

Ethics and Research Review Workbook

A Resource for Manitoulin Area First Nations for the Review and Evaluation of Research Proposals

This workbook accompanies the
Guidelines for Ethical Aboriginal Research on Manitoulin Island (GEAR)

Created by Marion Maar, Lorrilee McGregor & Lenore Manitowabi in
collaboration with the
Manitoulin Anishinaabek Research Review Committee

*Revisions approved by Noojmowin Teg Health Centre Board of Directors
on December 6, 2012*

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The workbook was created in partnership with Mnaamodzawin Health Services, Wikwemikong Health Centre, M'Chigeeng Health Centre and the seven First Nations in the District of Manitoulin.

Several drafts of this workbook were compiled by Marion Maar, Lorrilee McGregor & Lenore Manitowabi in collaboration with the Manitoulin Anishinaabek Research Review Committee.

During the development of this Workbook the committee members were:

- Cheri Corbiere, Sheshegwaning Health Centre
- Donna Debassige, UCCM Tribal Council
- Joyce Helmer, Northern Ontario School of Medicine
- Phyllis Kinoshameg, Wikwemikong Health Centre
- Marion Maar, Noojmowin Teg Health Centre (Research &Evaluation)
- Lenore Manitowabi, Noojmowin Teg Health Centre (Research &Evaluation)
- Susan Manitowabi, Laurentian University
- Niki Naponse, Za-geh-do-win Information Clearinghouse
- Steven Radulovich, Ojibwe Cultural Foundation
- Marjorie Shawande, Noojmowin Teg Health Centre (Traditional Medicine Program)
- Lorrilee McGregor, Whitefish River First Nation
- Daughness Migwans, M'Chigeeng Health Committee

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Introduction

This workbook accompanies the *Guidelines for Ethical Aboriginal Research (GEAR)* developed between 1999-2003. The purpose of this workbook is to provide the Manitoulin Anishinaabek Research Review Committee (MARRC) and local First Nation communities with a tool to assist in the assessment of research proposals. The guidelines were initially developed to address health research issues, however as recommended by local communities, the MARRC broadened the scope of research review to develop guidelines and tools that apply to research from any discipline.

The information and tools provided in this workbook are based on First Nations community consultations in the Manitoulin area which included a community-based research conference, discussion groups with an Elders Advisory group, presentations and feedback from all Manitoulin area Band Councils and health boards/committees research workshops, an ethics workshop co-facilitated by the National Council on Ethics in Human Research (NCEHR) and a focus group with members of the Manitoulin Anishinaabek Research Review Committee.

The questions in this work book serve as a guide and a starting point for discussions during the review of research projects; they should not limit reviewers from asking additional questions. The MARRC and the Ethics Review Sub-committee will use this workbook to conduct a formal research ethics review and provide recommendations on how to proceed with a proposed research project. The MARRC and the Ethics Review Sub-committee respect the autonomy of First Nations communities. The final decision on how to proceed with a proposed research project rests with the community.

The MARRC should review and revise this workbook, the forms and the review process on an annual basis.

This workbook contains:

1. Overview of the Aboriginal research principles
2. Description of the research review process
3. Roles and responsibilities of the ethics committee
4. Ethics review application form (to be filled out by lead researcher)
5. Questions for discussion for committee members during the review process
6. Standardized feedback form and scoring sheet

Aboriginal Research Principles

As outlined in the GEAR document, research ethics should be based on the seven grandfather teachings. These teachings include respect, wisdom, love, honesty, humility, truth and bravery. Other guiding principles for research, outlined in the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans¹, include: respect for human dignity, respect for free and informed consent, respect for vulnerable persons, respect for privacy and confidentiality, respect for justice and inclusiveness, balancing harms and benefits, minimizing harm and maximizing benefit. For more detailed explanations please see pages 6 – 10 of the GEAR document.

Based on consultations with Elders, researchers, leadership, service providers and other community members of the First Nations on Manitoulin Island the key principles of ethical research are:

- Research must emphasize a direct benefit and impact on local community health
- Research should incorporate traditional values into the research approach
- Issues surrounding the protection of traditional knowledge must be addressed
- Methodologies must be culturally acceptable at the community level
- Research project must have the guidance of a local steering committee

These key principles are discussed in more detail in the GEAR document. The Ethics Review Application Form and discussion questions are based on these principles.

