



# Considerations and Templates For **Ethical Research Practices**

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## Introduction

The First Nations Centre (FNC) @ NAHO has developed the *Considerations and Templates for Ethical Research Practices* as a companion document to the first *Ethics Tool Kit*<sup>1</sup> (2003) that focused on the emerging issues surrounding ethical research practices in First Nations.

The *Considerations and Templates for Ethical Research Practices* is an adaptation of the Assembly of First Nations' 1999 paper entitled *Template for a Community Code of Ethics in Research and Data Sharing Protocols* that provides practical guidance to communities interested in developing their own research policies and protocols. The most useful feature of this guide is its three templates to assist First Nations in the development of research policies and agreements.

The first template provides a model *Code of Research Ethics*. This model contains useful policies and procedures that need to be considered in governing, managing, or guiding research activity in First Nations.

The second template is a model for a *Collaborative Research Agreement*. This includes the basics needed to ensure a full and equal partnership between the community and the research partners in all aspects of the research process.

The final template is a model for a *Data-Sharing Protocol* between the First Nation and research partners. It establishes ownership of the data, including how and under what conditions the data may be shared. The protocol also sets out the principles and obligations that partners must adhere to when they collect, use, store, and disclose individual or aggregate information.

The participatory research approach of the three templates is grounded in the principles of Ownership, Control, Access, and Possession (OCAP<sup>2</sup>) of information and data.<sup>3</sup> Some communities may find that our templates serve their purposes with little change necessary. Most will likely adopt some of the elements along with new, community-specific elements. In either case, communities are empowered

with knowledge and the tools for planning research. Further, it is hoped that this guide will create an increased awareness among the non-First Nations research community that endeavours to engage in research with First Nations.

The FNC offers other useful materials including:

- **Understanding Research;**
- **Health Surveillance;**
- **Privacy;**
- **Ethics in Health Research; and,**
- **OCAP: Ownership, Control, Access and Possession.**

## Background

In recent years, there has been a growing concern among First Nations of the need to regulate research and data collection activities in or about their communities. Expressions of concern with research grew during the 1950s in response to a wave of disrespectful and ethnocentric anthropological research.

Since the 1990s, First Nations have become increasingly aware of inappropriate or harmful research that generally originates from external research proposals. Consequently, they are seeking to better manage research affecting them, avoiding harm and ensuring that good is done through research.

First Nations have begun to establish their own regulations, committees, and procedures to protect their information, culture, traditional knowledge, and rights. In so doing, First Nations are asserting their rights to self-determination, cultural distinctiveness and dignity.

*Our Considerations and Templates for Ethical Research Practices* can assist in regulating health research in your community. Health research in First Nations has become extremely important to the many people involved in trying to reduce the large gaps between the health of First Nations people and Canadians generally. Health research is equally important to the people who deliver health services to First Nations people. A complete and holistic view of community health requires a good understanding of the “determinants of health”.<sup>4</sup> Therefore, a well-developed and respected community code of research ethics will result in a general policy framework that can regulate most or all types of research.

A community code of research ethics and related processes will help to influence change, encourage positive research, and improve the culture and practice of research in general. The result should be better, more useful and appropriate research for the community.

So, let us continue in the spirit that research *can* be good . . . if done respectfully and appropriately.

## What is Participatory Research?

As with OCAP, the movement towards participatory research has been the result of the inadequacies of past research projects that were seen as having little local relevance and that did not contribute to community development.

Participatory research is a process that involves collaboration between researchers and the people researched or otherwise affected by the research. It endeavours “to balance interests, benefits and responsibilities between the [researchers and the community] concerned, through a commitment to equitable research partnership.”<sup>5</sup>

In this collaboration, all partners are involved in the entire scope of the research project through the planning, implementation, data analysis and reporting stages. Guidelines for participatory research need to reflect this sharing of leadership, responsibilities and decision-making for both the researchers and the community.

The main goal of participatory research is “to empower research subjects to assume ownership of the research process and to use the results to improve their quality of life.”<sup>6</sup> It is research for the purposes of reciprocal education, taking action and/or effecting social change as a result of research questions that are relevant to the community.

A participatory research project can take various forms. For example, the community can be the sole researcher; a community-based researcher can collaborate with one or more outside researcher(s); or there may be a complex multi-party arrangement involving several communities, several universities and different levels of government.

Various factors may influence the level of community involvement desired, including: level of interest of the community; amount and method of local data collection; potential capacity building and/or other employment opportunities; amount of resources available to hire local researchers/workers; need for other types of local expertise; need for specialized expertise not available in the community; and the

need for cultural interpretation.

All partners need to negotiate a common set of issues related to the research:

- 1) the research process;
- 2) goals, objectives, methods and duration of the research project;
- 3) terms of the partnership with community researchers or others in the community who play a part in supporting the project;
- 4) confidentiality and privacy of collective and personal information;
- 5) evaluation process and content;
- 6) control and access to data, including data stewardship and analysis;
- 7) dispute resolution; and,
- 8) methods to disseminate the resulting information to stakeholders including communities, health care professionals, the academic world and funding bodies.

Participatory research is, first and foremost, built on mutual respect and partnership between the community and the researchers. It requires that the community insist on the application of ethical principles at both the individual and community levels.

While recognizing the importance of individual informed consent, community codes of research ethics often require collective community consent in addition to consent by individual research subjects. This must be informed consent. In other words, all information about the proposed research project must be provided to the participants and community. Empowered with this information, the community and its members can make an informed decision about their participation. They are better able to understand the process, the expected benefits and risks, the provisions for confidentiality and/or anonymity, the access to and ownership of the data and so on. They can also make decisions on what terms the research should be conducted. Community consent,

like individual consent, is not a static, one-time event but a process extending through all phases of the research, including analysis, interpretation and dissemination.

Participatory research has positive aspects for all concerned. Indeed, it is difficult to argue against its overwhelming benefits. The Assembly of First Nations identified some of these benefits:

- greater mutual trust;
- a receptive environment for collaboration with researchers;
- participation in certain types of research, which can result in health-promoting activities by participants;
- greater receptivity by research subjects to involvement in a project if the research questions are deemed relevant to the community and the data collection methods are agreeable to all parties;
- ongoing capacity development of community-based researchers, such as training and infrastructure, data collection and data storage;
- richer contextual information and increasingly meaningful conclusions through community participation in data interpretation and analysis, leading to greater cultural and internal validity of the results;
- a stronger community voice in policy;
- self-employment generated by increasing the community's awareness of its ability to contribute to research protocols, develop skills and solve problems; and,
- increased autonomy and control by the First Nation, which is linked to the overall process of self-determination.

## What is a Code of Research Ethics?

A code of research ethics is a framework of principles and procedures to regulate and guide all research in a community. A code typically applies to the community, community-based researchers and to outside researchers.

The purpose of a code of research ethics is to:

- a) Regulate research activities in the community, whether it is research done by the First Nation, by outside researchers, or in partnership.
- b) Provide standards of conduct to ensure that neither individuals nor the community is harmed or exploited as a result of research.
- c) Protect the rights, values, and traditional knowledge of the participants and the community.
- d) Establish a framework, based on the principles, values, traditions and beliefs of the First Nation, to determine how research will be *managed* in the communities.
- e) Identify key ethical considerations to govern all research in or about the community.
- f) Protect the First Nation's individual and collective data, and safeguard information interests and rights.
- g) Ensure that informed consent is obtained from individual participants and the community as a whole.
- h) Promote trust, respect, responsibility and honesty.
- i) Ensure appropriate and meaningful First Nation participation in all stages of research, including whenever possible through employment and training opportunities.
- j) Identify all issues to be negotiated between the partners in a collaborative approach to research.

k) Foster a trusting relationship built on mutual respect and understanding between the First Nation and the outside researcher(s) investigating them.

l) Identify the procedures to be complied with in reviewing research requests, with which potential researchers must comply in order to obtain permission to conduct research of any kind on the First Nation community.

