Guidelines for Completing the Application for Ethics Review of Research Involving Human Participants

1. PURPOSE

These guidelines are intended to assist researchers in completing the application for Ethics review. Any concerns or questions not addressed by these guidelines can be directed to the REB Chair.

2. RESEARCH PARTICIPANT INVOLVEMENT

- Any project (research or other studies) connected with VCC that involves *living human participants* or *human biological materials* must be reviewed and approved by the VCC Research Ethics Board (REB) before work is started.

- *Clinical* projects are those that involve the administration of *health-related interventions* including but not limited to the following: surgery, the administration of drugs, medical imaging, diagnostic techniques, biopsies, the collection of blood or other biological materials, and/or the review of medical records. Clinical projects involving the administration of drugs must also be approved by the Therapeutic Products Directorate of Health Canada.

- *Behavioural* research engages participants with questionnaires, interviews, observations, testing, video and audio taping, and/or other non-invasive activities.

3. TCPS TUTORIAL

The Interagency Advisory Panel on Research Ethics' online TCPS 2 (Tri-Council Policy Statement) Tutorial Course on Research Ethics (CORE) has been adopted by the VCC REB as the minimal level of research ethics training required for researchers seeking approval for their research projects.

All principal investigators applying for ethics approval are required to complete the online TCPS 2 tutorial.

4. SUBMISSIONS TO THE BOARD

- Submissions to the Research Ethics Review Board must be made on the attached Request for Ethical Review (Form 1).
- Because this form is designed to deal with a range of possible projects across the institution, not every question is applicable to every project. Applicants should simply enter 'N/A' when this situation occurs.
- Contact the Research Ethics Review Board via the Centre for Instructional Development for more information.
- Submissions that do not conform to these guidelines may not be reviewed by the REB.

5. HELP

Help with any aspect of the submission may be obtained from the chair of the Research Ethics Board.
Responses to some specific questions (FAQs) related to FORM 1 "Request for Ethical Review" can also be found on Page 8 of this document: please see if your answer is there before contacting the REB Chair.

6. MEETINGS

- Research Ethics Board (REB) meetings are held throughout the year. For meeting dates, check with the Centre for Instructional Development.
- Submissions are reviewed on an ongoing basis.

7. SUBMISSIONS

- One electronic copy of the complete *Request for Ethical Review* (FORM 1) containing all attachments must be submitted to the Research Ethics Board Chair through REBsupport@vcc.ca, subject line "ATTN: REB CHAIR".

- Submissions to the REB must be in compliance with the *Checklist for Submissions to the VCC Research Ethics Board* (FORM 7). Submissions that are not in compliance with these stated requirements may not be reviewed.

- NOTE: Forms used for REB applications are revised periodically. Please be sure you have the most recent version of the forms . The CID website will hold the most recent versions of these forms. Applications using other than the most recent version may not be reviewed.

- Please include the research protocol/research plan in the application package.

8. DELEGATED REVIEW

- Delegated Review of proposed or ongoing research is conducted by the Chair and two Board members rather than by the entire Research Ethics Board. Delegated review will entail the same degree of detail but will be conducted by a representative group within the REB.

- Situations which may be dealt with by delegated review include the following:

  (a) non-invasive collections of hair, nail clippings, deciduous teeth, excreta, external secretions for research purposes
  (b) placenta or amniotic fluid collected as a consequence of normal labour and delivery
  (c) recording of data using non-invasive procedures routinely employed in clinical practice (e.g. EEG or EKG)
  (d) moderate exercise by healthy volunteers
  (e) the study of existing data, documents, records, pathological specimens or diagnostic specimens

- Delegated Review may also be used in these cases:

  (a) the applicant's response to provisos issued by the Research Ethics Board
  (b) amendments

(c) annual review
(d) open label extensions

- For applications involving minimal risk, the REB Chair may perform the appropriate duties independently and report back to the delegated review panel at the first opportunity.

The Chair may determine that any of the above categories should be reviewed at a Research Ethics Board meeting.

9. SPONSORED RESEARCH

- All *Requests for Ethical Review* must include information regarding source(s) of funding in BOX 5 and BOX 41. Please list expected funding sources (may be multiple). If funding has not been requested for the project, list as unfunded.

- Where funding requires ethical review, there must be a direct title and sponsor match between the grant application and the Certificate of Approval.

- Where research is receiving funding, a copy of the application for funding should be included with the submission (BOX 41).

- Where research is receiving funding, a statement of any relationship between the funder and the recipient of the funding should be included with the submission (BOX 42).

10. INTERIM APPROVALS

- Written proof of agency consent is required for projects carried out at other institutions. When agency approval cannot be obtained without prior approval by the Research Ethics Review Board, a letter of conditional approval will be issued for submission to the agency if all other aspects of the protocol are satisfactory. Applications should be submitted concurrently to the Research Ethics Board and the agency.

- Projects which require ethical review in order to obtain research grant funds with which to develop questionnaire, survey, or interview materials may receive conditional approval with the understanding that any part of the project dealing with research participants cannot commence until the Board has formally approved a final protocol. Provide as much detail as possible on the preliminary *Request for Ethical Review* (FORM 1) making it clear that conditional approval is being sought.

