Ethics review in northern Canada

ORIGINAL ARTICLE

Review of procedures for approval of health studies in northern Canada

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ABSTRACT

Objectives. This article describes the review processes required for research being conducted in Canada’s 3 northern territories. When conducting research involving human subjects in northern Canada, researchers must go through a 2-step process by submitting protocols to both their university or hospital ethics review boards as well as to northern research institutions. Canada’s northern territorial governments have requirements for attaining licensure before any research can be conducted.

Methods. A document review was the method used to gather data, and an Internet search of the literature and documents was conducted to gather information.

Results. Generally, university and hospital-based ethics review boards have been concerned with the rights of individuals in research. Northern Canadian research protocols require review by territorial government institutions and communities with respect to community rights.

Conclusions. The 3 territorial governments of northern Canada take the concept of community and individual participation in research seriously and have enacted processes so that opportunities for such approaches to research are ensured.

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INTRODUCTION

Scientists are required to submit their research protocols for review to ethics boards or committees, traditionally situated at primary research sites such as universities and hospitals. These boards or committees examine the ethics of the research, namely, the protection of research participants to ensure their rights as research subjects are upheld. More recently, Indigenous communities have asked for similar rights; that is, that rights of communities, as well as individuals, be upheld so that the community members have opportunities to fully engage in and be fully informed about all research processes, that nothing is published without the consent of the community, that community values and world views are understood by the outside researcher and that community confidentiality is respected.

This article describes the principles and practices in place to conduct research with human subjects in Canada’s northern territories. People living in the northern parts of Canada’s 10 provinces are often also considered northerners by their more southern counterparts and for the purposes of classifying research; however, this paper focuses on research being conducted only in the northern territories. Conducting research with populations anywhere in Canada may require a 2-step process: first, a review from a university-based or hospital-based ethics review committee and, secondly, from the jurisdictional authority governing that population (for example, a school board or a First Nations Band Council). For the majority of protocols, that second step is not required since there is no single jurisdiction, or because no ethics review process has been set up to undertake that review role. For research conducted in the 3 territorial governments, both steps are required because of the procedures set up to review research. This is in contrast to research that falls within the geographical borders of the provinces, where no provincial governance exists, with the exception of the province of Newfoundland and Labrador, where research ethics review processes are governed by the Health Research Ethics Authority Act (1). As well, within the geographic area of Newfoundland and Labrador, the Nunatsiavut Government has a review process through the Labrador Inuit Land Claims Agreement. In that province, the university ethics review committee comes under the Act, and therefore 2 reviews may or may not be necessary depending on the nature of the research.

This paper focuses on governance of research within the geographical region of the 3 northern territories of Yukon, Northwest Territories and Nunavut. When conducting research, protocols must be submitted to an ethics review board if funding is granted from any federal research funding agency and, as it is in most cases, if funding is granted from provincial or other funding agencies. Canada’s 3 northern territorial governments have laws in place that require licensure before conducting research within those territories. The application process requires a description of the interaction researchers have had with communities prior to beginning any research, and is one of the criteria that must be met before being granted licensure to conduct research in northern communities. Ethics review in the northern territories takes in multiple stakeholders, including First Nations, Inuit and health authorities.

A document review was the method used to gather data for this manuscript, and an Internet search of the literature and documents was conducted to gather information. This paper is meant to give a broad overview of the regulatory requirements rather than an inclusive perspective of the stakeholders.
Purpose and principles of ethics review

The purpose of a Research Ethics Board (REB) has been defined by Pahl (2):

The purpose of ethics review is to protect the dignity, rights, safety and well-being of all actual or potential research participants... The [REBs] are the committees convened to provide the independent advice on the extent to which proposals for research studies comply with recognised ethical standards. [REBs] and others responsible for ethics reviews are responsible for acting primarily in the interest of potential research participants and concerned communities, but they should also take into account the interests, safety and well-being of researchers. (p. 9)

The international standards for medical research are set out in the Declaration of Helsinki (3), which notes that although the Declaration is intended primarily for physicians, the World Medical Association recommends the use of the principles for anyone conducting medical research. It sets out 20 principles covering informed consent, positions of power when the research participant is a patient of the researcher and so on. The Declaration of Helsinki is the basis of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) (4), which describe the standards and principles for research in Canada. No researcher who is awarded funds from any of the 3 Canadian national funding agencies can gain access to the funds until the research protocol has gone through an ethics review process, with the TCPS2 setting the standards for such reviews. The 2 principles for conducting research with human subjects are well established: respect for persons and concern for welfare and justice (4, p. 8–10). These overarching principles are operationalized through processes that include free and informed consent, consideration for vulnerable persons, high standards for privacy and confidentiality of research participants and the general principles of justice and inclusiveness. Benefits from the research must be maximized and harms minimized. Generally, ethics review committees examine protection of individuals, although new guidelines have been drafted with respect to research with Aboriginal people and their communities.

