Developments in Canada: Research Ethics Policy Guidelines for Research Involving Aboriginal Peoples

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Aboriginal critiques of research

• Perception of best interest of research as driver rather than Aboriginal well-being

• Research hypotheses and data interpretation often do not incorporate an Aboriginal perspective and often not consistent with community priorities and interests

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Aboriginal concerns

• Individual and group identity will not be protected

• Adequacy of protections from potential harms posed by research

• Voluntariness of participation

• Research focus on deficits and problems leads to stigmatization of individuals and communities

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Example

• In 1985, Co-investigator took blood samples of 833 Nuu-Chah-nulth people under the auspices of carrying out research to explore the high rate of arthritis in that nation.

• After the original study, the blood samples were kept.

• **Without consent**, the samples were then used to isolate DNA and carry out research relating to the researchers own secondary analysis and publications in genetic anthropology.
Community Harms

- Physical (distrust of all research and care interventions)
- Psychological (self-stigmatization, disruption of group values)
- Social (external stigma and external genetic determinism)

(Freeman, Romero, Kanade, 2005)

“… some research involving Aboriginal individuals may also involve the communities or groups to which they belong. The Agencies affirm that in developing ethical standards and practices, Aboriginal peoples have rights and interests that deserve recognition and respect by the research community.”

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CIHR Guidelines

Health Research Involving Aboriginal Peoples
Project Strategy

- “Bottom Up” process consistent with traditional values and culture
- Community and Elder Dialogues on cultural values and ethics
- Guidelines based on background and issues papers and traditional values and ethics
- Consultation process included Aboriginal, institutional and research communities
- Broad vetting with 3 communities

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Founded on a Partnership

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Background Paper on Issues of Group, Community or First Nation Consent in Health Research

By:
Joseph Kaufert, Professor, University of Manitoba
Kathleen Cranley Glass, Director Biomedical Ethics Unit, McGill University
William L. Freeman, Director of Community Health Programs, Northwest Indian College
Research Ethics in Community-Based Health

• Community is an actor rather than just an aggregate of subjects.
• Communities like individuals must be seen as the focus for impact assessment in research.
• Communities are increasingly being represented by First Nations governments which control what research will be done in member communities.

The effects of research on groups present particular problems for the governance of research ethics.

Consent is the usual framework for balancing risks of research with benefits.

Interests of groups, aggregates or collectives difficult to manage through conventional consent frameworks.

Framework for assessing range of research effects on individuals and collectivities.
<table>
<thead>
<tr>
<th>Respect for person or community</th>
<th>Individual Person</th>
<th>Community</th>
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<tr>
<td>• People are autonomous; researchers must give them required information &amp; obtain their fully informed consent.</td>
<td>• Aboriginal communities are autonomous; researchers must give them required information and obtain their fully informed consent.</td>
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(Autonomy)

<table>
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<td>• The research does only what is consented to. For instance, people are not identified in results without their explicit consent; they can refuse or withdraw their participation without pressure. • Special people have special concerns. For instance, IRBs should include members with expertise and such concerns.</td>
<td>• The research does only what is consented to. For instance, communities are not identified in results without their explicit consent they can refuse or withdraw their participation with pressure. • Aboriginal communities have special concerns. For instance, IRBs should indicate tribal members with expertise about such community concerns.</td>
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WHAT AM I CONSENTING TO?

A TRADITIONAL DOCTOR-PATIENT RELATIONSHIP!
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<th>Justice</th>
<th><strong>Individual Person</strong></th>
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<td></td>
<td>• People with less power should not be asked to undergo risky research that is of little benefit to them.</td>
<td>• Communities should not be asked to permit risky research that can be of little benefit to their members or themselves.</td>
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<tr>
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<td>• People with less power should be included in potentially beneficial research.</td>
<td>• Communities should be included in potentially beneficial research.</td>
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<td>• Communities should share in resources derived from the research process</td>
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Added principal: Respect for and Protection of the Rights of Communities

• “A reasonable formulation of the principle of respect for communities confers on the researcher an obligation to respect the values and interests of the community in research and, wherever possible, protect the community from harm.” (Weijer et.al 1999)
Problems in Community-Based Health Research