A code of research ethics has many benefits such as increasing public awareness of First Nations' policies, principles, protocols, and rights in relation to research. Its very existence serves as a foundation to assert self-determination over research in the community (i.e., assertion of OCAP).

A code is also useful in reviewing proposals, managing research partnerships, overseeing research and researchers, and monitoring, evaluating and reporting on the code's implementation and use.<sup>7</sup>

A meaningful code of research ethics addresses ethical and political issues, and reflects the local culture, needs and interests of the community. It maximizes collaboration between the research partners. It is the responsibility of all the partners to respect the code and to observe its principles and protocols. Research partners rely on trust built ideally on honesty, respect, transparency, accountability and good communications. As a rule, a community's code of research ethics should be referenced in, or appended to, all research contracts between the community and parties undertaking the research or subsequent analysis. It is also reasonable to ask that the research products mention the code and the fact that the research was in compliance with it.

Although the development of a code of research ethics may be triggered by a specific project, it can be written in general terms in order to address and guide future research initiatives. The development process itself is critical to a successful community code of research ethics. Effective processes are required to develop, approve, manage and evaluate the code.

There is a need for adequate input from many dif-



ferent interests and groups within the community to achieve community support and make the code more than a piece of paper. It may also be helpful and valuable to solicit input from external research partners, particularly those who are trusted and those with whom there is a long-standing relationship. In addition to careful development, it is also important to establish a process for ongoing monitoring, evaluating and reporting on the code's implementation and use.<sup>8</sup>

A working group is a good way to ensure that the development process is efficient and stays on track. Community leaders, elders, health professionals, the community administrator and trusted outside experts are potential members. Success is usually more certain if one person, such as a band employee, is tasked to be the co-ordinator. Someone is needed if only for continuity and for drafting the actual code. It is probably also worthwhile putting the code and its template contracts to the First Nation's legal counsel for opinion. Formal adoption by community authorities is a critical and valuable step.

The *Template for a Code of Research Ethics* in **Appendix A** is a useful starting point in developing research policies and protocols. It is recognized that each community is unique and as such, the template is not intended to be adopted as is. Rather, the template may be modified to address the needs and ideals of the community. The template provided in Appendix A is organized into the following sections:

1. Introduction
2. Purpose
3. Policy Statement
4. Guiding Principles
5. Definitions
6. Obligations of the Partners
7. Operational Procedures
8. Evaluation of New Research Applications

## **What is a Collaborative Research Agreement?**

A collaborative research agreement represents a

formal summary of rights, responsibilities and expectations between the research parties. Information regarding the principal researchers and the research project is usually included in the agreement. It ensures that the research process is transparent, that interests are appropriately balanced, and that all parties understand and agree on a range of issues. Although verbal agreements and trust are important, documentation is often vital in dealing with external researchers and is useful in avoiding misunderstandings and potential conflicts. A collaborative research agreement is generally co-written by the researchers and the First Nation to ensure an equal research partnership. It should also be produced in languages appropriate to the First Nation.

**Appendix B**, *Template for a Collaborative Research Agreement*, covers the following issues:

- purpose, goals and duration of the research project;
- scope of the project, and types and extent of activities the research will involve;
- expected outputs and products;
- potential risks and benefits to the community;
- extent of involvement and participation of each party (roles and responsibilities), identifying specific obligations and commitments;
- time commitments required from community members involved in the research in various capacities, and amount of financial or other compensation (if any) to be paid to them;
- research methods and procedures involved;
- research capacity to be built in the community (training and participation);
- process and form for obtaining informed consent of individual participants and the community as a whole;

- reporting obligations by the research institution (progress reports);
- mechanisms in place to ensure regular and effective communication between the First Nation and the research institution, including conflict resolution mechanisms and how these will be implemented;
- measures to ensure confidentiality (coding, maintenance, and storage of data);
- access to, ownership of, and restrictions on use of the data during and after the project, including terms and conditions for future use of the data;
- involvement by community in the data analysis, interpretation and dissemination of the research findings;
- conditions relating to formal publication (how acknowledgements and differences in interpretation of the data will be addressed);
- financial and logistical responsibilities of the partners (e.g., funding, salaries, equipments, office space, accommodation, supplies and transport costs);
- provisions for benefit-sharing in circumstances where intellectual property rights or other forms of economic gain may be negotiated;
- the course of action to be followed by both parties if the research is stopped due to an unforeseen inability to reach its objectives or as a result of a collective decision by the First Nation to no longer wish to participate; and,
- a termination clause.

This list is not exhaustive and may be expanded according to need. The descriptions of the issues should be discussed, understood and agreed upon by the researchers and the community.

If the research agreement is intended to be legally binding, it should be reviewed by a legal expert before signing.

## What is a Data-Sharing Protocol?<sup>10</sup>

A data-sharing protocol is a formal agreement between the community and research partner(s) which summarizes the conditions and arrangements for sharing the community's information or data. The agreement sets out the fundamental principles and obligations that the research partners must adhere to when they collect, use, store and disclose individual or aggregate data. It also describes why information or data is being shared, and when and how information can be shared. This kind of agreement is a useful tool in protecting individual and community interests, information and privacy. It is also important in maintaining appropriate standards and in preventing misunderstandings over responsibilities.

A code of research ethics focuses on new research and new data collection and the rules, roles and relationships that govern such an endeavour. It does not completely address the situation where a First Nation already owns, controls, and possesses data, and a request is received from an outside party to access or use this data for research purposes. This data might involve individual records (e.g., individual survey responses or clinical charts) or aggregate data (e.g., statistics). There are also situations involving research or analysis based on existing data (this is called "secondary research"), sometimes requiring the identification of First Nations individuals within general databases. Although new data is not being collected, First Nations may still wish to assert their jurisdiction. If research is to proceed, a data-sharing protocol or agreement may be required.

Some situations in which a data-sharing agreement might be useful are listed below:

- a community has collected and analyzed data for a research project and a researcher approaches the community with a request to further analyze the data, possibly linking it with another data set;
- the provincial government is interested in looking at hospital utilization among First Nations and requires demographic information in order to identify First Nations

individuals in the general hospitalization data base;

- a community has been approached by a provincial health authority to share communicable disease and immunization data from their health clinic; or,
- a community wishes to compare certain health data (e.g., survey data) with similar survey data from another community.

**Appendix C** - A *Template for a Data-Sharing Protocol* is provided and may be developed to meet the specific needs of the situation under consideration. In some cases, a legal review of the terms and conditions of the data-sharing agreement may be required. The template is organized into the following sections:

1. Introduction
2. Definitions
3. Purpose
4. Information to be Shared
5. Use of Data or Information
6. Mechanism for Information Sharing
7. Data Ownership
8. Publication and Dissemination
9. Data Security and Confidentiality
10. Retention and Disposition of Information
11. Intellectual Property
12. Duration and Renewal
13. Expiration or Revocation of the Agreement
14. Signing Authorities

## Endnotes

<sup>1</sup>Available at the following website: [http://www.naho.ca/firstnations/english/pdf/Ethics\\_Toolkit.pdf](http://www.naho.ca/firstnations/english/pdf/Ethics_Toolkit.pdf)

<sup>2</sup>First Nations Centre, *Ownership, Control, Access and Possession (OCAP) or Self-determination Applied to Research: A Critical Analysis of Aboriginal Research Practice and Some Options for Aboriginal Communities* - first prepared for the First Nations Information Governance Committee, Assembly of First Nations (Ottawa: National Aboriginal Health Organization, 2005), p. 2.

<sup>3</sup>OCAP supports that First Nations have the right to assert self-determination over all research in their communities, to protect information about their peoples and their traditional knowledge. A community that asserts its OCAP rights is able to make decisions regarding why, how, and by whom information is collected, used, and shared for research, evaluation and planning purposes.

<sup>4</sup>Report on the Health of British Columbians: Provincial Health Officer's Annual Report 2001, *The Health and Well-Being of Aboriginal People in British Columbia* (British Columbia: British Columbia Ministry of Health Planning, 2001), p. 2. Determinants include the social, economic, physical and environmental factors that interact with one another and influence the health of a population. In a holistic approach to health and well-being, more consideration is given to the non-medical, cultural, and spiritual determinants of health.