The Manitoulin Anishinaabek Research Review Committee

The Manitoulin Anishinaabek Research Review Committee (MARRC) is hosted by Noojmowin Teg Health Centre. The main function of the Manitoulin Anishinaabek Research Review Committee (MARRC) is to evaluate research proposals and make recommendations to ensure that research projects are: culturally appropriate; protect the rights of individuals and communities; and meets ethical guidelines. The MARRC also aims to build capacity for ethical Aboriginal research in the Manitoulin Island First Nations communities.

The Manitoulin Anishinaabek Research Review Committee is comprised of 12 members. Representation on the committee is as follows:

- 1 Noojmowin Teg Health Centre
- 1 Mnaamodzawin Health Services
- 1 M'Chigeeng First Nation
- 1 Wikwemikong Unceded Indian Reserve
- 1 Sheshegwaning Health Services

¹ Available at <http://pre.ethics.gc.ca/eng/index>

- 1 Zhiibaahaasing Health Services
- 1 Sheguiandah Health Services
- 1 Aundeck Omni Kaning Health Services
- 1 Whitefish River Health Services
- 1 Traditional Elders/Cultural Advisors
- 2 Academic or Community Researchers

Resource Members

The committee shall also have **Resource Members**, up to a maximum of 5 members. These members shall complement the MARRC through their expertise and provide their input during Ethics Review Sub-committee meetings.

Ethics Review Process

Research proposals should be forwarded to the Secretary/Treasurer of the MARRC by a local community or community organization. Academic researchers must first contact the participating community and obtain written approval for research before submitting an application to the MARRC unless they have been specifically asked to do so by a local organization or the community leadership.

The Secretary/Treasurer notifies MARRC members that a research proposal has been received. A minimum of three members and maximum of four members of the MARRC and/or Resource Members will be asked to volunteer to participate on an Ethics Review Sub-committee. A representative from the affected First Nation or organization will also be invited to participate in the ethics review. The Chief or Health Director will be asked to appoint a representative to participate in an Ethics Review Sub-committee. The date, time and location will be confirmed by the Secretary/Treasurer. The Ethics Review Sub-committee shall meet either in person or via teleconference within eight weeks of receipt of a research application.

Steps for reviewing an ethics application:

1. At the start of an Ethics Review Sub-committee meeting, one person shall volunteer to chair the meeting and another person shall volunteer to take notes.
2. The sub-committee can use the “Questions for discussion during an ethics review sub-committee meeting” (see pages 14 - 16) as a guide when completing the Ethics Review Recommendations Form (see pages 17 & 18).
3. Decision-making at the Ethics Review Sub-committee is by consensus.

4. Once each section of the application has been discussed and recommendations made, the ethics review sub-committee decides whether
 - a. the project meets ethical standards;
 - b. the project can meet ethical standards with minor changes; or
 - c. the project does not meet ethical standards and major changes are required.
5. The note taker shall summarize the discussion and complete the Ethics Review Recommendations Form then circulate it to the rest of the sub-committee members until all are satisfied with the recommendations.
6. The completed Ethics Review Recommendations Form is provided to the MARRC Secretary who then forwards the completed form to the lead investigator(s) and the community partners.
7. Revisions should be submitted in the original application using the track changes function and re-submitted to the MARRC Secretary. The MARRC secretary will then forward the revised application form to the Ethics Review Sub-committee who conducted the original review. The Ethics Review Sub-committee shall review the revised application and determine whether it now meets ethical standards.
8. Once the Ethics Review Sub-committee agrees that all recommendations or comments have been addressed, the Chair of the Ethics Review Sub-committee will ask the MARRC Secretary/Treasurer to prepare an ethics certificate to be signed by the MARRC Chair or the MARRC Vice-Chair.
9. The lead investigator will be mailed an original copy of the ethics certificate. Electronic copies may also be emailed to the lead investigator and the community partners for expediency.
10. The Chair of the Ethics Review Sub-committee is responsible for reporting the results of the ethics review at the next regularly scheduled MARRC meeting.

