the consent of the researchers, the individual participants and the community. If the third party is to engage in secondary use of the transferred data or samples, then a further consent to that use must be obtained. Consent should address how confidentiality and privacy will be respected.

In any case, secondary use of the data or biological samples requires new consent unless such use is specifically agreed to in the research agreement.

Notwithstanding the above, individuals retain the right to access data about themselves.

Where the research is a governmental activity, other standards for protecting privacy may apply, flowing, for example, from the *Canadian Charter of Rights and Freedoms* or privacy legislation.

2.13 BIOLOGICAL SAMPLES ON LOAN

Article 13 Biological samples should be considered “on loan” to the researcher unless otherwise specified in the research agreement.

This Article reflects Aboriginal philosophies regarding “full embodiment”, in which it is held that every part and product of the body is sacred, and constitutes an essential part of the person.

Most Canadian Aboriginal communities advocate a participatory approach in the collection, use, storage and potential future use of human biological samples. These should be negotiated as part of the research agreement. In keeping with this model, the researcher needs to understand that his or her beliefs may not be reflective of the community's and should be respectful of the latter.

Therefore, the researcher should be considered the steward, rather than the owner, of the samples.

The research agreement and consent process should address the conditions of collection, place of storage, research lab/researcher involvement, industry roles, plans for governance and potential future use.



Unless samples have been destroyed or anonymized, requests by an individual to withdraw, return or dispose of samples should be accommodated, in accordance with the terms of the research agreement and any applicable law.

In the case of existing tissue banks, consultations with the community and the individuals should be held to determine under what circumstances the samples can be used for future research.

2.14 INTERPRETATION AND DISSEMINATION OF RESULTS

Article 14 An Aboriginal community should have an opportunity to participate in the interpretation of data and the review of conclusions drawn from the research to ensure accuracy and cultural sensitivity of interpretation.

Article 15 An Aboriginal community should, at its discretion, be able to decide how its contributions to the research project should be acknowledged. Community members are entitled to due credit and to participate in the dissemination of results. Publications should recognize the contribution of the community and its members as appropriate, and in conformity with confidentiality agreements.

Expectations regarding co-authorship and copyright should be set out in the research agreement.

The Aboriginal community should have the opportunity to review the research results before they are submitted for publication to ensure that confidential cultural information is not divulged to the public and that errors are corrected prior to wider dissemination. This is important because research involving Aboriginal communities and people is susceptible to misinterpretation when data are analyzed without sufficient consideration of the cultural characteristics that make the community in question.

This should not be construed as the right to block the publication of legitimate findings. Rather, it refers to the opportunity given to the community to contextualize the findings and correct any cultural inaccuracies.

A researcher should promote the dissemination of research results, and of other knowledge that may be revealed by the research, to other interested Aboriginal communities, and should, where possible, advise the community as to what can be done to address any problems or issues brought to light by, or as a result of, the research.

2.15 MEMORANDA OF UNDERSTANDING AND RESEARCH AGREEMENTS

Where a researcher does not have a prior relationship with an Aboriginal community, the latter may have expectations regarding what the researcher should do in order to be prepared for, and to be accepted by, the community – prior to negotiation of a formal research agreement. The expectations of the community and of the researcher may be appropriately addressed in a non-binding Memorandum of Understanding, which would also include the steps to be taken to reach a binding research agreement. However, the relationship-building process is contextual and community-specific, and there is no set formula for building such a relationship.



Once an effective and respectful research relationship is established, it is appropriate to negotiate and to 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 and the researcher should then be worked out.

The agreement should detail issues of data ownership, use and 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 the data. There should be prior agreement on the respective roles of the parties, desired outcomes, measures of validity, control over the use of data, funding and the dissemination of research findings.

The research partners should inform participants, in their own language, about the use of data-gathering devices, such as tapes, video recordings, photos, and physiological measurements, and how the data will be used. For example, abstracts of publications should be translated into the local language and made available to local communities where 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.

The strength and usefulness of a research agreement is directly related to the quality of the research relationship among the research partners. A respectful relationship is developed on the same basis as an effective agreement. Elements of both include good communication, honesty, transparency and trust. A sample research agreement is included in the Appendix.

The foregoing respects the spirit of the OCAP principles (ownership, control, access and possession) of data and information obtained from research involving Aboriginal people.



