Attachment B
Guidelines for free & informed consent

CCNM's **Research Ethics Board** requires that researchers obtain free and informed consent from each prospective subject or participant they wish to use in their research project or study[1][1]. Free and informed consent is normally obtained in writing through the use of a two-part document:

- 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. [2][2]

- 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).

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[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**.

[2][2] Adapted from Dalhousie University's *Submission Guidelines for Faculty and Graduate Thesis Research: Social Sciences and Humanities Research Ethics Board*

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 that will be involved in the research project and how the goals of the project will be achieved.
7. A clear description of the potential benefits to the prospective subject that may arise from participation, if any.
8. A clear and complete description of what the research subject will be asked to do (including a description of any test or instruments used in the study).
9. A realistic estimate of the expected length of time that the subject will be involved in the study.
10. A clear description of any foreseeable harm to the subject (physical, emotional, or psychological) that may arise from participation, or a statement that there are no known harms anticipated, if that is the case.
11. A clear explanation of how the subject's confidentiality will be protected or how the subject's anonymity cannot be guaranteed.
12. A clear statement of how the researcher plans to dispose of the data collected during the project.
13. Complete details of any compensation that the prospective subject will receive for participating, including when the subject will be compensated.
14. Details about how the subject can obtain a completed copy of the research results or report.
15. The name and contact information of the researcher and research supervisor/thesis advisor (if applicable), whom the subject can contact at any time during the project with inquiries or concerns about the research project.

CCNM's **Research Ethics Board** requires that you include the following 4 items in the free and informed consent form that you develop.

1. The title of the research project (as written on your application to the **Research Ethics Board)**.
2. The subject's name.
3. A statement that the subject has read the detailed description of the research project, has had any questions answered to his/her satisfaction, and has agreed to participate in the research project as it has been described.
4. A statement that the subject understands that they are free to withdraw from the study at any point and identifying the consequences (if any) of this withdrawal.
5. A space for the date and for the subject to print and sign his/her name.

CCNM's **Research Ethics Board** also requires that no statement appear in the information letter or the free and informed consent form to indicate that subjects or participants consent to limit or waive their legal rights or that indicates that subjects or participants can or will release the researcher, the researcher's sponsor and/or affiliated institution from liability for negligence.

Example of an Information Letter and Free and Informed Consent Form

The sample below contains an information letter and free and informed consent form that you can use as a template to develop these items for your research project.

SAMPLE Information Letter

for

[Title of Research Project]

Date

Dear Madam/Sir,

I am requesting your voluntary participation in my research project, which is entitled (in bold) _____.

My name is **[Principle Researcher (PR)]** and I am a student in the Doctor of Naturopathic Medicine program at CCNM. I am independently conducting a qualitative research project, which will fulfill partial requirement for my diploma. This research project is supervised by my advisor, _____ _____, who is professor of **[discipline]**. Consequently, **[research supervisor/professor's name]** can be reached at anytime during this research project to verify everything that I outline in this information letter and to answer any questions about the project that you may have. His/her contact information is listed at the bottom of this letter along with my contact information.

The purpose of my research project is to learn more about…**[outline details of the purpose]**
What I learn as a result of this research may benefit…**[if applicable, outline how groups may benefit from the research and how the subject may benefit directly]**.

I intend to accomplish the goal(s) of the research by **[specify the general approach to the research, e.g., conduct interviews with approximately x subjects over a x-month period…]** The project will begin…**[specify start and end dates for the research project]**.

As indicated in the opening sentence above, participation in this research project is voluntary and not binding. If you choose to participate, you may decline or withdraw from further participation at any time during the research project without negative consequences.

As a participant in this research project, you will be asked to do the following:
[provide a clear and complete description of what subjects will be asked to do, including a description of any test or instruments used in the study]

Example of Descriptions:

1. Complete a questionnaire to provide background and demographic information (age, gender, education…) **[provide complete details including why this information is collected]**;
2. Take part in two interviews concerning **[subject matter of interview]**, which will take place…; and **(continue description of 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 confidentiality 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 compensated]**.

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 Supervisor'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 **[PR]** at any time during the research project. I also understand that I may decline or withdraw from participation at any time without negative consequences.

My signature below verifies that I have agreed to participate in the **[title of research project]** as it has been described in the Information Letter. My signature below also verifies that I am fully competent to sign this Consent Form and that I have received a copy of the Information Letter and the Informed Consent Form for my files.

Agreement to Participate

_____ _____

Participant's Signature Date

_____

Print Name