Reporting process

Within 6 months of completion of a research project, a report on the completed research project should be submitted to the MARRC. The one page report shall include information on the following:

- completion date of the study;
- the number of research participants;
- whether any problems were encountered during the course of the research (such as participants leaving the study);

- description about how Aboriginal knowledge, involvement of the Elders, use of Seven Grandfather teachings, and/or Aboriginal research ethics was incorporated, as well as lessons learned; and
- a narrative report with a summary of the results, outcomes, impacts, and lessons learned.

Published articles or publications would also be appreciated so that the MARRC can build a virtual resource library and added to the Noojmowin Teg website.

Amendment process

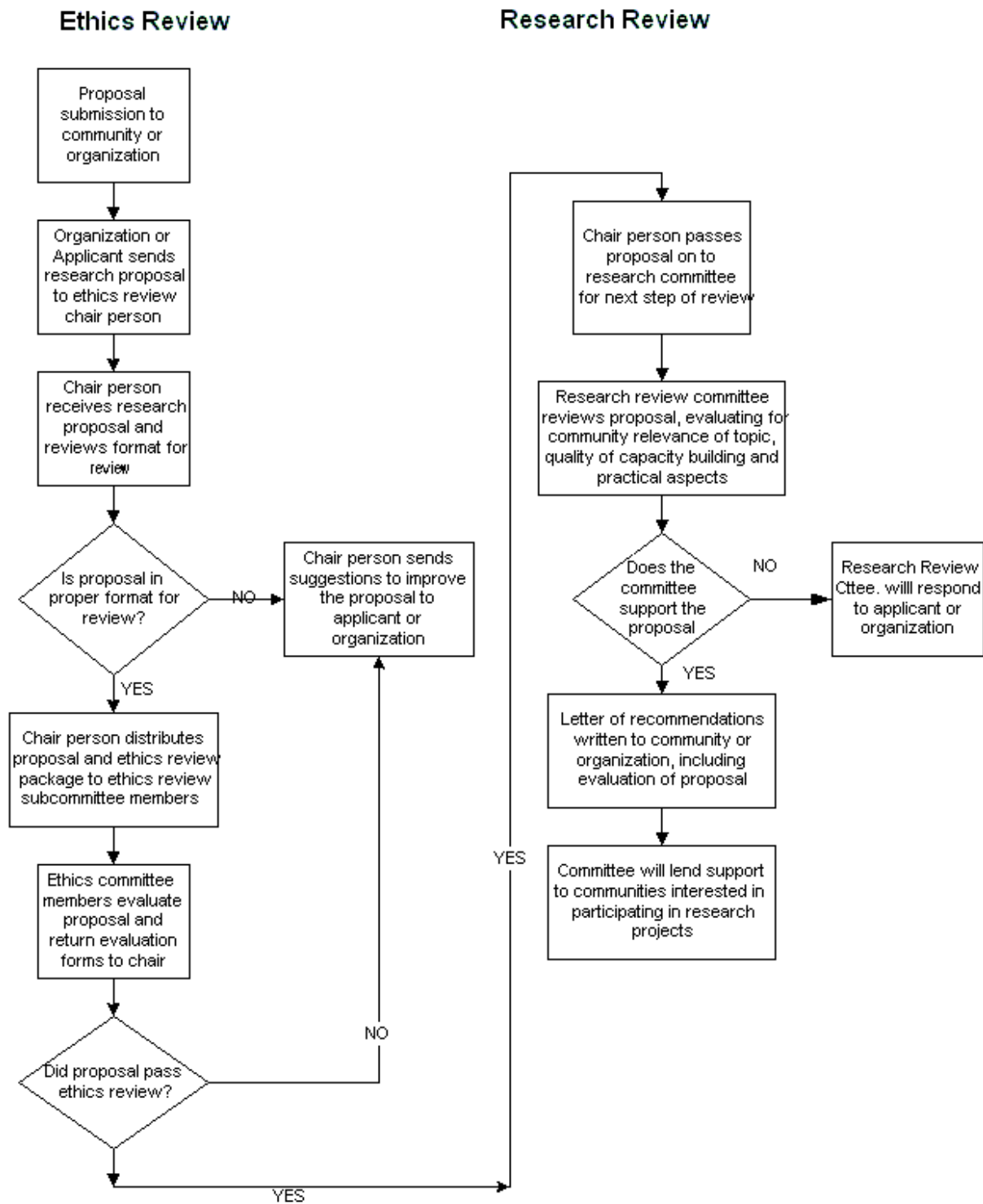
1. Should a lead investigator wish to make any changes in recruitment, procedures, letters of information, consent forms, or questionnaires a letter outlining the proposed changes must be re-submitted to the MARRC Secretary/Treasurer prior to the commencement of research activities.
2. The MARRC secretary will forward the letter to the Ethics Review Sub-committee who reviewed the original submission and determine:
 - a) whether the changes do not significantly compromise the ethics; or
 - b) whether another review is necessary.
3. If the changes do not compromise the ethics of the research proposal then a letter will be provided to the lead investigator acknowledging the changes to their original submission and giving ethics approval to proceed.
4. If the changes are significant, the Ethics Review Sub-committee will reconvene and follow the steps for reviewing an ethics application.