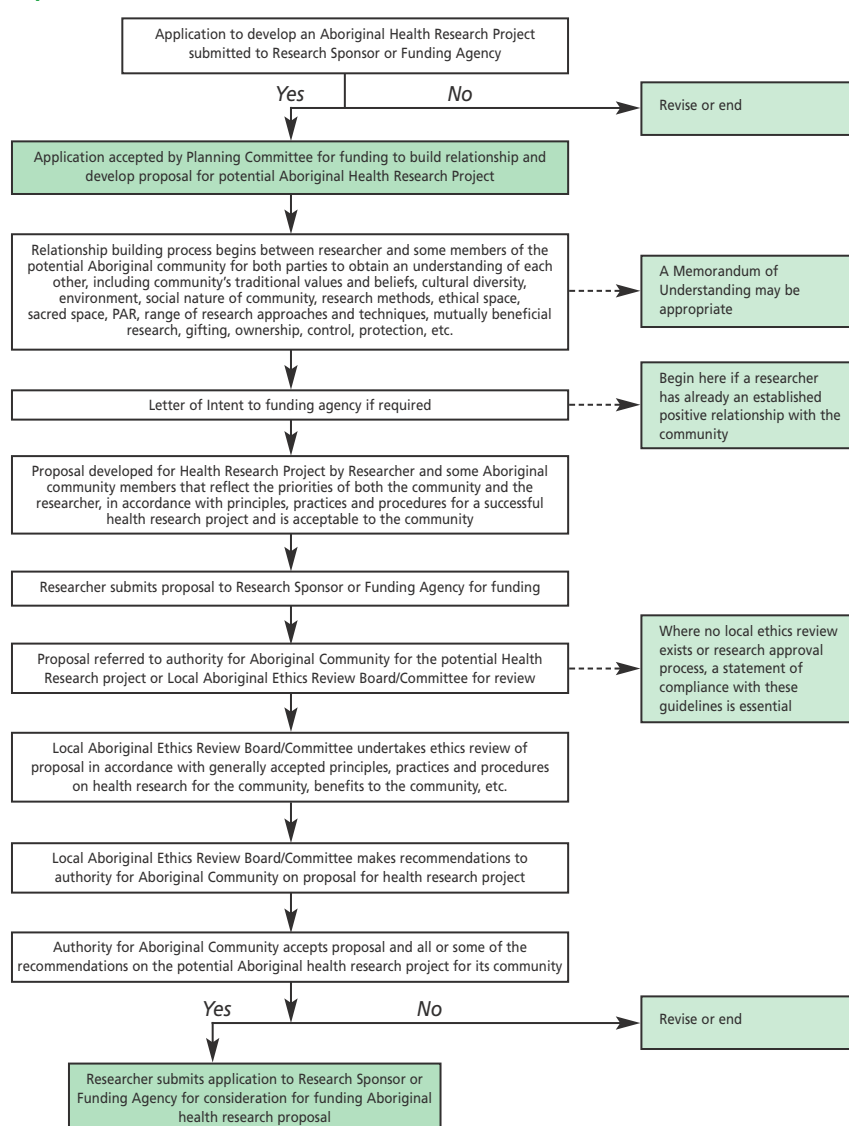
Section III – Procedure, Protocol and the Research Process