Problems of defining the “community”
- Self-definition versus political or demographic boundary
- Problems of communities within urban centres
- Political representation of communities through First Nations or Tribes
- Problems of multiple communities including conflicting stakeholder perspectives based on gender, lineage or genetic interest
Unique Features of First Nations and Tribal Communities

• Political and legal status
• Geographical isolation, boundaries
• Recognized leadership structure
• Established processes for determining the views of the wider community
• History and cultural context
CIHR Guidelines
Health Research Involving Aboriginal Peoples
CIHR Guidelines - Formalize Relationships

- Memorandum of Understanding to outline expectations of the community and researcher (where no relationship exists)

- Research Agreement a binding agreement covering terms of the project and issues raised ("best practices" model agreement)
When Do Guidelines Apply?

• CIHR funded research when:
  – research hypothesis relates to Aboriginal people
  – recruitment criteria includes membership in Aboriginal community for entire study or sub-group
  – analysis of research data will use Aboriginal community membership as a variable
  – findings will refer to Aboriginal peoples, language, history or culture

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Aboriginal Nation or Community?

• **Community:**
  Defined as the system of relationships* within Indigenous societies in which the nature of person-hood is identified.

*This system of relationships not only includes family, but also encompasses the relationships of human, ecological and spiritual origin.*
Community Jurisdiction and Approval Process

• Authority in the area of research is based on the assumption that Aboriginal communities have Aboriginal or treaty rights to regulate research within the community;

• Research involves the activity of seeking knowledge, an activity that is culturally specific and fundamental to all societies;
Hierarchy of Jurisdiction

• Aboriginal communities have a ground-up structure of political authority

• Researchers and participants cannot assume that one political body has the authority over research.
Complex Authority Structures

- Legal authorities of a community may include:
  - Band elders
  - Traditional leaders
  - Municipal leaders
  - Tribal leaders
  - Confederation leaders
  - Regional leaders
Free, Prior and Informed Consent

- Research conducted in an Aboriginal community must obtain free, prior and informed consent from the Aboriginal community and individual participants as appropriate.
Community Research Ethics Review

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

• A researcher would not only have to submit their proposal to their own institution’s Research Ethics Board (likely a university) but also the Aboriginal community’s Research Ethics Board [REB].
Issues for University-Based Research Ethics Boards in Evaluation of Community Consent

- REB culture and emphasis on external science context
- External REB knowledge gaps related to historical and cultural context of Aboriginal relationships with researchers
Research as a Partnership

- Relevant communities and individuals should be involved at all stages of the research process, from formulating projects and methods, to determining research outcomes and interpreting results.
Community Consultation

• Appropriate community consultation would involve:
  • Discussing the research with individuals, in groups, and in other ways that will become apparent from initial discussions and contact (such as public meetings in the community).
Ownership and Cultural Knowledge

• There must be clear guidelines stating that Indigenous peoples and their respective communities retain ownership of any traditional knowledge, cultural practices and traditions that are shared with the researcher(s).
Secondary Use of Data

- Respecting community jurisdiction

- Recognizing and respecting a community’s proprietary interest in the collection, use, storage and potential future use of data

- Biological research samples are “on loan” to the researcher

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Problem Identification and Benefit Sharing

• On a community level, there is the basic expectation of the relevancy of the context to the community involved.
  – In this context, the community not only expects the research to address needs within the community, but also be a derivative of their cultural distinctiveness.
Comparing Conventional and Participatory Models of Research Collaboration Between First Nations and University Based Researchers

<table>
<thead>
<tr>
<th>PROBLEM IDENTIFICATION</th>
<th>PROTOCOL DEVELOPMENT AND TEAM BUILDING</th>
<th>RESEARCH ETHICS REVIEW AND CONSENT FRAMEWORK</th>
<th>DATA COLLECTION</th>
<th>DATA ANALYSIS, INTERPRETATION AND POLICY DEVELOPMENT</th>
<th>DISSEMINATION OF RESEARCH AND DATA STEWARDSHIP</th>
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<tr>
<td>CONVENTIONAL</td>
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Step 1: Partnership Development

Application to develop an Aboriginal Health Research Project
Submitted to Research Sponsor or Funding Agency

Yes

Application accepted by Planning Committee for
funding to build relationship and Develop proposal for
potential Aboriginal Health Research Project

No

Revise or end

Relationship building process begins between researcher and some
members of the potential Aboriginal community for both parties to obtain an
understanding of each other, including community’s traditional values and
beliefs, cultural diversity, environment, social nature of community, research
methods, ethical space, sacred space, PAR, range of research approaches
and techniques, mutually beneficial research, gifting, ownership, control,
protection, etc.