<sup>5</sup>World Health Organization, *Indigenous Peoples and Participatory Health Research: Planning and Management - Preparing Research Agreements* (retrieved from [www.who.int/ethics/indigenous\\_peoples/en/print.html](http://www.who.int/ethics/indigenous_peoples/en/print.html) on October 19 2006).

<sup>6</sup>Kahnawá:ke Schools Diabetes Prevention Project, *KSDPP Code of Research Ethics* (retrieved from <http://www.ksdpp.org/code.html> on October 19, 2006).

<sup>7</sup>First Nations Centre, *First Nations Health Information Governance: The Importance of Policy-making*, a presentation taken from the FNC training session, *How to Use Data for Effective Community Health Planning* (Ottawa: National Aboriginal Health Organization, 2004).

<sup>8</sup> Ibid.

<sup>9</sup>World Health Organization, *Indigenous peoples and participatory Health Research: Planning & Management - Preparing Research Agreements*.

<sup>10</sup>Adapted from: Assembly of First Nations, *Template for a Community Code of Ethics in Research and Data Sharing Protocols* (Ottawa: Author, 1999) and; First Nations Information Governance Committee and First Nations Centre, *RHS License to Use Agreement* (Ottawa: National Aboriginal Health Organization, 2004).

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## Appendix A - Template for a Code of Research Ethics

### 1. Introduction<sup>i</sup>

*The introduction identifies the First Nation community or organization, the jurisdiction and types of activities (i.e., research) affected by the Code. It briefly summarizes the obligations and responsibilities of those undertaking research within the jurisdiction. It may be appropriate to identify the formal status of the Code (e.g., date of adoption by a band council resolution).*

*The introduction also provides background information about the development of the Code, the reason it was developed, who was involved, the underlying principles and intended uses. Any sources (including templates) used in the Code's development should be referenced.*

*It may identify an individual(s), committee or group to be a representative(s) responsible for the Code as a contact. The representative(s) may also specifically be given responsibility to fully oversee the community-based research, including documentation of approved projects.*

#### **Sample text:**

At the \_\_\_\_\_ First Nation meeting on \_\_\_\_\_, the Band and Council appointed a Working Group of community leaders, elders, educators and other professionals to develop a draft of principles and guidelines to protect individual and community data and information, as well as intellectual and cultural knowledge. The Working Group's work resulted in a draft Code of Research Ethics to protect their people's rights and assert the OCAP principles, which is self-determination applied to research.

The draft Code of Research Ethics was reviewed and ratified by the Band and Council on \_\_\_\_\_. All members of the Working Group share an understanding that research on community issues impacts on local policy and planning, and should contribute to the well-being of the community in which research is being conducted. These factors contribute to First Nation control of information and surveillance as tools for effective health planning and advocacy.

Community-based participatory research acknowledges that there must be respect for the beliefs, culture, traditions and practices of the \_\_\_\_\_ First Nation.

The Code of Research Ethics seeks to ensure that the right of ownership of the community's knowledge and heritage rests with the \_\_\_\_\_ First Nation. Researchers are expected to respect and follow the principles and protocols set out in the Code of Research Ethics to ensure the highest standards of research appropriate to the \_\_\_\_\_ First Nation.

The Working Group members include: \_\_\_\_\_.

### 2. Purpose

*Under this heading, the purpose of the Code is established. This may include information on what the Code will address as well as identifying the objectives of the Code.*



**Sample text:**

The \_\_\_\_\_ First Nation has designed this Code as a tool to assist in the protection and well-being of its members and the community in research activities, and to facilitate cultural self-determination and preservation.

The purpose of this Code is to establish the framework for principles and procedures that will govern all research and data collection activities involving the \_\_\_\_\_ First Nation, whether involving human subjects or not, and all research regarding materials, wherever located, of which the \_\_\_\_\_ First Nation has a claim of intellectual, cultural, or other ownership, legal or equitable.

This Code outlines the obligations and responsibilities of each partner in a research project (community, external researchers and community-based researchers) through all phases including research design, implementation, data collection and analysis, and the dissemination of information.

### **3. Policy Statement<sup>ii</sup>**

*The policy statement identifies the rationale for the Code and the research policy goals it pursues. These can include community and individual benefit, community empowerment through capacity development (research expertise), cultural development and preservation, and other community interests. It also serves to inform the public of the community's policies for the regulation of research. It should reflect the attitudes, beliefs, values, principles and cultural traditions of the First Nation towards research. The principles of OCAP or self-determination in the area of research may be key concepts in the policy statement.*

**Sample text:**

It is recognized and respected that the right of self-determination of the \_\_\_\_\_ First Nation includes the authority and jurisdiction to make decisions about research in their community, and also to assume ownership, control, access and possession over information in the course of, and resulting from, research activities. The community and individual community members should be strengthened by the benefits of the research. Research should facilitate the community in learning about health and the well-being of their people, in taking control and management of their information, and in assisting in the promotion of healthy lifestyles, practices and effective program planning. The \_\_\_\_\_ First Nation promotes strengthening the social, cultural, physical and spiritual well-being of its community and fulfilling its traditional responsibility of caring for its members.

### **4. Guiding Principles<sup>iii</sup>**

*The guiding principles encompass the fundamental values. They express the standards, rights and values of the First Nation with respect to research activities. They should reflect the aspirations of the community and can help to create awareness among researchers and community members. Researchers must observe and be respectful of the guiding principles set out in the Code throughout all processes of research. The principles can be used to help contextualize, or if necessary, interpret other sections of the Code. The principles provided in the template are general in nature and, as with other sections, will likely need to be revised to reflect local realities and perspectives.*



**Sample text:**

a) The \_\_\_\_\_ First Nation recognizes the highest standards of research practice and will ensure the principles of OCAP (Ownership, Control, Access, and Possession) will be respected. OCAP is self-determination applied to research.

**Ownership:** The notion of ownership refers to the relationship of a First Nations community to its cultural knowledge/data/information. The principle states that a community or group owns information collectively in the same way that an individual owns his or her personal information. It is distinct from stewardship or possession (see Possession).

**Control:** The aspirations and rights of First Nations to maintain and regain control of all aspects of their lives and institutions include research and information. The principle of “control” asserts that First Nations, their communities and representative bodies are within their rights in seeking to control research and information management processes that impact them. This includes all stages of research projects, and more broadly, research policy, resources, review processes, the formulation of conceptual frameworks, data management and so on.

**Access:** First Nations people must have access to information and data about themselves and their communities, regardless of where these are currently held. The principle also refers to the right of First Nations communities and organizations to manage and make decisions regarding access to their collective information.

**Possession:** While “ownership” identifies the relationship between a people and their data in principle, the idea of “possession” or “stewardship” is more literal. Although not a condition of ownership, possession (of data) is a mechanism by which ownership can be asserted and protected. When data owned by one party are in the possession of another, there is a risk of breach or misuse. This is particularly important when trust is lacking between the owner and possessor.

b) The \_\_\_\_\_ First Nation must be involved as a full partner in all aspects of the research. Feedback, input, consultation and participation in the analysis, interpretation and communications should always characterize the research partnership.

c) Research should support the transfer of skills to members of the \_\_\_\_\_ First Nation and increase the capacity of the community to manage its own research.

d) Mutual respect is important for successful partnerships.

e) All must respect \_\_\_\_\_ First Nation local community laws, regulations and protocols.

f) All research partners must show respect for the language, traditions and standards of the \_\_\_\_\_ First Nation on which they seek to conduct research to ensure ethical research practices. All researchers are encouraged to familiarize themselves with the cultures and traditions of local communities.

g) The research must respect the privacy and dignity of the people in the community.

h) The \_\_\_\_\_ First Nation authorities must approve data collection in their communities through written permission.