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

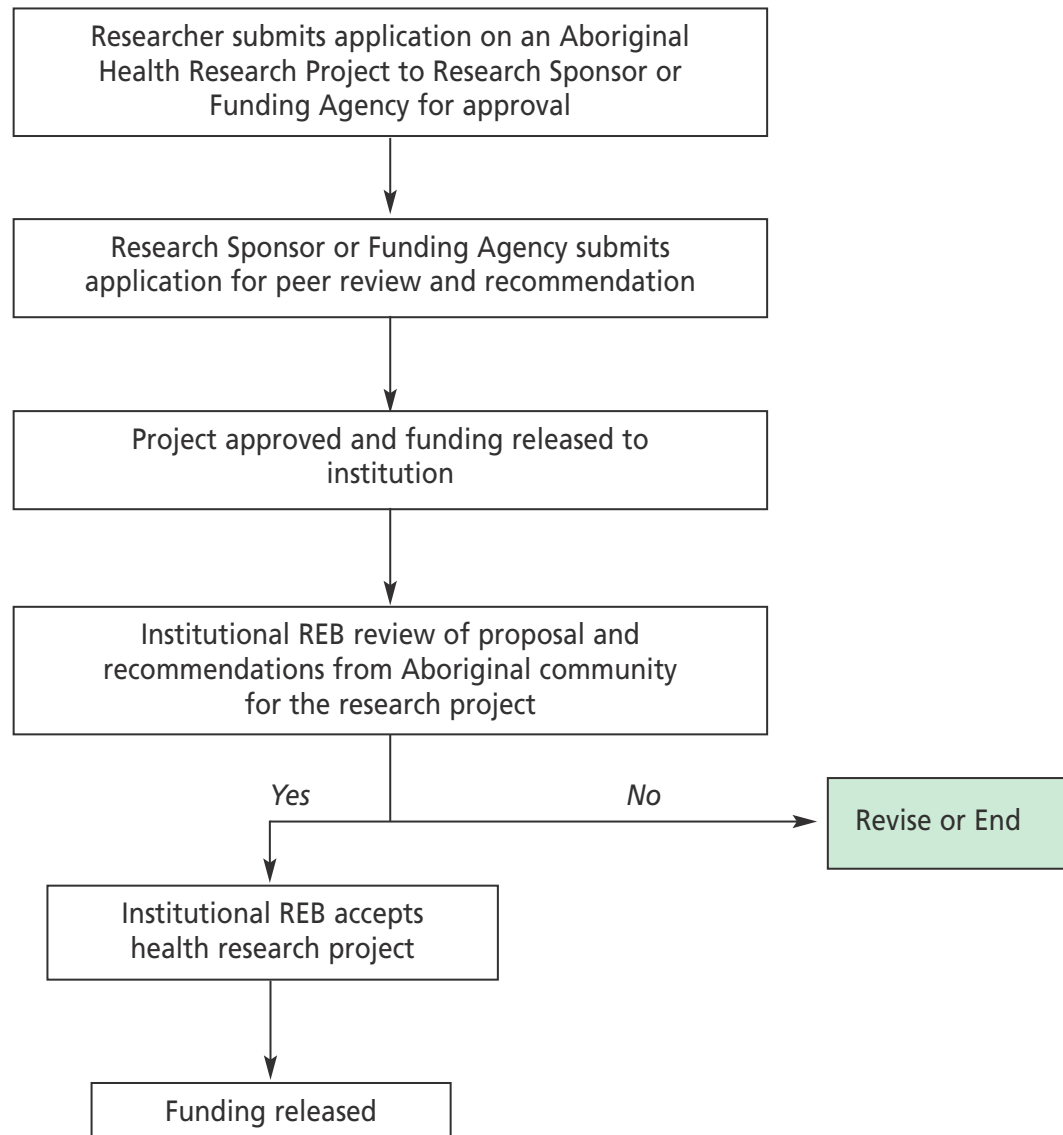
3.1 STEP-BY-STEP PROCEDURE

This section of the Guidelines offers a model of a step-by-step process for engaging in a research project with an Aboriginal community. The specific steps and their order may vary depending on the capacity and priorities of the Aboriginal community(ies) involved.