In the past few decades there have been changes made to research practice and to the ethical practice of conducting research. These changes include the following:

• increased understanding of the need to protect individuals who participate in research and in establishing procedures to ensure that protection;
• better definition of accepted methods for, approaches to, and funding for community-based participatory research involving human participants;
• expression from Indigenous communities for more control over research results, interpretation and reporting;
• multi-site research becoming common;
• concern about legal positions of REBs; and
• establishment of REBs in non-traditional sites (that is, hospitals and universities).

With an increased interest and practice in community-based research, a body of literature has developed on ethical issues on community-based research approaches (for example, see 5–13) and on research with Indigenous communities (for example, see 14–17). As well, concern has been expressed about the inadequacy of the review process and about the need to consider protection of communities (for example, see 18–23).
Protection of both individuals and communities

An important development in some countries, including Australia, New Zealand and Canada, is an understanding regarding the protection of Indigenous communities as well as individuals. Australia’s National Statement notes a need to protect not only those individuals actively participating in research, but also any humans who may be impacted by the research (24). Weijer posed the challenges of protecting communities, asking: “If a new principle of respect for communities is required, how ought it to be implemented?” (22, p. 506). Such practices, their implications and related ethical and political issues were discussed at a workshop of northern people in 1995 (25).

Canada’s Canadian Institute of Health Research (CIHR) Guidelines for Health Research Involving Aboriginal Peoples (26) provide 15 principles or “articles” for researchers working with First Nations, Inuit or Métis people (see Table I). These are the basis for chapter 9 of the recently re-drafted TCPS1 (4). Article 9.1 indicates the requirement of community engagement in Aboriginal research under specific conditions:

Article 9.1 Where the research is likely to affect the welfare of an Aboriginal community, or communities, to which prospective participants belong, researchers shall seek engagement with the relevant community. The conditions under which engagement is required include, but are not limited to:

(a) research conducted on First Nations, Inuit or Métis lands;
(b) recruitment criteria that include Aboriginal identity as a factor for the entire study or for a subgroup in the study;
(c) research that seeks input from participants regarding a community’s cultural heritage, artefacts, traditional knowledge or unique characteristics;
(d) research in which Aboriginal identity or membership in an Aboriginal community is used as a variable for the purpose of analysis of the research data;
and
(e) interpretation of research results that will refer to Aboriginal communities, peoples, language, history or culture. (4)

For the most part, documents that refer to the protection of communities are referring to the protection of Aboriginal communities, for example, Australia’s National Statement document (24) and Canada’s TCPS2 (4). Not all people living in the 3 northern territories are Aboriginal, First Nations, Inuit or Métis; in fact, the majority of people living in the Yukon Territory are of British descent.

Review process for research northern territories – licensure

Each territory has legislation in place that requires researchers to fully engage with communities when conducting health and social research in northern Canada. The result is that researchers working within these geographic regions of northern Canada have at least a 2-step process; that is, a review by the university or institution of the researcher and licensing for the research by the northern territorial governments. For those working in schools or other institutional settings, or in multiple community settings, more approvals are required.

Researchers planning to conduct studies in the Yukon, the Northwest Territories (NWT) and Nunavut are required to apply for a licence or permit through the Yukon Science Institute, the Aurora Research Institute and the Nunavut Research Institute, respectively. The requirements fall under the Yukon Scientists and Explorers Act (2002) (27), the Scientist Act R.S.N.W.T. 1988
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Table 1. Tri-Council Policy Statement: Ethical Conduct for Research Involving Human, articles from chapter 9 regarding research involving the First Nations, Inuit and Métis peoples of Canada (4, pages 105–33) – abbreviated and paraphrased.

