Application for Research Involving Human Subjects

IMPORTANT NOTE

1. Researchers who wish to access CCNM patients, faculty or students as research subjects must seek administrative approval from the Dean. Approval of ethical review applications does not constitute permission to access CCNM patients, faculty or students.

2. Researchers who wish to access CCNM staff, excluding faculty, as research subjects must seek administrative approval from the Executive Director, Human Resources. Approval of ethical review applications does not constitute permission to access CCNM staff.

3. Applications for ethical review at CCNM must be submitted using this form without modification to the format. Questions about this form should be directed to CCNM's REB Chair, REBChair@ccnm.edu

Date of Submission: (Day-Month-Year)

Date of Revision(s), if applicable: (Day-Month-Year)

SECTION I: TYPE OF REVIEW REQUESTED

* Refer to CCNM's *Policy for Research Involving Human Subjects* for guidance on type of review to request

[ ] Expedited Review by Chair or delegate

[ ] Full Review by Research Ethics Board

SECTION II: BACKGROUND INFORMATION

1. Name, Contact Information, and Educational or Other Affiliation of Principal Investigator

2. Name(s) and Contact Information of Co-investigators (s) Involved in the Proposed Research

3. Title of Proposed Research Activity

4. Dates:

    a. Proposed Start: (Day-Month-Year) _____
    b. Proposed Completion: (Day-Month-Year) _____ of the Study.

5. List of Funding Sources (including status of funding applied for and approved, if applicable)

6. Explanation of whether the research, as proposed in this application, will proceed even if funding is not obtained.

SECTION III: APPROVAL BY THE DEPARTMENT OF RESEARCH & CLINICAL EPIDEMIOLOGY

This application has been reviewed and approved for submission to the Research Ethics Board by either the Executive Director or the Director of Research. Please indicate who provided approval for the submission.

Approved by: _____

SECTION IV: DETAILS OF PROPOSED RESEARCH PROJECT

1. **Describe the Study Type (e.g. Pilot Study; Clinical Trial, Phase #; Observational Cohort Study; Qualitative Study).**

2. **If this study is related to another previously approved research please provide the proceeding study title and the CCNM REB identification number.**

3. **If tissue samples will be taken as a component of this research please specify type:**

   Blood Urine Feces Saliva Hair

   Other: _____

   Will genetic analyses be conducted? Y/N

4. **Please describe the intervention**

5. **Health Canada Approval**

   If the intervention involves the use of natural health products, prescribed substances, drugs, or medical devices, a clinical trial application must be submitted to the appropriate Health Canada agency.

   - Health Canada Application/Approval is attached
   - **Health Canada Application/Approval will be forwarded**
     Expected date: _____

6. **Other review or approvals**

   If the protocol is to be reviewed by another internal review board or research ethics board, please provide details. If none required state 'none'.

   a. **Other review board:** _____
   b. **Letter of approval attached: Yes ___ or date expected:** _____

Please submit a Research Study Proposal and include the following headings:

1. **Title and the name of the Principal Investigator.**

2. **Background Purpose and Objectives (5 page max including references)**

   a) Please state clearly the hypothesis to be tested in lay terms
   b) Provide the rationale for the study
   c) What are the broad and specific objectives of the study
   d) Describe the significance of the proposed study

3. Recruitment

a) How will the research participants be identified and recruited?
b) Describe any incentives (if any) used to encourage recruitment

4. Sample size determination

a) How did you decide on the sample size used?
b) If not a pilot study, provide a power analysis to justify the sample size**.**

5. Description of Population

a) Inclusion criteria
b) Exclusion criteria

6. Methodology (max 8 pages)
Include a summary of methods and procedures to be used in the study including (state n/a if not applicable):

a) Treatment (s)
    a. Intervention group(s)
    b. Control group
b) Randomization
    a. Describe the process of sequence generation and allocation concealment
c) Flow of participants or human data through the study
d) Study setting
e) Outcomes measured
f) Frequency of follow up visits and data collection
g) Data management
h) Statistical analyses
i) Study timetable

7. Risk and patient safety (include references)

a) Potential adverse effects
b) Other potential risks
c) Assurances of maintaining patient/participant confidentiality

8. Investigator Team

Provide information on the different roles of the investigators involved. Clearly state which investigators will have direct contact with research participants or identifying or confidential information. Indicate who will be responsible for the conduct of the informed consent process.

9. Resources

Provide justification that you have the required financial and human resources to effectively complete the study.

10. Informed consent

Provide an informed consent form as described in attachment B. Participants must be given adequate time to read and understand the informed consent and have the chance to discuss the study and consent with the coordinator. The setting in which the informed consent will be given should be described.

11. File and data storage

Health Canada requires that clinical trial data be kept for a minimum of 25 years; CCNM requires that other research data be retained for a minimum of five years. Please describe the mechanism through which you propose to maintain any data and files you generate and how confidentiality will be ensured. Also, how will the research information be disposed of.

12. Fee for submission and renewal

In cases where there are no employees of CCNM as members of the study team, there will be fees. There will be a $1000.00 fee for the initial submission; this will ensure a full review by the Research Ethics Board. If only expedited review is required and the application meets the standards for this and minimum risk then only $500.00 fee is required for review. Annual renewal for the study under primary supervision by CCNM's REB requires a $300.00 renewal fee. Substantive amendments to the protocol that require full board review will incur a fee of $200.00. For small amendments that do not require board review, no fee is charged. Requests and permissions to have fees adjusted will be handled by the Executive Director, Research, or Director, Research.

Your signature(s) below verifies that you have read and understood CCNM's ***Policy for Ethical Review of Research Involving Humans*** and that you have had the opportunity to seek clarification about the Policy. It also verifies that you understand your obligation to conduct research in an ethical manner and to provide any updates, and fees as outlined in the Policy that may apply to your research activities throughout the duration of the research.

	Principle Investigator
(Print Name)	(Position)

(Signature)	(Date)
(Print Name)	Co-Investigator (Position)
(Signature)	(Date)
(Print Name)	Co-Investigator (Position)
(Signature)	(Date)
(Print Name)	Co-Investigator (Position)
(Signature)	(Date)
(Print Name)	Co-Investigator (Position)
(Signature)	(Date)
(Print Name)	Co-Investigator (Position)
(Signature)	(Date)

	Co-Investigator
(Print Name)	(Position)
(Signature)	(Date)