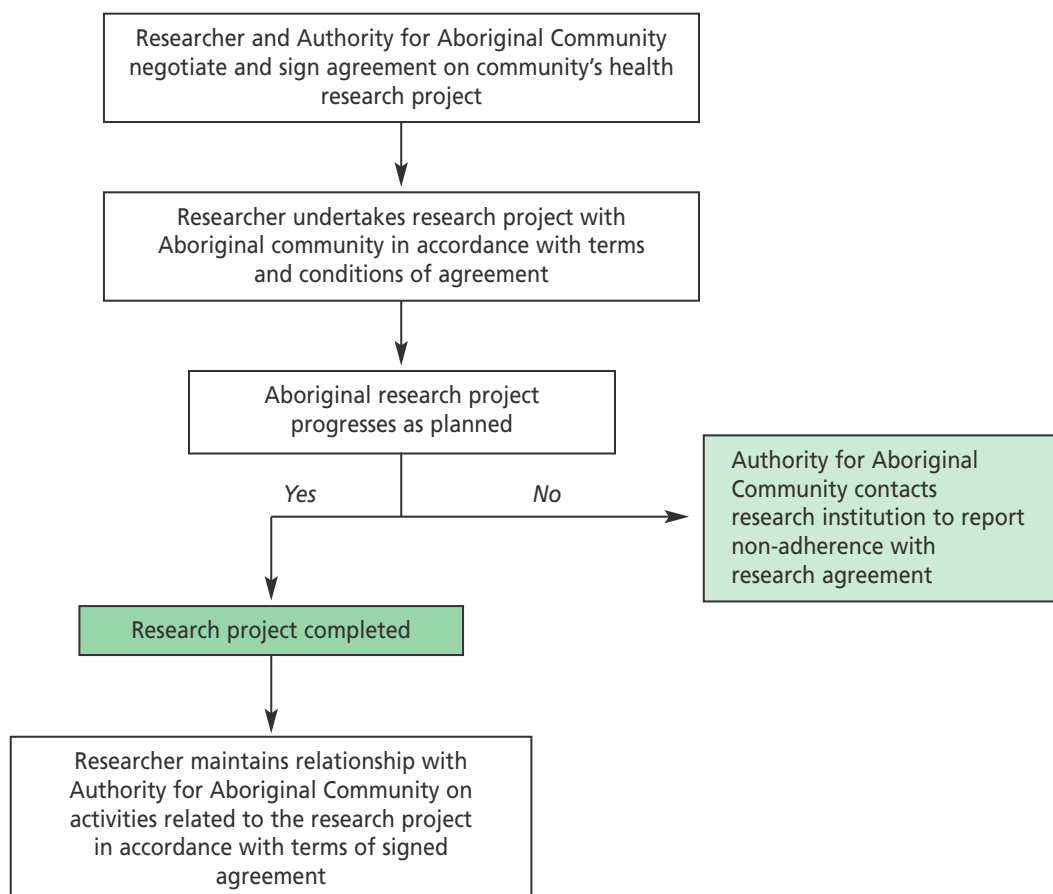
STEP 1: Relationship Development for Aboriginal Health Research – A Representative Model



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 to be considered in 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 Aboriginal communities as available.
 - Should explain any relevant work that has been completed.

Significance

- Explains the importance of the proposed research to Aboriginal individuals and their community.
- Explains how the proposed research is new or different from other similar research.
- Explains any potential benefits, risks and harms for Aboriginal individuals and their community.

Methods

Approval

Should explain:

- How Aboriginal group approval will be obtained, e.g.:
 - Band/tribal/community council health director, health board, and/tribal/community council
 - Resolution
- How funding agency approval will be obtained.
- How research ethics board approval will be obtained.

Sampling

Should explain:

- Who will be included, e.g.:
 - Males and/or females, and why.
 - Adults and/or children, and why.
 - Random or pre-selected, and why.
 - What is required of research participants, and for how long.
- Technical assistance should be provided to research participants and others as appropriate so that they can understand the proposed research in some depth.

Recruitment

Should explain how participants will be recruited into the study:

- Advertisement in local health newsletter, Aboriginal organization newsletter, etc.
- Whether participants will be recruited on the basis of their health status.
- Measures to optimize convenient participation.
- Personalized letters, e.g., chief writing to encourage participation.
- Inclusion of Aboriginal group members in assisting with recruitment.

The Consent Form should:

- Be written in understandable language, at the 8th grade level, so that participants understand clearly what they are being asked to participate in.



- Include all requirements of the TCPS and these Guidelines, and a clear statement that the study constitutes “research”.
- Include a clear statement of all research objectives.
- Explain how and why prospective participants were selected.
- Explain expected duration of volunteers’ participation.
- Disclose reasonably expected benefits, and reasonably foreseeable discomforts and risks.
- Disclose whether the protocol involves interventions (treatment) or only observation or questions.
- Explain alternatives to the research project’s diagnostic method or treatment (applicable primarily to research on 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 reduce compensation):
 - Consequences of a volunteer’s withdrawal from the research.
 - When a researcher may terminate a volunteer’s participation without his/her consent.
- Whether biological samples will be collected, conditions of storages, and arrangements for return of the samples (if possible, and desired by the research participant).
- Plans to inform volunteers of significant research findings during or after the study relevant to their continued participation or treatment (applicable primarily to clinical trials or to “deception” research where debriefing at the end of the project is a standard procedure).
- If more than minimal risk: “In case of injury or severe adverse effect...”
 - Will medical care be given for adverse effects? By whom? Where?
 - Is compensation for adverse effects available? How?
 - Who should a volunteer contact in case of injury or adverse effect?
- Identification of, and contact information for, individuals who will respond to questions from participants about the research itself.
- Mechanisms to assure confidentiality and privacy.
- Who will answer other concerns, complaints or grievances? (in Regulations, this is called the “subject rights”; usually the Research Ethics Board, with telephone number – collect call or toll-free number if long distance).
- Financial factors (extra costs of participation, details about sponsorship or funding).
- Extent of participation of the community.
- Other elements that a reasonable person would want to know.
- Non-coercion disclaimer.

