

FIRST NATIONS CONCEPTUAL FRAMEWORKS AND APPLIED MODELS
ON ETHICS, PRIVACY, AND CONSENT
IN HEALTH RESEARCH AND INFORMATION

SUMMARY REPORT

Introduction

This report contains findings from a collaborative project between Research Director Youngblood Henderson of the Native Law Centre of Canada and the First Nations Centre (FNC) at the National Aboriginal Health Organization (NAHO), presented to the Canadian Institutes of Health Research (CIHR). The project supports the fulfillment of CIHR Objective #4, *Developing New Conceptual Paradigms for Addressing Privacy Challenges* of the strategic initiative, *Compelling Values: Privacy, Access to Data and Health Research*.

The objectives of the project were to identify and articulate First Nations (FN) conceptual frameworks and models on ethics, privacy and consent related to health research and information, based on FN perspectives, values and norms. The research study was iterative and conducted in three phases: Phase 1 involved a comprehensive literature review and analysis, and the development of a list of key FN participants; Phase 2 involved data collection with discussions, focus groups, and voved Dialogue Circles with selected FN participants; and Phase 3 involved the analysis and synthesis of research findings of the literature review, focus groups and dialogues, and the preparation of a final report.

The center pole of the research lodge was the voved Dialogue Circles (8 to 10 participants each). The structural framework of the voved Dialogue Circles conformed to Blackfoot ceremonialist and Elder Crowshoe and Manneschmidt's book, *Akak'stiman. A Blackfoot Framework for Decision-Making and Meditation Process* (1998). Blackfoot scholar Leroy Little Bear provided the substance of the voved Dialogue Circles. This framework was selected by the network as an appropriate FN methodology for identifying and discussing the bundle of issues: FN perspectives for the development and implementation of culturally relevant and responsive frameworks and models for ethics, privacy, and consent in FN health policy, research, and information.

Need for a New Conceptual Framework

The Dialogue Circle participants viewed the current emphasis on conceptual frameworks, ethics, privacy, consent, and knowledge translation activities by national health research agencies as based on a continuing failure to translate health research results on FN into positive health outcomes for FN. They urged good faith attempts to connect a proposal for the reorganization of health services for FN with the reorientation of consciousness and conceptual frameworks. They stated that FN resistance and mistrust of Eurocentric

conceptual frameworks and paradigms involving ethics, privacy, and consent will continue to compromise the application of ideas to improve FN health.

Constitutional Basis for a New Conceptual Framework

FN health and related issues are linked to the larger issue of how Canada as a country should address Aboriginal and Treaty Rights (ATR) in a manner consistent with the recognition and affirmation of those rights in s. 35 of the *Constitution Act, 1982*. The Supreme Court of Canada has interpreted ATR as having embedded within it the honour of the Crown that regulates the activities of the divided Crowns and governance. It is interrelated with the constitutional and statutory fiduciary obligations that arise when FN transfer something of value to the Crown, like the transfer of Aboriginal title for the promise of medical or health care. Both are legally enforceable notions and provide remedies that uniquely protect citizens of FN. These protections are stronger than other legislative or ethical standards. The honour of the Crown does not allow for any administrative or regulatory avoidance of ATR by federal or provincial governments. It protects the relationship with First Nations and treaty nations from outside interests, including the Canadian public.

According to participants, the key change in conceptual frameworks for FN health involves the recognition of ATR as the foundation and key organizing principle in FN health policy and research. FN health issues have to be addressed from the vantage point of ATR, which affirm health as a constitutional right, separate from the federal, territorial and provincial statutory regions. Indeed, Canada has affirmed in its Political Accord with the Assembly of First Nations that every policy framework should be reviewed for consistency with ATR. The ATR approach to health is not advocacy or an optional discussion; it is an innovative part of the constitutional order of Canada.

Participants stated that the special historic and constitutional status of FN peoples is not well understood by the Canadian public or health and medical professions. The existing framework has failed them, denied their special rights, and ignored the price they paid for treaty rights to health and education. Creating a connection between ATR and conceptual frameworks in FN health will accelerate the improvement of health delivery to FN and lessen the gap between their quality of life and that of other Canadians.

The most interesting proposal to emerge from the vowed Dialogues was ATR catchment jurisdictions for health care delivery and services, based on the existing Aboriginal and treaty boundaries rather than on provincial and territorial boundaries. They should be treated as a constitutionally enshrined part of federalism equivalent to provinces or territories and should be funded by formula similar to provincial appropriations. The concept was cautiously approached, slowly analyzed, and generally accepted as a good demonstration program for the ATR catchment area.

The ATR catchment jurisdiction should be viewed as either a modern treaty on health or as an intergovernmental agreement under s. 35 for FN, federal, provincial, and territorial

governments. The agreement would apply not only to the health sector but to other sectors as well in order to have a real and measurable impact on the broad determinants of health. This would not necessitate any changes to the existing health care delivery system, which can be viewed as a minimum standard. It should be viewed as dealing with issues that exceed the ordinary health care of Canadians. The participants noted that general health and medical care is provided by the Federal, provincial, and territorial governments, but that ATR justify specific and extended health care to close the gaps, and the catchment concept to manage the crises. They noted that the ATR catchment jurisdictions should be used to integrate FN health and healing traditions into contemporary health and medical systems.