- i) Informed consent must be obtained from each individual and the community participating in the research prior to collecting personal information.
- j) Researchers must provide information about the purpose and nature of the research activities to the individuals and/or community participating in the research. They should also explain the potential beneficial and harmful effects of the research on individuals, the community and the environment.
- k) Confidentiality of information must be respected and assured. Participant information will remain anonymous whenever possible when the results are reported.
- l) All data collected belongs to the \_\_\_\_\_ First Nation and must be returned as grouped (aggregate or de-identified) results.
- m) The First Nation will participate, as much as possible, in fact-finding and data analysis, allowing the community to determine which issues should be addressed and how.
- n) All research results, analysis and interpretations must be reported to the First Nation to ensure accuracy and avoid misunderstanding.
- o) The strengths, culture, expertise, language and traditional norms of the community must be respected and drawn upon wherever possible. The incorporation of relevant traditional knowledge into all stages of research is encouraged.

## 5. Definitions

*Definitions are useful in clarifying the meaning of certain terms to avoid any misunderstanding.*

### **Sample text:**

**Community:** A community is a population that may share “cultural, social, political, health, or economic interests”,<sup>iv</sup> but is not limited to a particular geographic location.

**Research:** Research is the use of systematic methods to investigate, gather and analyze information for the purposes of discovering or interpreting facts, proving or disproving a hypothesis, evaluating concepts or practices, or otherwise adding to knowledge and insight in a particular discipline or field of knowledge.

Research methods that are commonly used at the community level include: surveys (phone or mail), needs assessments and public opinion polls; interviews; focus groups or talking circles (informal discussions with a group of experts in a particular discipline or field); and case studies (re-examining existing information).

**Research institution:** A research institution is a recognized institution or organization (academic, government, non-profit), whose primary objective is to undertake research for the purposes of advancing knowledge, facilitating policy-making, or creating strategies and solutions to problems and conditions relevant to the study population.

## 6. Obligations of the Partners

*In this section, the obligations of the partners are established. The template uses the typical example of three partners (community, community-based researchers and external researchers) but may be adapted to reflect other situations. The First Nation or organization would be the community partner. Community-based researchers are individuals employed within the community. They can also be referred to as co-investigators. External researchers typically include consultants and people working at research institutions or other organizations involved in research (e.g., universities, federal or provincial governments, health authorities, non-profit organizations and for-profit companies).*

*The template is general in terms of content. It may be useful to add more precise and detailed obligations for specific projects (e.g., training, hiring and reporting or accountability requirements). These may be incorporated into the Code itself or other documents related to the project.*

### **Sample text:**

#### **External Research Partner**

- To do no harm to the community.
- To involve the community in active participation of the research process and to promote it as a community-owned activity.
- To ensure the research's design, implementation, analysis, interpretation, reporting, publication and distribution of its results are culturally relevant and in compliance with the standards of competent research.
- To undertake research that will contribute something of value to the community.
- To ensure that new skills are acquired by community members, such as research design, planning, data collection, storage, analysis, interpretation and so on.
- To be stewards of the data until the end of the project if requested or appropriate.
- To promote the dissemination of information to society at large if desired and appropriate through both written publications and oral presentations.
- To be involved in any future analysis of the data after the data is returned to the community, if requested.
- To abide by any local laws, regulations and protocols in effect in the community or region, and to become familiar with the culture and traditions of the community.
- Within their respective roles as researchers and community representatives, to advocate and address health, social or other issues that may emerge as a result of the research.

- To ensure that the community is fully informed in all parts of the research process including its outcomes through publications and presentations, and to promptly answer questions that may emerge regarding the project and its findings.
- To communicate equally with the other partners in all issues arising in the project.
- To ensure that research carried out is done in accordance with the highest standards, both methodologically and from a First Nations cultural perspective.
- To support the community by providing resources as a matter of priority (e.g., research funding to support community research coordinator).
- To abide by their own professional standards, their institution's guidelines for ethical research and general standards of ethical research.

### **Community-Based Researcher**

In addition to the obligations listed for the external research partners, the community researcher is obligated:

- To provide a link between the research project team and other community members, and provide relevant, timely information on the project.
- To place the needs of the community as a first priority in any decision where the community researcher's dual roles of community member and researcher may be in conflict.
- In situations where a research project is promoting healthy lifestyles or practices, to promote the intervention objectives of the project by working closely with community health, social and/or education professionals.
- To be stewards of the data until the end of the project if requested or appropriate.

### **Community Partner**

- First and foremost, to represent the interests, perspectives and concerns of community members and of the community as a whole.
- To ensure that research carried out is done in accordance with the highest standards, both methodologically and from a First Nations cultural perspective.
- To communicate the results of the research to other communities, and to share ideas as well as program and service development for mutual benefit and involvement.
- To serve as the guardian of the research data during and/or after completion of the project.
- To offer the external and community researchers the opportunity to continue data analyses before the data are offered to new researchers.

## 7. Operational Procedures

*This section further lays out the roles of the partners and establishes ground rules and formal expectations in all aspects of the research process. The community should consider creating an addendum to the Code or an agreement with specific researchers for specific projects to address issues such as the selection of a data storage site, determination of target audiences for reports, data analysis procedures, publication of results, a communications strategy and release policies, authorship on publications and activities to improve community capacity in research.*

### **Sample text:**

#### **Partnership**

**Full and Equal Participation:** The community, external researchers and community-based researchers are full and equal partners in all aspects of the research process.

**Accountability:** The Principal Investigators representing all partners are fully accountable for all decisions in the research project, including the decisions of subordinates.

#### **Community at Large**

**Expertise and Knowledge:** The strengths, culture, expertise, language and traditional norms of the community must be respected and drawn upon whenever possible.

**Consultations:** The research design and data analysis should as much as possible incorporate broad participatory community input in the areas of priorities, interventions and future directions of the research. A determination of the extent of community consultation should take into account the relevant cultural considerations and the type of research involved.

#### **Capacity Development**

Sound participatory research will endeavour to transfer new skills to the community and, where possible, enhance local benefits that may result from research. Meaningful capacity development is reciprocal, since researchers gain invaluable knowledge from the community (e.g., cultural, traditional and holistic knowledge). Meaningful capacity development involves the transfer of resources to the First Nation for community economic and institutional development.

#### **Confidentiality**

The confidentiality of all information received from research participants must be assured. All personal information provided by individuals will be made anonymous whenever possible. Research protocols will be developed and reflected in a research agreement to ensure confidentiality of collected data. In an agreement, if confidentiality cannot be guaranteed, the research participants must be informed of the possible consequences of this before becoming involved in the research.

#### **Participants**

**Voluntary Participation:** Participation in any research activity is voluntary for all community members.

**Expressed Informed Consent:** The informed consent of participants providing information to the re-

search project must be obtained prior to the use of any information- gathering technique. Individuals must not be subjected to undue pressure or influence when approached to participate in the research process.

**Full Disclosure:** An interactive process should be used to obtain informed consent, whereby a brief, comprehensive and reader-friendly written document, which provides contextual information on the problem and the proposed intervention, is accompanied by a verbal explanation from the researcher. The objectives of the research should be stated in the context of the local benefits that are expected to accompany increased knowledge as a result of research. Researchers should clearly identify the sponsors of the research, the source of financial support and the principal investigators. A description should be provided of any potential harmful effects of the research to individuals, the community or the environment.

**Withdrawal:** An individual participant has the right to withdraw from the research process at any point. If this occurs, all information already collected on the individual should be destroyed or returned to the individual.

## Research Data

**Data Collection:** The data collection process should be in accord with community values and norms, and competent and ethical research practice.

**Ownership:** The community or group owns the research information collectively in the same way that an individual owns his or her personal information. This is distinct from stewardship or possession.

**Data Storage:** The storage of raw data acquired in the research project should be negotiated among all partners before the commencement of the project and renegotiated during the project as priorities change. There is a preference for local community storage if capacity exists and confidentiality requirements can be met. All de-identified grouped data results must be returned to the community.

