Appendix A
Procedures for Implementing this Policy

P1. Full Review

Individuals who believe their proposal **does not** meet the standard of **minimal risk** will submit their proposal to the **Research Ethics Board** for a full review.

Application Procedures – Full Review

Applicants submitting proposals for full review will be required to submit:

(i) an *Application for Research Involving Human Subjects* that has been signed and dated by the researcher(s) involved (see Attachment A);

(ii) a sample *Information Letter* and *Free and Informed Consent Form*, if applicable to the proposed research (see companion document, Attachment B, *Guidelines for Free and Informed Consent*); and

(iii) a brief covering letter addressed to the Chair of the **Research Ethics Board** that clearly outlines the ways in which the proposed research is **beyond** the standard of **minimal risk** (see Attachment C).

All submissions are to be sent to the Research Department.

P2. Expedited Review

The **Research Ethics Board** may provide an **expedited review** of research proposals that meet the standard of **minimal risk**. For expedited review, the Chair of the **Research Ethics Board,** or other individuals designated by the Board, may approve and provide a statement of approval for applications that are confidently expected to involve no more than minimal risk. If the Chair, or designated official believes the application does not clearly meet the standard of minimal risk, the application will be brought to the **Research Ethics Board** for a full review.

All applications that are approved through expedited review will be reported in a timely manner to the full **Research Ethics Board** to enable the Board to maintain surveillance over the decisions made on its behalf[i][i].

P2.1 Application Procedures – Expedited Review

Individuals who believe their proposal meets the standard of minimal risk will be required to submit:

(a) an *Application for Research Involving Human Subjects* that has been signed and dated by the researcher(s) involved (see Attachment A);

(b) a sample *Information Letter* and *Free and Informed Consent Form*, if applicable to the proposed research (see companion document, Attachment B, *Guidelines for Free and Informed Consent*); and

(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 based on their affiliation with CCNM. The second type of expedited review focuses on the status of on-going research. The following provides details of both types of expedited review.

(a) **Expedited Review by the Chair of the Research Ethics Board:** The Chair of the **Research Ethics Board** may provide expedited review for research projects that clearly involve no more than minimal risk.

Common Cases of Expedited Review by Chair of Research Ethics Board

Proposals that have been reviewed by another Canadian **Research Ethics Board** must also be reviewed by CCNM's **Research Ethics Board.** However, submission of a copy of the researcher's previous Research Ethics Board approval may help eliminate duplication and expedite the review, where the proposed research meets the standard of minimal risk.

(b) **Annual Renewal:** The **Research Ethics Board** must receive an update on the status of research once every twelve months (until the research is complete) for any research that continues beyond a one-year period. This is required for research proposed to take more than one year to complete, as well as any research originally expected to be completed within one year, but which continues beyond a year.

With annual renewal, it is **expected** that there has been no change in the research design specified in the most recent proposal approved by the **Research Ethics Board.** If there has been no change in the research design, this will be stated explicitly in writing in a brief memo from the principal researcher addressed to the Chair of the **Research Ethics Board**.

P3. Monitoring the Status of Research

The **Research Ethics Board** will monitor the status of on-going research to verify that it conforms to the research proposal approved by the Board. The principal researcher will be responsible for providing any of the following types of updates that may apply during the life of her/his research project. The three primary types of up-dates are: **annual renewal**,

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 REB must be satisfied that the design of a research project meets appropriate standards of scholarly review. Depending on the nature of the project, the REB may insist that it pass appropriate peer review and may when necessary establish an ad hoc independent external peer review committee. The report of the peer reviewers will be shared with all members of the REB.

In carrying out its review, the REB will take a proportionate approach based on the general principle that the more invasive the research, the greater should be the care in assessing it. Accordingly, full review by the REB is the default requirement for all research involving human subjects and expedited review will only occur when the Chair of the REB is confident that the project will not exceed the minimal risk threshold. Any course-based research will be reviewed by the Director of Research, in consultation with the Chair of the REB, to determine whether REB review is required.

Individuals preparing applications for ethical review are advised to consult the Tri-Council Policy Statement for more detail about the ethical considerations involved in ethical review. The Statement is available online through the following websites: www.cihr.ca, www.nserc.ca, and www.sshrc.ca.

P4.2 Decisions of the Research Ethics Board

Where feasible, the **Research Ethics Board** will endeavour to reach decisions by consensus. In accordance with the Tri-Council Policy, in the event that consensus cannot be attained, a decision will be reached under the procedural rule that requires a simple majority of fifty percent plus one, which will be the standard required in a vote by the **Research Ethics Board** to approve or reject a research proposal. The principal researcher will be given written communication of the decision by the **Research Ethics Board** (with reasons for negative decisions) as soon as possible.