The overarching theme of the ATR catchment jurisdictions is a long-term vision of a sustainable, effective, and integrated health system in which:

- FN have access to quality health services in a seamless way, through better integration under their ATR and adaptation to their needs;
- FN have equitable access to health services under their ATR with no less access than other Canadians living in comparable geographic locations;
- FN have an increased role and capacity in the planning and delivery of health services within their Aboriginal and treaty territories; and
- FN benefit from all health promotion and disease prevention measures that will have the greatest impact in reducing the gap in health status.

Implications for Ethics, Privacy and Consent

Existing policies and statements concerning FN research ethics do not acknowledge the constitutional and statutory jurisdiction of FN over their culture, heritage, knowledge, and political and intellectual domains. This denial has prevented the formation of adequate ethical guidelines for FN. FN scholars have stated that any ethical statements must explicitly recognize these unique jurisdictions. Appropriate mechanisms need to be established by the three granting agencies, in concert with FN, that respect this constitutional jurisprudence and the jurisdiction for the approval and review of research proposals involving FN.

The participants in the vowed Dialogues viewed Eurocentric ethics and research through a cynical or bad faith lens. They acknowledged that research involving human beings can be driven by the desire for new knowledge and understanding, and may have a number of benefits: to alleviate human suffering, to validate social or scientific theories, to dispel ignorance, to analyze or evaluate policy, and to understand human behavior or the human condition. However, in the FN context, they asserted that the bottom line is that most research does not benefit either particular communities or FN society as a whole. That is the reality of FN health.

They also agreed that the overarching aim of ethics is the maintenance of trust between the research community and society as a whole and, particularly, actual and potential research subjects, but pointed out this is not the actual reality of research, past or present.

Research involving FN would benefit immensely from partnerships with Elders and knowledge keepers. Some of the participants argued for a “treaty” on research with the Tri-Council. While the university-to-university linkages are very important, it is also critical that CIHR and Tri-Council promote the creation and utilization of self-governing College Elders, knowledge keepers, and workers in health and healing. Not only do they have much to offer in terms of framing the research issues and providing critical observations on proper and respectful research, they are likely to be the largest teachers and users of the research. One of the significant lessons that the participants learned over the years is that Elders and knowledge keepers are only able to really use research undertaken in universities if they are somehow connected with the research as it is undertaken.

Regarding privacy and consent, in a FN context these terms must be understood as crucial to the concept of protected autonomy. The Supreme Court of Canada has established that the purpose of providing constitutional protection of ATR is to facilitate the survival of Aboriginal peoples as distinctive peoples, communities, and cultures. The participants noted that every community is on a healing journey due to past infringements on their culture and health and emphasized the need for a healing space – a safe place, to mend the cognitive imperialism of past centuries. They stressed that this journey needs autonomy to allow communities to stabilize and reorient themselves. The participants struggled for FN words and concept to express privacy. This issue needs further exploration; however, it is clear that distrust of and resistance to research is firmly grounded in their concept of autonomy and privacy.

The constitutionally protected right to privacy under the Charter is not monolithic, nor is it absolute. The Supreme Court of Canada has created a sliding scale of privacy protection that recognizes that the more sensitive the information, the more compelling is the reasonable expectation of privacy. The Supreme Court of Canada has consistently emphasized the highly private nature of medical records.

The current focus on the protection of FN personal health information revolves around five key issues of definition, collection, use and disclosure, consent and substitute decision-making, and safeguarding, retention and destruction. These issues are particularly relevant during a time when all levels of government are considering the development of electronic health records and telehealth. The participants thought that the principles articulated by the *CSA Model Code for the Protection of Personal Information* can be viewed as a conceptual framework for privacy for making reference to secondary and tertiary use of information: working with major stakeholders to support and facilitate the development and harmonization of personal health information protection policies and practices; generating maps of all FN information initiatives to the privacy principles, with special emphasis on issues of consent for access to and disclosure of personally identifiable information; and ensuring compliance of all FN information management with legislative and ethical frameworks.

They noted that CIHR has developed a national health conceptual data model that may work FN. The rationale for the model for FN health care is that it helps all provinces and

territories to collect and exchange comparable data and therefore develop nationally and provincially/territorially comparable indicators of performance and outcomes. Specific elements of the data model include the unique patient identifier and the development of a minimum or core data set of FN information.

Informed consent to collection, use, and disclosure of individuals' personal health information is at the core of privacy protection. Since an individual must necessarily divulge personal information in order to obtain services, consent is the only means by which individuals can exercise control over their personal information, control that individuals have the right to exercise. From a patient's rights perspective, patients should have the right to have their health records maintained in confidence and not used for any purpose other than to provide them with public health services unless they expressly consent to another use or disclosure to a third party.