**Analysis:** All partners should review research results, analysis and interpretations for accuracy and appropriateness, and approve these prior to any public release or publication.

**Secondary Data:** Community secondary data generated through analysis of general population databases (e.g., provincial hospital and physician databases) should be governed by a data-sharing protocol. This protocol between the community and the database steward (e.g., provincial government) embodies the relevant principles of this Code. The community should negotiate ownership, control and access provisions based on the circumstances of the analysis.

**Access:** First Nations should have access to their data, as reaffirmed by the OCAP principles. However, communities must ensure that the proper protections are in place regarding who has access to the data.

## Communications

**Research Process:** The community at large should have access at all times to descriptions of the research objectives and methods.

**Anonymity:** Research results will be presented in a grouped manner such that individuals cannot be identified. In some instances, an individual or community may request that their statements be specifically attributed to them. In this case, the wishes of the individual and community should be respected.

**Priority of Communications:** The community will be the first to receive research results and the first invited to provide input and feedback on the results. The results should be returned in a format that is language appropriate and accessible to the community. All communications will be respectful of the community and presented in a beneficial, non-harmful manner.

**Preparation of Communications:** It is part of the shared responsibility of the researchers to prepare communications for the community and society at large. All partners must jointly make guidelines about the publication and distribution of all or parts of the research results. Ideas for specific communications (articles in scientific journals; oral presentations at meetings; oral or written presentations to community health professionals, band council, or community at large; or educational materials) must be initially presented to all research partners and the Code's designated representative. All research partners (community researchers, community partner and external researchers) must approve the final version of the communication before use or submission.

**Language:** Communications directed to the community, such as research summaries, should be written using accessible, community-friendly language and in an appropriate format. Where required by the community, materials should also be provided in the language of the community.

**Research Results:** No results or data are released or disseminated without approval from all parties.

**“Right to Dissent” on Communications:** In the event of a disagreement among the partners regarding a written or oral communication about the research results, the partner who disagrees must be invited to submit their own interpretation of the same data, which will accompany the main communication. All partners agree to not distribute the communication until the alternative interpretation is added, provided that the disagreeing partner(s) does not unduly delay the distribution process. An alternative approach to the issue of disagreement is this: best efforts will be made to reach consensus regarding the interpretation of results for publication. In the event that a reasonable measure of consensus cannot be reached, no publication will be released.

## 8. Evaluation of New Research Applications

*Communities may wish to develop processes for the handling and evaluation of external applications for research that may be received without solicitation. This process can be tailored to the specifics of each community, and should consider:*

- *establishing a mechanism to make the community's Code of Research Ethics available to interested research partners;*
- *setting up a screening body that can conduct a preliminary evaluation of the research proposal prior to a wider community consultation or committee review. Some First Nation organizations, such as the FNC ([www.naho.ca/fnc](http://www.naho.ca/fnc)), may provide advice or information support;*
- *developing a list of written requirements or a standardized form(s) to be completed by the researchers submitting the proposal. The form could require the following types of information presented in plain language: names, titles, affiliations, contact information and credentials of researchers, a summary description of the proposed research in plain language, proposed funding sources, a time frame for the project and reporting of results, and expected outcomes, including the benefits to the community and contributions to the advancement of knowledge in the subject area;*



- *if appropriate, arranging a meeting between the researchers and the screening body to present the proposal verbally;*
- *establishing a series of considerations or a formal review or scoring tool to aid in the evaluation of the proposal;*
- *setting a time period for the screening body (e.g., \_\_\_days) to make a decision and the method of decision (consensus, majority vote);*
- *devising an appropriate method to seek wider community consultation if a proposal is approved by the screening committee;*
- *establishing a time frame to provide the final decision to the researcher as a result of the community consultation; and,*
- *developing a process for identifying any specific conditions the community has for participation (e.g., changes to the protocol, resources for a local coordinator, local steering committee), and negotiating these as needed.*

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<sup>i</sup>Adapted from: Mi'kmaq College Institute, *Mi'kmaq Ethics Watch: Principles and Guidelines for Researchers conducting Research With and/or Among Mi'kmaq People* (Antigonish, Nova Scotia, 1999) p.1 and; First Nations Regional Longitudinal Health Survey, First Nations Centre, *First Nations Regional Longitudinal Health Survey (RHS) Code of Ethics* (Ottawa: National Aboriginal Health Organization, 2004).

<sup>ii</sup>First Nations Regional Longitudinal Health Survey, First Nations Centre, *First Nations Regional Longitudinal Health Survey (RHS) Code of Ethics*, p.3.

<sup>iii</sup>Adapted from: Association of Canadian Universities for Northern Studies, *Ethical Principles for the Conduct of Research in the North* (Ottawa: Author, 2003), p. 5; Kahnawá:ke Schools Diabetes Prevention Project, *KSDPP Code of Research Ethics*; First Nations Centre, *First Nations Regional Longitudinal Health Survey (RHS) Code of Ethics*, pp. 3-4 and; Mi'kmaq College Institute, *Mi'kmaq Ethics Watch: Principles and Guidelines for Researchers Conducting Research With and/or Among Mi'kmaq People*, p.3.

<sup>iv</sup>World Health Organization, *Indigenous Peoples and Participatory Health Research: Planning and Management - Preparing Research Agreements* ([www.who.int/ethics/indigenous\\_peoples/en/print.html](http://www.who.int/ethics/indigenous_peoples/en/print.html)).



## Appendix B - Template for a Collaborative Research Agreement <sup>1</sup>

Project title \_\_\_\_\_

THIS COLLABORATIVE RESEARCH AGREEMENT is made this \_\_\_\_ day of \_\_\_\_, 2006.

BETWEEN:

Principal Researchers(s)

Name(s): \_\_\_\_\_

Supporting Agency \_\_\_\_\_

Address: \_\_\_\_\_

Telephone: \_\_\_\_\_

Facsimile: \_\_\_\_\_

Email: \_\_\_\_\_

AND

\_\_\_\_\_ First Nation Community

Contact person(s): \_\_\_\_\_

Organization: \_\_\_\_\_

Address: \_\_\_\_\_

Telephone: \_\_\_\_\_

Facsimile: \_\_\_\_\_

Email: \_\_\_\_\_

The principal researchers, as named, and the \_\_\_\_\_ First Nation agree to conduct the named collaborative research project in accordance with the guidelines and conditions described in this document.

*These pages can be photocopied to be shared or re-used as necessary.*

## 1. Purpose of the Research Project

*This section should describe the general topic that is being researched, and also the purpose of doing the research (e.g. to increase awareness/understanding, enhance well-being, improve programs, etc.). A statement of purpose is usually fairly brief (2-5 sentences) and not too specific.*

### **Sample text:**

The purpose of this research project, as discussed with and understood by the \_\_\_\_\_ First Nation in the community of \_\_\_\_\_, is to investigate \_\_\_\_\_

The results of this research may be used to \_\_\_\_\_

## 2. Scope of the Project

*This section provides a more specific and detailed description of the project. It should cover the following areas:*

- *Specific research objectives or question(s);*
- *Types of information that will be gathered (e.g. statistics, interviews, etc.);*

### **Sample text:**

The project has the following objectives and/or aims to answer the following questions: \_\_\_\_\_

In order to meet the objectives or answer the questions stated above, the following types of information will be gathered:

## 3. Methods and Procedures

*This section describes how research data will be gathered, recorded, analyzed and reported. Issues that should be addressed in this section are listed below. Involvement of First Nation community members in the project is addressed in this section, but a separate section could be created to deal with that issue since it is usually an important consideration for communities.*

- *Research (or data-gathering) methods; depending on the nature of the project, these might include: collecting information/statistics from databases; collecting environmental samples; conducting surveys, interviews or focus groups;*
- *The extent or amount of data to be obtained should be specified (e.g. statistical variables, number of interviews/surveys, number of samples, etc.) and explained;*
- *The role of community members in the research (or data-gathering) phase (as participants in interviews, etc. and/or as paid researchers, fieldworkers or guides);*

- *Procedures for obtaining consent (individual or collective) must be described in detail;*
- *Methods to be used for recording and storing data;*
- *Procedures for ensuring confidentiality and security of data;*
- *Methods of analysis or interpretation of data to generate findings and conclusions;*
- *Opportunity for community members or community researchers to participate in data analysis, or to verify the results of the analysis;*
- *Preparation of the final report; will community members have an opportunity to revise and approve it before it is finalized?*
- *Format for presenting findings to the general public and the community (e.g. article, final report, presentation, etc.)*

**Sample text:**

Data will be gathered using the following methods or procedures: \_\_\_\_\_

\_\_\_\_\_

The amount of data that is required for this project is \_\_\_\_\_.