Appeals process

In cases when a lead investigator and the MARRC cannot reach agreement through discussion the following steps will be taken:

1. If an investigator appeals the recommendations, the entire MARRC shall review the recommendations with an option for the investigator and community partner to present to the MARRC.
2. Following the presentations, the MARRC will discuss whether any changes to the original recommendations are necessary and provide a written response to the investigator and the community partner.
3. The community partner has the final decision about whether to proceed with the research.

Flowchart for Ethics and Research Review



What can communities and researchers expect from the Manitoulin Anishinaabek Research Review Committee?

An ethics review is a service to First Nation communities on Manitoulin Island and Aboriginal organizations to provide information they require to make decisions on proposed research projects and to help in the planning and implementation of community-based research projects. The MARRCs role is, therefore, to review proposals and to provide recommendations to the researchers, First Nation communities and/or Aboriginal organizations. Although the MARRC can provide an ethics review as a service to the First Nation communities and Aboriginal organizations on Manitoulin Island, we are not responsible for the actions of the researchers during the research project.

Researchers will be asked to provide the MARRC with a completed Application for Research Ethics Review. The form will be forwarded to applicants in electronic format and is also accessible from the Noojmowin Teg Health Centre website. The principal investigator is also asked to forward their current curriculum vitae (cv).

An Ethics Review Sub-committee will provide an ethics review of submitted applications, based on local Aboriginal ethics as well as guidelines set by the Tri-Council Policy Statement. A form will be provided to the researcher, including recommendations for the research project. The committee can also provide recommendations on how to improve the cultural safety of proposed research projects.

Every effort will be made to conduct the review within **eight weeks** of receipt of the Ethics Application Form. Results of the ethics review will be communicated back to the lead researcher and any community partners.

Important notes:

- 1) The review is an evaluation of research ethics as presented in the research proposal. It is not a guarantee or an endorsement of the proposed research. The committee respects the autonomy of communities and individuals to make the final decision regarding their willingness to participate in research projects.
- 2) In order to assist with administrative costs for the MARRC a fee will be charged to conduct an ethics review (contingent upon funding approval for the research proposal). The fees charged to a research proponent for an ethics review shall be as follows:
 - projects under \$5,000 shall be charged \$300;
 - projects between \$5,001 to \$10,000 shall be charged \$500;
 - projects between \$10,001 to \$20,000 shall be charged \$1,000; and
 - projects above \$20,000 and \$50,000 shall be charged 5% of the total research project costs; and
 - projects above \$50,000 shall be charged \$2,500.

Manitoulin Anishinaabek Research Review Committee Application for Research Ethics Review

Please forward the completed proposal to the MARRC Secretary / Treasurer via email: lenore.mayers@noojmowin-teg.ca

A. Project Overview

Title of the Research Project:

1. Investigator Information

	Name	Position and role on this project	Address	Phone number and Email
Lead investigator				
Community organization				
Other research collaborators				

2. Proposed Timeframes

Start date:

Date of completion:

3. Proposed Location of Research

4. Project Funding

Have you applied for funding for this project?