11. THESIS OR DISSERTATION RESEARCH

- Applications to do research for a thesis or dissertation must include a letter from the thesis or dissertation advisory committee verifying that the research proposal has been approved (BOX 10).

12. CLASS PROJECTS

- Class projects that involve research participants and entail minimal risk will require a *Request for Course Designation* (FORM 12). For further details, contact REBsupport@vcc.ca.

13. CONSENT

- VCC policy requires written consent from the research participant(s) in all cases other than those limited to questionnaires completed by the participant (whereby completion of the questionnaire is understood to require the participant's consent). The necessary components of a consent form are listed under Item 15 of this document. A sample copy of the principal investigator's proposed consent form must be included with the *Request for Ethics Review* (FORM 1) and reviewed and approved by the Research Ethics Board before the participants are approached. Post-approval changes to the consent form must be submitted to the REB along with a *Request for Continuing Review or Amendment of an Approved Project* (FORM 3).

14. DECEPTION

- If your study involves deception, you must complete FORM 1A, *Deception*, in addition to the *Request for Ethics Review* (FORM 1). Partial disclosure or deception in research may be permitted under exceptional circumstances.

15. PARTICIPANT RECRUITMENT AND CONSENT FORMS

- Ideally, individuals should make the initial contact about participating in a research project. Whenever the relationship between investigator and research participant is such that coercion could be perceived (e.g. a principal investigator's students, staff, or family members who are invited to participate in a study), non-coercive means for inviting participation should be used. An example would be the posting of notices to invite volunteers from the entire group concerned (e.g. the whole student body rather than a class, or all employees at the institution).

- *Telephone Contact:* Contacting potential participants by telephone as the initial contact is discouraged. However, in surveys where sample selection is based on information available in the public domain and not considered third-party (see below), initial telephone contact may be allowed. If your study involves such contact, you must also complete FORM 1B, *Telephone Contact*, in addition to the *Request for Ethics Review* (FORM 1).

- *Third Party Recruitment:* When participants' names must be obtained from a third party who is obligated to maintain confidentiality (i.e. the physician/patient relationship, instructor/student), the third party must ask the individuals for permission to release their names to the researcher. This may also be done by asking the third party to distribute an introductory letter describing the study, with details on how to contact the researcher if they are interested in participating. Details of how third-party recruitment will be accomplished and copies of any letters sent to either the third party or to the subject via the third party must be provided. If the researcher already has some form of contact with the individual (i.e. a nurse's contact with a patient) the circumstances of that contact must be fully described.

16. CONFIDENTIALITY OF SUBJECT INFORMATION

- The Board recognizes sponsor companies' need to monitor their studies; however, release of identifiable records is a contradiction of the statement required in all consent forms that assures that the identity of the individuals will be kept confidential.

- In order to allow monitoring but at the same time protect confidentiality, the Board has formulated the following practice:

  (a) Records may be made available to a scrutineer from the sponsor company or granting agency provided that it is done in the presence of the principal investigator or a designate and that the scrutineer sign the VCC REB's *Confidentiality Agreement* (FORM 11).

  (b) Any material sent to the sponsor company or granting agency must be identified by code numbers (held in confidence by the principal investigator) or not identified at all.

- The Board strongly believes research participants should not be identified individually. Where this is not possible, pseudonyms or random letters should be considered. It is the investigator's responsibility to ensure the protection of the research participants. In addition, the research participants must be made aware of how they will be identified, and such procedures should be in bolded in consent forms.

- An example of an acceptable confidentiality statement for the consent form is as follows:

  "Any information resulting from this research study will be kept strictly confidential. Your medical record may, however, be inspected by Health Canada (HC) or a representative of the sponsor Company in the presence of the Investigator or a designate. Copies of relevant data which identify you only by code number may be required by HC or the sponsor Company, but you will not be identified by name, initials, or date of birth."

17. COMPENSATION FOR INJURY

- The Research Ethics Board requires, as a matter of practice, the deletion of all statements that refer to compensation for injury.

- The consent form is part of the process of providing individuals with enough information about the research and their prospective role to enable them to decide whether or not to participate. It is not a legal document and should not include any statements that may be misunderstood as waiving any of a participant's rights or privileges.

Examples:

(a) *Medical Insurance*:
Statements regarding medical insurance or the cost of medical care to the participant are inappropriate in Canada as there is universal coverage both for routine care and care related to consequences of research studies.

(b) *Compensation*:
If a study offers payment for the time, inconvenience, or loss of wages involved, the details should be provided in the consent form. If payment of this sort is not offered, it is better to say nothing, rather than the following *unacceptable* statement, "No other compensation is available."

The following compensation statement is *acceptable:*

"There will be no costs to me for participation in this study. I will not be charged for the study drug(s) or any research procedures. In the event that I become ill or injured while participating in this study, necessary medical treatment will be available at no additional cost to me through my medical plan."

18. BOARD PRACTICE

- Submissions that do not comply with Board policy regarding confidentiality and compensation for injury will not be put forward for review.

