Attachment B
Guidelines for free & informed consent

CCNM requires an information letter and
- a free and informed consent form.

A copy of each of these documents must be submitted with the application for ethical review.

The information letter is intended to provide the prospective subject with the details of your project, with particular emphasis on what participation will involve for the subject.

The free and informed consent form is used to obtain written confirmation from the subject that s/he has received an explanation of your project, understands what participation will involve, and consents to participate in the research.

In situations where prospective human subjects may not have the capacity to provide informed consent as the result of a language or communication barrier or where prospective subjects are not legally competent to provide informed consent, informed consent must be obtained from a third party.

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- In the case of a language or communication barrier, informed consent must be sought using an interpreter of the prospective human subject's choosing who is fluent in the prospective subject's language of preference or fluency and in the researcher's language of preference or fluency.

- In the case of a prospective human subject who is not legally competent, informed consent must be obtained from an individual who is responsible for decisions concerning the well-being of the subject (e.g. parent, guardian, or care-giver).

In situations where a third party is used to gain free and informed consent, the design of the information letter and free and informed consent form must reflect this fact.

Designing the Information Letter and Free and Informed Consent Form

CCNM's Research Ethics Board requires that you address or include the following 15 items in any information letter that you develop.

1. The name of the principal researcher, co-investigators (if any), and research supervisor (if supervised).

1[1] In accordance with the Tri-Council Policy Statement, an exception to the requirement of free and informed consent applicable at CCNM will be research conducted through naturalistic observation (refer to article 2.3, Tri Council Policy Statement, for details about naturalistic observation). Please note: use of the naturalistic observation method does not exempt a research proposal from ethical review. Researchers who intend to use the naturalistic observation method must have their research reviewed by CCNM's Research Ethics Board.

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2. The researcher's educational affiliation, or sponsoring agency.
3. The title of the research project (as written on the application to the Research Ethics Board).
4. A clear statement indicating that the prospective subject has been asked to participate in the research project.
5. A clear statement indicating that the subject's participation is voluntary and not binding, and that s/he has the right to decline or withdraw participation at any time without negative consequences.
6. A clear statement of the purpose or goals of the research, description of the procedures

Your participation in all of these activities will take approximately [Specify total amount of time and the amount of time required for each activity] .

[Specify whether there are any known harms that might arise from participation for the subject. If there are harms anticipated, specify what they might be, how serious they might be, the probability of occurrence, the precautions that will be taken to minimize the probability of occurrence, and the actions that will be taken to minimize harm if it should occur.]

The information you provide/Your identity…[explain how confidential ity will be handled in the project] .

Once I have had my thesis/research report accepted by advisor/faculty research committee…[explain how the data collected about the subject will be disposed] . Once my thesis has been accepted, you can obtain a free copy of it by…[specify when and how the subject can obtain a copy of the research] .

You will be compensated for your participation…[provide details of any compensation that might be offered, including conditions that may apply and when the subject will be com pensated] .

I have listed my contact information for you below. Should you choose to participate in the research, you can contact me at any time during the research project with any questions that you may not have yet considered. Also listed is the contact information for my Research Supervisor, Professor ___ _____, whom you can contact at any time to verify the accuracy of this information letter.

Thank you for considering participation in my research project.

Sincerely,

[PR's Name] [Research S upervisor's Name]
[PR's Contact Information] [Research Supervisor's Contact Information]

Free and Informed Consent Form
for
[Title of Research Project]

I, _____, have carefully read the attached Information Letter for the [title of research project] . [PR's name] has explained this project to me and has answered all my questions about it. I understand that if I have additional questions, I can contact

Agreement to Participate

_____ _____

Participant's Signature Date

_____

Print Name