P4.3 Reconsiderations

An applicant has the right to respond in writing to a negative decision by the **Research Ethics Board.** The applicant will be invited to be present to discuss the application with the Board prior to a decision. The applicant may not be present when the Board is making its decision. If the Board decision remains negative, then the decision is final and the applicant will be advised promptly. An applicant may resubmit a revised protocol for the same research project but the revised protocol must address all of the issues of concern identified by the Board.

P5. ALLEGATIONS OF MISCONDUCT

Any allegations of misconduct by any of the research team members on a specific research project must be made in writing to the College's legal counsel. All allegations will be promptly investigated pursuant to the CCNM Policy on Integrity in Research and Scholarship.

P6. Research Ethics Board

P6.1 Membership

In accordance with the Tri-Council Policy Statement, CCNM's **Research Ethics Board** will consist of at least five members, including both men and women, of whom:

a) at least two members have broad expertise in the methods or in the areas of research that are covered by the **Research Ethics Board**;
b) at least one member is knowledgeable in ethics;
c) at least one member is knowledgeable in the relevant law; this is advisable but not mandatory for other areas of research; and
d) at least one member has no affiliation with the institution, but is recruited from the community served by the institution.

Quorum for any REB meeting requires the presence of these minimum membership requirements.

P6.2 Meeting Protocol

The **Research Ethics Board** will meet at least on a quarterly basis and more frequently if required to review research applications and to discuss issues pertaining to their mandate. Minutes of the meetings will document clearly all decisions of the **Research Ethics Board** in reviewing research applications; reasons for rejection of applications shall be recorded with particular care. The research application itself will be retained as part of the minutes.

P6.3 Schedule of RESEARCH ETHICS BOARD Meetings

The **Research Ethics Board** will meet each year in September, November, February and May and additionally at the call of the Chair on an as needed basis.

P6.4 Conflict of Interest

When the REB is reviewing research in which a member of the REB has a personal interest (e.g. as a researcher) that member is required to declare such conflict of interest and that member is not permitted to be present when the REB is discussing or making its decision. In the event there is a dispute as to whether a conflict of interest exists, the Chair will make a final determination. The research proposer is entitled to know why a REB member has been excluded and is entitled to offer a rebuttal.

P7. Appeals

If a researcher is not in agreement with a decision of the REB and has been unable to resolve the matter through discussion and reconsideration, the researcher may appeal the decision to the Research Ethics Appeal Board. The Board's membership will comply with requirements of the Tri-Council and will operate pursuant to the same procedures as the REB except that they will only meet on an as needed basis. The Appeal Board will be

provided with the previous decision of the REB. There will be no overlap in membership of the REB and the Appeal Board.

P8. Review Procedures for Ongoing Research

All research studies must be reviewed on an annual basis. The REB may require that research that poses significant risk be reviewed more frequently. Additionally, the REB might require:

- Formal review of the process of free and informed consent;
- Establishment of a safety monitoring committee;
- Periodic review by a third party of the documents generated by the study;
- Review of reports of adverse events;
- Review of patient's charts; and/or
- A random audit of the process of free and informed consent.

P9. Review of Research in Other Jurisdictions

The fact that a research proposal has been approved by another REB or its equivalent or that the research will be performed outside of the jurisdiction of CCNM or outside of the country does not absolve the CCNM REB from carrying out its mandate. Any research to be done outside of Canada must be done in accordance with the Helsinki Accords and other international standards of ethical research.

P10. Free and Informed Consent

Applicants must demonstrate that all prospective research subjects, or authorized third parties, have been given the opportunity to give free and informed consent. This consent will ordinarily be obtained in writing and when necessary an interpreter must be used. The REB may permit research to be done that alters or waives these requirements if it is satisfied that:

- The research involves no more than minimal risk to the research subjects;
- The research does not involve a therapeutic intervention
- It is unlikely to adversely impact the rights and welfare of the research subjects;
- It would not be practical for the research to be carried out without the alteration or waiver;
- After participation the research subjects will be provided with additional relevant information whenever possible and appropriate.

P11. Review of Research Involving Vulnerable Persons

In order to protect vulnerable persons, individuals who are not legally competent will not be permitted to become research subjects unless the research question can only be addressed using individuals with that identified group, if free and informed consent is sought from the authorized representatives of the individuals and if the research does not expose such individuals to more than minimal risk without the potential for direct and proportionate benefits for them.

At a minimum, the REB will insist that the following conditions are met:

- 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.