BCIT Research Ethics Board

GUIDELINES FOR COMPLETING APPLICATIONS FOR ETHICAL REVIEW OF ACTIVITIES INVOLVING HUMAN PARTICIPANTS

1- PURPOSE

These guidelines are intended to assist researchers in completing the application for ethics review. If the guidelines cannot answer any questions you may have please direct your queries to the Chair of the REB at research_ethics@bcit.ca.

2- HUMAN PARTICIPANT INVOLVEMENT

- Any project (research or other studies) involving human participants carried out under the auspices of BCIT must be reviewed and approved by the Research Ethics Review Board (REB) before work is started. Generally, REB review and approval is required if:
  (a) any of the researchers associated with BCIT,
  (b) any of the participants is associated with BCIT,
  (c) if the recruitment of participants is done by anyone associated with BCIT.
  In this context, "associated with BCIT" means that the individuals are participating as part of their association with BCIT. If individuals choose to participate in a project as private citizens, they will not be considered as "associated with BCIT".

- Clinical projects are those involving surgery, the administration of drugs, medical imaging or other diagnostic techniques, biopsies, the taking of blood or other specimens, the review of medical records or use of medical devices, where the risks to the participant could include physical harm etc. Clinical projects involving the administration of drugs must also be approved by the Therapeutic Products Directorate of Health Canada.

- Behavioural research includes questionnaires, interviews, observations, testing, video and audio taping, and other activities.

3- SUBMISSIONS TO THE REB

- Submissions to the Research Ethics Review Board must be made on the Request for Ethical Review
- Because this form is designed to deal with a range of possible projects across the Institute not every question is applicable to every project. Applicants should simply enter 'N/A' when this situation occurs.
- Contact the Research Ethics Review Board at research_ethics@bcit.ca for more information.
- Submissions that do not conform to these guidelines may not be reviewed by the REB.

4- HELP

- Help with any aspect of the submission may be obtained from the Chair of the Research Ethics Review Board at research_ethics@bcit.ca.
- Responses to some specific questions related to Request for Ethical Review can be found at the end of these Guidelines. Please see if your answer is there before you contact the REB.

5- MEETINGS

- Research Ethics Review Board (REB) meetings are held throughout the year. For meeting dates, check with the REB Administrator at research_ethics@bcit.ca.

- There is no specific deadline for submission of applications to the REB. How long the review process takes depends on whether a full review or a delegated review is required.

6- SUBMISSIONS

- An electronic copy of the complete Request for Ethical Review form including all attachments must be submitted to the Research Ethics Review Board at research_ethics@bcit.ca. This electronic copy need not include signatures. In addition, the applicant must submit one hard copy of the application with original signatures to the REB Administrator, Jenna Nordin, Applied Research Liaison Office, British Columbia Institute fo Technology, 3700 Willingdon Ave, Burnaby, BC, V5G 3H2.

- Submissions to the REB must be in compliance with the Checklist for Submissions to the BCIT Research Ethics Board. Submissions that are not in compliance 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. Applications using other than the most recent version may not be reviewed.

- Please include the research protocol/research plan in the application. Forms and attachments must be *collated and stapled or clipped together* - Do not use covers, binders, or file folders. Be sure to copy both sides of two-sided pages when copying. The REB will not check the content of each copy.

7- DELEGATED REVIEW

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

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

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 for:

a) the applicant's response to provisos issued by the Research Ethics Review Board
b) amendments
c) annual review
d) open label extensions

- For applications involving minimal risk the Chair may perform these duties 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 full Research Ethics Review Board meeting.

8- SPONSORED RESEARCH

- All *Requests for Ethical Review* must include information regarding source of funding in box 5 and box 41. Please list expected funding sources (may be multiple). In particular, list any funding that is from sources external to BCIT. If BCIT is providing the principal support then the project can be described as "BCIT funded", If no funding is involved the project may be described as "unfunded" or "self-funded".

- In some cases where an external funder requires the ethical review, there must be a direct title and sponsor match between the grant application to that funder and the *Certificate of Approval*.

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

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

9- INTERIM APPROVALS

- For projects carried out at other institutions, BCIT's REB will require written proof that the other institution has consented to the project being conducted before issuing its approval. When the other institution's approval cannot be obtained without prior approval by BCIT's REB, a letter of conditional approval will be issued for submission to the other institution, provided all other aspects of the protocol are satisfactory. Generally, we recommend that ethics applications should be submitted concurrently to BCIT's REB and to the other institution's REB.

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

10- THESIS OR DISSERTATION RESEARCH

- Applications to do research for a post-graduate thesis or dissertation (most commonly these situations arise when the researcher is associated with BCIT, or using participants associated with BCIT, and the researcher is also a post-graduate student at another institution). In these and similar cases, the researcher must include a letter from their thesis or dissertation supervisor indicating that the research proposal has been accepted by the external institution (box 9).