| 1. Requirement for community engagement in Aboriginal research. | 12. Researchers and community should consider a participatory approach. |
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| 2. Nature and extent of community engagement is to be determined jointly between researcher & community. | 13. Research should be relevant to community needs and priorities, when possible. |
| 3. Where research will be conducted First Nations, Inuit or Métis lands jurisdiction, researchers should engage the formal leaders of the community. | 14. Research projects should support capacity building through enhancement of the skills of community personnel in research methods, project management and ethical review and oversight. |
| 4. For the purposes of community engagement and collaboration, researchers and REBs shall recognize Aboriginal organizations. | 15. Researchers should engage the community in identifying Elders or other recognized knowledge holders to participate in design and execution of research. |
| 5. Where alternatives to securing the agreement of formal leadership are proposed, community processes and documents should be used. | 16. Researchers and community partners shall address privacy and confidentiality for communities and individuals early in the community engagement. |
| 6. In engaging territorial and organizational communities, researchers should take into considerations all relevant sectors. | 17. Researchers should afford community representatives engaged in collaborative research an opportunity to participate in interpretation of data. |
| 7. Research that critically examines the conduct of public institutions, First Nations Inuit or Métis governments may be conducted ethically. | 18. In collaborative research, intellectual property rights should be discussed by researchers, communities and institutions. Those rights should be specified in the research agreement. |
| 8. Researchers have an obligation to become informed about, and to respect, relevant customs and codes of research practice in any community. | 19. As part of the community engagement, researchers should specify the rights and proprietary interests of individuals and communities in the research agreement. |
| 9. Research ethics review by community REBs will not be a substitute for institutional REBs. | 20. Secondary use of data and human biological material identifiable as originating from an Aboriginal community or peoples requires REB review. |
| 10. Researchers shall advise their REBs how they have engaged the relevant community. | 21. When research relies only on publicly available information, community engagement is not required. |
| 11. Researcher and community should set out terms in a research agreement. | 22. When the research links 2 or more datasets or data associated with biological materials and data could be identifiable as originating from a specific community or segment of a community, REB review is required. |

(28) and the Scientist Act R.S.N.W.T. (Nu) 1988 (29). Applications for all 3 jurisdictions require a project description, curriculum vitae of the research team, travel itinerary, description of the project’s impact and information about communications with communities or First Nation governments, and agreements or approvals made with First Nations. Questions on the application forms are very specific about communication with communities and therefore take into consideration community consent and agreement more specifically than has been required of institutional REBs in universities, hospitals and elsewhere across Canada to date.

**Principles for conducting research in the NWT, Yukon and Nunavut**

Each of the territories has its own principles for governing research and each has an institute responsible for the proper conduct of researchers according to its statute and regulations. For the NWT, the Aurora Research Institute guides
researchers through the licensure process (30). Researchers are referred to 4 documents with respect to ethical principles:

1. Ethical Principles for the Conduct of Research in the North (31)
2. A Participatory Research Process for Dene/Metis Communities – Exploring Community-based Research Programs for Aboriginal Northerners (32)
3. Negotiating Research Relationships with Inuit communities: A Guide for Researchers (33)
4. The Tri-Council Policy Statement (4)

The first 3 of these guides direct researchers to participatory research approaches, as does the CIHR Guidelines for Health Research Involving Aboriginal Peoples, which are likely to become part of the Tri-Council Policy Statement (26).

Guidelines and requirements for research in the Yukon follow the Association of Canadian Universities for Northern Studies (ACUNS) (31) document regarding research in the North. The Yukon’s Department of Health and Social Services (DHSS) reviews any licensing applications for that territory, including any research involving human participation in the health and social services areas, any involving body fluids or tissue, and any involving traditional knowledge. In addition to the general application for research, the Yukon DHSS requires additional information and documentation, including the following:

- letters of approval from community representatives;
- statements on how the research will benefit and potentially harm communities and individuals;
- what deliverables will be made to the community;
- who will act as data stewards;
- reporting mechanisms for both First Nation and non-First Nation populations;
- ethics approval applications from other jurisdictions; and
- a copy of the consent form (34).

The ACUNS (31) document outlines 20 “principles” covering a range of topics, including respect for cultural and sacred knowledge, appropriate community consultation, respect for privacy, and informed consent. Abbreviated versions of these 20 principles are shown in Table II.

The Nunavut Research Institute is the territorial licensing agency that issues scientific research licences under the Nunavut Scientist Act, a requirement for all health and social research. It has co-authored the document Negotiating Research Relationships with Inuit Communities: A Guide for Researchers (33). Health-related research requires approval from the territorial Health and Social Services Department, Nunavut Tunngavik Incorporated (the organization representing Inuit), the municipality in which the research will take place, and other authorities. As well, “representative Inuit organizations and community authorities are involved in all application reviews…” (33). The review includes an assessment of the benefits of the project to Nunavut residents generally, and Inuit specifically, noting that “Inuit stakeholders are given decision-making powers as members of the research team” (33).