A Memorandum of Understanding may be appropriate

Letter of Intent to funding agency if required

Begin here if a research has already an established positive relationship with the community.
Step 1: Partnership Development (cont’d)

Proposal developed for Health Research Project by Researcher and some Aboriginal community members that reflect the priorities of both the community and the researcher, in accordance with principles, practices and procedures for a successful health research project and is acceptable to the community.

Research submits proposal to Research Sponsor or Funding Agency for funding.

Proposal referred to authority for Aboriginal Community for the potential Health Research project or Local Aboriginal Ethics Review board/Committee for review.

Local Aboriginal Ethics Review Board/Committee undertakes ethics review of proposal in accordance with generally accepted principles, practices and procedures on health research for the community; benefits to the community; etc.

Where no local ethics review exists or research approval process, a statement of compliance with these guidelines is essential.

Step 1: Partnership Development (cont’d)

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Where no local ethics review exists or research approval process, a statement of compliance with these guidelines is essential.
Local Aboriginal Ethics Review Board/Committee makes recommendation/s to authority for Aboriginal Community on proposal for health research project

Authority for Aboriginal Community accepts proposal and all or some of the recommendations on the potential Aboriginal health research project for its community

Research submits application to Research Sponsor or Funding Agenda for consideration for funding Aboriginal health research proposal

Revise or end
Step 2: Submitting Proposal

1. Researcher submits application on an Aboriginal Health Research Project to Research Sponsor or Funding Agency for approval

2. Research Sponsor or Funding Agency submits application for peer review and recommendation

3. Project approved and funding released to institution

4. Institutional REB review of proposal and recommendations from Aboriginal community for the research project

   - Yes
   - No

   Yes: Institutional REB accepts health research project

   No: Revise or end

5. Funding released
Step 3: Maintaining the Relationship

Researcher and Authority for Aboriginal Community negotiate and sign agreement community’s health research project

Researcher undertakes research project with Aboriginal community in accordance with terms and conditions of agreement

Aboriginal research project progresses as planned

Authority for Aboriginal Community contacts research institution to appear decision on health research project

Yes

No

Research project completed

Researcher maintains relationship with Authority for Aboriginal Community on the related activities to the research project in accordance with terms of signed agreement
Policy Implications

• Researcher and institutional compliance will be required for grants and awards

• REB will need to make a determination of appropriate community involvement

• May require additional time for relationship building – lengthening process

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Policy Implications

• Establishing partnerships means working with communities before REB approval

• Peer reviewers and REBs need to better understand community-based research

• More direct involvement in education of researchers

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Policy Models In International Indigenous Frameworks for Community Research Ethics Review and Consent

- Canada, Australia, United States and New Zealand
- Review of historical context of policy development and innovative features of each system
- Four Levels of Policy development- national science governance, national level indigenous policies, regional level policies and review bodies, Tribal or First Nation frameworks and codes
Figure 1 – International, National and Local Frameworks for Determining Community Consent

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<tr>
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1] National Level Research Ethics Guidelines in Government Science Policy
Figure 1 – International, National and Local Frameworks for Determining Community Consent (Continued)

<table>
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<tr>
<th>Community/ Tribe/ First Nation-Based Frameworks and Review Boards</th>
<th>Canada</th>
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<tbody>
<tr>
<td>Local Advisory Committees and Kahnawake Schools Diabetes Research Code</td>
<td>Tribal Health Boards and IRBs consistuted by specific Tribal Communities (e.g. Zuni, Mowhawk, Navajo, Cherokee of Oklahoma and others)</td>
<td>Community Boards (e.g. Koorie Health Partnership Committee)</td>
<td>Requirements for Māori representation on local REBs</td>
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