In order to make an informed decision about whether to consent to the collection, use, or disclosure of one's personal health information, an individual must be informed of the purpose for which that information is being collected. An increasing volume of evidence and supporting comments from the dialogue participants indicates that the informed consent process is severely flawed in many cases. Often, participants either are given insufficient information or do not comprehend the data they receive. Studies reveal instances where participants did not realize they were involved in particular research, or had little understanding of the informed consent forms they had signed. The common problem is confusion about the differences between research, clinical treatment, and knowledge translation processes.

Participants identified significant difficulties and barriers to FN translations of health and medical terminology. In this sense, many FN people are vulnerable individuals and entitled—on grounds of human dignity, caring, and fairness—to special protection against abuse, discrimination, deception or exploitation. Ethical obligations to vulnerable individuals in the conduct of research will often necessitate special procedures to protect their interests; these must be demonstrated where appropriate.

Individual consent to research is in itself a problematic issue for FN peoples in light of the collective knowledge concept and other FN jurisprudence. In making explicit the point about collective knowledge and the issue of individual consent, Brascope and Endemann explained, "Indigenous knowledge frequently has intangible and spiritual manifestations that relate to a community or nation rather than to an individual".ⁱ Recent guidelines have gravitated towards group consent as the first stage for acquiring individual consent to participate in research. For example, *The Mi'kmaq Research Principles and Protocols* support the idea of collective consent—"knowledge is collectively owned, discovered, used, and taught and so must also be collectively guarded by appropriate delegated or appointed collective(s)."ⁱⁱ

Numerous authors (especially those supporting a participatory action research methodology) argue that informed consent is an ongoing process and not merely a hoop

to jump through before heading into the field to conduct research.ⁱⁱⁱ They recommend four broad ethical actions in order to ensure the circular nature of informed consent:

- Negotiate responsibilities prior to seeking free and informed consent;
- Obtain free and informed consent from the relevant authorities, the collective and the individual;
- Confirm consent to ensure that consent is ongoing; and
- Complete the circle: provide the community with data.

Enhancement of protections for FN participant's consent is necessary. These protections will undoubtedly impose added costs for clinical research. Increasing the number of FN REB professionals will require funding by private and governmental research sponsors. A conscientious effort to obtain meaningful consent may delay recruitment of subjects and completion of research. A valid informed consent process may require several hours or even repeated conversations over a few days. Furthermore, if patients fully understand all components and risks of a protocol, they may more often refuse to enroll, making some studies difficult or, in rare cases, impossible to conduct. These negative consequences, however, are outweighed by the advantages of enhancing the integrity of health and medical research, bolstering participant protection, and reducing the likelihood of liability associated with clinical studies.

The honour of the Crown is essential to research involving FN. Research sponsors, institutions, and REB that are funded by the Crown need to be aware they stand as proxy for the honour of the Crown and in a fiduciary relation to FN. These constitutional obligations and duties require more than a first-order, unsupervised commitment to ethical research practices; they require appropriate institutional and inter-institutional governance arrangements to ensure ethical performance and accountability. It involves effective oversight and appropriate accountability. It engages and strengthens the existing fiduciary or trust relationships among the research institutions and FN.

Summary of Recommendations

1. Health sector providers must understand and respect ATR concerning health, which establish the honour of the Crown and special fiduciary relationships with the federal and provincial Crown.
2. FN have a constitutional right to integrated and timely access to health services regardless of their economic status, age, gender, or place of residence.
3. Existing conceptual frameworks have generated poor delivery and are disconnected from responsibilities; new reoriented conceptual frameworks are needed.
4. All jurisdictions have a critical role in results-based planning and must learn to act in accordance with the innovative rights-based health and medical services of FN.

5. To be effective, the reoriented conceptual framework needs to be committed to the creation of ATR catchment areas pertaining to policy, program, and delivery, rather than relying on existing provincial and territorial schemes.
6. Such catchment areas can best resolve the complex issue of FN ethics, privacy, consent, and related issues of FN representivity.
7. ATR catchment areas of FN represent a distinct and essential element in a fully coordinated, consultative, and meaningful health service for FN.
8. Aboriginal and treaty rights catchment areas of FN must work in competitive partnership with Canada, the provinces and territories, and with all levels of the health sector in the development of policy and conceptual frameworks aimed at improving FN health.
9. A self-governing College of Elders needs to be established in each ATR area to establish protocols on ethics, privacy, and consent. Without such collaboration, governance of research will be ineffective.
10. FN jurisprudence and the honour of the Crown is the controlling law regarding ethics, privacy, and consent. These concepts are not connected to existing guidelines regarding ethics, privacy, and consent.

ⁱ S. Brascoupe & K. Endemann, (1999) *supra* note 36 at 2.

ⁱⁱ *Ibid.*

ⁱⁱⁱ N. Piquemal, "Free and informed consent in research involving Native American communities." (2001) 25(1) *American Indian Culture and Research Journal* 65-79 at 71.