Data Collection

- Explains what information will be collected, e.g., Aboriginal group name, participant name, age, height, tobacco use.
- Explains how the information will 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 will be kept, where, by whom.
- Explains data ownership; to whom does the data belong?
- Inclusion of Aboriginal group members in data collection should be clearly stated.
- Inclusion of Aboriginal group members should be 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 will be or might be used to compare the results.
- Technical assistance should be provided to Aboriginal group so that data analysis steps are clearly understood.

Interpretation

- Explains what steps will be taken in relaying results, e.g., tables with labels will be included in some proposals.
- Aboriginal leadership should be included at the interpretation stage.

Reporting and Dissemination

- Explains how the reporting of results will unfold, e.g., results will be shared with the health committee, band/tribal/community council, regional Aboriginal organization, participants in a community open forum, 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

- The project should specify follow-up or additional steps that will be pursued based on results.

References

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

Supporting Documentation

- Information sheets – a one-page explanation of the specifics of the study
- Informed consent form
- Data collection forms
- Band/tribal/community council or Aboriginal organization resolutions
- Research ethics board approval letter
- List of resources specific to the topic under study.

3.2.2 Research process

Funding

All aspects of funding should be explained to Aboriginal leadership so that there is a clear understanding between the community and researchers of limitations, timeframe, requirements and scope. This may include:

- 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.



Approvals

All necessary approvals should be sought and adequate time should be allowed for these processes. The levels of approval will range from local and institutional approval for single community projects, to regional or national approval and multi-university approval for multi-site projects. If the project targets a specific community, approval should be sought as the project is being developed. If the project aims to recruit several communities, it may be more practical to seek approval once the project receives funding. Research ethics board approval is required after a project receives funding.

The levels of approval may include, as appropriate:

- Research Ethics Board
 - Institutional
 - Aboriginal, if available
- Aboriginal community
 - Program director
 - Band/tribal/community council health director
 - Health board or committee
 - Band/tribal/community council
- Health services approval
 - Service unit director
 - Clinical director.

Approval from each individual participating Aboriginal community is necessary and may include the following components:

- Schedule of meetings held by local health program, health board, and band/tribal/community council should be obtained.
- Getting on the agenda – requests should be made to have an audience with the local health program, health board and band/tribal/community council.
- Travel to the meetings – as much as possible, an in-person presentation should be made to the health board and band/tribal/community council or Aboriginal group.
- Prepare materials for the presentation and be ready 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).

Research Timeline and Budget

- A clear project timeline should be established detailing how and when project activities need to take place; sufficient time should be allowed for necessary Aboriginal consultation.
- Establishing a budget to pay for personnel and project activities, i.e., personnel time, travel, consultants, supplies, indirect costs.
- 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 required to pay for personnel and project activities.
- Regular status updates to 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 group.
- Databases will be created and statistical software programs will be used to analyze the information; capacity building, including the training of Aboriginal personnel for data entry, analysis and interpretation, should be considered and incorporated to the project.
- As part of capacity building, the inclusion of Aboriginal group members in the project is recommended.

Interpreting Results

- The information gathered during the study should be relayed to the Aboriginal group, band, tribal or community council, to the research community, and to the general public.
- The numbers should be explained in understandable terms to the program director, band/tribal/community health director, health board and band/tribal/community council.
- Rates, numerator and denominator should be explained in understandable terms to the program director, health director, health board members, band, tribal and community council members and Aboriginal communities.
- The information will usually be:
 - stratified by age and sex,
 - compared with other data sources; these should be explained to the Aboriginal group.
- As the results are compiled, the Aboriginal group should be consulted on findings and description of Aboriginal identity.
- Consider the Aboriginal group as a co-author.

Publishing Results

- The information gathered during the study should be relayed to the Aboriginal and research community (and the general public, if appropriate, depending on the agreement between the researcher and the community). Researchers need to take into account community comments and allow for dissenting views to be expressed in publications if not resolved earlier.
- Community leaders should vet final reports, manuscripts and other dissemination materials for cultural and factual accuracy.
- The results should be shared with participants in newsletters, mailings, public forums etc.