Yes No

If yes, please specify agency and status of application.

5. Review of this Project

Please list who has reviewed this project to date and provide documentation of approval including funding sources, community organizations, other ethics boards and university faculty.

B. Summary of Proposed Research

6. Please describe the background and rationale for the research project, including research questions that will be addressed.
7. Describe the proposed methodology in detail. Include all procedures in sequence that research participants will be involved in (e.g. recording, interviews, focus groups, surveys, human tissue sampling etc.) Attach finalized or draft questionnaires or other instruments.
8. Describe the participants, including number, age groups, gender, residence, affiliation etc.
9. How will participants be recruited?
10. **Compensation of Participants**
Will participants be compensated for participating in this project?
 Yes No
If yes, please provide details, including how you will deal with compensation for participants who choose to withdraw.
11. What is your experience with this kind of research, particularly in First Nations communities?

C. First Nations Community Involvement in the Project

12. Describe how representatives of First Nations communities will be involved in the research design and implementation. Specifically comment on collaboration with a community-based group or organization.
13. How will you ensure that a representative cross-section of community members will be included in the research (as research participants or as investigators)?
14. Explain how this project matches local research priorities and addresses the needs of this community as identified by local First Nations.
15. List relevant previous research projects that have been conducted in the community.
16. Outline the research budget below, indicating portions that will be spent within local communities.

17. Will community staff or community members be employed in this project?

Yes No

If yes, please provide details below.

18. Will community staff or community members receive research training?

Yes No

If yes, please provide details below.

D. Ownership, Control, Access and Possession

19. Who will own the data, results, working papers and related materials?

20. Who will have access to this information? Will the communities have access to the data?

21. Where and how will the data be stored?

22. What are the limits on the use of the data?

E. Aboriginal Knowledge

Aboriginal knowledge is the knowledge system that Aboriginal people have gained through their relationship to their place and land. Aboriginal knowledge may include traditional healing knowledge, community specific information or traditional cultural information.

“Any research involving Aboriginal people will involve the sharing of some cultural knowledge, practices and/or traditions even when these are not the subjects of the study, as they provide necessary context.”²

23. Will Elders or people with Aboriginal knowledge be involved in this research?

Yes No

If yes, explain the protocol that will be used to ensure local culture and customs will be respected in this consultation.

24. Will the research process document any Aboriginal knowledge?

Yes No

If yes, how will Aboriginal knowledge be collected and protected?

25. How will Aboriginal knowledge or perspectives portrayed in research products be validated by Aboriginal people?

² CIHR Guidelines for Health Research Involving Aboriginal People (2007) pg 4.

F. Risks and Benefits for Participants and Communities

26. How will this research benefit and impact First Nations community health in the Manitoulin area over the next 5 years? (such as capacity building, economic and social health improvements, etc.)

27. Will participants or the community experience any of the following risks:

Possible Risks	Yes	No
Physical Risks to Participants (e.g.: bodily contact, administration of substances, venipuncture)	<input type="checkbox"/>	<input type="checkbox"/>
Psychological Risks to Participant (e.g. re-living traumatic experiences, embarrassment or other upset)	<input type="checkbox"/>	<input type="checkbox"/>
Social Risks to Participant (e.g.: loss of status or reputation, legal consequences)	<input type="checkbox"/>	<input type="checkbox"/>
Social Risks to First Nations community (e.g.: loss of status or reputation, legal or treaty consequences)	<input type="checkbox"/>	<input type="checkbox"/>
Loss of individual or community empowerment (e.g.: loss of control/stewardship of Aboriginal knowledge, loss of decision making over use of genetic material etc.)	<input type="checkbox"/>	<input type="checkbox"/>
Are there any other risks to the participant or the community as a whole?	<input type="checkbox"/>	<input type="checkbox"/>

If you have answered yes to any of these questions, please explain the risks in detail and how they will be addressed.

G. Free and Informed Consent

28. Describe the process that will be used to obtain community consent for this research project.

29. Describe the process that will be used to obtain informed consent from research participants. If written consent is culturally unacceptable, describe the process of obtaining culturally acceptable consent. Attach forms for written consent and scripts for verbal consent.

