Appendix A
Procedures for Implementing this Policy

P1. Full Review

Individuals who believe their proposal **does not**

(c) a brief cover letter addressed to the Chair of the **Research Ethics Board** (or the designated official) that clearly states the applicant's belief that the research proposal meets the standard of minimal risk (see Attachment D).

All submissions are to be sent to the Research Department.

P2.2 Types of Expedited Review

The **Research Ethics Board** may provide two types of expedited review:

Expedited Review by the Chair of the ***Research Ethics Board*** , and
Annual Renewal.

The first type of expedited review is intended for different individuals or groups

notice of change to research design and/or methods, and **notice of research completion**.

(a) **Annual Renewal:** Annual renewal serves as a mechanism for expedited review and provides the opportunity for the **Research Ethics Board** to monitor the status of on-going research. See subsection P2.(b) for a full description of annual renewal. For research posing significant risks, the REB may request reports at more frequent intervals.

(b) **Notice of Change to Research Design:** The principal researcher will immediately notify the Chair of the **Research Ethics Board** in writing of any changes to the research design and/or methods specified in the most recent proposal approved by the Board. The principal researcher will identify and explain in writing the way in which the research design has changed and clearly state whether the change **meets** or is **beyond** the standard of **minimal risk** (outlined in Policy Statement #4 above). This also applies if changes are to be made to the informed consent document.

(c) **Notice of Research Completion:** The principal researcher will notify the Chair of the **Research Ethics Board** in writing of the completion of research within one month of completion. Within this written communication, the principal researcher will:

i) identify the number of subjects who participated in the research, and
ii) detail any adverse effects observed that were associated with subjects' participation in the research.

P4. Assessment Criteria and Decisions of the Research Ethics Board

P4.1 Guidelines for Assessing Applications

In accordance with Tri-Council Policy Statement, CCNM's **Research Ethics Board** will be guided by considerations regarding the acceptability of a proposed research project involving human subjects that include the following:

Is it clear who is conducting the research and who will be responsible for its supervision and conduct?
Is it clear who the actual participants will be?
Is it clear what information will be provided to prospective participants?
Are participants easily able to refuse consent or withdraw from participation at any time?
Are all procedures outlined clearly and do they adequately protect the integrity and health of human subjects?
Is confidentiality safeguarded?
Are the benefits and risks clearly outlined and are the risks outweighed by the benefits?
Are the purposes and rationale of the research clear?
Is the research design outlined clearly?
Is conflict of interest avoided?
Are any direct benefits to the researcher or participants evident and acceptable?

The researcher must demonstrate how free and informed consent will be sought from the authorized third party and how the best interests of the legally incompetent persons will be protected;
No authorized third party may be the researcher or a member of the research team;
The continued free and informed consent of an appropriately authorized third party will be required to continue the participation of a legally incompetent subject in research, so long as the subject remains incompetent;
If during the course of the research project a previously incompetent person becomes competent, his or her informed consent must be immediately obtained as a condition of continuing participation;
Even if free and informed consent has been obtained from an authorized third party, the researcher must demonstrate that in circumstances where the legally incompetent person understands the nature and consequences of the research they have sought to ascertain the wishes of the individual and that individuals who have indicated their dissent will be precluded from participation.

P12. Research in Emergency Health Situations

It is not anticipated that CCNM researchers will be engaged in research involving emergency health situations. Research proposals in this area may be permitted but the REB will only permit research that involves health emergencies to be carried out without the free and informed consent of the subject or his or her authorized third party if all of the following apply:

All applicable legislative and regulatory requirements are met; and
A serious threat to the prospective subject requires immediate medical intervention; and
Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the subject in comparison with standard care; and
Either the risk of harm is not greater that that involved in standard efficacious care, or it is clearly justified by the direct benefits to the subject; and
The prospective subject is unconscious or lacks capacity to understand risks, methods and purposes of this research; and
Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and
No prior directive by the subject is known to exist.

When a previously incapacitated subject regains capacity, or when an authorized third party is found, free and informed consent must be immediately sought for continuation in the project.

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[i] The procedure outlined for expedited review is adapted from Section D1, Article 1.6, Tri-Council Policy Statement.