**Future directions**

The government of Canada, through its International Polar Year Federal Program, is working in partnership with northern organizations on the Canadian Arctic Research Licensing Initiative (CARLI) (35). This initiative was developed in part because of a general consensus that the various scientists’ acts are dated and may not be
Responsive to stakeholders’ needs (36). The objective is to examine where any improvements can be made in the application and approval processes, including possible coordination between the various licensing organizations, and with the current regulatory legislation. It aims to build relationships, improve communication and share best practices among the stakeholders. To date, an Advisory Committee has been formed, assessments of the current northern licensing application, approval and reporting processes have been conducted, and a series of workshops and consultations have taken place. Over the next 2 years, proposals will be funded from the territorial licensing regulators to develop licensing retrospectives, web-based tools, guidelines and training materials, and to sponsor workshops or meetings to deliver these initiatives. The CARLI work is inclusive of the regulators, Aboriginal organizations, researchers and industry of the 3 Canadian territorial governments’ organizations, as well as the Nunatsiavut Government, which is

Table II. Ethical Principles for the Conduct of Research in the North Association of Canadian Universities for Northern Studies (ACUNS) (31) – abbreviated.

| Researchers should abide by any local laws, regulations or protocols that may be in place in the region(s) in which they work. | The informed consent of participants in research should be obtained for any information-gathering techniques, for the uses of the information gathered, and for the format in which the information will be displayed or made accessible. |
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| There should be appropriate community consultation at all stages of research, including its design and practice. | The informed consent of participants should be obtained if they are going to be identified; if confidentiality cannot be guaranteed, the subject must be informed of the possible consequences before becoming involved in the research. |
| Mutual respect is important for successful partnerships. In northern research, there should be respect for the language, traditions, and standards of the community and respect for the highest standards of scholarly research. | No undue pressure should be applied to obtain consent for participation in the research project. |
| The research must respect the privacy and dignity of the people. | A community or an individual has the right to withdraw at any point. |
| The research should take into account the knowledge and experience of the people, and respect that knowledge and experience in the research process. | On-going explanations of research objectives, methods, findings and their interpretation should be made available to the community. |
| For all parties to benefit fully from research, efforts should be made, where practical, to enhance local benefits. | Subject to the requirements of confidentiality, descriptions of the data should be left on file in the communities from which it was gathered, along with descriptions of the methods and storage place. |
| The person in charge of the research is accountable for all decisions on the project. | Research summaries in the local language and research reports should be made available to the communities involved. |
| No research involving living people or extant environments should begin before obtaining the informed consent of those who might be unreasonably affected. | All research publications should refer to informed consent and community participation, where applicable. |
| In seeking informed consent, researchers should clearly identify sponsors, purposes of the research, sources of financial support, and investigators responsible for the research. | Subject to requirements for confidentiality, publications should give appropriate credit to everyone who contributes to the research. |
| In seeking informed consent, researchers should explain the potential beneficial and harmful effects of the research on individuals, on the community, and/or on the environment. | Greater consideration should be placed on the risks to physical, psychological, humane, proprietary, and cultural values than to contribution to knowledge. |
the regional Inuit government formed through the Labrador Inuit Land Claims Agreement.

This CARLI initiative, and the inclusion of the Nunatsiavut Government, demonstrates the continual need for communication between stakeholders, the need to be responsive to changing systems and the need to continue efforts that will improve existing systems and regulations.

Conclusions
In summary, the territorial governments in northern Canada each have a mandatory licence process for conducting research among individuals, communities and territories, including land and water. For health and social research, researchers must develop relationships with local communities, and it is unclear if a licence would be granted without community consultation and agreements. The research licensing process, therefore, is not merely an inventory of what research is taking place, but also provides an avenue for local people and community participation in research processes. In that sense, the governments act as stewards for the types of participatory research approaches found to be appropriate for working with the people of their territories.

Researchers wanting to conduct studies in any of the 3 territories in northern Canada are required to go through 2 steps: submission of protocols to their university ethics review boards and attaining a licence to conduct research in each or any of the territories. The first protects individuals (and, in the case of Aboriginal communities, protects communities), and the second protects and ensures benefit to communities. The process puts an extra burden on the researcher. On the other hand, the closer-to-home review of research protocols through the licensure process is likely to benefit the communities through their increased engagement in the research design, their participation in the study and their chance to gain experience in how to conduct research. The territorial governments of northern Canada take the concept of community and individual involvement in research seriously and have enacted processes so that opportunities for participatory approaches to research are ensured, with the premise that community members will benefit not only through the research results but also through employment, education about research processes and decision-making roles.

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