30. How will the following be communicated to the research participants?

	verbal	written
Research purpose	<input type="checkbox"/>	<input type="checkbox"/>
Voluntary participation	<input type="checkbox"/>	<input type="checkbox"/>
Identity of the researcher	<input type="checkbox"/>	<input type="checkbox"/>
Nature of participation	<input type="checkbox"/>	<input type="checkbox"/>
Description of research procedures and data that will be collected	<input type="checkbox"/>	<input type="checkbox"/>
How findings will be used	<input type="checkbox"/>	<input type="checkbox"/>

31. How will individuals not proficient in English be given the opportunity to give informed consent? (e.g. translator, bilingual interviewer, consent form written in Anishnabemowin, etc.)

32. How will alternate consent be obtained from authorized parties for the participation of minors or individuals who are not legally competent?

33. How will participants be informed of their right to withdraw from the project? Describe what will happen to data from an individual who chooses to withdraw.

H. Privacy and Confidentiality

Confidentiality refers to the obligation for safe keeping of information about individuals and ensuring that information is only used for the stated purpose. Data that can be linked to individuals should only be accessed by those who are involved in the research process. With anonymous information it is not possible for anyone (including the researcher) to connect the name of the participant with the collected information.

34. Briefly describe the type of data that will be collected.

35. Is the collected data anonymous? (Describe how the researchers will ensure anonymity of data during the research process and during the dissemination of

results. Address issues in the context of the relatively small First Nation communities.)

36. Will the data be treated as confidential? Describe how the researchers will ensure the confidentiality of data during the research process and during the dissemination process. (Address issues in the context of the relatively small First Nation communities.)

37. Is there a need to protect the identity of individual First Nation communities (regional studies)?

38. If the collected data will be linked to existing data on participants, explain this process in detail, including the consent process.

I. Dissemination of results and support for community action

39. Describe the process for the development of a knowledge transfer strategy that is acceptable to all research partners.

40. How will communities and participants be informed of the results? (e.g. community reports, community and staff presentations etc.)

41. Is it likely that the research will be published in a book or journal? Which journals are being considered? Will there be co-authorship with local researchers?

42. Describe how the community will be given the opportunity to react and respond to the research findings before the completion and/or publication of the final report and other written materials (such as journal articles)?

43. How will the researchers support communities to act on research results?

J. Respectful of the Seven Grandfather Teachings

44. How will the Seven Grandfather Teachings be respected throughout the entire research process?

(For more information about local interpretations of the Seven Grandfather Teachings, see pages 9 and 10 of the Guidelines for Ethical Aboriginal Research that is available at <http://www.noojmowin-teg.ca/Shared%20Documents/GEAR%20-%20FINAL.pdf>)

Questions for discussion for during an ethics review sub-committee meeting

The research ethics committee will review research projects based on the information provided by researchers in the ethics application.

The following questions are designed to provide a basis for discussion for the review process. If the answer to any of the questions is “No”, the project will normally require changes to improve cultural competency and ethical treatment of individuals and communities.

1. Research Overview and Summary (section A and B)

- Is the project relevant to the community?
- Is the overall design of the project community-based?
- Is the design of the project participatory?
- Is the design of the project culturally appropriate?
- Are researchers using the correct method to address the research questions?

2. First Nations Community Involvement in the Project (section C)

- Does the project employ meaningful collaboration (not token) collaboration?
- Does the project build capacity in terms of research skills or learning new community specific health information?
- Is there an appropriate steering committee?

3. Ownership, Control, Access and Possession (section D)

- Does the community maintain ownership (or joint ownership) of the collected data, results and publications?
- Is there local access to the information?

4. Aboriginal Knowledge (section E)

- Does the project protect Aboriginal knowledge and Aboriginal view points as much as possible? (Keep in mind that it is not really possible to completely protect Aboriginal knowledge once it is shared in the research process)
- Are people who provide knowledge or information acknowledged appropriately in the research process?
- Is the protocol for including Elders or traditional people culturally appropriate?
- Is the process transparent (research process, dissemination, etc.)

5. Risks and Benefits for Participants and Communities (section F)

- Are there risks to participants that are greater than those normally experienced on a daily basis?
- Are there risks to the community that are greater than those normally experienced on a daily basis?