This number/amount is required because \_\_\_\_\_.

Community members will assist or participate with the data-gathering phase in the following ways:

\_\_\_\_\_

\_\_\_\_\_

Individual consent to participate in the project will be obtained in the following way: \_\_\_\_\_

\_\_\_\_\_

Participants have the right to withdraw from the project at any time for any reason. In this case, that participant's data will be destroyed.

Research data will be stored in the following ways: \_\_\_\_\_

\_\_\_\_\_

The following persons will have access to research data: \_\_\_\_\_

Confidentiality of research data (if desired) will be ensured in the following ways: \_\_\_\_\_

\_\_\_\_\_

Data will be analyzed or interpreted through the following methods: \_\_\_\_\_

\_\_\_\_\_

Community researchers/participants will participate in the analysis of data, or the verification of results, in the following ways: \_\_\_\_\_

The final research report will be submitted to the community for review and approval.

Research findings will be presented to the community in a language and format that is clear and comprehensible to community members.

Research findings will be presented to the community in the following formats: \_\_\_\_\_

Research findings will be presented to the general public and/or any other audience in the following formats: \_\_\_\_\_

#### **4. Expected Outcomes, Benefits and Risks**

*This section sets out the expected outcomes and benefits of the research project. It is important to be clear and honest about expected benefits for both the researchers and the community. Benefits for the principal researchers may include financial gain (from publication, etc.) or indirect financial benefit through enhancement of professional status (to an individual or research institution). Benefits to the community may include the generation of information that will support future funding applications or that will enhance community programs/services; education and/or training for community members; or direct financial compensation to community researchers and/or participants.*

*Risks to the community as a result of the project should also be considered, as should any measure that could be taken to minimize those risks. These may include: environmental impacts; invasion of personal or collective privacy; portrayal of the community in a negative way and; disruption of other important community projects or issues.*

#### **Sample text:**

The expected outcomes of this research project are: \_\_\_\_\_

The project will benefit the principal (external) researchers in the following ways: \_\_\_\_\_

The project will benefit the community (individually or collectively) in the following ways: \_\_\_\_\_

The project poses the following risks to the community: \_\_\_\_\_

Measures that will be taken to minimize these risks are: \_\_\_\_\_

## 5. Obligations and Responsibilities

*This section is not specific to a particular research project. It describes general obligations and responsibilities of each partner (community, external researchers and community-based researchers) in a community-based research project through all phases including research design, implementation, data collection and analysis and the dissemination of information.*

### External Research Partner

- To do no harm to the community.
- To involve the community in active participation of the research process and to promote it as a community-owned activity.
- To ensure the research's design, implementation, analysis, interpretation, reporting, publication and distribution of its results are culturally relevant and in compliance with the standards of competent research.
- To undertake research that will contribute something of value to the community.
- To ensure that new skills are acquired by community members, such as research design, planning, data collection, storage, analysis, interpretation and so on.
- To be stewards of the data until the end of the project if requested or appropriate.
- To promote the dissemination of information to society at large if desired and appropriate through both written publications and oral presentations.
- To be involved in any future analysis of the data after the data is returned to the community, if requested.
- To abide by any local laws, regulations and protocols in effect in the community or region, and to become familiar with the culture and traditions of the community.
- Within their respective roles as researchers and community representatives, to advocate and address health, social or other issues that may emerge as a result of the research.
- To ensure that the community is fully informed in all parts of the research process, including its outcomes through publications and presentations, and to promptly answer questions that may emerge regarding the project and its findings.
- To communicate equally with the other partners in all issues arising in the project.

- To ensure that research carried out is done in accordance with the highest standards, both methodologically and from a First Nations cultural perspective.
- To support the community by providing resources as a matter of priority (e.g., research funding to support community research coordinator).
- To abide by their own professional standards, their institution's guidelines for ethical research and general standards of ethical research.

### **Community-Based Researcher**

In addition to the obligations listed for the external research partners, the community researcher is obligated:

- To provide a link between the research project team and other community members, and provide relevant, timely information on the project.
- To place the needs of the community as a first priority in any decision where the community researcher's dual roles of community member and researcher may be in conflict.
- In situations where a research project is promoting healthy lifestyles or practices, to promote the intervention objectives of the project by working closely with community health, social and/or education professionals.
- To be stewards of the data until the end of the project if requested or appropriate.

### **Community Partner**

- First and foremost, to represent the interests, perspectives and concerns of community members and of the community as a whole.
- To ensure that research carried out is done in accordance with the highest standards, both methodologically and from a First Nations cultural perspective.
- To communicate the results of the research to other communities, and to share ideas as well as program and service development for mutual benefit and involvement.
- To serve as the guardian of the research data during and/or after completion of the project.
- To offer the external and community researchers the opportunity to continue data analyses before the data are offered to new researchers.

## 6. Funding

*This section identifies funding sources and sets out the responsibilities of all partners with respect to funding requirements.*

### **Sample text:**

The principal researchers have acquired funding and other forms of support for this research project from these sources: \_\_\_\_\_

The funding agencies have imposed the following criteria, disclosures, limitations and reporting responsibilities on the principal researchers: \_\_\_\_\_

The community partner has the following responsibilities with respect to funding requirements\*:  
\_\_\_\_\_

*\*In most cases, responsibility to fulfill funding and reporting requirements falls primarily to the principal researchers, so this may not be applicable.*

## 7. Dissemination of Results

*This section should identify all the stakeholders (e.g. communities, the academic sector, funding bodies, professional bodies, government departments, etc.), to which research results will be disseminated. The methods for dissemination should also be described.*

*You may want to consider the degree of control that the community has over future publication or dissemination of research results.*

### **Sample text:**

Research results will be disseminated to the following stakeholders: \_\_\_\_\_

Research results will be disseminated in the following manner: \_\_\_\_\_

Any future publication or dissemination of research results, beyond what is described in this agreement, shall not be undertaken without consultation with the \_\_\_\_\_ First Nation community.

## 8. Data Ownership and Intellectual Property Rights

*The data gathered or produced through the research project is distinct from the research results. The First Nation community should clearly affirm ownership of its data, as well as any associated intellectual property rights. Conditions of data stewardship and use of data after completion of the research project should be considered by the community, but do not need to be specified in the research agreement since this is an internal protocol to be determined at the community's discretion.*

### **Sample text:**

The individual owns his or her personal information while the \_\_\_\_\_ First Nation owns the collective data.

The \_\_\_\_\_ First Nation retains all intellectual property rights (including copyright), as applicable, to the data offered under this agreement.

Access and stewardship of the collective data are negotiated and determined by the First Nation.

## **9. Communication**

*Guidelines for internal and external communication should be established in this section. 'Internal communication' means communication between research partners names in this agreement, while 'external communication' refers to communication about the project to other interested parties such as the media.*

### ***Sample text:***

Communication on all aspects of the research, including progress reports to the community, will be ensured in the following ways: \_\_\_\_\_

In the case of media inquiries during or after the project, designated spokespersons are:  
\_\_\_\_\_

The community will be the first to receive research results and the first invited to provide input and feedback on the results. The results should be presented in a format that is language appropriate and accessible to the community. Results will not be released without the approval of the community.

At the end of the study, the research partners agree to participate in community meetings to discuss the results and their implications.