11- CLASS PROJECTS

- Class projects which involve human subjects and which entail minimal risk will require review in accordance with individual School research ethics review practices. For further details, contact the Research Ethics Review Board at research_ethics@bcit.ca.

12- CONSENT

- BCIT policy requires written consent from the research participant in all cases other than those limited to questionnaires completed by the participant. The necessary components of a consent form are listed in this form. A sample copy of the investigator's proposed consent form must be included with the Request for Ethical Review and reviewed and approved by the Research Ethics Review Board *before* the participants are approached. Post-approval changes to the consent form must be submitted to the REB along with the appropriate amendment form (Form 3).

13- DECEPTION

- If your study involves deception, you must complete page 11 "Deception Form" in addition to pages 1 to 10 of the Request for Ethical Review. Partial disclosure or deception may be permitted under exceptional circumstances.

15-. PARTICIPANT RECRUITMENT AND CONSENT FORMS

- Ideally, participants 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 to be a factor (e.g. in the case of a Principal Investigator's students, staff *or family* who are invited to participate in a study) non-coercive means for inviting participation must be used. A typical example would be posting of notices to invite volunteers from the entire group concerned (e.g. the whole student body rather than a class, or all employees of the institution)

- **Telephone Contact:** Researchers contacting a potential participant 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 page 12 in addition to pages 1 to 10 of the *Request for Ethical Review Form 1.*

- **Third Party Recruitment** When participants' names must be obtained from a third party who is obligated to maintain the confidentiality of their relationship (i.e. the physician/patient relationship, instructor/student), the third party must ask the participants 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 participant via the third party must be provided. If the researcher already has some form of contact with the participant (i.e. a nurse's contact with a patient) the circumstances of that contact must be fully described.

16- CONFIDENTIALITY OF PARTICIPANT INFORMATION

- The REB recognizes that human participants have a right to privacy and that as a general rule, projects will be designed so as to keep the identity of participants confidential. Furthermore, consent forms will normally assure the participants that their identity will be kept confidential.

- However, in special circumstances, sponsors may require copies of audio or video recordings of participants as a contract deliverable, or the project may involve collection or transfer of data about the participants using of the internet. In these situations, and others, it may not be possible to fully guarantee the participants' privacy. The researcher's first responsibility is to design the study so as to protect the participants' privacy as much as possible. And then, if privacy cannot be fully guaranteed, the researcher must clearly inform the participants of any factors that may place their privacy at risk. This information must be provided on the Consent Form so that the participant can make an informed decision whether to participate, with a complete understanding of the privacy risks that may be involved.

- The REB recognizes sponsor companies' need to monitor their studies, however, release of identified records is a contradiction of the general principle that the identity of participants will be kept confidential.

- In order to allow monitoring but at the same time protect confidentiality, the REB 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 his or her designate and that the records are not copied or the names recorded.

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 REB strongly believes participants should not be identified by name, initials, or date of birth. Where this is not possible, scrambled or random letters should be considered. It is the investigator's responsibility to ensure the protection of the research participant. In addition, the research participant must be made aware of how they will be identified, and such procedures should be in bold in consent forms.

- An example of an acceptable confidentiality statement for the consent form is,

  "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 Principal Investigator or his or her 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."

- Particular care should be taken when data about participants is collected or stored in databases in the United States. The US Patriot Act (enacted in October 2001) gives US government authorities broad powers to examine all information on databases held by US agencies (both public and private), with the added provision that individuals may not be informed that their information has been examined. Consequently, it is not possible to promise confidentiality to participants if their personal data is held by organizations subject to the Patriot Act. While survey instruments such as "SurveyMonkey" are extremely convenient, we discourage their use when they are based in the United States and governed by the Patriot Act. Researchers who feel they must allow data about participants to be transferred to US organizations must inform their participants (on the Consent Form) that their privacy is not guaranteed, because of the US Patriot Act.

17- COMPENSATION FOR INJURY

- The Research Ethics Review 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 the participant with enough information about the research and his/her prospective role to enable him/her to decide whether or not to participate. It is not a legal document and should not include any statement that waives or may be *misunderstood* as waiving any of the participant's rights or privileges.

Example:

a) Medical Insurance:
Statements regarding medical insurance or the cost of medical care to the participant (often used on Consent Forms in the United States) 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.*"** Note that the following statement on a Consent Form would be acceptable:
"***There will be no costs to participants for participation in this study. Participants will not be charged for the study drug(s) or any research procedures. In the event that a participant becomes ill or injured while participating in this study, necessary medical treatment will be available at no additional cost, through the participant's 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 formal Request for Ethical Review has been sent to the Chair, Research Ethics Review Board may include:

  a) response to provisos (requested changes to a submitted protocol)
  b) amendments to an existing approved protocol
  c) additional material regarding an existing approved protocol (e.g. an updated version of an investigator's 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 Review Board approval number

  c) summarize and highlight the changes or amendments for the Research Ethics Review 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 then send it to the REB Administrator, Jenna Nordin, Applied Research Liaison Office, BCIT, 3700 Willingdon Ave., Burnaby, BC, V5G 3H2.

  g) Note: changing the Principal Investigator requires that the original Principal Investigator makes the request for the change, in writing. Furthermore, the sponsor of the study must also provide written confirmation for the change in Principal Investigator.