- Are there tangible benefits to this research to the community or participants?

6. Free and Informed Consent (section G)

- How will the researcher ensure that all participants are able to understand what they are consenting to?
- Are participants providing free and informed consent?
- Is consent provided in a culturally appropriate manner?
- Will a translator be available if necessary?

7. Privacy and Confidentiality (section H)

- Is the privacy and confidentiality adequately maintained in the research process?

8. Dissemination of results and support for community action (section I)

- Will the results be shared with the participants and the community in an acceptable manner?
- Is there a workable strategy to implement changes at the community or service level based on the research findings?
- Are the researchers and the community working as partners throughout this process?

9. Is the proposed research respectful of the Seven Grandfather Teachings?

- Are the participants and the community approached in a respectful way?
- Are the research instruments appropriate?
- Do participants have time and opportunity to get to know the research process?
- Does the researcher demonstrate an understanding of local cultures and customs?
- Will the research benefit participants or the community directly?
- Will the sharing of the results benefit future generations?
- Is the researcher willing to learn and be guided by local customs?
- Is the researcher willing to develop a trust based relationship?
- Is the community a true partner in the research process?
- Is the community's contribution acknowledged?
- Will the research likely lead to community action rather than harm?
- Is the researcher willing to support change based on the research results?
- Is the project designed to empower participating communities?

Ethics Review Recommendations

Title of Project:

Proposal Version:

Date proposal was received:

Date reviewed:

Please note:

This review is an evaluation of research ethics as presented in the research proposal. It is not a guarantee or an endorsement for the proposed research. The committee respects the autonomy of all communities and individuals to make the final decision regarding their willingness to participate in research projects.

Please check all appropriate comments:

- Project meets ethical standards
- Project meets ethical standards with minor changes
- Project does not meet ethical standards, major changes required as indicated

1. Research Overview and Summary (section A and B).

Comments:

2. First Nations Community Involvement in the Project (section C)

Comments:

3. Ownership, Control, Access and Possession (section D)

Comments:

4. Aboriginal Knowledge (section E)

Comments:

5. Risks and Benefits for Participants and Communities (section F)

Comments:

6. Free and Informed Consent (section G)

Comments:

7. Privacy and Confidentiality (section H)

Comments:

8. Dissemination of results and support for community action (section I)

Comments:

**9. Is the proposed research respectful of the Seven Grandfather Teachings?
(section J)**

Comments:

Additional remarks:

Manitoulin Anishinaabek Research Review Committee (MARRC)
Ethics Certificate

c/o Noojmowin Teg Health Centre

Attention: Lenore Mayers

Postal Bag 2002, Hwy 540

Little Current, ON P0P 1K0

Tel: (705) 368-2182 ext. 201

Fax: (705) 368-2229

lenore.mayers@noojmowin-teg.ca

This is to certify that the research proposal entitled INSERT PROJECT NAME HERE submitted by INSERT LEAD INVESTIGATOR NAME on DATE has passed an ethics review by a sub-committee of the Manitoulin Anishinaabek Research Review Committee.

Project Start Date:

Project Finish Date:

Conditions:

List any conditions

Please note:

This MARRC Ethics Certificate does not authorize a project to proceed. ***Projects must be approved by the respective First Nation community and/or organization.*** Although the MARRC can provide an ethics review as a service to the First Nation communities and Aboriginal organizations on Manitoulin Island, **we are not responsible for the actions of the researchers during the research project.**

This certificate covers only the documents submitted, in the language in which they have been submitted. During the course of research, no deviations from, or changes to the protocol, recruitment or the consent process and form may be initiated without prior written clearance from the MARRC. If you wish to modify your research project please submit a letter outlining the proposed changes to the MARRC Secretary.

Within 6 months of completion of a research project, a report on the completed research project should be submitted to the MARRC secretary. The report shall include information on the following: the number of research participants, whether any problems were encountered during the course of the research as well as the main findings. Published articles would also be appreciated so that the MARRC can build a virtual resource library.

Congratulations and best of luck with your research!

Sincerely,

Lorrilee McGregor, Chairperson
MARRC

Date: _____