Intellectual Property and Commercialization

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



Section IV – Articles

- Article 1** A researcher should understand and respect Aboriginal world views, including responsibilities to the people and culture that flow from being granted access to traditional or sacred knowledge. These should be incorporated into research agreements, to the extent possible.
- Article 2** A community's jurisdiction over the conduct of research should be understood and respected. This article should be read in the context of the discussion in Section 1.5, which addresses the application of this document.
- Article 3** Communities should be given the option of a participatory-research approach.
- Article 4** A researcher who proposes to carry out research that touches on traditional or sacred knowledge of an Aboriginal community, or on community members as Aboriginal people, should consult the community leaders to obtain their consent before approaching community members individually. Once community consent has been obtained, the researcher will still need the free, prior and informed consent of the individual participants.
- Article 5** Concerns of individual participants and their community regarding anonymity, privacy and confidentiality should be respected, and should be addressed in a research agreement.
- Article 6** The research agreement should, with the guidance of community knowledge holders, address the use of the community's cultural knowledge and sacred knowledge.
- Article 7** Aboriginal people and their communities retain their inherent rights to any cultural knowledge, sacred knowledge, and cultural practices and traditions, which are shared with the researcher. The researcher should also support mechanisms for the protection of such knowledge, practices and traditions.
- Article 8** Community and individual concerns over, and claims to, intellectual property should be explicitly acknowledged and addressed in the negotiation with the community prior to starting the research project. Expectations regarding intellectual property rights of all parties involved in the research should be stated in the research agreement.
- Article 9** Research should be of benefit to the community as well as to the researcher.
- Article 10** A researcher should support education and training of Aboriginal people in the community, including training in research methods and ethics.
- Article 11.1** A researcher has an obligation to learn about, and apply, Aboriginal cultural protocols relevant to the Aboriginal community involved in the research.
- Article 11.2** A researcher should, to the extent reasonably possible, translate all publications, reports and other relevant documents into the language of the community.



- Article 11.3** A researcher should ensure that there is ongoing, accessible and understandable communication with the community.
- Article 12.1** A researcher should recognize and respect the rights and proprietary interests of individuals and the community in data and biological samples generated or taken in the course of the research.
- Article 12.2** Transfer of data and biological samples from one of the original parties to a research agreement, to a third party, requires consent of the other original party(ies).
- Article 12.3** Secondary use of data or biological samples requires specific consent from the individual donor and, where appropriate, the community. However, if the research data or biological samples cannot be traced back to the individual donor, then consent for secondary use need not be obtained from the individual. Similarly, if research data or biological samples cannot be traced back to the community, then its consent for secondary use is not required.
- Article 12.4** Where the data or biological samples are known to have originated with Aboriginal people, the researcher should consult with the appropriate Aboriginal organizations before initiating secondary use.
- Article 12.5** Secondary use requires REB review.
- Article 13** Biological samples should be considered “on loan” to the researcher unless otherwise specified in the research agreement.
- Article 14** An Aboriginal community should have an opportunity to participate in the interpretation of data and the review of conclusions drawn from the research to ensure accuracy and cultural sensitivity of interpretation.
- Article 15** An Aboriginal community should, at its discretion, be able to decide how its contributions to the research project should be acknowledged. Community members are entitled to due credit and to participate in the dissemination of results. Publications should recognize the contribution of the community and its members as appropriate, and in conformity with confidentiality agreements.



Appendix: 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. The methods to be used, as agreed by the researchers and the community, are: _____
4. Community training and participation, as agreed, are 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 the 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 address of each researcher can be used at any time, should the respondent wish to contact the researcher(s) for additional information.



7. The names of participants and of 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 AND COMMITMENTS

Funding

The main researchers have received 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 their benefit in the following ways (for instance, by publishing the report and articles about it): _____

The researchers will submit a final report to the funding agency in 20XX. Scientific presentations in peer-reviewed publications and conferences will be made. The final report will be reviewed by community members prior to publication. Scientific presentations will be made and articles published after discussion with the respective community leaders.

The 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 or to be employed in this project.



- Keep informed about the progress of the project, and help in leading the project toward meaningful results.

The researchers' main commitment to the community is to: _____

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

The researchers agree to interrupt the research project in the following circumstances: _____

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

Signed by:

Date:

Date:
Community:

(Signature of Main Researcher)

Name:

Position:

(Signature of Community Contact Person)

Name:

Position:



Bibliography

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 Ethics Office of the Canadian Institutes of Health Research.



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