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

20- ADVERSE EVENT REPORTS

- Principal 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 Review Board.

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

  a) Copies of adverse event reports must be accompanied by a memo from the Principal Investigator's giving his/her assessment of the seriousness of the side effects and whether, in his/her view, 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.

21- CONTINUING RESEARCH

- In accordance with TCPS, the REB is required to implement procedures for continuing review of ongoing research that it approves. Box 50 of the Request for Ethical Review form requires that each submission include a proposal from the applicant on how they intend to comply with this requirement.

22- CONFIDENTIALITY OF REB APPLICATIONS

- With exceptions noted below, the REB will treat information provided in the application form and attachments as confidential. This means that applications and attached documentation may be shared in confidence with all the members of REB and with any external reviewers selected by the REB. The information on application forms may also be shared in confidence with members of BCIT's senior administration and BCIT's Board of Governors.

- The REB will treat the project title, the name of the Principal Investigator, and the name of the project funder, as public information.

- The REB, at its discretion, may accept a request from the applicant to treat the name of the project funder as confidential. Such a request should be presented to the REB in writing, accompanied by a justification.

- The REB, as part of BCIT, is subject to Freedom of Information legislation. Therefore, the commitment to maintain confidentiality may be overridden by an order from a court of law.

Instructions for completing ethics review applications (FAQ)

These instructions, in the form of "Frequently Asked Questions", have been developed to assist applicants for ethics review in the completion of their applications. Where reference is made to "boxes" in the following paragraphs, it refers to the corresponding box 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 the conduct of the research. The duties of a Principal Investigator are outlined (in part) in the BCIT "Integrity in Research" policy # 6600.

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 BCIT or another agency, or the faculty advisor (or equivalent) if the researcher is a student.

Box #3: Who is the BCIT contact?

A BCIT contact is required only if the Principal Investigator is external to BCIT. Usually, the BCIT contact would be a BCIT employee who would approach the appropriate authority (e.g a Dean) to provide approval for the research to be conducted using BCIT's facilities or resources.

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

See guideline Item 2. (**Human Participant Involvement**)

Box #7: What is meant by project period?

The project period requested here refers to the period for which REB ethics approval is requested. While approval decisions are for a period of one year, the total contemplated period of the project should be disclosed at this point.

Box #10: What title should be used for my research?

The project title is the principal identifier of the application, and is retained in the REB's records. The title in Box 10 will be used by the REB, unchanged, for the duration of the research. It will also be shown on the certificate of approval issued by the REB.

The project title will be treated by the REB as public information. Applicants should take this into account when selecting the title.

Normally, the REB expects that the project title is descriptive of the research being done under the application. In the case of a large project, it may be necessary to submit more than one application to the REB to cover activities being done under different phases of the project. In such cases, titles selected for each application should not be exactly the same – they can be distinguished by adding "Phase 1", "Phase 2", etc. or equivalent, to the descriptive wording.

The REB will generally accept whatever title is proposed by the applicant. If the REB has a concern (e.g. similarity to another application) it will suggest an alternative.

Where research is funded by public granting agencies, applicants should bear in mind that such agencies generally require that the project title remain consistent on all funding applications. In such cases, it may be important to the granting agency that the same title be used on the REB application.

Box #11: What is the difference between Box 11 and Box #15?

Box 11 requests a summary of the purpose and objectives of the research. Box 15 requests a summary of the methodology and procedures (the protocol) through which the objectives will be reached.

Boxes #12, 13, 14: 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. Discuss the situation with the Chair of the REB if you feel it is appropriate to do so.

Box# 17: What is a multi centered trial?

A multi centered trial is a research project that will be conducted within two or more physical sites. Normally Research Ethics 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 BCIT is one of several sites for a single study, our REB will need to review the application for ethics approval.

Box# 42: What funding information is required?

The REB must be in a position to reflect on the existence or absence of any conflict of interest with respect to the applications 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# 42: What start and finish date is required here?

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

Box# 44: What is meant by "Agency Officials"?

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

Box# 50: What is meant by continuing review?

Continuing review applies to ongoing research activities (i.e. no end date) or projects that will extend over more than a two years. Box 49 of the Request for Ethical Review form, in accordance with the TCPS, requires that each submission for ongoing research needs to include a proposal from the applicant on how they intend to comply with the requirement for continuing review. One may enter "N/A" in Box 50 for projects that will extend over less than two years.