## **10. Dispute Resolution**

*This section sets out the process for addressing concerns or resolving disputes related to the implementation, interpretation or release of research data and/or findings.*

### ***Sample text:***

In the event that a dispute arises out of or relates to this research project, both parties agree first to try in good faith to settle the dispute by mediation administered by an agreed upon neutral party before resorting to arbitration, litigation or some other dispute resolution procedure. A mediator will assist the parties in finding a resolution that is mutually acceptable.

If a dispute cannot be resolved to the satisfaction of both parties, the research project may be terminated according to the terms described below.



## 11. Term and Termination

*This section notes the duration of the project and sets out the course of action to be followed if either party to the agreement wishes to terminate the research project.*

### ***Sample text:***

This agreement shall have an effective date of \_\_\_\_\_ and shall terminate on \_\_\_\_\_.

This agreement may be terminated by the written notification of either party.

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<sup>i</sup>Adapted from: World Health Organization, *Indigenous peoples and participatory health research: Preparing research agreements*, Annex B: Example of a research agreement concluded between CINE and an indigenous community in Canada ([www.who.int/ethics/indigenous\\_peoples/en/print.html](http://www.who.int/ethics/indigenous_peoples/en/print.html)) and; Masuzumi, B., and Quirk, S, *Dene Tracking. A participatory research process for Dene/Métis communities: Exploring community-based research concerns for Aboriginal northerners* (Yellowknife, NT: Dene Nation, 1993) p. 14-16.

## Appendix C - Template for a Data-sharing Protocol<sup>i</sup>

THIS DATA-SHARING PROTOCOL is made this \_\_\_\_\_ day of \_\_\_\_\_, 2006.

BETWEEN:

\_\_\_\_\_ (First Nation community or organization)

AND

\_\_\_\_\_ (Research partner(s) or organization)

### 1. Introduction

*In general, the introduction provides some background information leading to the development of the Data-Sharing Protocol. What is the purpose of the Data-Sharing Protocol and why is it necessary? The introduction should identify the parties to the agreement, their names, titles, contact information and the names of their organizations. It may also include relevant policy statements, a mission statement, or guiding principles.*

#### **Sample text:**

The \_\_\_\_\_ First Nation promotes meaningful partnerships through working in collaboration with the \_\_\_\_\_ (research partner(s) or organization).

The \_\_\_\_\_ First Nation has agreed to enter into an agreement whereby the \_\_\_\_\_ (research partner(s) or organization) is authorized to use the \_\_\_\_\_ data (record level or aggregate data) from the \_\_\_\_\_ (name of past research conducted), as set out in this Agreement. This Data-Sharing Protocol will maintain the values, principles and protect the rights of the First Nation. This Protocol should not be used for any other purpose.

### 2. Definitions<sup>ii</sup>

*Relevant definitions may be included in this agreement for clarification of certain terms.*

#### **Sample text:**

**Information sharing:** The exchanging, collecting, using or disclosing of personal information by one organization with another organization for certain purposes, including First Nations, government bodies, educational institutions, non-profit organizations, etc. The sharing may be carried out using any transmission method and may take place over any time period.

**Data linkage or data profiling:** This is a computerized use of personal data obtained from a variety of sources, including personal information banks, to merge and compare files on identifiable individuals or categories of individuals for administrative purposes. This linkage or profiling generates a new body of personal information.

*These pages can be photocopied to be shared or re-used as necessary.*

**Personal information:** Recorded data or information that is related to an identifiable individual.

**Record level data:** Information that is specific to an individual or group of individuals, whether or not the person is identifiable by name.

**Aggregate data:** Aggregate data includes data collected from several sources that do not reveal the identity of any individual. It is collective data meant for developing statistics or for planning based upon that data (e.g., combining demographic data about clients from all primary care providers in a service area generates aggregate data about client characteristics).

### 3. Purpose

*The purpose and reason for the data-sharing agreement should be identified. If individual data records are being shared, the applicable federal, provincial and territorial legislation regulating the use and release of individual client information should be specified (e.g., freedom of information and protection of privacy acts, health information acts or other community protocols, such as a Code of Research Ethics or Privacy Code). The purpose of the data-sharing arrangement must be understood and formally agreed to by those entering into it.*

#### **Sample text:**

The purpose of this Data-Sharing Protocol is to:

- a) summarize the conditions and arrangements for data or information collection and sharing;
- b) set out the fundamental principles and obligations that organizations must adhere to when they collect, use, store and disclose personal information about members of the First Nation;
- c) describe why data or information is being shared, how and when data will be collected and shared, and by whom;
- d) protect individual and community interests, information and privacy;
- e) maintain appropriate standards and prevent misunderstandings over responsibilities; and,
- f) clarify issues of data ownership, control and access, intellectual property, aggregate data, confidentiality, use of information and further disclosure.

This Protocol provides a framework for the use of data that supports First Nations principles of OCAP in relation to research, and supports the data needs and capacity of the \_\_\_\_\_ First Nation and the \_\_\_\_\_ (research partner(s) or organization), with respect to the use of information for planning, advocacy, and determining community priorities and trends.

**Ownership:** Refers to the relationship of First Nations to their cultural knowledge/data/information. The principle states that a community or group owns information collectively in the same way that an individual owns his or her personal information.

**Control:** The principle of “control” asserts that First Nations people, their communities and representative bodies are within their rights in seeking to control all aspects of research and information management processes that impact them. First Nations control of research can include all stages of a particular research project from conception to completion. The principle extends to the control of resources and review processes, the formulation of conceptual frameworks, data management and so on.

**Access:** First Nations people must have access to information and data about themselves and their communities, regardless of where it is currently held. The principle also refers to the right of First Nations communities and organizations to manage and make decisions regarding access to their collective information. This may be achieved in practice through standardized, formal protocols.

**Possession:** While “ownership” identifies the relationship between a people and their data in principle, possession or stewardship is more literal. It refers to the physical control of data. Although not a condition of ownership per se, possession is a mechanism by which ownership can be asserted and protected.

#### 4. Information to be Shared

*Within the protocol, it is important to describe in detail the data to be shared.*

**Sample text:**

[Record level *or* aggregate] data from the \_\_\_\_\_ First Nation will be shared for the purposes of this agreement.

The data to be shared consists of \_\_\_\_\_.

#### 5. Use of Data or Information

*The agreement should clearly identify how the data or information shared under the arrangement will be used. For what purpose(s) are the data going to be used? It may state that the data will only be used for the stated purpose(s) and may not be used for any other purposes (further disclosure), without the explicit written approval, in advance, of the First Nation. The research partner(s) may not release the data for any purpose, unless agreed to in advance by all parties, and provided it is not in violation of provincial, territorial or federal legislation.*

**Sample text:**

The research partner(s) will use the data for the purposes of \_\_\_\_\_.

The research partner(s) will only use the data for the stated purpose(s) and the data may not be used for any other purposes (further disclosure) without the explicit written approval, in advance, of the \_\_\_\_\_ First Nation. The research partner(s) may not release the data for any purpose unless agreed to in advance by all parties, and provided it is not in violation of provincial, territorial or federal legislation.

## **6. Mechanism for Information-Sharing**

*The methods of data-sharing need to be identified. Some mechanisms for sharing include electronic transfer over a secure network or electronic transfer through password-protected external disks.*

### ***Sample text:***

The data-sharing will involve electronic transfer over a secure network. Data matching and linkage will be used. (Note: this is only an example; your community may use a different mechanism for sharing.)

## **7. Data Ownership**

*The agreement should address control and access to data by the requesting party. The requesting party may be deemed custodians or stewards of the data under the conditions defined in the agreement and, depending upon the specifics of the project, may receive either individual records or aggregate data. Users may be expressly prohibited from use of the data in the pursuit of any commercial or income-generating venture, either publicly or privately.*

### ***Sample text:***

The \_\_\_\_\_ First Nation owns the collective data. Access and stewardship are negotiated and determined by the First Nation.