19. AMENDMENTS, RESPONSE TO PROVISOS & ADVERSE EVENTS

- Information submitted after a *Request for Ethics Review* (FORM 1) has been sent to the Research Ethics Board chair may include the following:

  (a) response to provisos (requested changes to a submitted protocol)
  (b) amendments to an existing approved protocol
  (b) additional material regarding an existing approved protocol (e.g. an updated version of a brochure)

- Procedure:

  (a) submit any request for changes to an existing approved protocol on the *Request for Continuing Review or Amendment of an Approved Project* (FORM 3)
  (b) identify the protocol by Research Ethics Board approval number
  (c) summarize and highlight the changes or amendments for the Research Ethics Board
  (d) include a copy of the revised consent form with changes highlighted
  (e) do not send duplicates of unchanged documents; refer to already submitted documents
  (f) for a change of title that includes a change in the protocol, complete a *Request for Continuing Review or Amendment of an Approved Project* (FORM 3), obtain the necessary signatures and return it to the Research Ethics Board

*Note: In order to change the principal investigator, a request should be made in writing by the original principal investigator with written confirmation from the sponsor.

- The Chair may determine that any of the above alterations should be reviewed at a formal Board meeting.

20. ADVERSE EVENT REPORTS

- Investigators are required to report adverse events occurring at their own site to the study sponsor and adverse events occurring at all sites to the Research Ethics Board using FORM 4, *Adverse Event Report*.

- The Research Ethics Board has established the following requirements for the reporting of adverse events:

(a) Copies of adverse event reports (FORM 4) must be accompanied by a memo from the principal investigator giving an assessment of the seriousness of the side effects and whether they compromise on ethical grounds the continuation of the study.

b) The investigator's assessment must also indicate whether a change is required to the protocol or to the consent form. If a change is required, a revised copy of the protocol and consent form with the changes highlighted must be included in the submission of a *Request for Continuing Review or Amendment of an Approved Project* (FORM 3).

21. CONTINUING RESEARCH

- In accordance with Article 2.8 of *TCPS 2 (2014*), the REB is required to implement procedures for the continuing review of ongoing research that it approves. BOX 49 of the *Request for Ethics Review* (FORM 1) requires that each submission include a proposal from the applicant on how they intend to comply with this requirement.

Addendum to Guidelines: INSTRUCTIONS FOR COMPLETING THE ETHICS REVIEW APPLICATION AND FREQUENTLY ASKED QUESTIONS

These instructions have been developed to assist ethics review applicants: "boxes" in the following statements refers to the corresponding fields in the application form.

BOX #1: Who is the Principal Investigator?

The principal investigator of a research project is the person who has overall responsibility for conducting the research.

BOX #2: Who is the Supervisor of the Principal Investigator?

The supervisor of the principal investigator is the person to whom the principal investigator reports as an employee of VCC or another agency, or the thesis advisor (or equivalent) if the researcher is a student.

BOX #3: Who is the VCC contact?

The VCC contact information is required only if the principal investigator is external to VCC. Usually, the VCC contact would be in a position to provide the approval for the research to be conducted within the School/department (Dean or Department Head).

BOX #4 What is the difference between Clinical and Behavioural research?

See Item 2, page 1 of this document.

BOX #6: What is meant by project period?

The project period refers to the period for which REB approval is requested. While approval decisions are for a period of one year (after which the principal investigator may request an extension), the total contemplated period of the project should be disclosed at this point.

BOX #9: What title should be used for my research?

It is important that a title be chosen that will be used throughout your research. The title shown here will have implications for funding applications and for publication opportunities. The title shown here will also be shown on the REB *Notification of Status* (certificate of approval).

BOX #10: What is the difference between BOX #10 and BOX #14?

BOX #10 requests a summary of the purpose and objectives of the research. BOX #14 requests a summary of the methodology and procedures (the protocol) through which the objectives will be reached.

BOX #11, 12, 13: Do I need these signatures prior to submitting my application for ethics review?

Under unusual circumstances (normally related to timing) you may submit an application for review prior to securing the signatures. If you feel it is appropriate to do so, discuss this option with the chair of the REB.

BOX #16: What is a multisite trial?

A multisite or multi-centred trial is a research project that will be conducted within two or more physical sites. Normally REB approval will be required from each of the sites contemplated as part of the study. That may not be the case in all studies but where VCC is one of several sites for a single study, our REB will need to review the application for ethics approval.

BOX # 41: What funding information is required?

The REB must be in a position to reflect on the presence or absence of any conflict of interest (real or perceived) with respect to the projects we review that have received funding from any source. To do so we need to know where the funding is coming from and where it is going. The best way to do that is to request the funding applications that were made with respect to the research for which an application is being submitted.

BOX # 41: What start and finish dates are required here?

The start and finish date requested here refer to the start and finish date for the funding of the research.

BOX # 43: What is meant by Agency Officials?

Agency officials are individuals from a host agency or institute or corporation that will be used in conducting the research. For instance, School Boards generally require consent and approval for researchers to access their student population. If a study will be accessing any non-VCC agency or entity, we will be asking for a letter from Agency Officials confirming that the researcher has permission to access those sites.