## **8. Publication and Dissemination**

*Depending upon what kind of information you have allowed the research partner(s) to access, you may decide to specify that you are a co-author or a partner in the research project, particularly if the information is very sensitive. This may allow you to shepherd the information and retain some rights to the publication without sacrificing the integrity of the research results.*

### ***Sample text:***

The research partner(s) will not release data received as part of this agreement to other local or research institutions or organizations without express written agreement from the \_\_\_\_\_ First Nation. Other interested research institutions or organizations shall contact the First Nation directly.

## 9. Data Security and Confidentiality

*The data steward must maintain confidentiality and protect the data in a manner consistent with clearly defined principles, and according to formal and rigorous data protection standards and methods. The data steward will be responsible for upholding the principles, standards and methods. Custodians of data with personal identifiers must agree and take all steps necessary to ensure its privacy and security as described in relevant freedom of information and privacy acts, health information acts, or other legislation as well as their institution's protocols and community protocols, where applicable. If either party deems security and confidentiality inadequate, the stewardship should be revoked in favour of a more secure steward or destruction of the data.*

*Integrity and security of the data must be maintained by instituting regulatory controls, such as ensuring that only authorized users have access to the data and that electronic systems are properly maintained and managed.*

### **Sample text:**

All employees, agents and representatives of the \_\_\_\_\_ First Nation and the research partner(s) who will come in contact with data must take an Oath of Secrecy by completing and signing the standardized form. The First Nation shall record and document the names of all persons who have taken the oath and the date the oath was taken.

*The following is an example of an Oath of Secrecy.<sup>iii</sup>*

*I \_\_\_\_\_, do solemnly swear (or affirm) that I will faithfully and honestly fulfill my duties as an employee/contractor of the \_\_\_\_\_ in relation to its participation in the \_\_\_\_\_ research study. I swear (or affirm) that I will protect the privacy of individual respondents, communities and First Nations collectively, and maintain the confidentiality of all research data and related information pursuant to the policies, rules, regulations and instructions provided to me by \_\_\_\_\_ and the \_\_\_\_\_ First Nation. I will respect the \_\_\_\_\_ First Nation Code of Research Ethics and the provisions of the protection agreement. I will not, without due legal authority, disclose or make known any matter or thing that comes to my knowledge by reason of my work on the \_\_\_\_\_ research study. I will not release data or statistical outputs without appropriate authorization from regional authorities.*

*I understand that maintaining confidentiality is critical to the credibility of the research and of the organizations taking part in the research, and that a breach of confidentiality may result, among other things, in the immediate termination of my contract and legal action against me for damages.*

The \_\_\_\_\_ First Nation and the research partner(s) will each provide, for their own offices, all necessary equipment, supplies and policies to ensure the confidentiality of the survey data, including but not limited to:

- a lockable storage room and lockable filing cabinet;
- password protection for computers containing confidential data or information;
- controlled and restricted access, by lock and/or computer password, of all data or information, either hard copy or electronic; and,

- a firewall or similar software or hardware to protect the data or information that is stored on a computer that has access, directly or indirectly, to the Internet or any other type of data-sharing networks.

The \_\_\_\_\_ First Nation and the research partner(s) will ensure that at all times the data or information is either directly supervised by one of its employees or agents, or that it is safely locked in a secure cabinet.

## **10. Retention and Disposal of Information**

*The agreement should specify how long the shared data are kept or stored. Also, terms should be identified regarding the disposal of the data once the agreement has expired or been revoked. The data may be returned to the source or destroyed by the recipient, either physically or electronically.*

### ***Sample text:***

The \_\_\_\_\_ (research partner(s)) will store and maintain the data in a manner that ensures its use remains consistent with the terms and conditions of this agreement.

Upon expiration or revocation of this agreement, the \_\_\_\_\_ (research partner(s)) will immediately and permanently remove and destroy all copies, both physically and electronically, of the data provided under this agreement in accordance with relevant laws and policies (e.g., band bylaws and policies or government laws).

## **11. Intellectual Property**

*Although this may not be consistent with some First Nations perspectives, intellectual property arising from research in Canada is normally vested in the organization(s) that conducts the research. As a result, in situations where data is provided to an organization that may conduct further research, it may be important to specify in an agreement that the First Nation retains all intellectual property rights (including copyright), as applicable, to the data offered under this agreement, and this agreement constitutes only a license to acquire and use these data products. Furthermore, it may be specified that no title or rights be conveyed by this agreement.*

### ***Sample text:***

The \_\_\_\_\_ First Nation retains all intellectual property rights (including copyright), as applicable, to the data offered under this agreement, and this agreement constitutes only a license to acquire and use these data products. Furthermore, this agreement does not convey title or rights.

## **12. Duration and Renewal**

*A clause should include information on when the agreement will come into effect (e.g., the date of signing by the last of the parties), as well as how long the agreement will remain in effect. There can also be terms set out for renewal, extensions or amendments to the agreement, if necessary.*

***Sample text:***

This agreement will commence on and come into effect from the date of signing by the last of the parties, and will remain in effect for the duration of five (5) years.

This agreement may be renewed, extended or amended with the written consent of both parties at least sixty (60) days prior to the expiration of the agreement.

Notwithstanding paragraph 12.1, either party shall be entitled to terminate this agreement in the event the other party fails to fulfill any of its obligations as stipulated in this agreement by providing a written notice to the other party sixty (60) days prior to termination. Data access privileges are terminated immediately. At the end of the notice period all copies of the data will be removed and destroyed, as described in section 10.

### **13. Expiration or Revocation of the Agreement**

*There should be a clause outlining the terms for the expiration or revocation of the agreement.*

***Sample text:***

Upon expiration or revocation of this agreement, the research partners will immediately and permanently remove and destroy all copies, both physically and electronically, of the statistical outputs provided under this agreement in accordance with federal laws and Treasury Board Policy or any other federal government policy. (This refers to statistical outputs that may or may not be the subject of the agreement.)

In exceptional circumstances, such as discovery of repeated misuse or distortion of the statistical outputs, the \_\_\_\_\_ First Nation will advise the research partner(s) in writing of the inappropriate action and provide the them with sixty (60) days to correct the said inappropriate action. In the event that the research partner (s) does not correct the said inappropriate action within the sixty (60) day period, the research partner's license to use the statistical outputs may be revoked by the \_\_\_\_\_ Band Council on behalf of the \_\_\_\_\_ First Nation. Upon revocation, all copies of the statistical outputs will be removed and destroyed.



## 14. Signing Authorities

*The agreement should identify signing authorities, contact names, titles, addresses and phone numbers of the parties involved. The agreement should be signed and dated by the authorized representative of each party. This information is also used to allow the public to direct notices to the appropriate party.*

IN WITNESS whereof, this agreement has been executed on behalf of the parties by their duly authorized representatives:

\_\_\_\_\_  
Name and Title                      Date

\_\_\_\_\_  
Witness                                      Date

\_\_\_\_\_  
Name and Title                      Date

\_\_\_\_\_  
Witness                                      Date

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<sup>i</sup>Adapted from: Assembly of First Nations, *Template for a Community Code of Ethics in Research and Data Sharing Protocols* (Ottawa: Author, 1999) and; First Nations Regional Longitudinal Health Survey, First Nations Centre, *First Nations Regional Longitudinal Health Survey (RHS) Code of Ethics* (Ottawa: National Aboriginal Health Organization, 2004).

<sup>ii</sup>Adapted from Information Management, Access and Privacy Alberta Government Services, *Freedom of information and protection of privacy: Guide for Developing Personal Information Sharing Agreements* (Alberta: Government of Alberta, October, 2003).

<sup>iii</sup>Adapted from First Nations Regional Longitudinal Health Survey, First Nations Centre, *First Nations Regional Longitudinal Health Survey Data Protection and Stewardship Protocol* (Ottawa: National Aboriginal Health Organization, March, 2004).



**First Nations Centre @ NAHO  
Le Centre des Premières Nations de l'ONSA**



National Aboriginal Health Organization (NAHO)  
Organisation nationale de la santé autochtone (ONSA)  
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